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INTELLECTUAL PROPERTY AND TRADE

HEARINGS

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES, AND THE ADMINISTRATION OF JUSTICE

OF THE

COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

SECOND SESSION

ON

INTELLECTUAL PROPERTY AND TRADE

FEBRUARY 19, APRIL 23, AND MAY 21, 1986

Serial No. 60

FILE COPY



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INTELLECTUAL PROPERTY AND TRADE

WEDNESDAY, FEBRUARY 19, 1986

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The subcommittee met, pursuant to call, at 10 a.m., in room 2226, Rayburn House Office Building, Hon. Jack Brooks presiding.

Present: Representatives Brooks, Mazzoli, Schroeder, Frank, Boucher, Moorhead, Kindness, Coble, Swindall, and DeWine.

Staff present: Michael J. Remington, chief counsel; David W. Beier, assistant counsel; Thomas E. Mooney, associate counsel; and Audrey K. Marcus, clerk.

Mr. BROOKS. The subcommittee will come to order.

I ask unanimous consent that the subcommittee permit the meeting today to be covered in whole or in part by television broadcast, radio broadcast, and/or still photography, pursuant to rule V of the committee rules.

Without objection, so ordered.

This morning, the Subcommittee on Courts, Civil Liberties, and the Administration of Justice is conducting a hearing on the subject of intellectual property and trade. There are few subjects of such urgency pending before Congress as the problems of trade. As with many important subjects, addressing the trade problem poses some difficult policy choices. The hearing this morning will assess the nature of the problem and analyze some of the proposed responses and review criticism of these legislative responses.

There are three bills before the subcommittee this morning. The first one, H.R. 1069, by my distinguished and able colleague, Congressman Moorhead, relates to process patent protection; second, H.R. 3776, title II, relates to modifications in the enforcment of intellectual property rights in the International Trade Commission; and third, H.R. 3246, by the chairman of this subcommittee, Congressman Bob Kastenmeier, would implement a portion of the patent cooperation treaty.

Each of these bills addresses different problems confronting the owners of intellectual property. The first two measures, process patent reform and access to ITC remedies, are closely related to each other. During the last Congress, the House passed H.R. 6286, which in part reformed process patent law. The subcommittee hopes to review the claims about that bill as well as those measures currently before us. The third bill, H.R. 3246, is of a more technical nature.

This morning before we open I want to introduce Congressman Carlos Moorhead for a statement, the distinguished and able ranking Republican on this subcommittee.

Mr. MOORHEAD. Thank you, Mr. Chairman.

I would like to commend the chairman of our subcommittee, Bob Kastenmeier, for scheduling these hearings. The legislation before us this morning will go a long way in helping us to protect U.S. inventors from unfair competition by foreign manufacturers who are taking a free ride on U.S. research and development.

I introduced legislation 4 years ago to try to stop this sort of abuse. What sparked my interest then was a serious problem which a U.S. company had with a patented process it owned. The American company made an exciting breakthrough in the area of high technology. It applied for and received patents in the United States and foreign countries on the product and process—7 years after the patent was applied for in Japan, the patent was still not granted, but 1 year after the application was filed in Japan, three Japanese firms began to produce the product, effectively competing with the newly developed American markets. The International Trade Commission eventually ruled in favor of the U.S. company, but in the meantime the company lost millions of dollars in sales.

I introduced H.R. 1069, with the cosponsorship of Congressmen Fish, Hyde, Kindness, Hughes, DeWine, and Coble. Unlike the laws of our major trading partners, U.S. patent law does not give the holder of a process patent the right to stop the importation into the United States of goods made overseas by the use of a U.S.-patented process. During the last Congress we received many letters of support, one from the American Flint Glass Workers Union stating that they believe the inadequate process patent protection has cost their industry alone upwards of 50,000 jobs.

Title II of H.R. 3776, which I introduced, has the cosponsorship of Mr. Hughes, Mr. Morrison, Mr. Coble, Mr. DeWine, and Mr. Kindness. This bill is intended to strengthen the use and effectiveness of the International Trade Commission when hearing intellectual property cases. Under title II, intellectual property owners need not prove that a whole industry is threatened with destruction or substantial industry. Infringement is sufficient injury. Also an inventor would not have to prove that its industry is efficiently and economically operated. Some small high-technology firms may not have a chance to get started and to become economical before they are challenged by pirates. They are unable to seek relief before the ITC just as universities and individual inventors are unable to seek relief before the ITC.

With increased frequency foreign firms are pirating American inventions and then shipping these products back to the United States. Infringement of U.S. intellectual property costs Americans thousands of jobs and the Nation's businesses billions of dollars annually in sales. I believe we have an opportunity to do something about that, and I hope we can move this legislation as expeditiously as possible.

Mr. Chairman, that is the end of my statement, but in courtesy to our Member, Henry Hyde, I ask that the testimony of George C. Clark be submitted for the record. He is an attorney in Illinois.

Mr. BROOKS. Without objection, we will accept the statement.

[The statement of George C. Clark follows:]

Mr. BROOKS. I must say that I am chairing this committee this morning in the absence of the chairman, Bob Kastenmeier, a very fine Member of Congress, who unfortunately must be in Texas now with his wife because of the death of her father. He would like to have been here, and has a very keen interest in this legislation.

This morning we will hear from a representative of the administration, the Chairwoman of the International Trade Commission, two proponents of process patent reform, and one opponent of H.R. 1069.

Chairman Kastenmeier has asked me to indicate that a decision as to whether additional hearings will be held on this subject will be made after a thorough review of the testimony that we receive today. Parties who are interested in either testifying or submitting statements for the hearing record are encouraged to submit their views to the subcommittee for inclusion in the record.

Our first panel today will consist of Paula Stern, Chairwoman of the International Trade Commission, and Harvey Bale, Assistant U.S. Trade Representative.

We have copies of your statements, which will be made a part of the record. Dr. Stern, you may proceed as you see fit. Mr. Bale, you may then make whatever comments you feel appropriate. We will have a few questions after that.

Dr. Stern.

STATEMENTS OF PAULA STERN, CHAIRWOMAN, INTERNATIONAL TRADE COMMISSION, ACCOMPANIED BY LYN SCHLITT, GENERAL COUNSEL, AND ART WINEBURG, DIRECTOR, OFFICE OF UNFAIR IMPORT INVESTIGATIONS

Dr. STERN. Good morning.

Thank you for including me in this panel in consideration of the legislation affecting international trade and the protection of U.S. intellectual property rights. The Commission's day-to-day implementation of section 337 of the Tariff Act of 1930 has given it much expertise in this area, and I will be drawing on this experience in commenting on two of the bills before the subcommittee today: H.R. 3776 and H.R. 1069. Accompanying me today is our General Counsel, Lyn Schlitt, and our Director of the Office of Unfair Import Investigations, Art Wineburg.

Since 1974, the Commission has instituted 240 section 337 investigations—19 are currently active. Of the remaining 221, more than half, 127 to be exact, were voluntarily terminated by settlement, consent order, or withdrawal by complainant. In 40, no respondents chose to appear, and in 33 of these a remedy was put in place. The remaining 54 investigations, or about one-quarter, were fully contested by respondents.

Let me focus for a minute on the contested cases. An unfair act was found in 31 of these 54 investigations. An important fact is that in only 3 of these was there a finding of no violation of section 337 solely because complainant failed to carry its burden on the trade relief issues—namely, the existence of a domestic industry or substantial injury to, or prevention of establishment of, a domestic industry.

In another two investigations, a violation of section 337 was found, but the Commission concluded that the public interest precluded a remedy. In four investigations, the President disapproved of the Commission determination. In two of these, a subsequent remedial order was not disapproved by the President.

In sum, in the 54 contested cases under section 337, the Commission found a violation in 28, and a remedial order was issued in 23. I think these statistics reveal that section 337 is working: The straightforward cases are settled, and those in which the dispute is more complex are properly and fully litigated.

Title II of H.R. 3776 would make major changes in section 337. I would like to give you my observations on the most important of these and how they would change the administration of the law to protect domestic industries who are hurt by unfair competition.

The proposal is that: In section 337 investigations based on alleged patent, copyright, or trademark infringement, it would be unnecessary to establish either that there is a domestic industry or that the effect or tendency of the infringement is to destroy or substantially injure that industry or to prevent the establishment of that industry.

This would create an irrebuttable presumption that unfair acts found to exist have the effect or tendency to destroy or substantially injure a U.S. industry. This reflects the admirable objective of trying to strengthen the protection of U.S. intellectual property rights. I appreciate the efforts of those like Representative Moorhead and Senator Lautenberg in this area.

However, the transformation of the ITC into a forum to litigate purely intellectual property rights raises some concerns about private rights of parties involved in intellectual property disputes and about administration of judicial resources.

While the ITC would be, in many respects, indistinguishable from a Federal district court adjudicating private intellectual property disputes, we would retain certain procedures of a trade relief statute. Our in rem general exclusion orders would apply against persons not party to the investigation, and so someone not having an opportunity to litigate the intellectual property issues could nevertheless be branded an infringer.

Further, the bill would leave untampered our public interest role so we could theoreticallly deny relief to a party which has established its private right because we do not believe it is in the public interest to grant relief. And, the bill also leaves untouched Presidental review of our decisions which he may veto for policy reasons.

Neither our public interest review nor the President's policy review involve the issues of validity and infringement of the intellectual property at issue, and yet if we deny relief because of public interest, what is the status of our decision on the private rights between the parties? At least with respect to patent validity and enforceability, they are not res judicata nor binding on district courts.

The parties may not be able to seek review of our decision on the intellectual property issues, and so under the principles of res judicata and collateral estoppel, the decision would appear to have no effect on the rights of the parties. In fact, the legislative history of the 1974 amendments limits the effect of section 337 findings on

patent issues to the section 337 investigation itself, and according to the Senate Finance Report of the 1974 Amendment "should not have a res judicata or collateral estoppel effect in cases before [Federal district] courts." Thus, a finding of invalidity or unenforceability of a patent by the ITC would allow and perhaps encourage the patent holder to try another forum—a district court.

Similarly, a respondent faced with an unfavorable patent finding at the ITC may be able to pursue its other remedies in law—a declaratory judgment action in Federal court. A party bringing a declaratory judgment action in Federal court because it is convinced a patent is invalid or unenforceable, or that its actions are not infringing the patent may still be required to adjudicate the issues at the ITC.

However, section 337 is "in addition to" all other remedies at law. Thus, despite my above comments on res judicata, a Federal court that is confronted with an ITC determination on an intellectual property right might just decide for itself whether to try the dispute anew or to accept the ITC determination. And a patent owner who receives an unfavorable patent ruling at the ITC could, to its surprise, find that a district court will apply the ITC ruling.

This forum shopping runs contrary to principles of fairness, judicial economy, and finality. In sum, what we might see is even more duplication in U.S. litigation—patent disputes simultaneously being litigated in Federal court and at the ITC. Moreover, the ITC does not consider counterclaims, contrary to the judicial principle of resolving all disputes between the parties at one time in one forum. Further, no right to a jury trial is available at the ITC. And no money damages are available at the ITC.

Eliminating the domestic industry and injury requirement also has the effect of removing an important economic policy factor which Congress intended the Commission to consider and balance with that of the protection of intellectual property. According to the Senate Finance Committee report that accompanied the 1974 Trade Act, the overriding concern in our administration of section 337 is the "public health and welfare and the assurance of competitive conditions in the United States."

I interpret this directive to mean that the Commission is to balance both the public interest that is served by protecting intellectual property rights and that served by the entrepreneurial activity which results from a patent's exploitation. I am concerned that the proposed legislation can be read to elevate the protection of intellectual property rights—regardless of whether they are ultimately commercially exploited—over other important public interest goals.

After all, society benefits even more from the fruits of the inventor when intellectual property rights are exploited through the efforts and capital of the entrepreneur. It is this production-related activity which in turn spawns economic growth. Society does not benefit directly from protecting a particular invention unless that idea is ultimately exploited.

Certainly there is merit in encouraging widespread knowledge so that our laws protect intellectual property and the spirit of the inventor. Indeed, this is the job of the Federal courts. But I believe Congress wisely established section 337 as an additional place for relief that is merited only after the ITC has balanced the intellec-

tual property rights with the public benefits of competition and economic growth, which come only when the creativity of the inventor is combined with the tenacity of the entrepreneur.

The absence of a domestic industry requirement could leave the Commission arbitrating among importers jockeying for market share in the United States with no appreciable impact on production capability or workers' jobs in the United States. Eliminating the industry requirement would likely lead to a substantial increase in the use of section 337 by foreign companies.

The New York Times recently noted that 43 percent of all U.S. patents issued in 1984 were issued to foreign companies. It is also possible that we could serve a consumer-protection role relative to imported products, but there are others—namely the Consumer Product Safety Commission—who can already perform these functions.

The original intent of 337 was the protection and consequent encouragement of American production, American jobs, and American capital from unfair competition due to imports. This continues, I believe, to be an important public policy objective. If Congress intends for the ITC—as its primary function—to arbitrate importers' market shares and protect U.S. consumers, section 337's effectiveness as a trade statute will be reduced.

I therefore believe that to be consistent with the public-interest purpose of section 337, the domestic industry and injury standard should be maintained, and should continue to require more than the mere ownership of a U.S. intellectual property right.

I would be proud to stack up the professional staff of the U.S. International Trade Commission against an equivalent group in any governmental institution anywhere. And this applies in particular to our very able staff of administrative law judges and the Office of Unfair Import Investigations who are so important to the section 337 process. But I want you to understand that our great expertise, our great storehouse of knowledge, our particular genius, if you will allow me that, is in the microeconomic assessment of industries and their competitiveness, including the impact of trade; that is, imports.

I do not want to minimize the experience we have gained in the intellectual property field since 1974. But if the focus of section 337 is only to be validity, enforceability, and infringement, then perhaps the Commission is not the most appropriate location in the U.S. Government for this jurisdiction.

I now turn briefly to H.R. 1069 and title I of H.R. 1069 and title I of H.R. 3776, bills to protect patent owners from importation into the United States of goods made overseas by use of a U.S.-patented process.

Process patent owners cannot obtain relief in Federal court against a product manufactured outside the United States using a patented process and subsequently imported or sold here. At present, the process patent owner's only remedy against overseas infringers is to seek relief before the U.S. International Trade Commission under section 337.

H.R. 1069 and title I of H.R. 3776 would amend the patent statute to enable U.S. process patent owners to obtain relief in Federal court against importation of products made overseas by means of a

U.S.-patented process. Anyone who uses or sells within, or imports into the United States products produced by a U.S.-patented process would infringe the patent under proposed section 271(a)(2) of title 35, and would be subject to an infringement action in Federal court.

Under the current law, a patent owner seeking to enforce his patent in Federal court and at the Commission has the burden of establishing infringement before he can obtain relief. It has been our experience at the Commission, however, that overseas infringement of a process patent cannot always be determined from examining the accused product. Proof of infringement may be within the exclusive control of foreign manufacturers who are unwilling to comply with U.S. discovery procedures.

The Commission has responded to this problem by applying sanctions, including, when appropriate, adverse inferences of infringement against foreign respondents who refuse to comply with Commission discovery orders. The Commission's discovery rules, which are similar to discovery rules in Federal court, have provided process patent owners with an effective mechanism for obtaining relief against accused overseas infringers who refuse to comply with discovery requests.

The rule provides that the Commission will grant relief sufficient to compensate for the lack of any withheld evidence. It is the Commission's practice to rely on direct evidence when it is discoverable from other sources. Thus, even if discovery sanctions are imposed by the Commission, the burden remains on the complainant to make his case from direct evidence, when it is available.

The proposed legislation addresses the evidentiary problem in process patent cases by creating a rebuttable presumption of infringement in cases involving process patents. The Federal courts would be required to apply this presumption if the claimant establishes two preconditions: One, a substantial likelihood that the product was produced by the patented process; and two, that after making reasonable effort, the claimant was unable to determine the process actually used to make the product. In cases where the presumption applies, the accused infringer would have the burden of showing that his product was not produced by an infringing process.

In cases where discovery is available, the burden would remain with the claimant to establish by a preponderance of the evidence that the product was produced using a patented process. The overall approach is similar to the Commission's procedures in process patent cases under section 337.

The proposed legislation's rebuttable presumption most closely resembles the Commission's current default rule, in that it only applies if claimant goes forward with evidence of infringement and demonstrates that he is unable to make any better showing. However, proof of the first prerequisite to application of the presumption—a substantial likelihood that the product was produced by the patented process—might present a more formidable evidentiary hurdle in practice than the Commission's requirement of a prima facie case.

To establish a prima facie case before the Commission, the complainant would have to adduce reliable, probative, and substantial

evidence. If the intent is to create a standard similar to the Commission's current default rule, this should be made more clear.

The second prerequisite—that after reasonable effort, the claimant cannot make a better showing—is clearly similar to the Commission's current default rule, which requires complainant to make a good-faith effort to obtain evidence.

Relief afforded the patent owner under these proposals would not raise as many enforcement issues as a Commission exclusion order, because Federal court proceedings would be presumably in personam, involving only the parties named as defendants. Presuming that the remedies available in Federal court only affect the named defendants, the relief afforded by H.R. 1069 is not as far-reaching as the relief available under section 337.

Unless jurisdiction and venue can be obtained over all infringers in one Federal court, claimants seeking complete relief for a situation involving imports from many suppliers coming in through many ports of entry in a single proceeding may still wish to bring an action before the Commission.

This concludes my testimony. I would be pleased to answer any questions you may have.

[The prepared statement of Paula Stern follows:]

DR. PAULA STERN, CHAIRWOMAN

U.S. INTERNATIONAL TRADE COMMISSION

STATEMENT FOR THE SUBCOMMITTEE ON

COURTS, CIVIL LIBERTIES, AND THE ADMINISTRATION OF JUSTICE

HOUSE JUDICIARY COMMITTEE

FEBRUARY 19, 1986

INTELLECTUAL PROPERTY AND TRADE

I want to thank the Subcommittee for inviting me here today and for making the time in your busy schedules to consider fully the legislation affecting international trade and the protection of U.S. intellectual property rights. The Commission's day-to-day implementation of section 337 of the Tariff Act of 1930 has given it much expertise in this area, and I will be drawing on this experience in commenting on two of the bills before the Subcommittee today: H.R. 3776 and H.R. 1069. Accompanying me today is our General Counsel, Lyn Schlitt, and our Director of the Office of Unfair Import Investigations, Art Wineburg.

In my testimony, I will first provide background information on section 337, including a review of the history of the statute, a summary of the outcome of all cases filed under section 337, and a description of the timetable followed in section 337 investigations. I will then offer comments on the changes to section 337 proposed in Title II of H.R. 3776. Finally, I will make some observations on the Commission's experience with process patent protection and relate these to the changes proposed in H.R. 1069 and in Title I of H.R. 3776.

I would like to point out that the Commission is an independent, quasi-judicial agency and, as such, it does not take positions on proposed legislation. I will today present to you some of my personal views.

Background on Section 337 of the Tariff Act of 1930

From the beginning, section 337, which began as section 316 of the Tariff Act of 1922, has served to ensure that domestic industries are protected from injury arising out of

unfair methods of competition in the import trade. Since the 1940's, section 337 was rarely utilized and did not become actively pursued by domestic industries until the 1974 Amendments. Prior to 1974, determinations of violation and remedy under section 337 were made by the President after recommendation by our predecessor agency, the Tariff Commission. There were no time limits on a section 337 investigation and often by the time a determination was made, the domestic industry's interest in a determination had waned.

So, section 337 was amended as part of the Trade Act of 1974. Substantively, section 337 did not change. The statute still outlaws unfair methods of competition in the import trade that substantially injure, tend to substantially injure or destroy an efficiently and economically operated domestic industry. This has been section 337's purpose since 1922. But the 1974 Amendment provided more timely and effective remedies and at the same time a more rigorous and fair procedure for determinations of violation and remedy.

Let me briefly describe the changes encompassed by the 1974 Amendment. First, the ITC was given sole authority to order any remedy available under section 337, withdrawing from the President all power to revise Commission determinations except the power to disapprove determinations for "policy reasons." Second, Commission determinations of violation of section 337 are now made after a full due process hearing as set forth by the Administrative Procedure Act. Third, the Commission is authorized to consider "all legal and equitable defenses" including, for the first time, invalidity and

unenforceability of any patent or other intellectual property right at issue. Fourth, Commission determinations of violation and remedy are made within 12 months, except "complicated" investigations can be extended to 18 months. Fifth, the remedial power of cease and desist orders was added. The amendment also required that any remedial action taken against section 337 violations be consistent with the public interest. Sixth, the right of review of final Commission determinations to the Court of Customs and Patent Appeals (now the Court of Appeals for the Federal Circuit) was extended to all adversely affected parties including complainants. In 1979, section 337 was amended again to provide the Commission with a civil enforcement mechanism for cease and desist orders and to limit Commission jurisdiction under section 337 in situations which concurrently fell within both section 337 and dumping/countervailing duty jurisdiction.

Since the 1974 Amendment, the Commission has instituted 240 section 337 investigations. Nineteen are currently active. Of the remaining 221, more than half, 127 to be exact, were voluntarily terminated by settlement, consent order or withdrawal by complainant. In 40, no respondents chose to appear, and in 33 of these a remedy was put in place. The remaining 54 investigations, or about one quarter, were fully contested by respondents.

Let me focus for a minute on the contested cases. An unfair act was found in 31 of these 54 investigations. An important fact is that in only three of these was there a finding of no violation of section 337 solely because

complainant failed to carry its burden on the trade relief issues -- namely, the existence of a domestic industry or substantial injury to, or prevention of establishment of, a domestic industry. In another two investigations, a violation of section 337 was found, but the Commission concluded that the public interest precluded a remedy. In four investigations, the President disapproved of the Commission determination. In two of these a subsequent remedial order was not disapproved by the President.

In sum, in the 54 contested cases under section 337, the Commission found a violation in 27, and a remedial order was issued in 23. I think these statistics reveal that Section 337 is working: the straightforward cases are settled, and those in which the dispute is more complex are properly and fully litigated.

A look at the procedures for administering a 337 investigation might help to enhance my discussion of the proposed changes.

The Commission may institute a section 337 investigation on its own initiative or after the filing of a complaint under oath alleging violation of section 337. The filing of the complaint does not mark the beginning of the section 337 investigation. Instead, it triggers a 30-day period during which the Commission reviews the complaint for its adequacy and decides whether to institute an investigation. 19 C.F.R. (210.10(a). Unlike the notice pleading allowed in federal courts, in a section 337 complaint the Commission requires allegations to be supported by detailed statements of facts,

both to assure the Commission that there are factual bases for the allegations and to give respondents adequate and timely notice.

The Commission votes in a public meeting to institute a section 337 investigation and issue the Notice of Investigation. The investigation is then delegated to an Administrative Law Judge (ALJ), and the Notice of Investigation is published in the Federal Register. A copy of the Notice is served on complainant, and respondents are served with both the complaint and the Notice. Respondents located in the United States have 23 days after service in which to answer the complaint and Notice of Investigation. Because of the additional time required to effect service outside of the United States, foreign respondents have 30 days in which to answer. 19 C.F.R. ((210.21(a), 201.16(d).

The ALJ holds a preliminary conference approximately 45 days after an investigation is instituted. At this conference, the parties discuss the issues and their plans for discovery and the ALJ outlines the ground rules for the investigation. By and large, the Commission's Rules respecting discovery in Section 337 investigations are similar to the Federal Rules except that the time limits for responding to discovery in 337 investigations are shorter. As I mentioned, the Commission's proceedings to determine whether there is a violation of section 337 are now conducted in accordance with the Administrative Procedure Act.

In the case of requests for temporary relief, the ALJ has a limit of four months from the date of the Federal Register

Notice to issue an initial determination as to whether there is "reason to believe" the respondents are violating section 337. 19 C.F.R. (210.53(b). During this period, the parties conduct discovery and brief the issues, an evidentiary hearing is usually held, and the ALJ writes an opinion and findings of fact. Once the ALJ issues the initial determination, the parties have five working days in which to petition the Commission for review of that determination. 19 C.F.R. (210.54(a). Regardless of whether any of the parties petition for review, the Commission has 30 days after service of the ALJ's determination to decide whether it wishes to review some or all of the determination on its own motion. 19 C.F.R. ((210.53(h), 210.54(b), 210.55. If the initial determination on temporary relief is not reviewed within this 30-day period, the ALJ's determination becomes that of the Commission. 19 C.F.R. (210.53(h). If, however, the Commission does undertake review, it has up to 60 additional days to affirm, reverse or modify the ALJ's determination, and if necessary to fashion a remedy. 19 C.F.R. (210.56(d). Then, within 60 days of receipt of the Commission's determination, the President may disapprove the determination for policy reasons. 19 U.S.C. (1337(g)(2).

Fewer than one-quarter of all section 337 investigations have involved requests for temporary relief. Of course, all investigations involve requests for permanent relief, which must be decided by the Commission within one year after the Federal Register Notice, unless the Commission declares the investigation to be "more complicated." 19 U.S.C. (1337(b)(1).

With regard to permanent relief, the ALJ has a limit of

nine months to hold a hearing and determine whether there is a violation of section 337. 19 C.F.R {210.53(a). After service of the ALJ's initial determination, the parties have 10 days in which to petition the Commission for review, and the Commission has 45 days to decide whether to undertake review. 19 C.F.R. {{210.53(h), 210.54(a), 210.55. Assuming the ALJ takes his/her full nine months to issue a determination, if the Commission takes review, it has an additional 45 days after ordering review to affirm, reverse or modify the ALJ's determination, and to fashion a remedy if a violation is found. During the 60 days following receipt of the Commission's determination, the President may disapprove the determination for policy reasons. 19 U.S.C. {1337(g)(2).

In those investigations which are designated "more complicated" -- and only about 10 percent of section 337 investigation have been so designated -- the Commission has up to 18 months from publication of the Notice to complete the investigation. 19 U.S.C. {1337(b)(1). In such investigations, the ALJ has up to 14 months to issue a determination and the Commission has 45 days to decide whether to take review. 19 C.F.R. {{210.53(a),(h), 210.54(b), 210.55. Assuming the ALJ takes his/her full 14 months, the Commission then has up to two and a half months to issue its determination on both violation and remedy. Here again, there is a 60-day Presidential review period. 19 U.S.C. {1337(g)(2).

H.R. 3776 - Amendments to Section 337

Title II of H.R. 3776 would make major changes in section 337. As I read this bill, the principal features are:

1. In section 337 investigations based on alleged patent, copyright, or trademark infringement, it would be unnecessary to establish either that there is a domestic industry or that the effect or tendency of the infringement is to destroy or substantially injure that industry or to prevent the establishment of that industry.

2. In section 337 investigations in which it is alleged that the effect or tendency of respondents' unfair acts or methods of competition is to destroy or substantially injure the domestic industry, it would be unnecessary to establish that the domestic industry is efficiently and economically operated.

3. In section 337 investigations, respondents' unfair acts or methods of competition that impair the establishment of a domestic industry would be just as actionable as those that prevent the establishment of such an industry.

4. The Commission would rule on petitions for temporary relief within 90 days of the date on which the petition is filed and the Commission would be empowered to require the petitioner to post a bond as a prerequisite to the issuance of temporary relief.

5. The Commission would be explicitly empowered to issue cease and desist orders "in addition to" exclusion orders.

6. In cases in which the complainant seeks relief only against certain respondents and those respondents are in default, the Commission would presume the facts alleged in the complaint and issue relief limited to the defaulting respondents.

7. The Commission would be empowered to order seizure and forfeiture of goods imported in violation of section 337.

I would like to give you some observations on these proposals:

1.) In section 337 investigations based on alleged patent, copyright, or trademark infringement, it would be unnecessary to establish either that there is a domestic industry or that the effect or tendency of the infringement is to destroy or substantially injure that industry or to prevent the establishment of that industry.

This would create an irrebuttable presumption that unfair acts found to exist have the effect or tendency to destroy or substantially injure a U.S. industry. This reflects the admirable objective of trying to strengthen the protection of U.S. intellectual property rights. I appreciate the efforts of those like Senator Lautenberg and Representative Moorhead in this area. However, the transformation of the ITC into a forum to litigate purely intellectual property rights raises some concerns about private rights of parties involved in intellectual property disputes and about administration of judicial resources.

While the ITC would be, in many respects, indistinguishable from a federal district court adjudicating private intellectual property disputes, we would retain certain procedures of a trade relief statute. Our in rem general exclusion orders would apply against persons not party to the investigation, and so someone not having an opportunity to

litigate the intellectual property issues could nevertheless be branded an infringer.

Further, the bill would leave untampered our public interest role so we could theoretically deny relief to a party which has established its "private right" because we don't believe it is in the public interest to grant relief. And, the bill also leaves untouched Presidential review of our decisions which he may veto for policy reasons. Neither our public interest review nor the President's policy review involve the issues of validity and infringement of the intellectual property at issue, and yet if we deny relief because of public interest, what is the status of our decision on the private rights between the parties? At least with respect to patent validity and enforceability, they are not res judicata nor binding on district courts. The parties may not be able to seek review of our decision on the intellectual property issues, and so under the principles of res judicata and collateral estoppel, the decision would appear to have no effect on the rights of the parties. In fact, the legislative history of the 1974 Amendments limits the effect of section 337 findings on patent issues to the section 337 investigation itself, and according to the Senate Finance Report of the 1974 Amendment "should not have a res judicata or collateral estoppel effect in cases before [federal district] courts." S. Rep 93-1298, 93rd Cong. 2nd Sess. at 196 (Nov. 26, 1974). Thus, a finding of invalidity or unenforceability of a patent by the ITC would allow and perhaps encourage the patent holder to try another forum -- a district court.

Similarly, a respondent faced with an unfavorable patent finding at the ITC may be able to pursue its other remedies in law -- a declaratory judgment action in federal court. A party bringing a declaratory judgment action in federal court because it is convinced a patent is invalid or unenforceable, or that its actions are not infringing the patent may still be required to adjudicate the issues at the ITC. However, section 337 is "in addition to" all other remedies at law. Thus, despite my above comments on res judicata the federal court confronted with an ITC determination on an intellectual property right might just decide for itself whether to try the dispute anew or to accept the ITC determination. And a patent owner who receives an unfavorable patent ruling at the ITC could, to its surprise, find that a district court will apply the ITC ruling.

This forum shopping runs contrary to principles of fairness, judicial economy, and finality. Moreover, the ITC does not consider counterclaims, contrary to the judicial principle of resolving all disputes between the parties at one time in one forum. Further, no right to a jury trial is available at the ITC. No money damages are available at the ITC. What we might see is even more duplication in U.S. litigation -- patent disputes simultaneously being litigated in federal court and at the ITC.

As you know, section 337 investigations operate under severe time deadlines. Whereas practically all section 337 patent-based investigations are completed within 12 months, only half the patent-based trials in federal district courts are completed within 29 months. This time differential for

adjudication is significant and may provide tactical advantages that could translate into abridgment of rights. I would point out that the Commission takes its deadlines very seriously. We infrequently declare an investigation more complicated and even more infrequently take the entire six additional months permitted. In fact, the 12-month deadline is only a limitation and our responsibility is to process an investigation even more expeditiously if possible.

This bill, by making section 337 a purely intellectual property statute, will inevitably affect the rights of persons who hold U.S. patents, copyrights, and trademarks and those accused of infringing them. This change in section 337 would transform the ITC from a body applying trade remedy laws to a quasi-advisory board involving intellectual property disputes. However well meaning, this approach is fraught with potential problems.

First, eliminating the domestic industry and injury requirement has the effect of removing an important economic policy factor which Congress intended the Commission to consider and balance with that of the protection of intellectual property. According to the Senate Finance Committee Report that accompanied the 1974 Trade Act, the overriding concern in our administration of section 337 is the "public health and welfare and the assurance of competitive conditions in the U.S." I interpret this directive to mean that the Commission is to balance <u>both</u> the public interest that is served by protecting intellectual property rights and that served by the entrepreneurial activity which results from a

patent's exploitation. I am concerned that the proposed legislation can be read to elevate the protection of intellectual property rights (regardless of whether they are ultimately commercially exploited) over other important public interest goals. After all, society benefits even more from the fruits of the inventor when intellectual property rights are exploited through the efforts and capital of the entrepreneur. It is this production-related activity which in turn spawns economic growth. Society does not benefit directly from protecting a particular invention unless that idea is ultimately exploited.

Certainly there is merit in encouraging widespread knowledge so that our laws protect intellectual property and the spirit of the inventor. Indeed, this is the job of the federal courts. But I believe Congress wisely established section 337 as an additional place for relief that's merited only after the ITC has balanced intellectual property rights with the public benefits of competition and economic growth, which come only when the creativity of the inventor is combined with the tenacity of the entrepreneur. In this way section 337 will continue as well to serve as a spur to our great research institutions who hold the rights to large amounts of intellectual property to move this knowledge as quickly as feasible to domestic commercialization.

The absence of a domestic industry requirement could leave the Commission arbitrating among importers jockeying for market share in the United States with no appreciable impact on production capability or workers' jobs in the United States.

It is possible that we could serve a consumer protection role relative to imported products, but there are others -- namely CPSC -- who already perform these functions. The original intent of 337 was the protection and consequent encouragement of American production, American jobs, American capital from unfair competition from imports. This continues, I believe, to be an important public policy objective. If Congress intends for the ITC to arbitrate importers' market shares and protect U.S. consumers as primary functions, 337's effectiveness as a trade statute protecting U.S. productive capacity and workers' jobs will be reduced.

I therefore believe that to be consistent with the public interest purpose of section 337, the domestic industry and injury standard should be maintained, and should continue to require more than the mere ownership of a U.S. intellectual property right.

I would be proud to stack up the professional staff of the U.S. International Trade Commission against an equivalent group in any governmental institution anywhere. And this applies in particular to our very able staff of Administrative Law Judges and the Office of Unfair Import Investigations who are so important to the 337 process. But I want you to understand that our great expertise, our great storehouse of knowledge, our particular genius, if you will allow me that, is in the micro-economic assessment of industries and their competitiveness, including the impact of trade, i.e., imports. I don't want to minimize the experience we have gained in the intellectual property field since 1974. But if the focus of

section 337 is only to be validity, enforceability, and infringement, then perhaps the Commission is not the most appropriate location in the U.S. Government for this jurisdiction.

Second, a large portion of our 337 caseload is based on multiple unfair acts which almost always include allegations of patent, copyright, or trademark infringement as well as activities such as false advertising and misleading packaging. Should the standards for domestic industry and injury be eliminated for patent, copyright and trademark infringement but continue to be required for other unfair acts, the Commission will find it difficult to apply different standards in cases involving both types of unfair acts. Further, the absence of an industry and injury requirement will exacerbate the potential for problems in determining primary responsibility for areas such as false advertising between ourselves and the Federal Trade Commission.

Beyond the above administration of justice concerns, there are serious trade policy concerns. Eliminating the industry requirement would likely lead to a substantial increase in the use of section 337 by foreign companies. The New York Times recently noted that 43 percent of all U.S. patents issued in 1984 were issued to foreign entities. Under the proposed statute, a foreign company whose only connection to the U.S. was ownership of a U.S. patent, could have an action under 337 against its U.S. competitor, who might be importing components of the product at issue. Thus, foreign owners of U.S. intellectual property rights could prevent the industries of

the future from being established in the United States. This is a particularly frightening scenario if a pioneer patent were to be involved. If this bill is read to elevate intellectual property rights over other public interest goals, then it will be difficult for the Commission to prevent this use of 337 remedies for the exclusion of the United States from the potential industries of the future.

Intellectual property is on the table for the new round of trade negotiations in the General Agreement on Tariffs and Trade. Section 337 is covered by the "Grandfather Clause" of the GATT Protocol of Provisional Application as long as its substance is preserved as it existed on October 30, 1947. A change to the injury requirement could have repercussions in the GATT. Our injury standard, while not very stringent, is perceived by our trading partners as an offset to aspects of 337 to which they object, such as time limits and different evidentiary standards. In fact, the European Community is currently processing a complaint against section 337, under its new Regulation No. 2641/84.

The GATT negotiation issue relative to the industry requirement might be the question of giving foreign owners of intellectual property access to 337 without getting anything in return in the negotiations. Further, should we at a later time wish to undo this grant of access, we would have clearly given up our "grandfather" rights.

I note that the proposal uses the term "trademark" without qualification as to the type of trademark. It is thus unclear whether the bill is intended to cover both registered

trademarks and common-law trademarks or only registered trademarks. If the bill is intended to cover only registered trademarks, which are arguably more akin to patents and copyrights than are common-law trademarks, then it might be preferable to use the specific term "registered trademark."

2.) In Section 337 investigations in which it is alleged that the effect or tendency of respondents' unfair acts or methods of competition is to destroy or substantially injure the domestic industry, it would be unnecessary to establish that the domestic industry is efficiently and economically operated.

The present efficient and economic operation requirement may enlarge the discovery record and the hearing record with concomitant additional costs to the parties and the Commission. It may also place large amounts of confidential information at risk. However, using our trade statutes and border control enforcement in a situation where the domestic industry is inefficient and will not be economically viable is a waste of resources. It is not in the public interest that relief be given to an industry unable to utilize it.

I recommend moving this criteria to the list of public interest factors considered by the Commission in deciding whether to issue a remedy. Section 337(d) requires that if the Commission finds a violation of the statute, prior to ordering relief, it must consider the effect of relief on the public health and welfare, competitive conditions in the United States economy, production of like goods in the United States, and consumers. This is not part of the APA determination of

violation, but rather a separate finding made by the Commission on the advisability of issuing a remedy. Efficient and economic operation could be one of the factors considered in this phase of the investigation. This would remove the issue from potential discovery abuse in the APA proceedings before the ALJ, and yet retain the principle that we do not protect industries which are not economically viable.

3.) In section 337 investigations, respondents' unfair acts or methods of competition that "impair" the establishment of a domestic industry would be just as actionable as those that prevent the establishment of such an industry.

In my opinion, the Commission is not so legalistic that it could not accomplish the same result intended by the proposal under the current language. In fact, where faced with the question, under the material retardation standard in our dumping/countervailing duty jurisdiction, we have reached a similar point. Of course, the statutory language and the legislative history could be considered ambiguous in so far as it is not clear whether "impairment" and "prevention" are completely analogous, and thus both actionable. Thus, should reform in this regard be deemed necessary, I would suggest that the word "substantial" be added to "impairment." This would prevent the misinterpretation that any nuisance was actionable.

4.) The Commission would rule on petitions for temporary relief within 90 days of the date on which the petition is filed, and the Commission would be empowered to require the petitioner to post a bond as

a prerequisite to the issuance of temporary relief.

The proposed 90-day deadline from date of filing would create severe procedural and practical difficulties for both complainants, respondents, and the Commission. Under present Commission procedures, the ITC does not normally institute an investigation until 30 days after a complaint is filed. Because ITC Rule 210.24(e)(2) encourages the filing of motions for temporary relief along with the complaint, the time period for acting on the request for temporary relief would be effectively reduced to 60 days.

During this 60-day period, the parties may need to take discovery, a hearing may have to be held, the ALJ would have to make a determination based on the hearing and other evidence of record, and the Commission would have to determine whether the ALJ's decision warrants review and/or reversal. It is thus quite possible that such a 60-day time limit could deny complainant an adequate opportunity to take discovery necessary for a showing of likelihood of success on the merits, deny respondents the opportunity to prepare a defense as to irreparable harm, and limit the available time at the hearing for the parties to confront and contradict adverse evidence.

Moreover, the proposal makes no provision for lengthening the 90-day temporary relief deadline (to, perhaps, 135 days) in cases designated "more complicated." A longer temporary relief deadline for "more complicated" investigations may be appropriate in light of the greater complexity of such cases. The Commission currently has within its discretion the ability to provide complainants with effective temporary relief within

the parameters of the statute as it currently stands. The APA does not absolutely require full evidentiary hearings, including cross-examination and complete discovery, in all section 337 temporary relief proceedings.

The ALJ's can improve Commission procedure where discretion allows. They can, for example, substitute written for oral testimony in the case of hearings for temporary relief. Certain limitations, when exercised reasonably, do not offend due process; are within the Commission's discretion under APA proceedings; and would guard against delays frustrating the purposes of section 337. On this issue, I would refer you to my recent additional views in Certain Products with Gremlins Character Depictions, Inv. 337-TA-201.

While the absence of alacrity cries out for attention, an inflexible 90-day time limit may not be the answer. Admittedly, this provision might be less problematic if the industry and injury requirements were removed.

The proposed legislation also empowers the Commission to require complainants to post a bond as a prerequisite to the issuance of temporary relief. This would conform Commission practice more closely to that of the federal courts. It also might give more confidence to the Commission in the exercise of its discretion to grant temporary relief. It is a good idea.

The bill does not specify whether respondents or the United States are to receive the bond in the event that it is forfeited. It also does not specify on what basis the bond is to be calculated.

I note that the bill does not amend the portion of

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subsection (e) of section 337 which deals with circumstances where the Commission has found temporary relief to be warranted, and importation continues by the respondents under bond during the pendency of an investigation. Under 337(e), the bond is posted by respondents. If forfeited, it goes to the United States Treasury. Thus, H.R. 3776 makes it possible for a situation to arise wherein both complainant and respondents must post bonds during portions of the investigation.

5.) The Commission may issue cease and desist orders "in addition to" exclusion orders.

I have always found it proper under the current statutory scheme to consider issuing a cease and desist order as well as an exclusion order, if it is appropriate. In the past, the Commission has issued both an exclusion order and cease and desist orders in the same investigation; but the different types of remedial order were directed to separate and distinct unfair acts. In a recent case, however, the Commission issued both an exclusion order and a cease and desist order covering the same unfair act (Metal Cutting Snips, 337-TA-197). Thus, authorizing the Commission to issue cease and desist orders "in addition to" exclusion orders, would confirm current Commission practice.

There are circumstances where it is in the public interest to issue both an exclusion order and cease and desist orders for the same violation. For example, a cease and desist order prohibiting a domestic respondent from selling the product may be appropriate when the infringing product has been stockpiled

and in addition an exclusion order may be appropriate to exclude future shipments of the infringing product. I would refer you to the views of Commissioner George Moore and myself in Doxycycline, 337-TA-3. Should the bill be enacted, it would be without legal question that the Commission has authority to order such relief when the Commission determines that both remedies are necessary. It is a good idea.

6.) In cases where the complainant seeks relief only against certain respondents and those respondents are in default, the Commission must presume the facts alleged in the complaint and issue relief limited to the defaulting respondents.

The Commission currently issues relief against respondents found in default only if the record developed establishes a prima facie case of violation (or reason to believe there is a violation) of section 337. The proposal requires the Commission, upon request of complainant, to issue relief against a defaulting respondent, provided the respondent has been served with the complaint and the Commission's notice of investigation.

The Commission has rejected an automatic default rule because it is subject to abuse. For example, a complainant can bring a section 337 complaint involving a dubious charge of unfair competition and name as respondents entities which it has reason to believe will default. Large numbers of small, foreign respondents are, of course, common. Under the proposal, the complainant could exclude articles of its

competitors even though no unfair act or method of competition had occurred.

The Commission's default standard is also founded in a recognition that we are doing more than processing private business disputes in section 337. We are making decisions to serve the public interest. 337 offers an extraordinary, stringent remedy following procedures whose time limits pressure completeness.

It costs the U.S. taxpayer to enforce these remedies through the auspices of an already heavily utilized U.S. Customs Service. I would submit that refraining from triggering this mechanism on the basis of mere allegations serves the national interest. The requirement for "substantial, reliable and probative evidence" is not onerous.

In the five cases decided under the current Commission default rule, the complainant has obtained relief in three instances. Certain Foam Earplugs, Inv. No. 337-TA-184 (1984); Certain Bag Closure Clips, Inv. No. 337-TA-170 (1984); Certain Trolley Wheel Assemblies, Inv. No. 337-TA-161 (1984). No violation was found in Certain Products With Gremlins Character Depictions, Inv. No. 337-TA-201 (1985), and Certain Softballs and Polyurethane Cores Therefor, Inv. No. 337-TA-190 (1985).

The problem with default lies not in our prima facie standard, but what our ALJ's have interpreted as necessary to establish a prima facie case. The default rule has been interpreted to mean that the evidentiary showing required in a default situation necessarily entails a full evidentiary hearing under all circumstances. Although many cases involving

default have been based on a record which includes an evidentiary hearing, there is an earlier line of cases which demonstrates that a showing of "substantial, reliable and probative evidence" to establish complainant's prima facie case does not necessarily require it. I would again refer you to my recent views in Gremlins.

7.) The Commission would be empowered to order seizure and forfeiture of goods imported in violation of section 337.

Importation of goods in violation of our outstanding exclusion orders can constitute Customs fraud and the Customs Service can already seize the goods and require forfeiture in certain situations. I would refer you to 19 U.S.C. 1592. The Commission should have authority to enforce its orders, but we should not duplicate the powers which already exist at Customs.

In addition to the enforcement of our orders, the remedy of seizure and forfeiture is presently available under the Customs regulations for trademark and copyright violations without a 337 proceeding. I refer you to 19 C.F.R. Section 133.52. The Copyright Statute, 17 U.S.C. Section 603, provides that articles forfeited for violation of the copyright laws should be destroyed and further provides that the articles may be returned to the country of export whenever the importer had no reasonable grounds for believing that his or her acts constituted a violation of law.

The Customs law also specifically sets forth at 19 U.S.C. Section 1526 provisions for the treatment of goods which are in

violation of the trademark laws. The Customs regulations, in carrying out these provisions, provide that articles bearing a counterfeit trademark shall be disposed of, after obliteration of the trademark, by government use, gift to charity, sale of destruction. Articles that are in violation of that trademark laws, other than articles bearing a counterfeit trademark, shall be disposed of in accordance with the procedures applicable to forfeitures for violations of the Customs law, after removal or obliteration of the trademark.

I would also note that our agency currently does not exercise any police power and that this provision could move us into that arena.

Additional Amendments to Section 337

Before moving on to a discussion of H.R. 1069 I would like to mention a few minor changes to Section 337 which are not currently addressed by this bill, but which I would suggest deserve some consideration.

A provision should be added to section 333 of the Tariff Act, 19 U.S.C. Section 1333, prohibiting the Commission from disclosing to any person information submitted to it which is designated as confidential by the person submitting it, unless the person submitting it consents to its release, or the Commission releases the information pursuant to an administrative protective order that safeguards its confidentiality.

A great deal of information, which would harm the competitive position of the submitter if disclosed, is collected as part of the record in Commission investigations.

In some investigations, such as those under section 337, this information is disclosed to outside counsel involved in the investigation under protective order, but not to the public. Companies are justly worried that in the future the Commission might change its policies regarding release, and decide to release information it no longer considers confidential, despite the fact that the submitter does.

A similar concern prompted passage of section 777(b)(1) of the Trade Agreements Act of 1979, 19 U.S.C. Section 1677f(b)(1). That provision prohibits unconsented release, except under protective order, of information designated confidential by the submitter in investigations conducted under Title VII of the Tariff Act of 1930. Arguably that provision is broad enough to cover all information submitted in confidence to the Commission because on its face it is not limited to investigations under Title VII of the Trade Agreements Act. However, a reading of the section as a whole strongly suggests that it may be limited to Title VII investigations, and the Commission has read it as applying only to those investigations. Congress should make explicit its prohibition on the Commission's unconsented release of information submitted to it in confidence except under protective order.

Section 337 now requires an affirmative determination that imports have the "effect or tendency" to destroy or substantially injure the domestic industry. The Commission requires a present "effect" since requiring only a present "tendency" would read "effect" out of the statute. The

Commission considers tendency to be the analogue to threat of injury in other trade relief statutes. The "tendency to destroy or substantially injure" language in section 337(a) should be clarified to conform with the current Commission practice to make clear that it is a "tendency in the future" to injure domestic industry.

Another point which could use clarification is the "no force or effect" language of section 337(g)(2) relative to the status of a Commission order following a Presidential disapproval. Some believe that the Commission order remains alive and capable of modification following disapproval. This leads to serious problems in preventing political considerations from entering into the remedy recommendation process. The executive branch could, for example, say we are disapproving a remedy, but if the Commission recommended another less restrictive remedy, the President would approve it. This approach frustrates the intent of the 1974 Amendment removing the President's power to revise Commission determinations. I would refer you to my dissenting opinion in Certain Headboxes and Papermaking Machine Forming Sections for the Continuous Production Paper, and Components Therefor, 337-TA-82A, and my additional views in Certain Molded-In Sandwich Panel Inserts and Methods for Their Installation, 337-TA-99 (Modification Proceeding). The system will produce the most objective, best economic results if the President is forced into a clear up or down decision with no room for the executive branch to negotiate with the Commission for the most politically palatable relief. Therefore, the ambiguous term

"no force or effect" should be replaced by the clarity of "null and void". Of course, if equitable circumstances dictated, the Commission could self-initiate a new investigation following a Presidential disapproval, adopt the record from the previous proceeeding, update the record, and issue new remedy orders.

Process Patent Protection

I would like to turn now to H.R. 1069 and Title I of H.R. 3776, bills to protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

A process patent is a patent on the method or technology used to make a product. Process patent owners cannot obtain relief in federal court against a product manufactured outside the United States using a patented process and subsequently imported or sold here. At present, the process patent owner's only remedy against overseas infringers is to seek exclusion relief before the U.S. International Trade Commission under section 337 of the Tariff Act of 1930, 19 U.S.C. (1337.

H.R. 1069 and Title I of H.R. 3776 would amend the patent statute to enable U.S. process patent owners to obtain relief in federal court against importation of products made overseas by means of a U.S. patented process. Anyone who uses or sells within, or imports into the United States products produced by a U.S. patented process would infringe the patent under proposed section 271(a)(2) of title 35, and would be subject to an infringement action in federal court.

Process Patent Infringement

Under the current law, a patent owner seeking to enforce

his patent in federal court and at the Commission has the burden of establishing infringement before he can obtain relief. It has been our experience at the Commission, however, that overseas infringement of a process patent cannot always be determined from examining the accused product. Proof of infringement may be within the exclusive control of foreign manufacturers who are unwilling to comply with United States discovery procedures. The problem may be compounded by foreign statutes which block compliance with U.S. discovery orders. Thus, enforcing a U.S. process patent against overseas infringers often involves difficult problems of proof for the patent owner.

The Commission has responded to this problem by applying sanctions, including, when appropriate, adverse inferences of infringement against foreign respondents who refuse to comply with Commission discovery orders. The Commission's discovery rules, which are similar to discovery rules in federal court, have provided process patent owners with an effective mechanism for obtaining relief against accused overseas infringers who refuse to comply with discovery requests. The Commission currently has proposed rules out for public comment to strengthen our sanctions by adding the imposition of attorneys fees and costs against a party for several types of discovery abuse. You can find these in the Federal Register of February 11, 1986.

Rule 210.36 of the Commission's Rules of Practice and Procedure, 19 C.F.R. (210.36, provides in pertinent part:

> If a party . . . fails to comply with [a discovery order], the administrative law judge, for the purpose of permitting resolution of relevant issues and disposition of the investigation without unnecessary delay despite failure to comply, may take such action in regard thereto as is just, including, but not limited to, the following:
>
> (1) Infer that the admission, testimony, documents, or other evidence would have been adverse to the party;
> (2) Rule that for the purposes of the investigation the matter or matters concerning the order or subpoena issued be taken as established adversely to the party;
>
> (3) Rule that the party may not introduce into evidence or otherwise rely upon the testimony by the party, . . . or documents, or other material, in support of his position in the investigation;
>
> (4) Rule that the party may not be heard to object to introduction and use of secondary evidence to show what the withheld admission, testimony, documents, or other evidence would have shown; and
>
> (5) Rule that a motion or other submission by the party concerning the order or subpoena issued be stricken or rule by initial determination that a determination in the investigation be rendered against the party, or both. . .
> 19 C.F.R. (210.36(b).

The rule provides that the Commission will grant relief sufficient to compensate for the lack of any withheld evidence. It is the Commission's practice to rely on direct

evidence when it is discoverable from other sources. See the views of Commissioner Rohr and myself in Certain Alkaline Batteries, Inv. No. 337-TA-185.; and also the unreviewed Initial Determination in Certain Amorphous Metal Alloys and Amorphous Metal Articles, Inv. No. 337-TA-143. Thus, even if discovery sanctions are imposed by the Commission, the burden remains on the complainant to make his case from direct evidence, when it is available.

As I mentioned earlier, the Commission has an additional procedural rule concerning respondents who decline to respond to the complaint and notice of investigation, and are therefore found in default. Rule 210.25 of the Commission's Rules (19 C.F.R. (210.25) requires the complainant to establish a prima facie case before relief will be issued, but provides for the application of adverse inferences with respect to issues for which complainant has made a good faith, albeit unsuccessful effort to obtain evidence.

The Commission's opinion in Certain Multicellular Plastic Film, Inv. No. 337-TA-54, illustrates these rules in operation. In that case, complainant alleged unfair methods of competition in the importation and sale of multicellular plastic film swimming pool covers. The covers were allegedly made by a process which, if practiced in the United States, would infringe the method claims of complainant's patent. One of the foreign respondents, Conform, filed a response to the complaint and notice of investigation, but did not comply with the Commission's discovery orders. The Commission imposed sanctions against Conform; specifically that adverse inferences

were drawn; Conform was prohibited from introducing evidence under its control in support of its position; and Conform was precluded from objecting to the use of secondary evidence to show what the withheld evidence would have shown.

Another respondent, Unipak, failed to file a response to the complaint and notice of investigation, and was found to be in default. The administrative law judge ruled that "without further notice to Unipak, the facts may be found to be as alleged in the complaint and notice of investigation." Based on the sanctions against Conform and Unipak, the Commission found that both respondents' pool covers were made by a process that would infringe the complainant's method claims if practiced in the United States. Thus, the net effect of the Commission's discovery and default rules is to require the accused infringer to submit to discovery and defend himself, or risk having relief entered against him based on procedural sanctions. In addition, the Commission's office of Unfair Import Investigations attempts to develop as complete a record as possible without the use of inferences.

The proposed legislation addresses the evidentiary problem in process patent cases by creating a rebuttable presumption of infringement in cases involving process patents. The federal courts would be required to apply this presumption if the claimant establishes two preconditions: 1) a substantial likelihood that the product was produced by the patented process; and 2) that after making reasonable effort, the claimant was unable to determine the process actually used to make the product. In cases where the presumption applies, the

accused infringer would have the burden of showing that his product was not produced by an infringing process.

The legislative history of a predecessor bill (S. 1543) indicates that the statutory presumption is intended to provide the claimant with an effective remedy when discovery is unavailable from the accused infringer. (S. Rep. 98-663, 98th Cong., 2d Sess., at 6, October 5, 1984.) In cases where discovery is available, the burden would remain with the claimant to establish by a preponderance of the evidence that the product was produced using a patented process. The overall approach is similar to the Commission's procedures in process patent cases under section 337.

H.R. 1069's rebuttable presumption most closely resembles the Commission's default rule, in that it only applies if claimant goes forward with evidence of infringement and demonstrates that he is unable to make any better showing. However, proof of the first prerequisite to application of the presumption -- a substantial likelihood that the product was produced by the patented process -- might present a more formidable evidentiary hurdle in practice than the Commission's requirement of a prima facie case. To establish a prima facie case before the Commission, the complainant would have to adduce reliable, probative, and substantial evidence. See the Commission's decision in Certain Attache Cases, Inv. No. 337-TA-49. If the intent is to create a standard similar to the Commission's current default rule, this should be made more clear.

The second prerequisite -- that after reasonable effort,

the claimant cannot make a better showing -- is clearly similar to the Commission's default rule, which requires complainant to make a good faith effort to obtain evidence.

Relief Available

Several remedies are available if the Commission determines that there is a violation of section 337: (1) a general exclusion order may be entered, requiring the Customs Service to deny infringing products entry into the United States, regardless of their source; (2) a limited exclusion order may be entered, requiring the Customs Service to deny entry to a particular foreign respondent's products; or (3) cease and desist orders may be entered to preclude the sale of infringing products already in U.S. inventory. In cases involving process patents, fashioning appropriate relief raises some trade policy issues that are pertinent here.

The principal difficulty lies with entry of general exclusion orders. General exclusion orders afford complainants the broadest relief available from the Commission. By their nature, they carry the greatest risk of disrupting legitimate trade. In several Commission investigations, overseas manufacturers argued for narrower forms of relief, claiming that it was extremely difficult, if not impossible, to determine from a physical sample of an imported product whether it was manufactured by means of the complainant's patented process. See Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Product, Inv. No. 337-TA-148/169; Certain Amorphous Metal Alloys and Amorphous Metal Articles,

Inv. No. 337-TA-143; Certain Multicellular Plastic Film, Inv. No. 337-TA-54.

Balancing the domestic industry's need for complete relief in a single proceeding against the risk of disrupting legitimate trade, the Commission has however in some situations issued general exclusion orders in cases involving process patents. The inability to identify products made by infringing processes from their physical appearance was not at issue in Certain Aramid Fiber, Inv. No. 337-TA-194 (1984), because the parties agreed that the process used by complainant and respondent was the only known process for producing aramid fiber. A general exclusion order was entered in Certain Methods for Extruding Plastic Tubing, Inv. No. 337-TA-110, Commission Opinion at 21 (1982), because the Commission found that imported products made by infringing processes were readily identifiable by the Customs Service from visual inspection. To minimize the potential for disrupting legitimate trade, the Commission permits prospective importers to petition the Commission to institute further proceedings, to determine whether the products they seek to import are not infringing and therefore should be allowed entry. This places the burden of establishing non-infringement on the would-be importers, rather than requiring complainant to prove infringement repeatedly.

The ITC cannot award U.S. process patent owners money damages for infringement of their intellectual property rights. H.R. 1069 would provide the additional remedy of money

damages for process patent owners injured by overseas infringement.

Relief afforded the patent owner under H.R. 1069 would not raise as many enforcement issues as a Commission exclusion order, because federal court proceedings would be presumably in personam, involving only the parties named as defendants. Presuming that the remedies available in federal court only affect the named defendants, the relief afforded by H.R. 1069 is not as far-reaching as the relief available under section 337. Unless jurisdiction and venue can be obtained over all infringers in one federal court, claimants seeking complete relief for a situation involving imports from many suppliers coming in through many ports of entry in a single proceeding may still wish to bring an action before the Commission.

This concludes my testimony. I would be pleased to answer any questions you may have.

Mr. BROOKS. Thank you, ma'am. We will hear from Mr. Bale first, and then we will have questions of both of you as a panel operation.

The gentleman is recognized.

Mr. BALE. Thank you, Mr. Chairman.

Mr. BROOKS. We have your statement. You know that.

Mr. BALE. Yes, sir, and I will try to be brief and summarize my prepared statement, which I submit for the record.

I appreciate the opportunity to appear before you in support of the principles proposed in H.R. 1069 and title I of H.R. 3776, as well as title II of H.R. 3776. I have been requested to address the trade aspects of these bills, and will defer to the greater expertise of our Patent and Trademark Office and others for comments on H.R. 3246 and the nontrade aspects of H.R. 3776.

Again, the administration supports the principles represented by the changes in the law that H.R. 1069 and H.R. 3776 embody. We believe that the bills are complementary. Their passage would make more certain, and improve, the ability of Americans to protect their rights and the value of their intellectual property against foreign misappropriation and piracy, and enhance our ability to compete in the global marketplace. This means more jobs and economic growth. Our economy has been for some time now inseparable from this world market, and know-how is an important element in our continued competitiveness.

H.R. 1069 and title I of H.R. 3776 address an anomaly in our law which prevents process patent owners from effectively enforcing their rights against products made abroad with the process. H.R. 3776, title II, would improve the ability of U.S. intellectual property owners to obtain relief against unfair imports through section 337 proceedings before the ITC. In effect, these proposals would reduce the uncertainties and limits to current relief options.

Over the past several years we have had an ever-increasing number of complaints from our industries about the trade-related problems associated with inadequate intellectual property protection. Although this is a relatively new issue for the U.S. Trade Representative's office, it has quickly become one of the most important. In fact, intellectual property protection is rapidly becoming one of the most critical trade and investment issues of this decade and beyond.

To counteract the problem of intellectual property infringement the administration has undertaken a number of initiatives, some very recently, in connection with the President's increased efforts in the area of international trade to deal with unfair trade practices and provide greater market access for U.S. goods, services, and investment. These steps include multilateral initiatives aimed at developing a more effective international regime based upon trade principles—such as dispute settlement and enforcement—and bilateral measures aimed at resolving existing trade problems.

In the bilateral area the administration is making vigorous use of U.S. trade laws to pursue improved protections for Americans and fight international piracy. Last November, at the direction of the President, Ambassador Clayton Yeutter exercised the authority granted by section 301 of the Trade and Tariff Act of 1984, and initiated an investigation of Korea's intellectual property laws. Korea

has been a particular problem for counterfeiting, patent infringement, and pirating of copyrighted works. Despite several rounds of consultations prior to the 301 investigation, there had been virtually no progress. Consequently the administration felt that a section 301 investigation was merited. The administration is prepared to initiate additional investigations under section 301 as warranted.

In addition to the multilateral and bilateral approaches, we need to look at our own laws. I would like to turn to the bills H.R. 3776 and H.R. 1069.

With regard to these bills, the administration is convinced that we would realize concrete trade benefits from improvements in protection like those embodied in H.R. 3776 and H.R. 1069. The most innovative American industries would derive the greatest benefits. These include such forefront industries as biotechnology, amorphous metals, solid state electronics—including semiconductors—pharmaceuticals, and optical fibers. For some of these industries the proposed process patent law changes are critical: for instance, biotechnology developers depend almost exclusively on process patents for protection.

H.R. 1069 and title I of H.R. 3776 address an anomaly under current U.S. law in reference to the use of a patent process outside the United States, and the succeeding importation of a product made through the process, which does not constitute an act of infringement. Under today's laws, U.S. process patent holders have two ways to protect themselves against imports made with the process without the patent owners' permission. These Americans can bring a case before the ITC under section 337 or they can apply for patents abroad and seek to enforce them in foreign courts. Both remedies have their shortcomings.

H.R. 1069 would bring American practice into conformity with that of our other principal industrial trading partners. H.R. 1069 would make it an infringement of a U.S. process patent to use or sell in the United States or import into the United States a product made abroad using a process patented in the United States. Since a U.S. process patent owner can already prevent the use of his patent if the product of the process is produced domestically, the amendment's principal effect will be to redress any advantages now given to foreigners. This amendment will not give extraterritorial effect to U.S. patent laws, since foreigners would not be precluded, under the legal remedies the subcommittee is considering, from using the process if their products never entered U.S. commerce. But the bill will present circumvention of U.S. laws by allowing U.S. process patent owners to prevent importing into the United States of products made by his process without his permission.

The office of the U.S. Trade Representative has examined H.R. 1069 and the proposed amendments from the point of view of consistency with international obligations. Our conclusion is that the bill's provisions are consistent with our international obligations under the General Agreement on Tariffs and Trade. I know that a previous version of this bill would have altered the law in such a way as to affect only imports made with a patented process. Such a formulation would have violated our GATT obligations if passed.

In short, we support amending our process patent laws for three reasons: without these changes, infringers are allowed to leap our borders and sell the products made with patented processes without the permission of the patent owner; second, under current law, the patent owner's only remedy is through the ITC, and if he does not get relief from the Commission he is left without any remedy at all; and finally, even if the ITC does grant relief, he cannot recover damages under section 337 for the losses he has sustained.

With regard to title II of H.R. 3776, section 337 is a broad statute which applies to all forms of unfair trade practices, including those involving intellectual property rights—copyrights, trademarks, product patents, as well as process patents, and in many cases 337 has proven to be an effective tool for preventing foreign piracy of U.S. intellectual property rights. It has a number of advantages, including a fast-track approach.

But 337 has a number of deficiencies, primarily connected with uncertainties as to relief. For example, in our opinion the need to establish an efficiently and economically operating industry imposes a burden on U.S. intellectual property owners which makes it harder for them to enforce their rights. Part of the problem is due to the ITC having to deal with conflicting principles. A patent, trademark, or copyright enables its owner to prevent competitors from producing a like product. On the other hand, an industry is made up of a number of companies making like products, and trying to reconcile these concepts produces difficulties. Consider what happens with a patent case when it is brought to the ITC. To find an industry in a patent case the ITC must find that the activities described in the patent claim are carried out in the United States. The time, energy, and money of the patent owner, the respondent, and the Commission are expended to determine whether a real "efficiently and economically operated" industry exists.

In addition, the industry requirement prevents intellectual property owners such as universities and research institutions from using the ITC for enforcing their patents, copyrights, and trademarks because they are not in business.

In the past the ITC has issued vague, and in some instances conflicting, guidelines on the requirement to prove an industry. In a recently-decided case the Commission wrote that it:

> Does not adhere to any rigid formulas in determining the scope of the domestic industry, as it is not precisely defined in the statute, but will examine each case in light of the realities of the marketplace.

I understand that there are vigorous proponents of keeping the industry test in the law. The principal argument is that without the test our proceedings could be used to enforce the rights of say a French company, with a valid patent in the United States, against infringing imports of a third country. This prospect does not disturb me, however, very much. In fact, I would hope that other countries would also develop laws to enable U.S. intellectual property owners to protect their foreign markets against third countries which tolerate piracy. Other countries are not likely to amend their laws to help us when we restrict a very useful enforcement tool of our own.

Turning now to the other principal change proposed in title II of H.R. 3776, establishing "injury" can also be an uncertain and expensive process. To prove injury the U.S. patent owner must not only show a loss of customers, sales, jobs, and market share, but also must establish a link between these losses and the unfair acts of the foreign company using his right without permission. This can prove an insurmountable requirement when the U.S. plaintiff is still making a profit, even if it is a very small one. In effect a U.S. owner of intellectual property has to meet a stronger test in getting relief from the ITC against infringing imports than against domestic infringers.

I understand that some of the proponents of retaining the injury test have argued that its elimination would violate U.S. international obligations under the General Agreement on Tariffs and Trade. However, the 1982 report of the GATT panel, a panel of trade experts in Geneva, on the U.S. Imports of Certain Spring Assemblies, concluded that the injury test was from the panel's perspective "irrelevant." At paragraph 72 the panel noted, in effect, that the injury criterion could only be considered irrelevant from the perspective of the GATT's articles.

The Office of the U.S. Trade Representative has reviewed the provisions of title II which would remove the industry and injury tst from the current law, and has concluded these changes do not give rise to GATT violations.

In summary, Mr. Chairman, the administration supports the principles embodied in H.R. 1069 and title II of H.R. 3776. We believe the bills would promote innovation in some of our most dynamic sectors, but most importantly, it would improve the protection available to Americans against the actions of foreigners which severely diminish the value of Americans' intellectual property rights.

Thank you very much.

[The prepared statement of Harvey Bale follows:]

STATEMENT OF

HARVEY E. BALE, JR.

ASSISTANT UNITED STATES TRADE REPRESENTATIVE

FOR

TRADE POLICY AND ANALYSIS

BEFORE THE

SUBCOMMITTEE ON

COURTS, CIVIL LIBERTIES AND THE ADMINISTRATION OF JUSTICE

COMMITTEE ON THE JUDICIARY

UNITED STATES HOUSE OF REPRESENTATIVES

FEBRUARY 19, 1986

Mr. Chairman and Members of the Subcommittee:

I appreciate this opportunity to appear before you in support of the principles proposed in H.R. 1069 and Title II of H.R. 3776. I will be addressing the trade aspects of these bills. I defer to the expertise of the Patent and Trademark Office, and others, for comments on H.R. 3246, and the non-trade aspects of H.R. 3776.

The Adminstration supports the principles represented by the changes in the law that H.R. 1069 and H.R. 3776 embody. We believe these bills are complementary. Their passage would make more certain and improve the ability of Americans to protect

their rights and the value of their intellectual property against foreign misappropriation and piracy -- and enhance our ability to compete on the global market. Our economy has been for some time now inseparable from this world market, and know-how is an important element of our continued competitiveness. As you well know piracy, misappropriation and infringement of U.S. intellectual property rights is a growing problem.

H.R. 1069 addresses an anomaly in our law which prevents process patent owners from effectively enforcing their rights against products made abroad with the process. H.R. 3776 would improve the ability of U.S. intellectual property owners to obtain relief against unfair imports through Section 337 proceedings before the International Trade Commission.

I. THE PROBLEM

Over the past two years we have had an ever increasing number of complaints from our industries about the trade-related problems associated with inadequate intellectual property protection. Although this is a relatively new issue for the U.S. Trade Representative's Office, it has quickly become one of the most important. In fact intellectual property protection is rapidly becoming one of the most critical trade and investment issues of this decade and beyond.

American competitiveness is increasingly dependent on our ability to enjoy the benefits of our technological innovations. This requires adequate and effective protection for patents, copyrights and trademarks. Unfortunately too many of our trading partners, both developed and developing countries, do not have adequate laws, fail to enforce them, or, their laws cannot prevent infringement of U.S. intellectual property rights. Thus, there is a need for vigorous efforts to increase the level of domestic and international protection.

For many countries, especially developing ones, the inadequacy of intellectual property protection often reflects these nations' misguided development strategies. In order to supplement the competitive edge of their products due to lower labor costs, they also adopt policies which attempt to make technology available within their economies at the lowest possible short-term price. Often this means tolerating the appropriation of foreigners' intellectual property rights, without compensation.

These policies cause three types of trade problems for Americans. First, U.S. companies can lose sales and the value of investment in the market where the American patent, trademark or copyright is appropriated without authorization. Second, America can lose sales to third markets, when unauthorized products are sold in third countries. Finally, and most relevant for the bill you are considering, U.S. companies may lose sales in our own country to

imports which are made using American know-how without adequate compensation.

II. Adminstration Actions

To counteract these problems the Administration has undertaken a number of initiatives -- some very recently in connection with the President's increased efforts in the area of international trade to deal with unfair trade practices and provide greater market access for U.S. goods, services and investment. These steps include multilateral initiatives aimed at developing a more effective international regime based on trade principles -- such as dispute settlement and enforcement -- and bilateral measures aimed at resolving specific existing trade problems.

Internationally, one of our priorities is completing work on the GATT anti-counterfeiting code. Stopping trade in counterfeit goods is important because they diminish the value of trademarks and a good business reputations, and they create special dangers of fraud and safety for consumers. The proposed Code is aimed at curtailing trade in goods bearing counterfeit trademarks. Basically we have completed work on the Code. But, quite frankly, some of our developed country trading partners have not been willing to put the Code into effect because of their concerns about the strong objections of developing countries. If the industrial nations could agree to sign and implement the Code, we

would make great strides toward solving the counterfeit problem, since most counterfeit products are sold in these markets.

The Adminstration is also developing a program to improve international norms and protections in the critically important copyright and patent areas. Among the most troublesome practices in the patent area are: compulsory licensing rules; non-patentability of many important classes of products such as pharmaceuticals and chemical compounds; and patent terms that are unreasonably short. We would also like to see improved international protection in important new areas such as semiconductor chip mask works and industries generating advances in biotechnology. In the copyright area, many nations do not offer protection for traditional forms of expression such as books and sound recordings, and in many cases where protections do exist they are not enforced.

To address these problems, the Administration is actively exploring with our trade partners the recommendations of the President's Advisory Committee on Trade Negotiations to negotiate a binding agreement or code in the GATT on intellectual property similar to the codes negotiated in the Tokyo round. We hope that such a GATT code would supplement existing international conventions, and the efforts of the World Intellectual Property Organization. The GATT approach in addition to developing better international norms, would also yield improvements in such areas as dispute

settlement and enforcement.

Complementing these efforts is a vigorous program of bilateral consultations and negotiations with some of the most problematic nations. Over the past months we have held talks in Asia and Latin America, including Taiwan, Singapore, Korea and Mexico. We have also held a series of bilateral consultations with some thirty countries pursuant to the provisions on intellectual property in the Trade and Tariff Act of 1984. As you know, changes in the Generalized System of Preferences law contained in the 1984 Act direct the President to include treatment of intellectual property rights among the factors which are considered in our general review of continued eligibility for tariff concessions. We are optimistic that this review will provide an important incentive for developing countries to improve their treatment of intellectual property rights.

The Administration is also ready to make vigorous use of U.S. trade laws to pursue improved protections for Americans and to fight international piracy. Last November, at the direction of the President, Ambassador Yeutter exercised the authority granted by Section 301 of the Trade and Tariff Act of 1984, and initiated an investigation of Korea's intellectual property laws. Korea has been a particular problem for counterfeiting, patent infringement and pirating of copyrighted works. Despite several rounds of consultations, there had been virtually no progress.

Consequently the Administration felt that a Section 301 investigation was merited. And the Administration is prepared to initiate additional investigations under Section 301 when appropriate.

III. THE BILLS

The Administration is convinced that we would realize concrete trade benefits from improvements in protection similar to those embodied in H.R. 3776 and H.R.1069. The most innovative American industries would derive the greatest benefits. These include such forefront industries as biotechnology, amorphous metals, solid state electronics, pharmaceuticals and optical fibers. For some of these industries the proposed process patent law changes are critical: for instance biotechnology developers depend almost exclusively on process patents for protection.

H.R. 1069

Because of an anomaly under current U.S. law, the use of a patented process outside the United States, and the succeeding importation of a product made through the process does not constitute an act of infringement. Under today's laws, U.S. process patent holders have two ways to protect themselves against imports made with the process without the patent owners' permission. These Americans can bring a case before the International Trade Commission under

Section 337 of the Tariff Act of 1930, or they can apply for patents abroad and seek to enforce them in foreign courts. Both remedies have of shortcomings.

I will address shortly the specific measures which would make Section 337 a more effective tool in the context of the changes proposed in H.R. 3776. The other option, obtaining and enforcing patents in a number of foreign countries is expensive, sometimes unavailable, and may prove an empty victory since so many foreign countries do not effectively enforce their laws.

H.R. 1069 would bring American practice into conformity with that of the other principal industrial nations. H.R. 1069 would make it an infringement of a U.S. process patent to use or sell in the United States, or import into the United States a product made abroad using a process patented in the United States. Since a U.S. process patent owner can already prevent the use of his patent if the product of the process is produced domestically, the amendment's principal effect will be to redress any advantages now given to foreigners. This amendment will not give extra-territorial effect to U.S. patent laws, since foreigners would not be precluded, under the legal remedies the Subcommittee is considering, from using the process if their products never entered U.S. commerce. But the bill will prevent circumvention of U.S. laws by allowing U.S. process patent owners to prevent importing into the U.S. of products made by his process without

his permission.

The Office of the U.S. Trade Representative has examined H.R. 1069, and the proposed amendments. Our conclusion is that the bill's provisions are consistent with our obligations under the General Agreement on Tariffs and Trade. I know that a previous version of this bill would have altered the law in such a way as to affect only imports made with a patented process. Such a formulation would have violated our GATT obligations if passed.

We also endorse H.R. 1069's concept of shifting to the importer the burden of proving that the patented process was not used in making the challenged import once certain elements are established. The Administration believes that this would not place an unreasonable burden on the importer, since he is in a better position to establish whether or not the process was used, than the U.S. process patent holder.

To prevent possible abuse, the Administration supports H.R. 1069's requirements that, before the burden of proof would shift to the importer, the American patent holder establish a substantial likelihood that the patented process was used, and, that after a reasonable effort to determine the actual process used, he was unable to do so.

The Administration supports the thrust of to H.R. 1069, but we believe, for example, the statute should apply only to products

directly produced by the patented process. We recognize that there is a danger associated with this change: some products may enter the United States which contain an important component made with the patented process, while the final product was not. Patent experts within the Administration are prepared to work with your Committee to find an appropriate solution.

In short, we support amending our process patent laws for three reasons: without these changes, infringers are allowed to leap our borders and sell the products made with patented processes without the permission of the patent owner; second, under current law the patent owner's only remedy is through the ITC, and if he does not get relief from the Commission he is left without any remedy at all; and finally, even if the ITC does grant relief, he cannot recover damages under Section 337 for the losses he has sustained.

TITLE II of H.R. 3776

Section 337 is a broad statute which applies to all forms of unfair trade practices involving intellectual property rights -- copyrights, trademarks, product patents, as well as process patents. In many cases Section 337 has proven to be an effective tool for preventing foreign piracy of U.S. intellectual property rights. Its advantages include: a fast track approach, an ITC decision is generally due within one year; and the remedies available are for many cases adequate -- it can issue an exclusion

order -- although monetary damages to compensate for the losses incurred are not available.

But Section 337 has a number of deficiencies which make it unnecessarily uncertain for U.S. intellectual property owners -- including process patent owners -- to obtain relief. There are important industries for whom the current Section 337 laws do not provide an adequate remedy. In large measure this is because the ITC may grant relief only if it is proven that the alleged infringer has engaged in unfair acts the effect or tendency of which is to substantially injure or destroy an industry efficiently and economically operated in the United States. It is the application of these provisions which are unnecessary, may prevent the protection of domestic intellectual property, and which Title II of H.R. 3776 addresses.

In our opinion the need to establish an efficiently and economically operating industry imposes a burden on U.S. intellectual property owners which makes it harder for them to enforce their rights. Part of the problem is due to the ITC having to deal with conflicting principles. A patent, trademark, or copyright enables its owner to prevent competitors from producing a like product. On the other hand, an industry is made up of a number of companies making like products. Trying to reconcile these concepts produces obvious difficulties. Consider what happens with a patent case, when it is brought to the ITC. To find an industry in a patent case the ITC must find that the activities

described in the patent claim are carried out in the United States. The time, energy, and money of the patent owner, the respondent and the Commission are all expended to determine whether a real "efficiently and economically operated" industry exists.

In addition, the industry requirement prevents intellectual property owners such as universities and research institutions from using the ITC for enforcing their patents, copyrights and trademarks because they are not in business.

In the past the ITC has issued vague, and in some instances conflicting, guidelines on the requirement to prove an industry. In a recently decided case, Certain Softballs and Polyurethane Cores Therefore, Inv. No.337TA-190, USITC Pub. No.1751 (USITC, 1985), the Commission wrote that it "...does not adhere to any rigid formulas in determining the scope of the domestic industry, as it is not precisely defined in the statute, but will examine each case in light of the realities of the marketplace." (Emphasis added.)

I understand there are vigorous proponents of keeping the industry test in the law. Their principal argument is that without the test our proceedings could be used to enforce the rights of say a French company, with a valid patent in the United States, against infringing imports from a third country. This prospect does not disturb me too much. In fact, I hope that other countries will

also develop laws to enable U.S. intellectual property owners to protect their foreign markets against third countries which tolerate piracy. Other countries are not likely to amend their laws to help us when we restrict a very useful enforcement tool of our own.

Turning now to the other principal change proposed in Title II of H.R. 3776, establishing "injury" can also be uncertain and expensive. To prove injury the U.S. patent owner must not only show a loss of customers, sales, jobs and market share, but must also establish a link between the these losses and the unfair acts of the foreign company using his right without permission. This can prove an insurmountable requirement when the U.S. plaintiff is still making a profit, even if it is a very small one. In effect a U.S. owner of intellectual property has to meet a stronger test in getting relief from the ITC against infringing imports than against domestic infringers.

I understand that some proponents of retaining the injury test have argued that its elimination would violate U.S. international obligations under the General Agreement on Tariffs and Trade. The 1982 report of the GATT Panel on United States Imports of Certain Spring Assemblies concluded that the injury test was from the Panel's perspective "irrelevant". At Paragraph 72 the Panel noted:

> Another such element was the reference in subsection (a) of Section 337 to substantial injury to a United States industry which is efficiently and economically operated. The Panel recognized that this injury criterion could work to the

> advantage of a respondent in an ITC investigation, in that it represented an additional requirement to be satisfied by the complainant. However, in the Panel's view, it could reasonably be said that considering what were the essential elements in legislation dealing with patent based cases an injury criterion could only be considered irrelevant. (Emphasis added.)

The Office of the U.S. Trade Representative has reviewed the provisons of Title II which would remove the industry and injury tests from the current law, and has concluded these changes do not give rise to GATT violations.

IV. CONCLUSION

In summary Mr. Chairman, the Administration supports the principles embodied in H.R. 1069 and Title II of H.R. 3776. We believe the bills would promote innovation in some of our most dynamic sectors, such as: pharmaceuticals; solid state electronics; new types of metals; and and industries making use of developments in biotechnology. Their adoption would bring U.S. laws into conformity with those of the other industrial nations. But most importantly, it would improve the protection available to Americans against the actions of foreigners which severely diminish the value of American's intellectual property rights.

Mr. BROOKS. Thank you very much. First, Mr. Bale, in the last Congress the staff of the U.S. Trade Representative claimed that H.R. 6286, relating to protection of infringing imports, violated the General Agreement on Tariffs and Trade. Is this still your view?

Mr. BALE. May I seek counsel for 1 second.

Mr. BROOKS. All right. Check. Be sure. We have no pride in this organization.

Mr. BALE. I certainly have none, Mr. Chairman. This was an earlier version of the current process patent proposal.

Mr. BROOKS. Is that still your view?

Mr. BALE. Yes; it is. This is the early version of the process patent bill which is being addressed currently in 1069 and title I of H.R. 3776.

Mr. BROOKS. In the spring assembly case brought by Canada in 1981, there is some indication in the panel discussion that existing ITC procedures run afoul of GATT. In light of these comments and the fact that section 337, as it currently exists, could be upheld because it is grandfathered in, predating the entry by the United States into the GATT agreement. Should we not be extremely cautious before we modify the Tariff Act?

Mr. BALE. Mr. Chairman, we do not believe that the so-called grandfather provision excuses us from maintaining laws contrary to the GATT. The purpose of the grandfather clause was to allow countries time to bring their laws into conformity with the GATT. We have never argued in the GATT that the provisions under section 337 are covered by a grandfather clause; rather, the provisions of section 337 are protected in our view of section 20(d) of the GATT, which is a provision that allows countries to protect their intellectual property rights, regardless of other provisions of the GATT. And that argument has been upheld by the spring assemblies decision that you referred to yourself, sir.

Mr. BROOKS. I have one other question and then I want to submit some questions to you, Mr. Bale.

Mr. BALE. I would be happy to receive them, sir.

Mr. BROOKS. Opponents of the process patent legislation have argued that such legislation is merely a thinly disguised attempt to extend American law extraterritoriality, to countries which do not protect process patents. What is your view on this?

Mr. BALE. We disagree with that view, Mr. Chairman. The process patent bill would apply to products coming into U.S. commerce. In fact this bill would not apply to that extraterritorial commerce. Our approach to protecting our process patents abroad would have to go through other provisions of U.S. trade law, primarily our unfair-trade statute, section 301. So, our position is that this is not an extraterritorial application of U.S. law.

Mr. BROOKS. To the distinguished chairwoman, I had a couple of questions I wanted to ask you, and I will submit a few more for you, Doctor, if I may.

In the recent Duracell battery case, which involved allegations of gray marketing or parallel importing, the President reversed the ITC on policy grounds. Subsequently, the court of appeals for the Federal circuit found it had no jurisdiction to review the President's decision.

Should the CAFC have jurisdiction in such cases, or should the ITC remedies be supplemented, as some do suggest, to permit antitrust exemptions by industries adversely affected by unfair trade practices?

Dr. STERN. I believe that the court properly refused to review the President's decision based on the policy grounds. When we make our decisions and send them on to the President, we have decided first on the question of the law, is there a patent—is it valid? Is it enforceable? Has there been injury? And then the President can review our decision not on that basis, but on the basis of policy, is it consistent with the GATT for other reasons? The courts certainly do review our reading of the law, and whether there has been substantial evidence, on the record, upon which we have made our decision. But I think it was proper that they refused to review the President's decision, to turn down the majority's recommendation based on policy grounds.

I might say as an aside that I was in the minority on the question of remedy in that case, and ultimately his decision was consistent with the minority position that I was in.

Mr. BROOKS. Then I can understand your agreement with it. But what if you had been on the other side and the President just turned it over?

Dr. STERN. My position is on the question of the principle, of whether the court should review the President's policy decision.

Mr. BROOKS. And you think they should not.

Dr. STERN. My point on my personal view was an aside.

Mr. BROOKS. I would just say, though, that I wonder what happens to people that, they have no real court accessibility to the President changing. Yet even old Bill Safire on February 18, in the Times spoke about former White House people, distinguished folks like Mr. Deaver, and their South Korean millions, representing South Korea. What if he represented those people? He has access to the White House better than I do, better than Carlos Moorhead, better than any of these people, and maybe better than you. He was there more often. Safire pointed out that when the President and his office, the executive, make these kind of policy decisions, distinct from their own appointed independent agencies, Safire put it very nicely: He said it brings about failure to see, the incipient corruption in the excess of access. I give him credit for that one; I think it is kind of nice. I am going to use that one.

Dr. STERN. Mr. Brooks, if I could.

Mr. BROOKS. Yes; you had a comment on that?

Dr. STERN. Yes; I do.

Mr. BROOKS. You know Mr. Deaver. He is a fine man.

Dr. STERN. No; I have never had the pleasure of meeting him, and you are quite right about my access to the White House, or lack thereof.

Mr. BROOKS. That is normally the case. It is not a reflection on your own capability.

Dr. STERN. Well, I hope it is a reflection on the independence of the Commission.

Mr. BROOKS. It is not. No, no, no.

Dr. STERN. But I do think that we are talking about a distinction between how you apply the trade laws, whether you are going

to emphasize the legal system or the political system, and I think our trade laws are full of examples of both. Section 201, escape clause action, is an example where the President does review our recommendation. I would say that as far as access to the courts, I do not believe this precludes the Duracell people. In this case it is Duracell against Duracell. As you know, it is a gray market case. It does not preclude going to the courts. This is not a process patent. I know today we have been talking about two separate issues here, and I just want it very clear that the Duracell battery case is not a process patent case. They can also go to the court.

Mr. BROOKS. But some of these people feel that going to the courts is in that instance a legitimate opportunity, but it is an opportunity that will not do much for them if you have a fast-moving technology. For example, a chip operation in California, I am not particularly familiar with it, but it is a fast-moving technology. If you are in court for 2 years, the chip about which you are arguing is a dead issue, it is passé. They have passed you. They are producing something else, and the incentive is lost, and you have lost your whole case. There is no way, if you cannot decide it fairly soon, that you are going to get any justice. They have to decide pretty quickly, like yesterday, to go into production or that chip is going to be a dead issue, and sometimes that delay is pretty bad for our people.

Dr. STERN. Well, we have had one gray market case, and that is the Duracell batteries. The Commission was very clear that there was a violation and that where the members differed was on the proper remedy, whether to exclude the goods entirely, these batteries, or require additional labeling. The minority felt that if the imported Duracell batteries had been properly labeled as clearly gray market, that would have dealt with the injury.

Mr. BROOKS. Doctor, when the President changed the Commission's policy on that, did you lobby him for your minority view?

Dr. STERN. I hope that my opinion was persuasive, the opinion that is published and is available. I think that Mr. Bale, who is part of the executive branch, could better tell you how the decision—whether Mr. Deaver was involved or not.

Mr. BROOKS. Well, I guess he does a lot of heavy reading on those things.

Mr. FRANK. Mr. Chairman, will you yield for one question?

Mr. BROOKS. Mr. Frank.

Mr. FRANK. The problem I have with your approach is this. You say it was a clear violation. I assume that means it was not accidental, they did not accidentally come up with fake Duracell batteries.

Dr. STERN. These were the real thing. This was gray market. This was not a counterfeit.

Mr. FRANK. So nobody made a mistake.

Dr. STERN. These were Duracell batteries made in Belgium.

Mr. FRANK. When the remedy is labeling and nothing else, what is the disincentive for trying? If the only penalty for doing something that violates the law is to be told henceforth do not do it, where is the disincentive from trying until you are told not to do it any more?

Dr. STERN. If Congress wants to change a law, that is great, but the way we were trying to administer the existing law in keeping with what Customs has been doing is that the injury is in the confusion to the consumer who then will not go and buy in the future.

Mr. FRANK. I understand that, but my question is, and you can talk about the policy as well, what is the disincentive to the person who perpetrated the injury if the only remedy is that once you are caught you can no longer fool people, then you have no disincentive for the people who are so inclined to keep fooling people until they are told to stop. That is why I do not understand, why does everybody get a shot until they can get away with it and then you say stop it? But there is no disincentive, from now on they have to label them. That is the problem. Where is the disincentive? And if you think that is what the law does not allow you to do, would you think the law ought to be changed? Because it seems to me there ought always to be, for a deliberate lawbreaker, which sounds like what you are talking about, that there is no question that this is a deliberate violation, what is the disincentive to the lawbreaker?

Dr. STERN. At this point, given the remedies that are available under the law——

Mr. FRANK. Would you change the law, then? I know if we want to, we can, and I thank you for reaffirming that. What is your view?

Dr. STERN. There are no monetary damages. We do not award monetary damages.

Mr. FRANK. I am asking you your view. Do you think the law should be changed so that we could have some kind of disincentive, either banning the product for a period of years or something? Do you think as a policymaker, which you are in part, that we ought to change the law?

Dr. STERN. In the particular case of Duracell?

Mr. FRANK. No; I am not asking that particular case.

Dr. STERN. If you ban the product, then Duracell, the company who claim that they are being injured, the actual company, would be further injured.

Mr. FRANK. I am not asking you about this.

Dr. STERN. This is why we do cases case by case.

Mr. FRANK. Fine, and is there something in your charter that bars you from talking about the overall policy? I understand that. I am not disputing the case.

Dr. STERN. No; I have no problem if you would like to give full range.

Mr. FRANK. Please, please. I appreciate your affirmation of our constitutional right to do whatever we want. I am soliciting your opinion. Do you, having experience in this, think that it would be better if we amended the law so that you had as part of your arsenal an ability to give people a disincentive if you found that they had deliberately violated?

Dr. STERN. I believe that giving the Commission a fuller range in terms of remedies would be a fine policy approach. I have no difficulty with it. Given my experience, as you said, and you asked me to respond based on my experience, the Commission has had one case dealing with gray market, and that one case was the Duracell,

and that was the reason why I was trying to rely on that limited experience in order to respond to you.

Mr. FRANK. I understand, but I am asking for a general policy judgment.

Dr. STERN. General policy, if you feel that the International Trade Commission——

Mr. FRANK. No, no; please do not tell me "if I feel." I understand. I thank you for telling me if I feel something, I will do it.

Dr. STERN. As a general policy, I have always felt that the International Trade Commission is very limited, and I have spoken to that in section 201 cases as to the kind of remedy that we can recommend. The intellectual propertey case area is a more narrow area, but I would see no objection in having available to us a full range of remedies in the event that there was other injury and there needed to be greater disincentives to that violation.

Mr. FRANK. I want to separate out the injury from the disincentive. I mean, it may be that a particular penalty is appropriate to give people a disincentive, which may in fact have been disproportionate to the injury involved, because there may be no other way to create a disincentive.

Dr. STERN. Well, this gets to the problem of the International Trade Commission. We are, under the law, now supposed to be looking at injury.

Mr. FRANK. I am talking about changing the law. I mean, I understand.

Dr. STERN. If you took out injury entirely, you are right, you would not have to worry about this issue at all. You would not have to worry about the industry being injured. You could just stop the goods even if there was no injury. That is my objection to taking out injury.

Mr. FRANK. Which I did not propose. I am going to have to leave, and I apologize to the other members. I am a little disappointed at what seems to me your reluctance to want to talk about the policy questions. I would hope that that is the kind of advice we would get from the Commission.

Dr. STERN. Let me try to explain. What I have come to testify on has to do with both the process patent issue, which is not the question you are asking me about now, as well as the question of removing domestic industry, removing injury, and removing economically and efficiently operated from the law. That was what I was asked to come and testify on today. I frankly was not prepared to really give you my proposal on the gray market area.

Mr. FRANK. I did not think it was a trick question, to be honest.

Dr. STERN. I would be happy to further discuss it. I simply was trying to pull it back, because I had not been prepared on the gray market.

Mr. FRANK. I will tackle it in another forum. I apologize.

Dr. STERN. I would like to answer any further questions you might have.

Mr. BROOKS. He will have some more.

Dr. STERN. I would also like to send you the views of the Commission, both of the majority and the minority on this.

Mr. BROOKS. Doctor, I have some more questions for you, and I will submit them.

Mr. Carlos Moorhead.

Mr. MOORHEAD. Thank you, Dr. Stern. It was good of you to come this morning, and your testimony will be helpful.

I think one of the big concerns we all have—and I think everybody knows we are getting beaten over the head with unfair practices by people from abroad. I happened to be in Hong Kong this last August, and you could buy all kinds of computer chips and American products there for pennies on the dollar compared to what they are if you had to pay the companies that actually developed these products. It is very, very difficult to prove damage to an industry where you have a great invention, one that is obviously going someplace, going to develop a great industry, where the industry has not been developed as yet, because there has not been time, and before that industry we can get off the ground here, they are selling the same product from abroad.

What do you do about situations like that?

Dr. STERN. We have had, as I said, about 240 investigations since 1974 under section 337, and of those, 208 have involved patent, registered trademark, or copyright infringement. The great bulk of those, 192, involved patent infringement. We have had only one case where the industry was not able to demonstrate that they had been injured or that there was a tendency to injure or that they were unable because of the imports to establish themselves as an industry. It went off on the question of injury.

Mr. MOORHEAD. Are your figures not warped by the fact that many have not filed petitions knowing that there are these requirements? How many of those petitions have been filed by universities claiming that their industry has been damaged?

Dr. STERN. As I understand it under section 337 a university is not an industry.

Mr. MOORHEAD. That is what I have thought.

Dr. STERN. And the Congress, in fact we go on the congressional direction, obviously. In floor debate when the law was passed in 1922, the principal sponsors of the act referred to industries as including farming and mining as well as manufacturing.

Then again in debates in 1930 Senator Simmons at that time stated that section 337 applies "to all industries alike—wage-earner, farmer, stockman, producer, and legitimate businesses in general have everything to gain."

I will give you those cites after the hearing. Universities are not domestic industries, and the International Trade Commission has been established and has been given this jurisdiction in order to protect domestic industry. The Federal courts are there to protect the university, to protect those intellectual property rights. The Commission is an additional place to go for help when there are imports and when there is a domestic industry, and for that they have to show that there has been some impact on that industry from those imports which are allegedly infringing the patent right.

We want to encourage universities to put their intellectual properties into commercialization. In effect the existing law is an impetus to getting those ideas out of the ivory tower and into the factories and then into the marketplace. Changing that, taking out domestic industry, is a disincentive to commercialize.

Mr. MOORHEAD. But the university really does not have a very good remedy anyplace at the present time.

Dr. STERN. I guess I do not understand what you mean by that. I assume that the courts have been hearing intellectual property rights cases all along.

Mr. MOORHEAD. They hear them, but there is so much time that passes before they actually get into court that the purpose of the invention and the profit has been reaped abroad and it is too late to do anything about it.

Dr. STERN. Could you not give them deadlines?

Mr. MOORHEAD. Give deadlines, but——

Dr. STERN. I mean, the ITC——

Mr. MOORHEAD. The courts are so packed you cannot get in there many times.

Dr. STERN. I understand that problem.

Mr. MOORHEAD. I suspect that if you did not have this requirement, you would have had considerably more than 240 cases.

Dr. STERN. Oh, I agree with you. I think that we would have far—and we would have lots of foreign companies coming, because they would have the equal status with universities, and the university does not even have to be an American university.

Mr. MOORHEAD. Only if somebody was stealing their product and their invention. I would hope our companies would not do such a thing.

Dr. STERN. No, it could be foreign companies against foreign companies. If the foreign company has filed, and as I have mentioned in these statistics, the filings and the receipt of patents from the U.S. Patent Office by foreign companies has grown enormously, they would have standing against a U.S. company or a foreign company in the U.S. marketplace. We would be the arbiter as to who gets the marketplace among the importers. The domestic industry would have no leg up anymore in the International Trade Commission.

Mr. MOORHEAD. What do you do about a new cancer treatment in the biotech area like interferon or something of that kind? There is no industry yet at this time, it is something that there will be a great industry. They apply for a patent here and they apply for one in Japan; the Japanese are selling the product here before it can even get off the ground.

Dr. STERN. As it is now, if there is a demonstration to the Commission that they have been prevented from being established by those imports coming in that have violated a patent right or an intellectual property right, then the Commission would go affirmative.

Mr. MOORHEAD. But how are you going to show the damage to an industry if there is none?

Dr. STERN. We have never had a case that has gone negative based on that, and I can assure you in our other statutes, in our title VII investigations which deal with dumping and subsidization, we have had numerous cases where the industry has been able to prove where the standard is higher in section 337, that there has been a threat to retardation, we call it, in title VII, to the industry's existence.

They tried the retardation argument. We found that there was just the threat of injury.

Dr. STERN. In caulking guns we actually had a section 337 case where we went affirmative based on establishment of a domestic industry. So it has been demonstrated in existing section 337.

Mr. MOORHEAD. It would seem to me from the figures you have given to us that since 1974 there have only been 64 affirmative decisions in this area, when you just have to open your eyes and you can see there are hundreds if not thousands of situations where there are violations of this kind in our industry and our trade is being hurt. You are only scratching the surface, and probably the reason for that is that you have such a restrictive law here that you do not get an opportunity to do the job.

Dr. STERN. There have been only three cases—only one case where we have gone negative based on injury.

Mr. MOORHEAD. But you are not getting the cases filed because they know what you are going to do.

Dr. STERN. It is true, I cannot measure what has not come before me. You are right.

Mr. MOORHEAD. I would like to ask you one question I hope to get a positive answer from you on: Do you support H.R. 1069, the process patent bill?

Dr. STERN. Yes, I do. I think with the points that I made in my testimony about the need for clarification, particularly in the first requirement, in effect it embraces much of what we are doing already in section 337.

Mr. MOORHEAD. Mr. Bale, I just had a couple of questions for you. I agree with most of your testimony. Do you think there are areas in our imbalance of trade and enforcing the rights of Americans that we could benefit or correct by having a more extensive jurisdiction for the ITC and allowing them to hear cases where there is no proof at the present time of injury to an existing industry?

Mr. BALE. We believe so. We do not dispute the facts that Chairwoman Stern has raised in terms of the few number of problem cases so far, based upon historical measurement of the outcomes that have taken place. But the history in this area I am not sure is very much of a prolog to the present problem, because much has changed since 1974 and the number of piraters and the number of countries whose path to economic development we believe is chosen to be one of acquisition freely of intellectual property and the competition that has arisen therefore has become much more significant.

It is impossible to measure precisely or quantitatively those benefits unless based upon something that you would understand, sir—a vote of the industry and the people that we have heard on the complaints arising from infringement that affects marketing into this market, as well as sales in the third markets. This is a very serious problem. In our view the elimination of the injury test in particular would eliminate that uncertainty and cost to those potential applicants for section 337 relief. By eliminating the industry provision you would also open up the possibility to those individuals who have not or institutions including research institutions and universities the possibility to enforce their patent rights through the section 337 process without having yet put the patent

into working operation. So, in a word, we think that the changes that are suggested in H.R. 3776 and H.R. 1069 are very worthwhile.

Mr. MOORHEAD. I think one thing we have run across in this situation, we go home and we tell the general public at public meetings and other places that it is not going to be good for them to have restraint of trade to have all kinds of protectionism built into the law, but the problem is that we are getting an unfair set of rules from various countries. They will not enforce our patent laws or they do not enforce our copyright laws or they will not give our people permission to sell products in their country, and we tell them it is a slow thing and there is no remedy right now, and they say what is wrong with you people in Washington, we are getting eaten up alive, our industries are getting hurt, our people are unemployed, and yet you give us all kinds of excuses why you should not do anything. I think these bills are trying to do something.

Mr. BROOKS. Would the gentleman yield?

Mr. MOORHEAD. I would be happy to.

Mr. BROOKS. What is the trade deficit now, $148 billion last year? That is jobs and property, opportunities, and legal fees, lawyers, consultants, and accountants, not just jobs for people that work with their hands. There is a lot of high-technology supervision in there that we do not have; we are exporting it, $148 billion, and you act like it is no problem.

Mr. MOORHEAD. I want to thank you folks.

Dr. STERN. If I may, I did not give you an entirely complete answer on your universities. We did have a university come. They do have standing before us if they license their intellectual property right to a manufacturer, so universities do have standing if they license. They have to have that manufacturing there that is the hook that makes it a domestic industry. I do believe that the pirates out there are big and they are getting bigger and more diverse and talented, but I am at the ITC there to protect domestic industries, not the consumer as much as the domestic industry. The Consumer Protection Agency is there to protect the consumer, and the FTC.

Mr. BROOKS. Mr. Boucher.

Mr. BOUCHER. No questions, Mr. Chairman.

Mr. BROOKS. Mr. Kindness.

Mr. KINDNESS. Thank you, Mr. Chairman, and thank you, Dr. Stern, Mr. Bale, for your enlightening testimony this morning.

I can see, Dr. Stern, from your testimony that there are some problems to be very seriously addressed in having a duality of forum or approach to the enforcement of intellectual property rights. At the same time I share the concern that has been expressed about how we can have the most immediate, the quickest effect upon those practices that are viewed as unfair in international trade affecting our marketplace. I may indeed have some followup questions that I would like to submit, but for clarification right now, is it correct to assume that you would agree that we do have a governmental responsibility to protect intellectual property rights, and the question is what should be the forum? Is that basically a correct characterization of what you are presenting to the subcommittee?

Dr. STERN. I am satisfied with the ITC as a forum with the law as it exists. When you start taking out the question of the requirement of domestic industry, when you take out the requirement for injury, then I question why is the ITC still involved, given the fact that we are there also to take into account public interest and given the fact that we are a trade agency.

Mr. KINDNESS. I would like to get into the policy area and have your response to this sort of a suggestion, broad and generic in nature, but perhaps helpful in examining this intellectually at least. If there were to be a policy determination, the Congress passed legislation to implement it and the executive agreed, the President signed the bill and it provided for a rather arbitrary approach that let us say could be instigated by the injured or alleged injured industry or let us just say the intellectual property right owner could go to another Government agency, let us say the Bureau of Customs, and make an allegation, a complaint, that goods are being imported into the United States in violation of the intellectual property rights owned by that person, and that there would be a strictly abbreviated administrative proceeding that says these goods shall be barred unless and until the owner of the goods, the importer, or the provider of those goods from a foreign country were to go to court and use the court system to establish the right to have those goods imported into the United States, and this would take the ITC out of the cycle altogether, is that a policy direction that you would criticize or espouse?

Dr. STERN. No, sir. They already can do that now for copyrights and registered trademarks. That is why I was trying to discuss with Congressman Frank the Duracell battery case. I was so anxious that the ITC not apply a law that was different or read the law differently from the way our sister agency, the Customs Service, does in this trademark case. They, the Customs Service, already can do that at the border. I have been at the entry ports, and I have seen them do it when it comes to copyrights and registered trademarks.

Mr. KINDNESS. Right, and with respect to patents you would not differ.

Dr. STERN. I have no problem with that.

Mr. KINDNESS. Including the product of a process patent infringement.

Dr. STERN. I have no problem with that. You get into this whole evidentiary issue, and under our law we have to now use the Administrative Procedures Act. Some would say it is even more costly than just the existence of the injury standard. I mean, it is just that procedure which is the cause.

Mr. KINDNESS. As a matter of policy, under our international trade agreements and so on, would we be likely to be in violation of GATT agreements and bilateral agreements if we were to effect such a policy with respect to the products and the products of process patent violations?

Dr. STERN. I think this gets back to what Dr. Bale has pointed out, article 20, the U.S. claims in closing our intellectual property rights I assume under that interpretation would be GATT.

Mr. BALE. That is correct. There is also an element to the way we deal with domestic products vis-a-vis imported products as well.

There is a provision in the GATT, in fact it is article 3, paragraph 4, which is the so-called national treatment provision. So long as we do not discriminate the way we protect our intellectual property we do not somehow, and this is the concept underlying the GATT that we have benefited from internationally for many years— that our exports into France say do not receive any worse treatment in the protection in France of their intellectual property than French products do. That is one principle that also has to be looked at in the GATT context. But in a word, so long as that condition is met, there is no problem with that approach that you suggest.

Mr. KINDNESS. Even though there is not an opportunity for an immediate evidentiary hearing and process but there must be resort to the Federal court system in order for the importer or the owner of the noncomplying goods to perhaps take 2 years in court to deal with the matter. Well, I thank our witnesses. I think there are some important considerations there that indeed might suggest a less expensive way initially to deal with the problems we are confronting too in that the noncomplier or infringer would have to use the court system and it would be a sort of quick and dirty administrative process that would be involved in initially saying stop right here until this dispute is settled.

Dr. STERN. Mr. Kindness, if I might, I think that if it is not correct that all of the answers you have been given and that everything you have suggested is GATT-legal, and I suspect that the lawyers will go back over these answers on whether it is GATT-legal or not, then I would like to suggest perhaps even another middle ground, and that is retaining the domestic industry requirement, keeping the ITC in it, retaining the domestic industry requirement, retaining the current injury requirement but not for the patent, copyright, or registered trademark infringement cases. In those cases you could change the injury standard to require only that there had been some demonstration that sales had been lost, which is very easy to document, and removing the need to demonstrate that the effect of those lost sales was to hurt the domestic industry. Or if you even wanted to lower the injury standard even further you could establish a rebuttable presumption of injury for cases involving those infringements of patent trademarks and copyrights. And then you could take the requirement on the economically and efficiently operated out of the provisions where they are now where they have to be proven under the APA provisions, which can be subject to some discovery abuses, take it out of that and put it into our public interest section, which is not subject to a whole trial. In the event, which has never happened so far, that we found that there was a violation and there was an industry and there has been this lower standard of injury but for some reason the public required this product, such as penicillin or something, the public needed the product and there was at this point no U.S. industry that would be able to produce the penicillin because they were not economically efficient, and not willing to license then we could take that into account in the public interest area.

That would be the only reason why you would possibly want to keep efficient and economically operated. But you take it out of where it is now and put it in the public interest area. That I think

would deal with a lot of the desires to assure even greater access if there are people out there afraid to come to the ITC by lowering the injury standard and taking out the efficiently and economically operated from where it is and putting it in the public interest.

Mr. BROOKS. Thank you. Do you have any further questions.

Mr. KINDNESS. Mr. Chairman, I yield back. Thank you.

Mr. BROOKS. Thank you, Mr. Kindness.

Mrs. Schroeder.

Mrs. SCHROEDER. Thank you, Mr. Chairman.

Dr. Bale, I get the frustration that we all have, and the reason these bills keep getting generated is that if you really look at the United States and its trade imbalance and figure out where the jobs are going to be 5, 10 years from now, it is probably going to be intellectual property. I think smokestack industries are probably never going to be competitive again as we would like. One of the frustrations that I have is that we just see such blatant violation by supposedly allies at least in the military area, but they are certainly not allies in the trade area, and we keep letting it go by the board. Everybody talks about the Singapore ads that they run in the Washington Post, you know, free trip to Singapore, and all you have to do is carry the little briefcase, and of course in the little briefcase is loaded up with whatever it is they want to copy and serving on the Armed Services Committee when we were over there.

I asked Lee Kwan Yu about this and he acted like I had worn a bathing suit to church, and proceeded to give me a long lecture about how we, the Americans, were stopped from asking him such questions because we had allowed the Japanese to copy everything we had done, and that is how they had rebuilt, and everyone in Southeast Asia by golly was going to follow the Japanese pattern, and since we let them do it, we could not protest now, and on and on and on.

I literally got the same response from the Koreans and everybody else.

Now, I mean we are talking about how do we handle it here, but is there not anything the Trade Representative can get the administration to do about handling it over there so they just stop the copying? They all have laws that are way out of date or laws that they claim they look to me like they cover, but they say no, they do not, because you say it was written under the British, and at the time it was written there was only printed matter—oh, they have 45,000 reasons for everything. But meanwhile they are cleaning our clock, I mean there is no place over there where you cannot have American movies copied, anything American copied in gross numbers, and it is out on the street 24 hours a day and no one is doing anything about enforcement, so while I support these measures, what else can we do to get that message across, because as I read the Constitution really only the administration can do that.

Mr. BALE. Congresswoman, that is a very good question. In fact, if you went to Singapore, or Congressman Brooks' constituent went to Singapore, he certainly would be able to buy that watch for a lot cheaper than $85. In fact, I think he paid twice as much.

Mr. BROOKS. I will tell him he was ripped off.

Mr. BALE. He was ripped off. He is ripped off if he paid more than $35. The issue that is raised about enforcement at the source is a key question here. I would have to say that when you address this question to the Trade Representative's office, this issue has only historically been addressed as part of 337, and to some extent the domestic manifestations of this piracy issue have only been addressed in that way. In 1984 we worked very closely with the Congress on certain provisions regarding GSP, the generalized system of preferences. The countries that you mention, out in Asia, outside of Japan, are all current beneficiaries of the GSP, preferential tariffs given by the United States for the development of these countries. Should we be giving these preferences to these countries if they continue acts of piracy, either condoning them in a positive manner or at least passively sitting by while these activities continue? The answer clearly is "No."

Now, we do have a procedure which we are implementing and in consultation with the Congress. We have that provision of the 1984 act, renewal of GSP, to take those practices into account. That is one way to deal with that. And this year is a very critical year in that process, because this is a year in which the law kicks in the review of practices abroad with regard to the continued eligibility of countries under the GSP.

Second, the administration addressed the Korean problem as a first stop on the way to a more aggressive attitude toward these problems by initiating a section 301 unfair trade practice case against the Koreans which we are pursuing very vigorously. We would be happy to consult with you and other interested Members of Congress on the state of that play.

We are also pursuing the issue multilaterally. One thing we have got to do is to get our other developed trade country partners, the Europeans, the Canadians, the Japanese, to pursue the issue more vigorously internationally. We are out there almost alone currently with a very energetic program to deal with the problem. Other countries deal with it either more subtly on a case-by-case basis as a problem arises rather than more systematically. We are trying a systematic approach, and again, we would be most happy to go into this issue further if you would like further written comments.

Mrs. SCHROEDER. I thank you, because, as I say, my frustration is, while these bills are fine, I still see we are so far away from controlling the source, and I just do not understand why we cannot control the source. It seems to me the problem gets bigger every year and we keep talking about it, and I do not think the Canadians are ever going to join us because they do not have as much at stake. I mean, they are not—the people are not trying to copy Canadian movies and Canadian sitcoms and Canadian music, and the Japanese do not dare because all those countries turn around and say, hey, that is how you made it, right, right, OK, back off. And they know that, so they are not going to play, and I think we are going to be stuck out there by ourselves, and I think we just are going to have to be as aggressive as we can be. Maybe we will have to put Jack Brooks in charge of the program. He would straighten it out.

Mr. BROOKS. I do not think I will apply for that job. If I did, I do not think Reagan would appoint me to anything. And if he did, I would not accept it. Mr. Coble.

Mr. COBLE. Mr. Chairman, thank you. I apologize to you and to the witnesses, I have been in and out most of the morning because of other committee meetings. I thank Mr. Bale and Dr. Stern for appearing.

I will make a brief statement, Mr. Chairman. Oftentimes we see witnesses who come before this committee and almost without exception they come in here dressed in their bureaucratic straitjackets, and Dr. Stern, I want to read your statement, but you come across sort of as rigidly independent and perhaps inflexibly bureaucratic to me. I want to read your statement, and I hope the written word will have a different interpretation than has the spoken word.

I make this point, Mr. Chairman, because, like you say, we are drowning in red ink, and if we can have a good flow or good exchange here where you all can tell us what we can do to provide you with tools to help you get the job done and maybe cause some of that red ink to disappear, that should be our reason for being, and I thank both of you for appearing as witnesses.

Thank you, Mr. Chairman.

Mr. BROOKS. Thank you, Congressman.

Congressman DeWine.

Mr. DEWINE. No questions, Mr. Chairman.

Mr. BROOKS. I want to thank you, Dr. Stern and Dr. Bale, we appreciate your being here. Thank you very much.

Mr. BALE. Thank you, Mr. Chairman.

Mr. BROOKS. We will submit a few questions for both of you.

The second panel consists of two prominent patent attorneys also in management positions with two of the leading research based pharmaceutical and scientific products firms in this country: Thomas Kiley from Genentech will testify first, followed by Roy Massengill from Allied-Signal.

Gentlemen, if you will come up.

STATEMENTS OF THOMAS KILEY, VICE PRESIDENT, GENERAL COUNSEL, GENENTECH, AND ROY H. MASSENGILL, GENERAL PATENT COUNSEL, ALLIED-SIGNAL, INC.

Mr. BROOKS. Mr. Kiley, we have your statement, and I have read it. You might like to paraphrase it for us.

Mr. KILEY. I will do so, Mr. Chairman.

Thank you, Mr. Chairman. I am vice president for corporate development of Genentech. I have represented Genentech in patent matters since its inception in 1976. I joined the company full time in 1980, and for about 11 years prior to that, I engaged in the trial practice of intellectual property litigation in the California area.

Our company was founded to exploit the new science of genetic engineering. We are a leader in that in the world today. We employ about 900 people. We have been a productive company. As examples, I would cite human insulin, the first product of recombinant DNA technology to be approved for sale in the United States, and human growth hormone for the treatment of growth deficien-

cy, the first product to be developed, manufactured, and marketed by a biotechnology startup in this country.

Each of these products is old in itself, and yet it became available for the first time in significant quantity as a result of our development of processes for its commercial manufacture.

Now, the Congress has already recognized the importance of patents in the biotechnology industry. It did so by making special provision for process patents at our request in the Drug Price Competition and Patent Term Restoration Act of 1984.

The point of our testimony today is to urge the adoption of H.R. 1069, with the idea that the protection Congress has promised for process patents will be realized in fact rather than be conveniently sidestepped by offshore manufacture.

Now, Mr. Chairman, the first products of biotechnology are coming in the pharmaceutical area. I have mentioned human insulin; I have mentioned growth hormone, and many others are under development, agents for the treatment of heart attack, cancer, various viral and parasitical afflictions, agents for the promotion of wound healing, bone growth and many others.

This sort of research is expensive. And the means by which we raise the funds to conduct that research are critically dependent upon the perception by investors that will be able to protect the fruits of that research. Yet many of these products are old in themselves, and so it is on the process patents that we must critically rely.

We will see in biotechnology the emergence of products novel in their own right. But at present, and I think for many years to come, the great majority of the products of our new industry will be products old in the body, products drawn from the body's rich library of useful proteins.

There are a number of reasons for this. First, from a regulatory standpoint, these drugs are less forbidding. They are friendly drugs. They have evolved in the body over many years for specific and beneficial purposes. The problem is that when people get sick they don't have enough of them. Our new industry can make them available in the quantities required for the treatment of disease.

Product protection will be available in some cases and in many other cases it will not, in part because of the way we first find these. It is often the case that one group will discover and characterize one of these body products and make it available in minute quantities. Another group will then make it available, using biotechnology, in quantities that are commercially, medically, meaningfully significant. And it is that activity that we must encourage lest the discovery of these proteins be reduced to a matter of academic interest only.

Our industry, though it is beginning with the development of pharmaceutical agents, is by no means limited to that area. I think one recent example is especially pertinent to the subject of H.R. 1069. Our company, working with the Lubrizol Corp. of Ohio, recently developed a microorganism that greatly simplifies the manufacture of a commodity chemical, ascorbic acid, or vitamin C. Until the present that chemical has been manufactured by a tedious and capital intensive six-step process.

We have taken five of those steps and compressed them into a single bacterium that performs them in a single fermentation. The economics of that process are far better than the prior process, but the end product is the same: Vitamin C, and it can't be patented. Now shall we invest in domestic capacity for the utilization of this new process or can it be expected that our markets will be flooded with products made overseas by the use of that process? Must we be left to rely on process patents in such countries as the People's Republic of China, and Yugoslavia, two countries that currently are attempting to increase their export of vitamin C to the United States?

We have to remember that patents exist to protect marketplaces, not manufacturing locations. The American marketplace is a magnet for foreign producers. It is also the marketplace that is most accessible to startup companies in the United States, like our own. It is the market our company has targeted for the introduction of its first product. And for us and for any company intent on exploiting the products of its research in our domestic market, patent protection is of critical importance.

We have filed many patent applications around the world. That's an expensive process. Perhaps other companies are less able than we to engage in that expense. But beyond the expense of seeking patents, where in fact they are available, there are real problems in enforcement. If Genentech must go overseas to protect its domestic market and sue on a process patent in a first foreign country with the result that the competitor moves his operation to a second foreign country, what have we gained?

In this way, American manufacturers can be driven from pillar to post, while being denied in this country the process protection that in a single economic adjudication would protect their marketplace. For these reasons we urge passage of H.R. 1069. I think that it is something that is sensible, I think it makes for economy of adjudication and I believe it is of critical importance to our own industry and many other high technology industries.

I don't think the remedies before the Trade Commission are adequate substitutes for meaningful process patents. While I have discussed at some length in my statement some perceived inadequacies of ITC proceedings, I will leave that for the written statement and to the following witness.

I would like to say only that the proposed legislation, H.R. 3776, addresses many of the difficulties with ITC proceedings. But it doesn't go far enough. There are significant problems remaining, even if H.R. 3776 is adopted; no dollar damages; no preliminary injunction, at least as a matter of history; no trial by jury, a remedy increasingly favored by patentees out of the perception that jurors favor innovators, as should the Congress.

And so, while 3776 is a useful piece of legislation, to me H.R. 1076 is far more important.

In conclusion, I would like, if you will permit me, to engage in just a little flag-waving. In biotechnology our factories are the microorganisms that we call into being from genetic engineering. In building biotechnology in this country, we had to persuade the U.S. Supreme Court that we were entitled to patents on our factories and we succeeded in doing so in 1980.

Now the factories are moving overseas, but one thing is certain: Without meaningful process patents the products of those microbial factories and of the processes they perform are going to come roaring back onto our shores. From inception and until very recently the principal product of the biotechnology industry has been hope. Those hopes are beginning to be realized, and I think American industry is entitled to a substantial share of the credit for that.

Whether American industry will have its fair share of the reward for its investment in research is critically dependent upon the availability of sound patent protection and, at this juncture, upon the Congress.

I have not said anything in my written remarks about the bill, H.R. 3426. I think it is a relatively noncontroversial bill. Suffice it to say that Genentech supports the passage of that legislation as well.

That concludes my statement.

[The statement of Mr. Kiley follows:]

Genentech, Inc.

STATEMENT OF

THOMAS D. KILEY, ESQUIRE

VICE PRESIDENT, CORPORATE DEVELOPMENT

GENENTECH, INC.

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE
ADMINISTRATION OF JUSTICE
COMMITTEE ON THE JUDICIARY
UNITED STATES HOUSE OF REPRESENTATIVES

ON
H.R. 1069
TO PROTECT PROCESS PATENT OWNERS FROM
IMPORTATION OF CERTAIN GOODS INTO THE UNITED STATES

H.R. 3776
TO ENHANCE ENFORCEMENT OF INTELLECTUAL
PROPERTY RIGHTS IN INTERNATIONAL TRADE

February 19, 1986

Mr. Chairman, I am Thomas D. Kiley. I am Vice President for Corporate Development of Genentech, Inc. Prior to my arrival at Genentech in 1980, I practiced intellectual property law in Los Angeles for approximately ten years. I am also formerly employed by the United States Patent and Trademark Office.

Genentech is a California company founded in 1976 to develop products of the new science of genetic engineering. Today it is a leader among companies of the world pursuing the products of biotechnology. It employs approximately 900 highly trained and dedicated people and in 1986 will add significantly to its staff. As examples of the Company's productivity may be mentioned human insulin, the first human pharmaceutical product of recombinant DNA technology to be approved for sale in the United States, and human growth hormone for the treatment of growth deficiency, the first pharmaceutical product of biotechnology to have been developed, manufactured, and marketed by a biotechnology company itself. Each of these products, old in itself, became available for the first time in commercial quantities as a result of Genentech's development of practical processes for their large scale production.

Congress has already recognized the primacy of process patent protection for the biotechnology industry. In response to our showing of the importance of such patents to the industry, specific provision for them was made in the Drug Price Competition and Patent Term Restoration Act of 1984 (in

pertinent part, 35 U.S.C. 156). Today, we urge the adoption of H.R. 1069 to ensure that the protection Congress has promised for process patents will be realized in fact, rather than being conveniently sidestepped by offshore manufacture.

While the United States leads in the application of biotechnology, it is too soon to say that the industry is either established, economic or efficient in the United States. It is an industry undergoing its birth pangs. It is fragile, and like any infant needs to be nurtured if its hope and promise is to be realized.

The first products of biotechnology are coming in the field of pharmaceuticals, where long lead times to market and very large investments in clinical testing underlie the vital importance of proprietary protection. As companies bootstrap themselves into existence, licensing income, equity investment and tax-inspired investment in research and development partnerships all depend critically on the perception that the fruits of research will be protectable. Yet many of the products involved are old in themselves, and it is the patentability of the underlying processes upon which reliance must be placed.

In biotechnology we are beginning to see the emergence of novel products which might support patents in their own right. But the first generation of the industry's products, and the majority of those products for many years to come, will be drawn from the body's own rich library of useful

proteins. Here the regulatory barriers are less forbidding, because these are "friendly" drugs that have evolved in the body for specific and beneficial purposes. But in persons afflicted with disease, they are often not present in sufficient quantity to perform their intended service, nor available from sources other than those biotechnology can now provide. In addition to the human insulin and human growth hormone products now on the market, many others of this kind are now undergoing development: tissue plasminogen activator for the treatment of heart attack; factor VIII for the treatment of hemophilia; interferons and other products of the body's immune system, variously for treatment of cancer, viral and parasitic infections; and factors for the promotion of wound healing and bone growth, to name a few. Also under development are vaccines for diseases ranging from hepatitis and herpes to AIDS.

In some of these cases, product protection will be available to the companies that for the first time provide meaningful supplies of the life-giving product. In many cases it will not, owing to the prior existence of minute quantities of pure material. It is often the case that these agents of the body are discovered first by one group, and made available in quantity by another. It is the latter activity that we need most to encourage, lest the former become of academic interest only. The grant of meaningful process patents is the way to do it.

Biotechnology is not limited to the pharmaceutical case. As one example of the extension of the technology into other fields, I would like to mention ascorbic acid, commonly known as Vitamin C. In the past, Vitamin C has been produced by a tedious and capital-intensive six step process. In collaboration with Lubrizol Corporation, Genentech recently engineered a bacterium that replaces five of these steps with a single fermentation. The economics of the process are greatly advantaged, yet the end product will be the same: Vitamin C which cannot itself be patented. Should one now invest in domestic capacity for the new process, or can it be expected that our markets will be flooded with the unpatented product, made overseas by use of our process? Or should we be left to rely upon process patents, if available at all in such countries as Yugoslavia and The People's Republic of China, each of which is seeking to increase exports of Vitamin C to the United States?

The United States market is both a magnet for foreign producers and the market most accessible to biotechnology startup companies like our own. It is the market in which Genentech has made its first product introduction and the market for which we are targeting products of the future. For us, and for any company intent on protecting the United States market for products of its research, United States patents assume predominant importance. This is so because it is for

the protection of marketplaces, not manufacturing locations, that patents exist.

To begin with, it seems hard to require a company intent on commercialization of its product in the United States to seek patents in every country of the world that offers them, if the domestic market is to be protected. Even if the burden of patenting processes everywhere else in the world is assumed, one is often left with protection of uncertain character, particularly in the developing nations. Beyond these considerations, there is an important issue of practicality in enforcement. If Genentech seeks to protect its United States market by a patent suit in a first foreign country, with the result that our opponent simply relocates to a second foreign country, what have we gained? In this way, American manufacturers can be driven from pillar to post, seeking in one foreign proceeding after another the protection that their own country has made unavailable. On the other hand, if suit were possible in the United States for the import of products made abroad using a patented process, then in a single proceeding a single, definitive result could be obtained. It is that economy of adjudication we seek, and for that reason we urge the passage of H.R. 1069.

As presently constituted, International Trade Commission ("ITC") remedies available under the Tariff Act of 1930 (19 U.S.C. 1337) are inadequate substitutes for meaningful process patent protection:

- The necessity of demonstrating injury to an efficient and economically operated industry, or an effect or tendency to prevent the establishment of such an industry, is a burden beyond those present in conventional patent actions. It is a burden not shared by process patent holders in many other countries where protection like that in H.R. 1069 is already available. And foreign industry will invariably be more efficiently and economically operated if it can forego the burden and expense of original research.
- Tne Tariff Act contains no provision for the entry of exclusionary orders in the event of default by the party charged; the complaining party must still go forward with his proof.
- The entry of an exclusionary order, without more, is an inadequate deterrent to repeated attempts to move goods across our borders, as no provision is made for seizure and forfeit.
- Under current ITC jurisprudence, it is open whether relief is available to a patentee who does not himself manufacture and sell the goods involved. Under present law the rights of universities and individual inventors before the International Trade Commission are unresolved.

Each of the foregoing problems with pertinent sections of the Tariff Act of 1930 would be resolved by the passage of Title II of H.R. 3776. For those reasons, Genentech supports that legislative initiative. By itself, however, it is not enough.

The passage of legislation incorporating Title II of H.R. 3776 without the concurrent passage of H.R. 1069 would leave important problems unresolved:

- Process patent holders would remain subject to the discretion of the International Trade Commission. Where the Commission favored entry of an exclusionary order, the process patent holder would remain subject to veto by the Executive. More certainty is required than the act offers, if investment in research is to be encouraged.
- Under appropriate circumstances, preliminary injunctive relief is available in patent cases. The International Trade Commission has never granted preliminary relief.
- Monetary damages for past infringement are available in conventional patent actions. They are not available from the International Trade Commission.

- The jury trial of patent actions has increased in recent years, as a result of the perception that juries favor the innovator, as should the Congress. Manifestly, jury trial is unavailable in actions under the Tariff Act of 1930.

* * *

In biotechnology, our factories are the new micro-organisms that result from genetic engineering. In building biotechnology, we had to persuade the United States Supreme Court that we were entitled to patents on our factories and in 1980 we succeeded in doing so. */ Now the factories are moving overseas, but one thing is certain. Without meaningful process patents the products of those microbial factories, and of the processes they perform, are going to come roaring back onto our shores and into the United States marketplace. From inception and until very recently, the principal product of biotechnology has been hope. Those hopes are beginning to be realized, and American industry is entitled to a substantial share of the credit for that. Whether American industry will have its fair share of reward for its investment in research is critically dependent upon the availability of sound patent protection and, at this juncture, upon the Congress. We urge the adoption of H.R. 1069 and of Title II of H.R. 3776.

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*/ Diamond v. Chakrabarty, 477 US 303.

Mr. Chairman, this concludes my formal statement. I shall be happy to respond to any questions members of the Committee may have.

Mrs. SCHROEDER. Thank you very much. We appreciate it.

Now we will be happy to hear from Mr. Massengill, Allied-Signal.

STATEMENT OF ROY H. MASSENGILL, GENERAL PATENT COUNSEL, ALLIED-SIGNAL, INC.

Mr. MASSENGILL. Thank you, Madam Chairman.

I am the general patent counsel of Allied Signal.

The recent combination of Allied Corp. and the Signal companies has created one of the world's largest high technology corporations. In 1986 we will spend more than $1.2 billion in research, development and engineering. We are in high technology in such diverse fields as strategic materials, aerospace, electronics and electro-optics. In the years 1984 and 1985 the combined companies had issued in the U.S. Patent Office almost 600 patents each year. We are a large user of the patent system. About 40 percent of those patents are process patents.

I wish to thank this committee for holding these hearings today. It is very gratifying to see and hear the comments from this committee, because I think a lot of you have a very keen grasp on what is going on.

Since I have a written statement, I would like to offer that for the record, Madam Chairman.

Mrs. SCHROEDER. Without objection.

Mr. MASSENGILL. Since the other witnesses stated their legislative cases very well, I would like to use my time to tell you briefly what is going on in American industry, if I may take that time.

Mrs. SCHROEDER. Certainly.

Mr. MASSENGILL. Our corporation employs over 160,000 people. Most of them are in the United States. If there is one State in the United States where we don't have employees I would be surprised. But that number is going down, and I would commend you, Madam Chairman, for your keen observation earlier that our jobs are moving into the high technology area. That's where the action is going to be, and that is where we have to concentrate on the laws of this country—to update them to protect future industry and jobs.

We are operating under some laws that were developed in the 1920's and 1930's. Half of the products sold now weren't even in existence; they were not even dreamed of back at the time these laws were developed. The ITC, I think, does a good job with the tools they have to operate with. They just don't have enough tools or the right tools to do the job.

I think, quite frankly, the legislation, the amendments that are proposed to amend 337, in conjunction with process patent legislation as proposed in H.R. 1069, would give industry those tools, if this legislation were to be enacted as proposed.

I would like to comment briefly on Dr. Stern's concern about domestic industry and state Allied Signal's position. We do not object to having a requirement of some sort of business entity or a type of industry where there is an investment. Universities I think are a special case that would have to be an exception. But as far as Al-

lied's position, we can accept Dr. Stern's concern about some type of domestic entity.

But there are two very significant provisions in H.R. 1069 that I think that we should continue to pursue, and I don't think they should be precluded from that legislation.

One is the presumption of infringement where the American patent holder has taken every reasonable step to prove infringement but, because of the lack of discovery in foreign jurisdictions, he is unable to get the facts. After all, the infringer or, the manufacturer are the parties who have the facts, and they should be required where discovery is denied to come forward and establish that their process is not infringing.

I believe certainly in due process of law, and I think there are adequate safeguards even with a presumption of infringement where the patentee has made those reasonable efforts. Enforcing intellectual property rights is very difficult under the best of circumstances. Merely for the purpose of giving this committee some idea of the exposure that I have had in the protection of intellectual property, I have worked in the U.S. Patent Office as an examiner; I have worked for the Monsanto Co. as a patent attorney, and I have been with Allied for 19 years, Chief Patent Counsel during the last 15 of those years.

I have been responsible for looking after the intellectual property matters worldwide for this corporation that has approximately 1,200 locations in close to 100 countries. It is a very difficult problem. But I am not here to talk about the problem we have internationally in protecting our property rights.

Madam Chairman, you have touched on a very important area with regard to what is happening offshore, but I think what is disgraceful is what is happening onshore here with regard to process patents. Just to illustrate, insulin, that Mr. Kiley referred to, is not patentable. He develops a process in the United States at great expense to make insulin. Anyone can move offshore, to Canada, if you haven't filed for a process patent in Canada, or the Caribbean, anyplace, places that don't even have a patent system, where you can't protect your process even if you could afford it and make insulin by copying the process from the U.S. process patent and ship it back into the United States.

Surely, Congress will do something about that practice. I think that most of the industry certainly supports that action. I don't hear too much objection except in one area of industry, and I fail to understand what their problem is. Because practically every product can be made by a number of different processes, by this industry's own admission. It seems to me that if this legislation is enacted, no one is really being put out of business.

What it is really saying is that someone is going to be harmed. Well, I submit that someone is being harmed today. It's that person who commits his risk money, develops a new process and then finds out that there are many other uninvited people eating his lunch. And this is not very encouraging to keep committing capital.

I feel that U.S. industry is going to have to reconsider their practices in the way they handle their trade secrets and their patents. As you know, in order to get a patent under U.S. patent law you are required to make a full disclosure. We are required to make

that disclosure to get a limited exclusionary right. If someone can take that process that you have been required under our patent laws to disclose, move offshore and produce the product; we haven't received a full remedy. That's why we support H.R. 1069 very strongly.

With regard to the amendments of 337, I commented briefly on those earlier and I am skipping around, but I consider that both of those bills are essential for a complete remedy. As I mentioned earlier, enforcement of intellectual property rights is very difficult under the best of circumstances. Even in the United States where we have access to all of the courts it is still very difficult. But with regard to the amendments of 337 I think that the requirements that industry establish injury through showing they have an efficient and economically operated industry is too burdensome on a patentee.

Moreover, there are a lot of research projects as well as universities that cannot meet that requirement. To make matters worse, during the most crucial time in the commercialization of a product, when it is in its infancy and when you are trying to create capital to promote this product, to then see that someone else is copying your work and competing unfairly with you.

So I think that the requirements for injury should be merely showing that your intellectual property rights have been violated.

I would like to relate some of our experiences in dealing with this problem. We are the developers of amorphous metal. We created an industrial product out of what had theretofore been a laboratory curiosity. We brought an action in the ITC. We were able to establish an industry under their review, and we did get a general exclusion order, but only after we had produced probably 400,000 to 500,000 documents of all of our marketing plans, all of our strategic plans, everything that we had ever created in 14 years. That was a burden that we should, as an industry, not have had to have gone through. Needless to say, it cost several hundred thousand dollars.

I am concerned about small companies in this country where the employment is being generated. It is not being generated in large companies like ours because we can't protect ourselves in the smokestack industry. We are cutting back employment in spite of spending $1.2 billion a year in RD&E. The little companies can't afford an ITC proceeding. Maybe that's one of the reasons they haven't done so many.

I think that is a good point to touch on with Dr. Stern, in that by requiring going through an expensive exercise to establish injury, I think they are out of court before they get in, because they can't afford it. These ITC proceedings are very expensive. You would be shocked if I told you how much we have spent on our ITC proceedings. And this presumption of the burden shifting is another aspect I think that ought to be corrected.

No sooner than we got out of the ITC with the exclusion order than we were back in again and spent another million dollars on an advisory opinion to see whether or not the respondents had really generated a noninfringing process. So it never ends, even though admittedly to the world we are the recognized creators of a commercial product from amorphous metals.

So those are some of the things that are going on in industry that we are trying to deal with.

I was going to relate the Corning Glass problem, but I think I have used up my time. Let me just say that Corning Glass won their case and yet they did not get a remedy because they couldn't show injury. That's another reason, and certainly that is a good reason.

Just one more comment, if I may. There have been statements that we have lost our case and that we are just griping about it because we lost our case. We are capable of taking our lumps; we have taken them, and we have a lot of scar tissue to show for it in trying to enforce our intellectual property rights. But there are two cases—that may not seem like a lot—but if you are involved in one of them and you have spent $100 million developing something, you see it taken away from you, you don't have to have very many cases I don't think to be injured severely.

Thank you, Madam Chairman.

[The statement of Mr. Massengill follows:]

Testimony of

ROY H. MASSENGILL
General Patent Counsel
ALLIED-SIGNAL INC.

February 19, 1986

before the
HOUSE COMMITTEE ON THE JUDICIARY
Subcommittee on Courts, Civil Liberties
and the Administration of Justice

on

INTELLECTUAL PROPERTY AND TRADE
H.R. 1069, Title II of H.R. 3776, and H.R. 3246

I am Roy H. Massengill, General Patent Counsel for Allied-Signal Inc. The recent combination of Allied Corporation and the Signal Companies has created one of the largest high technology corporations in the world, with annual expenditures for research, development, and engineering of over a billion dollars in such diverse fields as strategic materials, aerospace, electronics, and electro-optics. We received nearly 600 U.S. patents in 1985. Worldwide, Allied-Signal has more than 35,000 patents granted or pending; and, nearly one-half would be considered process patents.

I wish to thank you, Mr. Chairman, for scheduling today's hearing on these most important issues. And, I particularly want to thank Congressman Moorhead for his leadership in this intellectual property concern.

While I am formally here on behalf of Allied-Signal Inc., I would like to point out to the Committee that the need for change in process patent law is actively supported by over 70 individual American companies and 12 major trade associations (Attached is an October 17, 1985, letter which lists those supporters.).

The one thing almost all those companies have in common is a most-active research program and a need to make certain that the fruits of their research are adequately protected from

unfair foreign usurpation. If we cannot adequately protect our process inventions in this country, we may have to reconsider our research investments in the future. A hypothetical example may help illustrate the problem:

> Suppose Company X finds a new way for producing insulin. As you know, the product (insulin) is not patentable since it is an already-existing substance. However, the process may be (and let us assume in this case it is). That patent would give Company X a right to sue for infringement anyone who uses that process in this country, but not someone who uses that process abroad and then brings that product into the U.S.

The change we are urging this Committee to support would make that foreign infringement actionable in this country. You may find it of interest to note that most of our trading partners do provide such protection to patented processes in their country: for example, the European Economic Community, Japan and South Korea. I believe it should be obvious why domestic industry needs such protection. We are in existence to make profits for our stockholders -- we need to be able to recoup and make a profit on our investments. If we cannot, the research activity and commensurate technological breakthroughs that bring to America the high standard of living we generally take for granted will be severely curtailed.

I know that no one has to remind the Members of this Subcommittee of the trade-offs that are inherent in our patent system: In exchange for an exclusive right to an invention, one must add to the knowledge base by completely disclosing to the public one's invention. In that way, subsequent inventors can build on that base and the whole industry will prosper. And, as you know, once a basic patent has expired, anyone can practice that invention or sell that product. It is only subsequent improvements that would be infringeable. If we are unable to obtain adequate protection for our inventions, there is no quid pro quo for teaching it to everyone else, and we may need to resort to trade secrets. I don't believe that it is in the nation's best interests; but, it is certainly an option that must be considered.

I would like to address directly the so-called generic drug problem. I know that you have heard, and will continue to hear, that giving domestic manufacturers process patent protection will cause generic drug prices to increase. Obviously, it would be better to have the brand name drug companies respond directly to that issue. However, I do know that one can always produce a product for less if one pirates someone else's technology without the need to recoup research and development expenses. We can only imagine the technology breakthroughs that might not otherwise occur without adequate patent protection. Our ancestors, in their wisdom, recognized that we may have to grant for a limited term a right to exclude

others in order to advance technology. Instead, our legislative opponents want us to invest in new technology so that they may use it abroad at no R&D cost to themselves. I hope that this Committee will take the present opportunity to ask representatives of the generic drug industry why prices would increase from this legislation unless their foreign suppliers are infringing U.S. process patents.

We must change the law in order to protect American technology, industrial growth, and jobs at home. That is why we support H.R. 1069.

We believe H.R. 1069 would create and protect jobs in the U.S. because, when domestic patent owners are protected from unfair offshore competition, they are more likely to manufacture those products in the U.S. The development of new technology and protection of that technology will permit U.S.-based companies to maintain and expand their operations in this country. Conversely, when a patent owner's U.S. competition can go abroad and infringe their process patents there is an obvious incentive for them to do so--thus exporting jobs. That is why we understand that a number of labor unions are supporting this legislation, and we hope that you will have an opportunity to hear from them.

There are several comments which I wish to make about H.R. 1069. We feel that it is extremely important that the

effective date and presumption of infringement sections be preserved.

Section 6 would make the bill apply to all products imported after the date of enactment. Without this provision, the legislation would do very little to create new jobs or protect existing ones for a number of years. Some earlier versions would not have applied to existing patents. Making the bill immediately effective with a fair grandfather clause to protect legitimate investments already made in reliance on present law seems a fair balance of jobs, trade deficits, and protection of domestic technology on one side and equity on the other. After all, U.S. patent owners are the ones who made the investments in research and development which resulted in the new technologies. And, the legislation would not affect the ability of the foreign manufacturers to sell their products in other countries. By making the bill effective with respect to imports occurring after the date of enactment, we will be protecting the competitive advantage which we enjoy as a result of our advanced technologies in a number of important areas such as biotechnology. Congress should consider not only the impact the bill will have on incentives to invest in the future, but also on investments in factories utilizing inventions already patented.

A most important aspect of any process patent legislation is a consideration of how a patentee is to prove

infringement when attempts at judicial discovery abroad are frequently thwarted. We support section 5 of H.R. 1069 which would create a rebuttable presumption under certain circumstances: First, the court would have to find that "a substantial likelihood exists that the product was produced by the patented process;" and second, "that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine." We commend the author of this legislation and strongly support his approach. The presumption is necessary because of the difficulty in finding out the processes actually used outside the U.S. to manufacture the goods in question. There is great difficulty in obtaining jurisdiction over foreign manufacturers, and discovery procedures in many foreign countries are non-existent or inadequate at best. In the case of infringement of a product patent, proof is relatively simple. Not so when it is a process practiced abroad. Nevertheless, a patent owner may be able to demonstrate by strong circumstantial evidence a "substantial likelihood" that the patented process was infringed. This would allow the Court to shift the burden of proof to the alleged infringer, who, after all, is closer to the allegedly infringed process. Furthermore, we understand that the bill's solution expresses an evidentiary rule similar to that already followed by the U.S. ITC in cases under section 337 of the Tariff Act when information cannot be obtained about processes practiced abroad.

We are aware some retailers have expressed concern over parts of this legislation. It is important for them to note that section 4 protects retailers and other purchasers from liability unless they knew of, or had been notified of, infringement. This provision, along with the Uniform Commercial Code and "hold-harmless" clauses in most contracts with suppliers, ensures that retailers will be no more likely to be sued for infringement of process patents under H.R. 1069 than they are for product patent infringement today. Retailers may not have enough information to judge whether a patent is being infringed, be it process or product. They may have to rely upon suppliers and manufacturers for that information. They cannot, however, be allowed to knowingly infringe another's intellectual property rights.

It is important that we strengthen both the patent law and Section 337 of the Tariff Act.

I will relate our own experience. Allied developed a process for the manufacture of amorphous metal strip, a thin metal film having a random structure more typical of glass than metal which exhibits extraordinary properties. Amorphous metals are harder, stronger and more corrosion resistant than stainless steel. They are more easily magnetized than any other known material. Applications for amorphous metals range from the substitution of gold in brazing jet engine components, eliminating the need to use a precious metal, to the magnetic

core materials of utility transformers, reducing power losses up to seventy-five percent or more. Allied has spent over $85 million and fourteen years developing amorphous metals technology, and we believe it will be key to the establishment of an entire new industry in the United States. There are estimates that this technonogy will support a billion dollar business in the foreseeable future. A significant portion of this technology is process technology and it is protected by process patents.

Our basic process patent was applied for in the U.S. in 1976 and granted in 1980. We applied for corresponding process patents in Japan and Germany in 1977. These patents finally were approved within the last year and were opposed by foreign competitors. While these patents have been delayed in their patent offices, Japanese and German companies have been using our process in Japan and Germany to manufacture amorphous metal strip and ship product into the United States.

Since there was no process patent protection under U.S. patent law, Allied initiated an action under Section 337 of the Trade Act before the International Trade Commission against these Japanese and German competitors in 1983. Ultimately, the ITC found that ten companies had engaged in unfair trade practices as a result of their use of our patented process abroad. A general exclusion order was issued by the ITC.

Some important aspects of the Allied case were:

* substantial research and development expenditures had been made.

* the size and strength of the future commercial markets had been determined.

* while significant commercial sales were not yet in hand, they were clearly anticipated.

* foreign competitors (who were held to have used the patented process to produce the imported product) had elected to enter those potential commercial markets at the same time that Allied had started to enter them.

While the issuance of the general exclusion order was gratifying, a slight shift in the economic history might have precluded that order on the basis that there was no injury to the domestic industry or that the industry was not yet "efficiently and economically operated."

This can better be illustrated by a brief history of the optical fiber section 337 case filed by Corning Glass Works against Sumitomo Electric Industries, Ltd. and Sumitomo Electric USA, Inc., which is presented here with their permission. The complaint alleged:

(1) the direct infringement of Corning's U.S. patent covering certain optical waveguide fibers, and

(2) the unauthorized importation of optical waveguide fibers manufactured abroad using Corning's process patent covering a method for making optical waveguide fibers.

The U.S. International Trade Commission (USITC) instituted an investigation. To get relief under Section 337, Corning had to prove:

* that Sumitomo had infringed Corning's patents;
* that there is an optical fiber industry in the United States;
*that the fiber optics industry is "efficiently and economically operated";
*that the infringement has had the effect or tendency of destroying or substantially injuring the domestic industry; and
* that the imposition of restrictions on imports of such infringing articles is in the public interest.

In contrast, if Corning had brought a suit against a U.S. manufacturer in a federal district court under U.S. patent law, it would only have had to prove that its patents had been infringed. However, Corning could not have brought a corresponding action in a federal district court because the patented process was being used outside the United States. Hence, Corning concluded that its only course of action on the

process patent was under Section 337.

The administrative law judge (ALJ) assigned to the case filed an initial determination that precluded Corning from getting relief under the law. Specifically, he found that Corning's patents were valid and enforceable, that the product patent was of "pioneer status," and that certain Sumitomo products infringed the product patent and the process patent. He also found that there were two domestic industries, one under each of the two patents and that both of these industries were efficiently and economically operated. However, he found that Sumitomo's imports did not have the effect or tendency to destroy or substantially injure either of those industries. He therefore found no violation of Section 337. The Commission reviewed the ALJ's determination and affirmed it.

The Commission determined that the substantial injury requirement had to be taken as an independent element of the law, even in intellectual property-based cases. It further determined that Corning had not been substantially injured despite the ALJ's finding of infringement which was also affirmed by the Commission. Corning has appealed this determination to the Court of Appeals for the Federal Circuit.

The amendments in Title II of H.R. 3776 are necessary to remove the unnecessary evidentiary burdens of the existing law. The fact is that it is very difficult and expensive for a

U.S. patent holder to get the enforcement protection of Section 337. The law has a number of conditions that must be met before a petitioner gets relief, and many of these conditions have no relevant rationale today, although they did when the law was originally crafted in 1922.

Section 337 has four conditions, in addition to infringement, that have to be met before relief is ordered by the USITC. We believe very strongly that some of these additional conditions are unnecessary in patent, trademark, and copyright cases. Specifically, we believe that Section 337 should be amended to eliminate, in intellectual property cases, the injury requirement and the requirement that the domestic industry be economically and efficiently operated. Title II of H.R. 3776 essentially does this. There is simply no economic or legal rationale for keeping these conditions in the law. Existing patent law does not require them in cases involving infringement within the United States. Furthermore, neither the General Agreement on Tariffs and Trade (GATT) nor any other international agreement requires them. In fact, in a 1982 GATT panel decision, the jurists found:

> "... in the Panel's view, it could reasonably be said that in considering what were the essential elements in legislation dealing with patent based cases an injury criterion could only be considered irrelevant." (emphasis added)

In essence then, by putting these additional, unnecessary conditions in Section 337, we are treating imports covered by domestic process patents more favorably than the corresponding domestic-manufactured products. Thus, we urge adoption of amendments which:

(1) ease the injury test for violations of intellectual property rights so that the intellectual property right violation itself satisfies the injury test;

(2) eliminate the requirement that the domestic industry be "efficiently and economically operated;" and

(3) ease the stringencies of the injury test so that injury to domestic industry can be found on the basis that the actions complained of only impair the establishment of the domestic industry.

It is these improvements which would protect U.S. innovation and know-how at its most critical phase of evolution, and I believe would protect this intellectual property against unfair trade. Let me elaborate. Scientific and technical innovation and know-how is most vulnerable to the effect of misappropriation as it goes from the research laboratory into the marketplace - at the threshold of commercial development. It is at this point that the

cumulative research and development costs are high, with usually no sales income, the technical feasibility certain and the commercial promise known. It is at this point that unfair competitors, with substantially lower costs because they merely copy, can pick off the commercial rewards of the technology with the least risk. The risk-benefit factors are most favorable for misappropriation at this point. On the other hand, the innovator is in a significantly less favorable position to establish injury under the present Section 337 injury criteria. Yet the injury to the innovation and know-how of the domestic industry is most destructive. The proposed amendments would conform Section 337 to the realities of bringing innovation and know-how to full commercial fruition.

There are a number of other provisions in Title II that we support. They are:

* the addition to subsection (e) which would require a decision within 90 days on whether or not to issue a temporary exclusion order;
*the amendment to subsection (f)(1) which would make it clear that the Commission can issue both an exclusion order and a cease and desist order;
*the amendment to subsection (f)(2) which would increase the maximum civil penalty;
* new subsection (g) which would add seizure and forfeiture to the list of remedies available;

*new subsection (h) which would facilitate the issuance of relief directed against a defaulting respondent;
*the amendment to re-designated subsection (i) which would specify that no seizure would be made under new subsection (g) until the Commission's determination becomes final provided that a bond is posted; and
* the amendment to re-designated subsection (j) which addresses and buttresses the finality of Commission determinations by confirming that the burden of proof in a further proceeding to modify, rescind or determine no violation is on the petitioner and that relief can be granted only on the basis of new evidence or evidence that could not have been presented in the prior proceeding. (It is essential that the Commission's determinations of violation have effective finality and that they not be impaired by a continuous recycling of the issues through repetitious proceedings to modify, etc.)

Mr. Chairman, now I would like to present the third component of my testimony, that is, the reason why we need both process patent legislation and amendments to Section 337 to secure adequate and effective protection of our intellectual property.

As I already explained, we need process patent legislation to protect U.S. patented processes from

infringement through offshore manufacturing. The remedy for such infringement provided in H.R. 1069 is a civil action in a district court against an importer or distributor who sells the foreign-made goods that are the products of such infringement. This is the case in current law with respect to product patent infringement by imports.

Section 337 authority is necessary to secure the enforcement of judgments against persons engaged in the practice of offshore infringement. A district court is, by virtue of its in personam jurisdiction, unable to easily enforce injunctions and damages against foreign persons operating in a foreign country. There are some instances where damages can be enforced, particularly when a foreign person has assets and sales in the U.S. market. But, as a general matter, an injunction against a foreign person who is manufacturing in another country can only be enforced by a foreign court.

In contrast to a district court, the USITC has in rem jurisdiction. Hence, it can take action against all imported goods manufactured offshore in violation of a U.S. patented process. Such action against goods can be enforced by the Customs Service at the border, thereby securing effective enforcement.

The limitation of the district court's in personam jurisdiction in cases of offshore infringement is probably best

described by a simple example. Let's assume that process patent legislation is enacted and Section 337 does not exist. Let's also assume that Company A, a U.S. process patent holder, wins a judgment in a district court against Company B, an importer of a product manufactured offshore in violation of Company A's process patent. An injunction is issued against Company B and damages are assessed. This remedy essentially stops the importation and sale by Company B of the product that is the result of offshore process patent infringement. But, it does not stop Company C, another importer, from importing and selling the same product in the U.S. market. Once Company C begins importing the product, Company A, the process patent holder, would have to initiate a civil action against Company C, just as it had with Company B. Hence, Company A could find itself engaged in continuous litigation at high expense merely to enforce its legitimate patent rights. The necessity of such action on the part of Company A could hardly be considered adequate and effective protection of its intellectual property.

Section 337 offers a solution to this problem by virtue of the USITC's in rem jurisdiction. In this example, Company A could seek relief from process patent infringement by filing a Section 337 complaint with the USITC against the foreign manufacturer. If certain conditions cited in Section 337 are met, including a finding of infringement, the Commission could impose an exclusion order on all imports of the product which are manufactured offshore in violation of Company A's patented

process. In seeking this form of relief, Company A avoids the duplicative litigation associated with suing virtually every importer or distributor who purchases and re-sells a product manufactured in violation of Company A's patented process.

If the proposed amendments to Section 337 of the Tariff Act of 1930 are enacted, legislation like H.R. 1069 will still be needed. Section 337 is a trade statute and therefore a different kind of remedy. Relief for patent owners under Section 337 is dependent upon public policy considerations which must be taken into account by the ITC and by the President of the United States.

A second deficiency in the Trade Act is the inability of the Commission to award damages for the unauthorized use of patented process technology. Only injunctive relief preventing future activity is available under Section 337. No monetary damages are available. Thus, infringers are given a free ride until an exclusion order issues. That is because, even if they lose before the ITC, they are able to keep their profits while litigation is pending. Those who argue that Section 337 is an adequate remedy do a gross disservice to American industry. Section 337 may let you win eventually, but there is no disincentive to foreign infringers in the meantime, and this leads to a loss in domestic jobs and injury to the economy.

In addition, attorney fees are not available. Temporary

relief is not available as quickly from the ITC as it can be in a Federal district court. Moreover, a patent suit in a district court may be less expensive for a patent owner, particularly if there are only a few infringers.

I want to mention that Allied-Signal also supports enactment of H.R. 3246, a bill which relates to implementation of the Patent Cooperation Treaty in the United States. The United States already participates in Chapter I of the treaty. By participating in Chapter II, the United States can obtain additional benefits for U.S. patent applicants who wish to obtain patent protection in other countries which are members of the treaty. The treaty has nearly 40 member countries.

The Patent Cooperation Treaty allows patent applicants to postpone some of the expense of obtaining patents abroad until after a search report under Chapter I and a preliminary examination report under Chapter II are completed. After receiving the search and examination reports, patent applicants are in a better position to judge whether to proceed with the substantial expenditures needed to obtain protection in a large number of countries. We believe therefore that H.R. 3246 will help U.S. industry obtain more effective patent protection abroad.

Mr. Chairman, again I want to thank you and your colleagues for your endeavors and the opportunity to discuss this important issue. I'd be happy to answer any questions at this point.

"APPENDIX"

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SUPPORTERS OF PROCESS PATENT LEGISLATION

We, the organizations listed below, support legislation giving the owner of a process patented in the U.S. the right to bring a suit for patent infringement against a party who imports a product which is manufactured abroad by using the process.

This legislation will keep foreign manufacturers from taking a free ride on R&D expenditures of U.S. companies. It will preserve jobs of U.S. workers. The proposed legislation is similar to provisions already in the patent laws of most industrialized countries.

We urge Congress to enact this legislation at an early date. If we can be of any assistance, please do not hesitate to call on us.

COMPANIES

AMERICAN CYANAMID CO.
Wayne, NJ

AGRIGENETICS CORP.
Boulder, CO

AIR PRODUCTS AND CHEMICALS, INC.
Allentown, PA

ALLIED-SIGNAL INCORPORATED
Morristown, NJ

ALUMINUM COMPANY OF AMERICA
Alcoa Center, PA

AMERICAN HOME PRODUCTS CORPORATION
New York, NY

AMGEN
Newbury Park, CA

AMOCO CORPORATION
Chicago, IL

ARMSTRONG WORLD INDUSTRIES, INC.
Lancaster, PA

ASHLAND PETROLEUM CO.
Ashland, KY

BATTELLE MEMORIAL INSTITUTE
Columbus, OH

BAXTER TRAVENOL LABROATORIES, INC.
Deerfield, IL

BECTON, DICKINSON AND COMPANY
Paramus, NJ

BIOTECHNICA INTERNATIONAL, INC.
Cambridge, MA

THE BLACK & DECKER CORP.
Towson, MD

THE BOC GROUP, INC.
Montvale, NJ

BMC INDUSTRIES, INC.
Saint Paul, MN

BORG-WARNER CORPORATION
Chicago, IL

BRUNSWICK CORP.
Skokie, IL

CALGENE, INC.
Donis, CA

CALIFORNIA BIOTECHNOLOGY INC.
Mountainview, CA

CATERPILLAR TRACTOR CO.
Peoria, IL

CETUS CORPORATION
Emeryville, CA

CHEVRON RESEARCH COMPANY
San Francisco, CA

CIBA-GEIGY CORPORATION
Ardsley, NY

COMBUSTION ENGINEERING
Stamford, CT

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Companies Continued
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CORNING GLASS WORKS
Corning, NY

CPC INTERNATIONAL, INC.
Englewood Cliffs, NJ

DAMON BIOTECH
Needham Hts., MA

DIAMOND SHAMROCK CHEMICALS CO.
Painesville, OH

DOW CHEMICAL CO.
Midland, MI

DOW CORNING CORPORATION
Midland, MI

DRESSER INDUSTRIES, INC.
Dallas, TX

DuPONT COMPANY
Wilmington, DE

ELI LILLY AND COMPANY
Indianapolis, IN

ENERGY CONVERSION DEVICES, INC.
Troy, MI

ENGLEHARD CORPORATION
Iselin, NJ

FMC CORPORATION
Philadelphia, PA

GENECOR, INC.
San Francisco, CA

GENERAL ELECTRIC COMPANY
Fairfield, CT

GENEX CORP.
Rockville, MD

GERBER SCIENTIFIC, INC.
South Widsor, CT

HOFFMANN-LA ROCHE
Nutley, NJ

ILLINOIS TOOL WORKS INC.
Chicago, IL

JOY MANUFACTURING COMPANY
Pittsburgh, PA

THE LUBRIZOL CORP.
Wickliffe, OH

MANVILLE CORPORATION
Dayton, OH

MERCK & COMPANY, INC.
Rahway, NJ

MILLIKEN RESEARCH CORPORATION
Spartanburg, SC

MONSANTO CO.
Saint Louis, MO

MORTON THIOKOL, INC.
Chicago, IL

MYCOGEN
San Diego, CA

PFIZER, INC.
New York, NY

PHILLIPS PETROLEUM COMPANY
Bartlesville, OK

POLAROID CORPORATION
Cambridge, MA

THE PROCTER & GAMBLE CO.
Cincinnati, OH

ROHM AND HAAS COMPANY
Philadelphia, PA

SCHERING-PLOUGH CORP.
Madison, WI

SHELL OIL COMPANY
Houston, TX

THE SINGER COMPANY
Fairfield, CT

SMITHKLINE BECKMAN CORP.
Philadelphia, PA

STANDARD OIL COMPANY OF OHIO
Cleveland, OH

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STAUFFER CHEMICAL COMPANY
Westport, CT

SUN REFINING AND MARKETING COMPANY
Philadelphia, PA

TECHNION, INC.
Irvine, CA

TEXACO DEVELOPMENT CORPORATION
White Plains, NY

3M
Saint Paul, MN

TRW
Cleveland, OH

UNION CARBIDE CORPORATION
Danbury, CT

UNITED TECHNOLOGIES CORPORATION
Hartford, CT

THE UPJOHN COMPANY
Kalamazoo, MI

VARIAN ASSOCIATES, INC.
Palo Alto, CA

WESTINGHOUSE ELECTRIC CORPORATION
Pittsburgh, PA

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ASSOCIATIONS

AMERICAN TEXTILE MANUFACTURERS INSTITUTE, INC.
Washington, DC

CHEMICAL MANUFACTURERS ASSOCIATION
Washington, DC

ELECTRONIC INDUSTRIES ASSOCIATION
Washington, DC

INDUSTRIAL BIOTECHNOLOGY ASSOCIATION
Rockville, MD

INTELLECTUAL PROPERTY OWNERS, INC.
Washington, DC

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
Washington, DC

NATIONAL ASSOCIATION OF MANUFACTURERS
Washington, DC

NATIONAL SMALL BUSINESS ASSOCIATION
Washington, DC

PHARMACEUTICAL MANUFACTURERS ASSOCIATION
Washington, DC

SMALL BUSINESS LEGISLATIVE COUNCIL
Washington, DC

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION
New York, NY

U.S. CHAMBER OF COMMERCE
Washington, DC

(Names of contact people in the organizations listed above may be obtained by calling (202)466-2396. Additional organizations will be added to the list shortly.)

Mrs. SCHROEDER. I thank both of you. I see the distinguished chairman has returned.

First of all, we are going to have a lot of questions I think which we will submit for the record in the interest of time. But mainly I hear from both of you that you support the legislation.

My comment is, make everybody in your companies look at it and make sure it goes far enough so we don't have to keep changing it every year. Also make sure that it's comprehensive enough, and that would be it.

Let me return the chair to the distinguished gentleman from Texas.

Thank you, Mr. Chairman.

Mr. BROOKS. Thank you, Mrs. Schroeder.

Did she submit some questions to you? We will submit some to you gentlemen.

I understand your problem; $100 million. Does that bother you some if you have that much invested and they are stealing it from you?

Mr. MASSENGILL. Quite a bit. I don't know how much longer we can continue to convince management that they should keep spending it.

Mr. BROOKS. I don't either.

The small entrepreneurs develop an idea and somebody steals it before they can get it in production. Big ones spend $100 million, and somebody steals that before they can get their nut back. We are not only giving those foreign traders our current business, we are giving them our future business. I think we ought to be barred from doing something like that. There may be some variation to this legislation; we need to work on it. I am not trying to disrupt the world, but the world is already pretty well disrupted. So I am ready to change it.

Whatever we are doing now is obviously wrong. If you think you can go do this in Switzerland you are crazy. You can't go make a living in Mexico; they are not going to let you make a living 100 miles from the border. We are the only country in the world that gives away our markets, just gives them away for nothing. We do not even insist that they buy the things that we can make like cattle, or lumber, simple commodities. They don't even allow us to export those. I think we ought to pull their chain, and I say God bless Harry Truman. Not only was he a Democrat but he understood what needed to be done.

Did you have any questions of these people?

Mr. MOORHEAD. I just have one or two but I wanted to say that even though you are a Democrat you understand what needs to be done.

Mr. BROOKS. You may submit them.

We have another witness.

Mr. MOORHEAD. OK; I'll waive the questions for this.

I do want to thank the witnesses and I appreciate their comments and I know how important this problem is to them and so many other people who want our country to be self-sufficient.

Mr. BROOKS. Mr. Kindness.

Mr. KINDNESS. Mr. Chairman, if I could just solicit quickly the opinions of our two witnesses, and I thank you for your testimony,

as to the proposition that I suggested or solicited Dr. Stern's opinion on.

That is, what about going to a quick administrative type of relief with no evidentiary hearing administered by the Customs Service to require the importer or the foreign seller of the product that is the result of infringing a process patent to go to court in order to get relief from the administrative order. Assuming that it is GATT legal and assuming that it meets the requirements of any bilateral agreements that we have, what is your feeling about that type of quick stoppage at the court or border?

Mr. KILEY. My own reaction, sir, is that such remedies would have utility but could be subject to great abuse unless hedged around with the same protections that we now offer those against whom preliminary injunctive relief is sought. So one must need show irreparable harm, likelihood of prevailing on the merits, and so on, and very quickly that relief becomes available only in the most extreme of circumstances.

I think in appropriate circumstances such relief would be appropriate. There are opportunities now before the International Trade Commission to seek preliminary injunctive relief. An administrative law judge has granted it in only one case, and the Commission overruled that judge. So that remedy is available to a limited extent before ITC now. But while the power is there it is not exercised.

Mr. KINDNESS. But that's a case in which the owner of the intellectual property has to go to the ITC and initiate a proceeding, as has been pointed out here, has costs associated with it, I mean considerable costs. I am thinking in terms of putting the burden of that costly proceeding on those who would seek to infringe upon a process patent.

Let them establish their right to bring the product into the United States, and of course, I envision that the result of such a procedure in our law would be offensive to a lot of other countries perhaps, but would tend to cause a stoppage of some of the problems we are talking about.

There would be fewer chances taken on trying to introduce the product into the United States to begin with, I would imagine. The risk then would be on the infringer, rather than on the intellectual property owner.

Subject, of course, I understand, to the potential of abuse, but the remedy for that abuse would be in the Federal court system.

Mr. KILEY. I am certainly in favor of taking advantage of the Federal court system. It is there. It is used to dealing with disputes of this kind. I have a high opinion of the Judiciary.

My trouble with your approach, I believe, lies in my own philosophy of free trade, fair trade, but let's not get carried away here to the point where we have created a remedy that is worse than the ill.

I think you would have to approach that very carefully.

Mr. KINDNESS. I realize there are risks involved and would invite any further comment that you might like to submit later with respect to what kind of abuses and dangers should be guarded against if we attempted such a thing.

Mr. KILEY. We will do so.

Mr. KINDNESS. Thank you.

Mr. MASSENGILL. If I may, I think if 337 were amended along the line offered in title II of 3776 with some other refinements, that could be achieved. The reason I would recommend is because the ITC has the investigative powers to ferret out any abusive or grossly unfounded claims or allegations.

They could very quickly solicit comments through publishing in the Federal Register. There is no reason why the ITC, 337, cannot be brought up to date where we could get guick relief to take care of Congressman Moorhead's statement about the chips and so forth. Our product life cycle is shortening each year as we get into higher technology.

Mr. KINDNESS. Yes.

Mr. MASSENGILL. We just have not caught up in the laws to stay up to date on that. It needs addressing immediately. It should have been addressed years ago.

Mr. KINDNESS. Yesterday.

Mr. MASSENGILL. Yes.

Mr. KINDNESS. But you prefer the ITC as a forum instead of an administrative action by the Customs Service.

Mr. MASSENGILL. From the standpoint of due process in the courts, I think Mr. Kiley stated that very well in saying that one would have difficulties in the Judiciary of trying to get action without any review of the nature of the patent or the infrigement aspects.

Mr. KINDNESS. I am talking about a process where the action occurs first and then the Judiciary reviews it upon the instance of those who seek to enter the goods into the United States.

Mr. Chairman, I guess I had better yield back at this point.

Mr. BROOKS. Thank you, Mr. Kindness.

Mr. DeWine.

Mr. DEWINE. In defence to my chairman, I will forego the questions.

Mr. BROOKS. You are a gracious man and we will extend you the opportunity to submit questions at your leisure.

Mr. DEWINE. Thank you, Mr. Chairman.

Mr. BROOKS. Thank you, gentlemen. I appreciate your concern and your forthright statement about the problem that confronts this country as well as your companies.

Mr. KILEY. Thank you, Mr. Chairman.

Mr. BROOKS. Our last witness is Ms. Dee Fensterer. She is president of the Generic Pharmaceutical Industry Association, and is accompanied by the association's counsel, Al Engelberg.

We have got a copy of your statement—I wondered if you would make a short statement of the thrust of it and what you want done about this, what your objection to it is.

I have a couple of questions that might be helpful. Then we will conclude.

But I did want to include it now and get this testimony while everybody is here, while the program is running.

STATEMENT OF DEE FENSTERER, PRESIDENT, GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION, ACCOMPANIED BY AL ENGELBERG, COUNSEL

Ms. FENSTERER. In the interest of time, if it would be all right to the committee, I would like to make a very brief summary statement, ask Mr. Engelberg to respond to some of the questions that have been posed here to other witnesses and then any other questions that the committee might have.

I want to make just two observations that I think have been overlooked this morning. As I sit before this microphone, I am wondering under 1069 if I am violating a process patent. I have not the vaguest idea how this microphone was made, nor do I care. I just want you to hear what I have to say.

The second observation is that this microphone, if I turned it over, I might find that it was made in Texas by good old Texas Rangers, but that under 1069, a Japanese company could come in and tell me that I am infringing their United States patent on this microphone.

I think those are two very serious problems with the bill.

In terms of the generic pharmaceutical industry, the major problem is that it is going to delay competition by making the generic companies liable for alleged action infringement that may or may not have been committed by our foreign suppliers of raw material. Without those raw materials, that is, the active ingredients of the drugs, we will not be able to supply American consumers with lower-cost drugs.

We import our active ingredients for a very practical reason. The former patent-holders, the product and therapeutic use patent-holders, will not sell to us, so we go abroad to worldwide suppliers who appreciate our business, of course, but they are certainly not dependent upon sales in the United States.

You have to remember that frequently prescribed prescription drugs have been available generically in Western Europe and Canada for many, many years. In terms of competition, we are just catching up in the United States.

I also hope you will remember that the cost of raw materials in the pharmaceutical business is miniscule compared to the final consumer cost of the tablet or capsule. John Pekinin gives an example of this in his 1973 book entitled "The American Connection, Profiteering and Politiking in the Ethical Drug Industry."

The raw material for valium at that time was $87 per kilo. Production costs liberally estimated brought the final dosage form cost up to $487 per kilo. The retail price, however, for valium at that time was $11,000 per kilo, 140 times the cost of the raw material.

Now, generic companies do not add on a $10,000 per-kilo-profit. Instead, we try to offer consumers medically necessary products at competitive prices and we do this only after the product and the therapeutic-use patent has expired.

This bill will make us liable for process patent infringement even though we have no knowledge of the manufacturing processes used abroad to make the active ingredients of our drugs.

I will skip here and say only further that these bills were also allow a foreign company, located abroad to enforce a process patent

long after the product-in-use patents have expired against an American generic pharmaceutical company that is producing not only jobs in the United States, but lower-cost competitive drugs for the American consumer.

If I am rushing through here, if I could give Mr. Engelberg a few minutes to respond to some of the questions that were not fully answered, I do not believe, earlier.

[The statement of Ms. Fensterer follows:]

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requirements which are now prerequisites to relief in the ITC and would allow a patent holder with no activity or injury in the U.S. whatsoever to seek an ITC Exclusion Order, based on an allegation of foreign infringing activity. It would also require the ITC to render a final decision within 90 days after commencement of any proceeding--a requirement which would eliminate any meaningful pre-trial discovery. In effect, the ITC would be empowered to grant the full equivalent of a permanent injunction by a District Court without any of the procedural or substantive safeguards which now exist to insure that invalid and fraudulently procured patents are not enforced, that patents are reasonably construed, and an infringement has in fact occurred.

THE PROPOSED LEGISLATION WILL NOT CREATE JOBS: IT MAY EXPORT JOBS.

Under current law, the only way in which it is possible to obtain extraterritorial enforcement of patents covering manufacturing processes is an action before the International Trade Commission under 19 U.S.C. §1337(a). The ITC will bar the importation of goods made abroad by a U.S. process but only if the patent owner or its U.S. licensees are actually practicing the patented invention in the U.S. If the patent is not being "worked" in this country, then there is no injury to U.S. economic interests or jobs.

The industry proponents of H.R.1069 and 3776 seek the elimination of the "domestic industry" requirement. Specifically, they wish to be able to enjoy full enforcement of process patents under circumstances where the patent owner is not using the patented process in the United States. But the elimination of the "domestic industry" requirement also eliminates the basic premise which has been relied

This superiority stems from several factors including:

(1) The ITC is required by law to render a final decision on a patent infringement claim under Section 337 within one year from the time the claim is first made. There is no time limit for patent infringement actions in the District Courts and the typical case usually lasts for several years before a judgment is entered. Indeed, last year the major drug manufacturers insisted that a minimum of 30 months was required to litigate drug patent controversies in the District Courts. For that reason, the Drug Price Competition and Patent Restoration Act of 1984 provides a 30 month delay in the FDA marketing approval for a generic drug if there is a patent controversy.

(2) A Section 337 action in the ITC is a suit against the goods and not against a particular party. For that reason, all parties who deal in the goods in the domestic market are usually notified and, in any event, are affected by the ITC's decision. The usual personal jurisdiction and venue problems which arise in District Courts when multiple parties are involved are avoided. For example, a patent infringement suit against a New York importer, which resulted in an injunction against further infringement, would not bar a California corporation from continuing to import the same product or a similar product from the same or another foreign

remedy assures that provable cases of infringement can be brought to a halt in five months or less. It is ludicrous to believe that the ITC or any other tribunal can give an accused infringer a fair opportunity to defend against a charge of infringement in the 90 day period which would be mandated by H.R.3776. If, in fact, such a system would be practical or fair, why has this Committee created and preserved the Federal Rules of Civil Procedure and made them applicable to patent cases? Why did the Congress provide a 30 month period to adjudicate drug patent controversies as part of the 1984 Drug Price Competition Act? The answers to these questions are obvious. Despite occasional abuses of the system of pre-trial discovery, that system is recognized as providing an essential safeguard against frivolous claims.

The proponents of H.R.3776 seem to believe that the proposed changes in the ITC are vital to protecting American industries from unfair foreign competition which is allegedly taking a "free ride" on American technology. The fallacy in this line of reasoning is that just as many important U.S. patents are owned by foreign and international organizations as by purely domestic entities and there is no reason to believe that these patent rights are being exploited in a manner which benefits the U.S. economy. It would not be at all surprising if the actual impact of H.R.3776 is to open the doors of the ITC to actions by Japanese corporations seeking to prevent U.S. companies from importing vital components of domestically assembled products. Do we really want to enact legislation which would give a Japanese automaker the ability to shut down a Detroit assembly line in 90 days because that assembly line uses an imported filter, seal or circuit board claimed in a Japanese-owned patent? Or would we prefer

method by which Valium was manufactured would only be infringed by the manufacturer because a process is "used" but obviously cannot be "made" or "sold." Thus, no one in the distribution chain either makes, uses or sells the process.

(6) Patents are territorially limited and infringement occurs only if the claimed invention is made, used or sold in the United States. Accordingly, the practice of a process abroad is not an act of patent infringement. This is true even though the product produced by that process is intended for export to the United States. Even in the case of a product patent, the imported product, itself, becomes an infringement only when it is used or sold in the United States.

A hypothetical example will serve to illustrate how the foregoing principles result in a logical distinction between product and process patents.

Suppose the compound in question is ordinary table salt and someone discovers a new process for extracting it from the ocean. It is certainly possible to obtain a patent on this manufacturing process if it is new. But the salt itself is old and is not patentable. The patent on the new process for making salt would certainly be enforceable against a competing manufacturer who "uses" the patented manufacturing process. But, the company that purchases the salt or who uses the salt is not liable for patent infringment because it did not make, use or sell the patented process invention. The product which it either sold or used was still ordinary table salt which could have come from a salt mine, from the ocean, or from any one of numerous known chemical reactions which produce salt as a by-product. These innocent purchasers neither know nor care how

> my job of determining or having it determined for me whether that is true, whereas it may be difficult, is relatively easy. You have two products. You can get a patent lawyer, and he can look at the prior art. He can attempt to establish how good the patent is and you compare the two products. There they are. Now, if I am an importer and somebody comes to me and says, "You are infringing not because the product is an infringing product, but it was made by a process which infringes my U.S. process patent," the only way I can determine or my lawyer can determine whether that is so is to make an investigation abroad in the country of origin and try to endeavor to find out whether the product that I have imported was in fact produced by an infringing process. That can be a very costly operation. (Emphasis added).

See, General Revision of the Patent Laws, 1967, Hearings on H.R. 5924, H.R.13951 before Subcommittee No. 3 of the Committee on the Judiciary, House of Representatives, 90th Cong. 1st. Sess., 146 (1967).

Those who would argue that innocent purchasers can put pressure on their supplier by withholding purchases or demanding indemnification agreements have not given full consideration to the realities of a marketplace in which there are often many layers in the chain of distribution between the manufacturer and the ultimate purchaser, and many purchasers who lack economic leverage over their sources of supply. For those reasons, lawsuits against customers rather than infringing manufacturers are a favorite tactic of litigators

for the manufacture of the drug product will be disclosed in the expired patent. Whether that process is the most efficient process or not is truly irrelevant to competition between generic and brand name drugs because the small amount of active ingredient used in each tablet is not as significant a factor as the vast price difference between generic and brand name drugs products. Indeed, in most cases, the bottles, labels and caps far exceed the cost of the tablets. Nevertheless, process patents can be used to impede the competition contemplated and desired by the 1984 Act by forcing generic makers to change suppliers or processes after an ANDA has been approved, thereby forcing them off the market until they rerun the gauntlet of the regulatory review process.

Congress enacted the 1984 Drug Price Competition Act at the request of the major drug companies in order to maximize protection for new products and new therapeutic uses and create the incentive for new inventions. That Act created special patent provisions for new inventions. Even if it can be established that additional process patent protection is needed in other industries, pharmaceutical patents should be exempted in view of the 1984 Act.

In summary, present law provides for the enforcement of process patents against imported products in the ITC and strikes an appropriate balance between the enforcement of patent rights and the protection of domestic industries. Unless and until a body of economic information is developed which would establish that a broader enforcement of U.S. patent rights would be beneficial to U.S. industries and U.S. jobs, there is no reason to enact additional laws, particularly in view of the obvious flaws and unfairness in H.R.1069 and 3776.

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The proponents of H.R. 1069 urge that, under current law, patents claiming manufacturing processes are unfairly treated in a manner which is inferior to the treatment accorded to product patents; that the protection afforded to process patents by the International Trade Commission is inadequate; that the failure to extend the protection of process patents in the U.S. is out of step with the patent law of other countries; and that the proposed legislation will protect or create jobs. None of these arguments can withstand any serious scrutiny. In fact, the present system of protecting and enforcing process patents works just fine! When all of the facts are considered, it is apparent that this legislation will have only two real results, which may surprise some of its proponents, but which for others may be the real source of their interests.

First, the legislation would for the first time create the ability to enforce a process patent in the United States even though the patent owner is not engaged in any domestic industry under the patent and is, itself, practicing the process abroad.

Second, the legislation would expand the use of threats of process patent infringement actions and the possibility of substantial attendant monetary damages against the innocent purchasers and distributors of imported products as an unfair means of capturing all or a substantial portion of that business by the patent owner irrespective of the merits of the purported patent infringement claim.

Any doubt about the true purpose of some of the proponents of H.R.1069 is dispelled by H.R. 3776 which seeks to accomplish directly precisely the same goals by emasculating Section 337 of the Tariff Act. H.R.3776 would eliminate the "domestic industry," and injury

requirements which are not prerequisites to relief in the ITC and would allow a patent holder with no activity or injury in the U.S. whatsoever to seek an ITC Exclusion Order, based on an allegation of foreign infringing activity. It would also require the ITC to render a final decision within 90 days after commencement of any proceeding--a requirement which would eliminate any meaningful pre-trial discovery. In effect, the ITC would be empowered to grant the full equivalent of a permanent injunction by a District Court without any of the procedural or substantive safeguards which now exist to insure that invalid and fraudulently procured patents are not enforced, that patents are reasonably construed, and an infringement has in fact occurred.

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The industry proponents of H.R.1069 and 3776 seek the elimination of the "domestic industry" requirement. Specifically, they wish to be able to enjoy full enforcement of process patents under circumstances where the patent owner is not using the patented process in the United States. But the elimination of the "domestic industry" requirement also eliminates the basic premise which has been relied

upon to attract Congressional support for this legislation, namely, that this bill will result in new jobs. In fact, this bill could result in the net export of jobs.

Simply put, the "domestic industry" requirement in current ITC law provides a substantial incentive for establishing U.S. manufacturing facilities for the practice of a patented process because that is the only way in which the patent owner can obtain the enforcement of the process patent against foreign manufacturers. This incentive will disappear if the proposed legislation is enacted. Patent owners will be free to move their domestic manufacturing operations abroad without losing any domestic patent enforcement rights.

The potential impact of the "domestic industry" requirement is not theoretical. Statistics published by the Intellectual Property Owners, Inc. indicate that the number of United States patents being issued to foreign individuals and corporations has been continuously rising and accounted for 42% of all U.S. patents issued in 1984. Overall, General Electric Co. and IBM, two multi-national corporations with worldwide manufacturing facilities, obtained the most U.S. patents during 1984. Close behind were Hitachi and Toshiba. Foreign firms, in general, captured 7 of the top 11 spots on the "most patents" list. Clearly, the elimination of the "domestic industry" requirement from the ITC proceeding or the enactment of H.R.1069 as a means of circumventing that requirement will not give these foreign corporations any incentive to build factories in the United States.*

*H.R.3776 which has been approved by the Committee on Energy retains the "domestic industry" requirement and is clearly preferable to H.R.3777. However, it also contains some of the objectionable provisions of H.R.3776 such as the elimination of the "injury" requirement and the requirement that cases be decided in 90 days.

Many of the proponents of this legislation have argued that U.S. Patent Law is out of step with the rest of the world in refusing to enforce process patents more broadly. This is not the case. In fact, until recently, many of the countries which provided extraterritorial protection for process patents, provided no protection at all for new compositions of matter such as drugs and agricultural chemicals. Further, the patent laws of most countries, such as England, Germany, Holland, Japan and the rest of the industrialized world, require that a patent be "worked" by actual use of the patented invention in that country. Compulsory licensing may be ordered if a patent is not "worked." Indeed, in England, for example, compulsory licensing may be ordered even in those instances where the patent is being "worked" but production is insufficient to make products available at reasonable prices. There are also other public interest situations where compulsory licensing may be invoked--patents covering drugs is one such area. In the final analysis, these economic overrides on the operation of foreign patent systems are comparable to the "domestic industry" requirement in ITC proceedings.

The expansion of the definition of process patent infringement is also clearly inequitable given other provisions of U.S. patent law relating to activities in foreign countries. For example, under 35 U.S.C. §104, a foreign applicant may not rely on any activities in a foreign country for the purpose of establishing priority of invention. Similarly, under 35 U.S.C. §102(a) and (b), the secret prior commercial use of a process in this country will invalidate a subsequent process patent but even a public commercial use of an invention in a foreign country cannot be relied upon as prior art

for the purpose of establishing patent invalidity unless it has been described in a printed publication. These statutory provisions have their roots in the long-held belief that the development and verification of evidence relating to foreign activities is too difficult and such evidence is inherently unreliable. Logic would appear to dictate that precisely the same evidentiary barriers exist with respect to proving infringement. Yet, the proposed legislation would place that burden on the innocent customer who has the least capability of dealing with the problem. In any event, if the expanded process infringement legislation is enacted without changing other parts of the patent law, it would be possible to find a foreign manufacturer guilty of infringement even though that manufacturer had been engaged in the actual commercial use of the patented subject matter for many years prior to the issuance of the U.S. patent. The inequity in such a result is self-evident. Moreover, that inconsistency demonstrates the difficulty in attempting to make important substantive modifications to the patent law on a piecemeal basis or on the basis of alleged parity with the patent laws of other countries. In that regard, it should be noted that many of the countries which enforce process patents where production occurs in a foreign country also permit reliance on prior public use or sale in a foreign country to establish patent invalidity.

THE CURRENT ITC PROCEDURE IS FAIRER AND FASTER THAN THE PROPOSED NEW INFRINGEMENT PROCEDURE.

Under 19 U.S.C. §§1337 and 1337(a), the International Trade Commission (ITC) is authorized to prevent the importation of a product manufactured abroad by means of a process covered by a U.S.

process patent. The following statutory provisions govern proceedings before the ITC:

19 U.S.C. 1337

"Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee or agent of either, the affect or tendency of which is to destroy or substantially injure an industry efficiently and economically operated, in the United States, or to prevent the establishment of such an industry...are declared unlawful.

19 U.S.C. 1337(a)

The importation for use, sale or exchange of a product made, produced, processed or mined under or by means of a process covered by the claims of any unexpired valid United States Letters Patent, shall have the same status for the purpose of Section 1337 of this Title as the importation of any product or article covered by the claims of any unexpired valid United States Letters Patent."

It has long been established law that the importation of a product covered by a valid, unexpired U.S. product patent is an act of unfair competition under 19 U.S.C. §1337.

The practices and procedures of the ITC in enforcing patent infringement claims are generally recognized by the patent bar as a remedy for patent infringement which is substantially superior to conventional actions for patent infringement in the District Courts.

This superiority stems from several factors including:

(1) The ITC is required by law to render a final decision on a patent infringement claim under Section 337 within one year from the time the claim is first made. There is no time limit for patent infringement actions in the District Courts and the typical case usually lasts for several years before a judgment is entered. Indeed, last year the major drug manufacturers insisted that a minimum of 30 months was required to litigate drug patent controversies in the District Courts. For that reason, the Drug Price Competition and Patent Restoration Act of 1984 provides a 30 month delay in the FDA marketing approval for a generic drug is there is a patent controversy.

(2) A Section 337 action in the ITC is a suit against the goods and not against a particular party. For that reason, all parties who deal in the goods in the domestic market are usually notified and, in any event, are affected by the ITC's decision. The usual personal jurisdiction and venue problems which arise in District Courts when multiple parties are involved are avoided. For example, a patent infringement suit against a New York importer, which resulted in an injunction against further infringement, would not bar a California corporation from continuing to import the same product or a similar product from the same or another foreign

source. In contrast, a Section 337 proceeding in the ITC is a proceeding against all goods of the same description irrespective of the identity or location of the foreign manufacturer or domestic user of the product. If infringement is found to exist, all goods of that description will be excluded from further importation.

(3) The ITC has a regular procedure for considering Temporary Exclusion Orders. A Temporary Exclusion Order (TEO) is comparable to a preliminary injunction in a District Court action. However, preliminary injunctions are rarely granted in patent infringement actions in District Court. In contrast, under ITC Rules, a decision on a motion for TEO must be decided within five months from the time the initial ITC investigation is commenced and such orders are granted in some cases.

(4) During an appeal from an Exclusion Order or TEO, the ITC normally requires the posting of a bond equal to 100% of the value of the goods. Bonds of this size completely discourage continued importation while the appeal is pending.

(5) The interpretation of patents with respect to issues of validity, infringement and enforceability is the same in the ITC as in the District Courts. Indeed, appeals from ITC decisions in patent-based Section 337 cases are heard by the Court of Appeals for the Federal Circuit which is the same Court

which hears appeals from all patent infringement cases tried in the District Courts throughout the country.

For all of the foregoing reasons, patent owners are flocking to the ITC in record numbers--even in those cases wherethe patent owner could have commenced a suit for patent infringement in a District Court. Indeed, although a great deal of attention has been focused on the ITC cases involving Allied Corporation (In the Matter of Certain Amorphous Alloys and Amorphous Metal Articles) and Corning Glass Works (In the Matter of Certain Optical Waveguide Fibers) as demonstrating the inadequacy of the ITC remedy and the need for this legislation, it is generally overlooked that Allied and Corning voluntarily chose that forum rather than the District Court and that Allied won its case. In fact, Corning chose both forums and, although it lost in the ITC because it could not prove any injury, it still has a pending case involving infringement of the same patents in the U.S. Court for the Southern District of New York (Civil Action 84-CIV-1955 WCC). Thus, in considering the need for this new legislation, one must be careful to distinguish between situations where a particular party is disappointed with the result in a particular case and situations which actually require new legislation. Otherwise, Congress runs the risk of becoming the court of last resort for every disappointed litigant.

It is true that the patent owner in an ITC proceeding must satisfy certain statutory requirements in addition to patent ownership, validity and infringement. Specifically, the patent owner must establish that it is engaged in a domestic industry; that the domestic industry is efficiently and economically operated; and that the importation of the goods has the effect or tendency to

destroy or substantially injure an industry or prevent its establishment. These requirements are not substantial barriers to patent enforcement by the ITC. For example, in the Allied (Amorphous Metals) case, the ITC found that a domestic industry existed because products were available for sale, the company was marketing the product, and the company had management and financial capabilities. These findings were made even though Allied's business was in its infancy, the evidence demonstrated that the prices for the products were too high, and that Allied was losing money in the venture. Moreover, the ITC found that Allied met the "injury" test, even though the infringers had only provided a few samples of their products to potential customers so that the products could be qualified for future sales to those customers.

The ITC procedure is particularly effective in cases involving process patents because the Commission maintains an Office of Unfair Import Investigations consisting of qualified attorneys representing the public interest whose mission is to investigate the allegations made by the patent owner to determine whether or not a substantial basis exists for the §337 claim of patent infringement. The role of OUII is particularly crucial in process patent investigations because the investigative staff can and does look behind the self-serving allegations of infringement set forth in a Complaint and assists the Commission in determining whether a substantial basis exists for a charge of infringement in those circumstances where the importers have no information with which to defend against the infringement allegation. Moreover, because an adverse decision by the ITC will affect the foreign manufacturer's entire business in the product in the United States rather than its business with a

single customer, as would be the case in a typical District Court proceeding, the potential for a general Exclusion Order provides a greater incentive for cooperation from the foreign manufacturer in producing evidence to establish the presence or absence of infringement. In any event, the Administrative Law Judges of the ITC can and do draw adverse inferences on the ultimate question of infringement if a foreign manufacturer refuses to cooperate in discovery proceedings. See, In Re Multi-Cellular Plastic Film, USITC Pub. No. 987 at 7 (June, 1979).

THE PROPOSED CHANGES IN ITC PROCEEDINGS ARE UNFAIR AND UNWISE.

Obviously, if H.R.3776 becomes the law the need of H.R.1069 would completely disappear since the only issue in either the ITC or the District Court would be whether the patent in suit is valid and infringed. No one is likely to choose the District Court as a forum if the ITC is compelled to decide the case within 90 days. Those who would argue that a District Court action is still necessary for the purpose of recovering damages cannot make a convincing case for that position. It has been generally recognized that it would be terribly unfair to award any damages for alleged infringement which occurred prior to actual notice of the claim of infringement. Thus, damages would only be available for the brief period of time required for the ITC to decide a case. There is no sound reason for permitting patent owners to bring process patent infringement damage claims against the innocent purchasers of imported products if swift injunctive relief is available from the ITC.

As previously noted, the ITC is empowered to grant Temporary Exclusion Orders under current law. The availability of this

remedy assures that provable cases of infringement can be brought to a halt in five months or less. It is ludicrous to believe that the ITC or any other tribunal; can give an accused infringer a fair opportunity to defend against a charge of infringement in the 90 day period which would be mandated by H.R.3776. If, in fact, such a system would be practical or fair, why has this Committee created and preserved the Federal Rules of Civil Procedure and made them applicable to patent cases? Why did the Congress provide a 30 month period to adjudicate drug patent controversies as part of the 1984 Drug Price Competition Act? The answers to these questions are obvious. Despite occasional abuses of the system of pre-trial discovery, that system is recognized as providing an essential safeguard against frivolous claims.

The proponents of H.R.3776 seem to believe that the proposed changes in the ITC are vital to protecting American industries from unfair foreign competition which is allegedly taking a "free ride" on American technology. The fallacy in this line of reasoning is that just as many important U.S. patents are owned by foreign and international organizations as by purely domestic entities and there is no reason to believe that these patent rights are being exploited in a manner which benefits the U.S. economy. It would not be at all surprising if the actual impact of H.R.3776 is to open the doors of the ITC to actions by Japanese corporations seeking to prevent U.S. companies from importing vital components of domestically assembled products. Do we really want to enact legislation which would give a Japanese automaker the ability to shut down a Detroit assembly line in 90 days because that assembly line uses an imported filter, seal or circuit board claimed in a Japanese-owned patent? Or would we prefer

that the domestic industry be afforded a full opportunity to mount an appropriate defense to the claim or, at least, the time to design around the problem without disrupting its production? Will the existence of draconian remedies in the ITC create a "winner take all" attitude and eliminate the licensing negotiations that now routinely take place when these types of problems arise? In the rush to do something about foreign competition, care must be taken to insure that the cure is not worse than the alleged disease.

CURRENT PATENT LAW DOES NOT DISCRIMINATE AGAINST PROCESS INVENTIONS: THE NEW PROCEEDING WOULD CREATE LIABILITY WITHOUT FAULT

An understanding of some basic principles of patent law is necessary to appreciate why current patent law does not discriminate against process patents. Those principles are:

(1) Title 35 U.S.C. §101 states:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefor, subject to the condition and requirements of this Title."

(2) The term "process" is defined in 35 U.S.C. §100 and means:

> "Process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

Translated into simpler language, the term "process" or "method" usually refers to the steps or procedures which are followed in manufacturing a product. The term "manufacture" which appears in

35 U.S.C. §101 actually means "article of manufacture" or "product." A chemical compound, on the other hand, is usually referred to as a "composition of matter."

(3) In the pharmaceutical field, the claims of a patent are either directed to the chemical compound, per se, (a "composition of matter" patent); to the method of using that compound for a therapeutic purpose (a "method of use" or "use" patent); or to a method of manufacturing a chemical compound (a "process" patent).

(4) Every issued patent ends with a series of numbered paragraphs which are called the "claims" of a patent. Infringement occurs pursuant to 35 U.S.C. §271 when someone makes, uses or sells a patented invention, as defined by the claims, within the United States during the unexpired term of the patent. A party can also be liable for infringement by actively inducing someone else to engage in infringement, or by contributing to the infringement by providing specialized components or compositions which are not staple articles of commerce and have no substantial non-infringing use.

(5) Under the foregoing definition of infringement, a patent covering an article of manufacture (product) or composition of matter (chemical compound) may be enforced against a much broader class of parties than a machine or process patent. This is so because everyone in the chain of commerce from the manufacturer to the ultimate consumer engages in the "use or sale" of the patented product invention. For example, if the patent claims Valium, it was "made" and "sold" by the original manufacturer, "sold" by everyone in the chain of distribution from the original manufacturer to the ultimate consumer, and "used" by the ultimate consumer. Thus, they are all infringers. In contrast, a patent claiming the

method by which Valium was manufactured would only be infringed by the manufacturer because a process is "used" but obviously cannot be "made" or "sold." Thus, no one in the distribution chain either makes, uses or sells the process.

(6) Patents are territorially limited and infringement occurs only if the claimed invention is made, used or sold in the United States. Accordingly, the practice of a process abroad is not an act of patent infringement. This is true even though the product produced by that process is intended for export to the United States. Even in the case of a product patent, the imported product, itself, becomes an infringement only with it is used or sold in the United States.

A hypothetical example will serve to illustrate how the foregoing principles result in a logical distinction between product and process patents.

Suppose the compound in question is ordinary table salt and someone discovers a new process for extracting it from the ocean. It is certainly possible to obtain a patent on this manufacturing process if it is new. But the salt itself is old and is not patentable. The patent on the new process for making salt would certainly be enforceable against a competing manufacturer who "uses" the patented manufacturing process. But, the company that purchases the salt or who uses the salt is not liable for patent infringment because it did not make, use or sell the patented process invention. The product which it either sold or used was still ordinary table salt which could have come from a salt mine, from the ocean, or from any one of numerous known chemical reactions which produce salt as a by-product. These innocent purchasers neither know nor care how

the salt was made. They are not liable as infringers under current law because the salt is not the patented invention and they, as distributors or consumers, did not make, use or sell the manufacturing process which was the patented invention.

The foregoing hypothetical example is not far-fetched. The vast majority of patents covering manufacturing processes do not produce new and patentable products. Rather, they are directed to new methods for producing old products. If the product itself is new, it will usually be the subject of its own patent. Thus, the current system of patent enforcement applies a consistent "make, use or sell the patented invention" standard to determine who is and who is not an infringer, irrespective of whether the patented invention is a machine, a manufacturing process or a product.

For the first time in the history of U.S. patent law, the proposed legislation would place a burden and liability for patent infringement on parties other than a party who made, used or sold the patented invention. It would make distributors, wholesalers, retailers and consumers liable for the infringement of a manufacturing process patent, even though they, themselves, never engaged in the making, using or selling of the patented invention. The buyers of ordinary table salt could be dragged into court and forced to defend a claim that the salt which they purchased was extracted from the ocean by a patented process rather than having been mined or produced by some other method. Obviously, the information needed to defend such an infringement claim is not apparent from inspection of the salt and is not in their possession. Moreover, they do not really care where the salt came from, provided that it is interchangeable with salt from other sources and is competitively priced.

The coerecive effect of a lawsuit against these innocent and unknowledgeable customers is self-evident. Faced with attorneys' fees, a damage claim of unknown amount and an inability to independently determine whether, in fact, any infringement has occurred, they will usually take the only practical avenue which is open to them, namely, to purchase salt from the party making the claim of infringement irrespective of the merits of that claim. As the U.S. Supreme Court wisely stated more than 75 years ago in recognizing the coercive nature of a patent infringement claim against a customer of an infringing manufacturer:

> "No one wishes to buy anything if with it he must buy a lawsuit." Kessler v. Eldred 206 U.S. 1065, 1068 (1907)

The foregoing thought was echoed by the Justice Department in opposing an attempt to pass similar process patent legislation almost twenty years ago. During 1967, Donald Turner, the Assistant Attorney General in charge of the Anti-trust Division, testified:

> "I would say that the two main questions we raised were these: (1) Has any need been shown which would make the proposal something of considerable importance? We were not aware that any extensive need had been shown, and the President's Commission report simply has the conclusory statement that there was.
>
> (2) A provision of this kind certainly in the blanket form in which it was proposed...would impose some very serious practical problems for importers of goods. If I am an importer of a goods, a product, and somebody comes to me and says this product infringes a product patent held by him, a U.S. product patent held by him,

> my job of determining or having it determined for me whether that is true, whereas it may be difficult, is relatively easy. You have two products. You can get a patent lawyer, and he can look at the prior art. He can attempt to establish how good the patent is and you compare the two products. There they are. Now, if I am an importer and somebody comes to me and says, "You are infringing not because the product is an infringing product, but it was made by a process which infringes my U.S. process patent," the only way I can determine or my lawyer can determine whether that is so is to make an investigation abroad in the country or origin and try to endeavor to find out whether the product that I have imported was in fact produced by an infringing process. That can be a very costly operation. (Emphasis added).

See, General Revision of the Patent Laws, 1967, Hearings on H.R. 5924, H.R.13951 before Subcommittee No. 3 of the Committee on the Judiciary, House of Representatives, 90th Cong. 1st. Sess., 146 (1967).

Those who would argue that innocent purchasers can put pressure on their supplier by withholding purchases or demanding indemnification agreements have not given full consideration to the realities of a marketplace in which there are often many layers in the chain of distribution between the manufacturer and the ultimate purchaser, and many purchasers who lack economic leverage over their sources of supply. For those reasons, lawsuits against customers rather than infringing manufacturers are a favorite tactic of litigators

in unfair competition and product patent infringement cases. The pressure which will be placed upon these innocent purchasers as a result of the time, expense and uncertainty of litigation will coerce them into changing their sources of supply, irrespective of the merits of the infringement controversy.

The industry proponents of this legislation are primarily very large corporations and are accustomed only to situations where they have leverage over their manufacturing suppliers. In that limited setting, it may well be that the purchaser has actual knowledge of the manufacturing processes or the means to gain access to that knowledge. However, this legislation is not limited to patent infringement issues arising between large industrial companies. To the contrary, it affects every product which moves in commerce in the United States. In actual practice, the foreign manufacturer's decision to defend patent infringement litigation may well be based on other factors such as the amount of business involved; the value of the trade secrets involved; the identify of the patentee; and the nature of the worldwide competition between the patentee and the accused infringer. Innocent buyers may well lose access to valuable sources of supply, even though there is no actual infringement simply because a foreign manufacturer legitimately refuses to make a disclosure of trade secrets to a competitor. Those who would argue that Protective Orders can be entered by the courts to protect trade secrets need only look at Coca-Cola's recent refusal to produce the formula for Coke despite the ruling of the Delaware Federal District Court that the formula was relevant to the litigation and that it would be protected from disclosure.

The proponents of this legislation have already implicitly recognized that the idea of bringing process patent infringement legislation against the purchasers and users of products is a bad and unfair idea. For that reason, the original version of the proposed legislation would not have created such liability in the case of products manufactured in the United States. The original bill limited suits for process patent infringement against innocent customers to imported products and required the owner of a process patent to sue the party actually alleged to be using an infringing process if the product was produced domestically. The bill, in that form, was opposed by the U.S. Trade Representative on the ground that it was unnecessarily discriminatory to foreign produced goods and would, therefore, violate this country's obligations under The General Agreement on Trade and Tariffs (GATT). That objection led to the current version of the legislation which eliminates the discrimination by authorizing customer suits irrespective of whether the products are manufactured here or abroad. In other words, an idea originally recognized as bad, namely, suits against customers, has been expanded.

The surest guarantee that patent infringement controversies will be decided on the merits, rather than by the coercive effect of litigation, is to ensure that, to the extent possible, controversies are litigated between the real parties in interest who have actual knowledge of the facts required to decide the merits of a claim. The ITC now provides such a forum.

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THE PROPOSED LEGISLATION UPSETS THE COMPROMISE ACHIEVED IN THE 1984 ACT WITH RESPECT TO DRUG PATENTS.

The negotiations leading to the compromise embodied in the 1984 Act recognized that there was a significant difference between patents covering processes and patents covering drug products for therapeutic uses. Specifically, Title I of the 1984 Act provides drug patent owners with an extraordinary remedy which is not available to any other class of patent owners. The patent certification procedure embodied in Title I provides the owner of a product patent or a therapeutic use patent with an automatic injunction for a period of 30 months. A pharmaceutical company gets that relief by merely identifying the product and use patents. If a generic manufacturer subsequently seeks ANDA approval during the life of those identified patents, it must certify that the listed patents are invalid or not infringed, and the generic manufacturer will be kept off the market for at least thirty months unless those issues are decided earlier.

Patents which cover manufacturing processes were deliberately omitted from the patent certification process of the 1984 Act for at least two reasons. First, it was recognized that there are almost always several different methods for manufacturing a particular product and that product and therapeutic use patents are the dominant means for protecting pharmaceutical inventions.

Second, and most importantly, it was recognized that U.S. generic drug manufacturers do not usually engage in the manufacture of the active drug ingredient but, rather, purchase those ingredients from third parties. In most cases, the third party is located abroad. The processes used by those third parties constitute

valuable trade secrets and are never disclosed to the generic dosage form manufacturers. Process patents were therefore eliminated from the patent certification scheme because it was recognized that expanded enforcement of process patents would permanently prevent generic competition. A generic manufacturer would be in no position to certify non-infringement without actual knowledge of the manufacturing process. Since it does not have the knowledge needed to make the certification, it could never obtain an ANDA approval so long as any process patent was listed.

The proposed new process legislation would make generic dosage form manufacturers liable for alleged acts of process patent infringement committed by their foreign suppliers and would shift the burden of proving or disproving the actual existence of infringement to them. Thus, it creates essentially the same problem that certification of process patents would have created under the 1984 Act. Worse yet, it places a substantial financial damage liability on generic manufacturers which will have a chilling effect on the ability of generic manufacturers to do business. The holder of a process patent, by simply asserting that there may be patent infringement (without even knowing if, in fact, that is the case) can create a potential financial risk for the generic manufacturer which makes it impossible for that manufacturer to do business on a rational basis. Since only a small amount of active ingredient usually goes into any tablet or capsule, the amounts of bulk materials which the generic industry imports are relatively small, and the dollar volume of the business in any product is not large. Thus, the foreign suppliers often lack any incentive to defend a claim of infringement. The processes, moreover, used by the suppliers often embody valuable

trade secrets which give them a competitive edge in the international marketplace. They are often unwilling to disclose those secrets, even under court ordered secrecy because the risk of inadvertent disclosure far outweights the minimal value of the business which they may lose on a particular product.

Those who would argue that the foregoing problem can be avoided merely by making sure that suppliers avoid infringement do not understand the complex workings of the patent system. Each of the pharmaceutical companies owns thousands of patents. They do not list the identity of the particular patents which are relevant to a particular product in some central place. It would cost tens of thousands of dollars to conduct the patent studies needed to determine the presence or absence of infringement, assuming the information in the processes used abroad was available to the generic manufacturer. There is a much simpler way--the patent holders should enforce their large foreign patent portfolios directly against the foreign manufacturers rather than bring coercive lawsuits against innocent purchasers.

At the time of the negotiations leading to the 1984 Drug Act, generic manufacturers were well aware of the fact that actions for infringement of process patents by acts abroad could be the subject of proceedings in the ITC. Indeed, a process patent action by Merck relating to Indomethacin was pending at the time the negotiations leading to the 1984 Act were in progress. We are not asking for repeal of the ITC procedure. Nor are we looking for a free ride in cases of proven process patent infringement. However, the ITC procedure serves as a filter for frivolous charges of infringement. Innocent purchasers of foreign made goods, who have no knowledge of how those products were made, are not faced with the coercive

effect of enormous damage claims. Rather, the ITC expeditiously determines if infringement exists and, if so, prevents the further importation of goods. Since, by law, ITC proceedings must be over within a year, the damages suffered by a patent owner are minimized by a rather short period of infringement--if, indeed, there is infringement.

Even the Patent Term Restoration portion of the 1984 Drug Act recognized that process patents should not play a significant role in the competition between brand name and generic drugs. The original drafts of Title II, which covers Patent Term Restoration, essentially excluded the possibility of extending any process patents except in the limited and unlikely circumstance that there were no relevant product or therapeutic use patents. Ultimately, in order to simplify administration of the Patent Term Restoration system, the holder of the approved NDA was given the ability to select either a product, process or therapeutic use patent for extension. However, extensions are only available in those circumstances where a new chemical entity is receiving FDA approval for the first time. Obviously, in the overwhelming number of circumstances, the patent to be extended will be a product patent or a therapeutic use patent. Indeed, none of the more than two dozen applications for patent extension which have been filed during the past year seek to extend the life of a process patent.

It seems obvious from the foregoing that pharmaceutical companies will seek to enforce process patents against generic manufacturers only after the extended product and use patent protection provided by the 1984 Act have expired. At least one process

for the manufacture of the drug product will be disclosed in the expired patent. Whether that process is the most efficient process or not is truly irrelevant to competition between generic and brand name drugs because the small amount of active ingredient used in each tablet is not as significant a factor as the vast price difference between generic and brand name drugs products. Indeed, in most cases, the bottles, labels and caps far exceed the cost of the tablets. Nevertheless, process patents can be used to impede the competition contemplated and desired by the 1984 Act by forcing generic makers to change suppliers or processes after an ANDA has been approved, thereby forcing them off the market until they rerun the gauntlet of the regulatory review process.

Congress enacted the 1984 Drug Price Competition Act at the request of the major drug companies in order to maximize protection for new products and new therapeutic uses and create the incentive for new inventions. That Act created special patent provisions for new inventions. Even if it can be established that additional process patent protection is needed in other industries, pharmaceutical patents should be exempted in view of the 1984 Act.

In summary, present law provides for the enforcement of process process patents against imported products in the ITC and strikes an appropriate balance between the enforcement of patent rights and the protection of domestic industries. Unless and until a body of economic information is developed which would establish that a broader enforcement of U.S. patent rights would be beneficial to U.S. industries and U.S. jobs, there is no reason to enact additional laws, particularly in view of the obvious flaws and unfairness in H.R.1069 and 3776.

Mr. BROOKS. Ms. Fensterer, you do a very fine job and you are the first person, I believe, in 34 years of congressional service, that has been able to capsule her statement and say what in the hell she meant without taking more time than it would have taken to read the whole thing. I want to congratulate you.

You brought your lawyer backup, but that is all right.

Ms. FENSTERER. Thank God I am not a lawyer.

Mr. BROOKS. I have got a couple of comments to make, but what do you want to add?

Mr. ENGELBERG. I would just like to point out that in 1984, after a lot of wrestling and negotiation, we enacted the Drug Price Competition Act and that did something in the area of drug patents that does not really exist in any other area. It provided, in effect, what Mr. Kindness has been questioning a number of witnesses about, and that is an administrative remedy for product-in-use patents which prevents an infringing drug product from getting on the market until after all the patent issues have been decided.

In effect, we left process patents out of that package at that time because of what Ms. Fensterer said, and that is that we do not know how these products are made, and as the two prior witnesses just pointed out in the case of vitamin C and in the case of drugs, there are always multiple methods of making a product.

We are liable, under current law, for patent infringement. We are liable in the ITC. The questions that have been discussed here this morning about domestic industry and injury rarely arise in drug cases because there are two commercial entities involved. What the ITC does, and what this bill would take away, is a filter, an opportunity to determine before anybody is hit with a damage claim, before anybody is put out of business whether vitamin C is made by the infringing process or made the old way, and whether or not there should be any liability.

This bill really tilts us toward a very cohersive type of litigation system.

Mr. BROOKS. All right, counselor.

Ms. Fensterer, I want you to understand that I am certainly concerned about generic drug operations and their ability to provide lower-cost drugs to people in this country. I sympathize with that and I support that. I think most of the Members of Congress do.

Ms. FENSTERER. And the Congress did in 1984.

Mr. BROOKS. I think most of Congress does. But we are not trying to put you out of business. At the same time, we have a serious problem and perhaps it can be resolved and not put you under any undue liabilities. But you have got to understand that the truth of the matter is what if you do know that it is made in violation of an infringement? What if you know that they are violating?

Ms. FENSTERER. We are subject to the ITC.

Mr. BROOKS. You never know or you just do not want to know? What if you did know? What if they told you, we are in violation, but we will sell it to you for $100 for 10 kilos? What would you do about that?

Ms. FENSTERER. I am certainly sure the patent-holder in that situation would take us before the ITC and that would be the end of it. There is not——

Mr. BROOKS. Could they get damages?

Ms. FENSTERER. In the ITC, there are not damages.

Mr. BROOKS. No damages. You just say, "Sorry. Don't you all tell me next time."

You know what I mean. In the real world, you have got to consider that. So I would just say that maybe you ought to think about a way to protect you from honest situations where you make a mistake—we are not trying to put you out of business, but we are going to do something about this matter.

We do not want to unnecessarily damage your operation, but something is going to be done, in my judgment.

Ms. FENSTERER. In 1069, however, Congressman, you are shifting the burden to somebody who does not know.

Mr. BROOKS. If you have been notified or knew.

Ms. FENSTERER. But there is no way you were going to be notified.

Mr. BROOKS. Maybe they could figure out a way.

Ms. FENSTERER. If you own a retail drugstore, do you know how those 20,000 products have been made that are in your store? You do not know.

Mr. BROOKS. I do not own a retail drugstore.

Ms. FENSTERER. If you did, sir, and there are many in your district, some of whom are members of the Generic Pharmaceutical Industry Association.

Mr. BROOKS. If they did not know, they would not be liable. But if they had been notified, then they would be.

Mr. ENGELBERG. Mr. Chairman, the notification that is built into 1069, together with the presumption has built into it a notion that the person asserting the infringement also does not know.

Mr. BROOKS. Counselor, you better figure out some amendments that will protect your case and let us pass this legislation. I believe——

Mr. ENGELBERG. I understand.

Mr. BROOKS. I am going to vote for some whether—I mean, let me rephrase that.

I believe that we will probably—Congress, in its wisdom—work out some legislation along this matter. If you have an interest and think that it is working to a disadvantage to those wonderful people who get low-cost drugs, you ought to think of some amendments that will be helpful and will do the job.

Mr. ENGELBERG. We have a number of ideas.

Mr. BROOKS. All right.

We will appreciate your submitting them to us. Let us take a look at them. We are openminded about trying to help you, but we are going to do something. There is too much pressure on this, too much difficulty about trade. $148 billion is too many jobs.

Ms. FENSTERER. I hope the Congress will also make a distinction between counterfeit gray goods and process-patent infringement. If you look at the record, at least in the pharmaceutical industry, there have been very few cases of process-patent infringement before the ITC. It is not a rampant problem. We live with process patents now. We are not trying to infringe those patents.

Also, Congressman, if I may, I would like to insert this brief three-page summary statement into the record as well.

Mr. BROOKS. Your statement and your summary will go, without objection, of course.

[The summary statement of Ms. Fensterer follows:]

SUMMARY STATEMENT OF

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

BEFORE THE

COMMITTEE ON JUDICIARY

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES

AND THE ADMINISTRATION OF JUSTICE

HOUSE OF REPRESENTATIVES

NINETY NINTH CONGRESS

SECOND SESSION

ON

H.R.1069 & H.R.3776

FEBRUARY 19, 1986

My name is Dee Fensterer. I am President of the Generic Pharmaceutical Industry Association. GPIA members account for approximately 85 percent of the generic drugs produced in the United States.

We oppose H.R.1069 because it will delay pharmaceutical competition by making generic companies liable for alleged acts of infringement that may or may not have been committed by our foreign suppliers of raw materials. Without those raw materials, we won't be able to supply American consumers with lower-cost drugs. And that is the real danger of this bill -- that consumers, especially the elderly and chronically ill, will be denied affordable medicine.

Generic manufacturers import the active ingredients of our pharmaceuticals for a very practical reason. The former patent holders won't sell to us. Our raw materials, therefore, are imported from worldwide suppliers who appreciate our business, but are in no way dependent upon sales in the United States. Please remember that generic versions of frequently prescribed drugs have been available in Canada and Western Europe for many years. When it comes to pharmaceutical competition, we are just catching up in the U.S.

Please also remember that the cost of raw materials in the pharmaceutical business is miniscule compared to the final consumer cost of the tablet or capsule. John Pekkanen gives an example of this in his 1973 book, "The American Connection: Profiteering and Politicking in the 'Ethical' Drug Industry." The raw material for

Valium at that time cost $87 per kilo. Production costs, liberally estimated, brought the final dosage form cost up to $487 per kilo. The retail price for Valium, however, was at that time $11,000 per kilo, 140 times the cost of the raw materials.

Generic companies of course don't add on a $10,000 per kilo profit, but instead offer consumers medically-necessary products at competitive prices. And we do this only after product and use patents have expired.

The proposed bill will make generic companies liable for process patent infringement even though we do not have knowledge of the manufacturing processes used abroad to make the raw materials for our finished dosage forms.

Further, the bill starts a damage clock ticking upon the mere notification that perhaps a foreign manufacturer may be using a process, or a step in a multi-step process, that has been patented in the United States. Not only are we put at great financial risk, we are guilty until we prove ourselves innocent.

You may ask why we can't avoid all this by making sure that the raw materials we purchase are not made by a U.S. patented process.

First, we try to do this whenever it is feasible. The record shows that there have been very few pharmaceutical process patent infringement cases brought before the International Trade Commission. If patent infringement was rampant, the record would reflect this.

Second, there is no Yellow Book Directory to process patents, no easy cross-references to the multitude of ways in which a product can be made. Allied advertised in the New York Times recently that it holds 25,000 U.S. patents. The same is true for each of the

domestic, foreign, and multinational pharmaceutical companies.

Third, the processes used by our suppliers often embody valuable trade secrets which give them a competitive edge in the international marketplace. Not only are our suppliers unwilling to disclose their manufacturing processes to us, their customers, they are also unwilling to reveal their trade secrets under court-ordered secrecy.

It is for these reasons that process patents were eliminated from the patent certification procedures of the 1984 Drug Price Competition Act. Under the Act, the major pharmaceutical companies were granted substantial concessions with respect to both length of patent terms and freedom from infringement of product and therapeutic use patents, unless and until those patents either expired or were declared invalid. Since process patents covering new chemical entities usually do not come into existence until after the product and its therapeutic use are developed, this legislation provides the major firms with increased opportunity to delay generic competition after basic product patent protection expires.

Finally, this is not a situation where the generic industry is looking for a free ride. We live with, and are willing to continue living with, the current ITC law which provides ample protection to injured patentees. ITC law does not hold a damage gun at our heads. It also gives us some assurance of an independent evaluation of the infringement claim by an administrative agency with investigative authority.

We do not believe the ITC system should be watered down as proposed by H.R.3776. That bill would give us no reasonable opportunity to defend ourselves, but would allow the major pharmaceutical companies to prevent competition even when they are not

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injured by the alleged infringement and even when they are not using their patents to produce products and jobs in the United States.

Ms. FENSTERER. Thank you.

Mr. BROOKS. I thank you very much. I am going to vamoose and turn this over to my distinguished and beloved colleague, Carlos Moorhead. It is not very often that I turn anything over to Republicans. But he is so responsible, reliable, dedicated, and true, that it is my privilege.

Mr. MOORHEAD. There are no Democrats left. [Laughter.]

Mr. MOORHEAD. [presiding]. I want to just make a brief comment. We all believe in your industry and we do not want you to get hurt.

Every industry that provides a product for the American people, and you do provide things that all of us buy. We buy things from the drugstore that the generic industry makes every day.

But you are also concerned, and the people that buy your products are concerned that our economy remains healthy, that our people have jobs and that we at least take care of the minimum needs of our society. You cannot do it without rules sometimes that may touch just lightly on a little toe, but it does not hurt you basically.

This bill will not hurt you particularly. No damages shall be recovered by the patentee for infringement under section 271 of this title from an infringer who did not use the patent process except on proof that such infringer knew of or was notified of infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such knowledge and notice.

So you are in no trouble about that microphone whatsoever. They cannot do a thing to you for using it because you have not been notified, even if it was an infringement.

I think that you are overly concerned. Actually, you know, even if you were notified if it were a false notification, if you were not infringing, you can establish that after you have been put on notice, and if you are not infringing, then you are in great shape.

But someplace, the person who owns the patent has to be protected. It is not just a question. He has to go all the way forever and ever in order to get some kind of support. You cannot go on, even though you know of the infringement and infringe his patents or his process without some liability, if it turns out that you, in reality, are infringing. If you are not, you are always safe.

Ms. FENSTERER. Sir, if I am the innocent user of this microphone and you put me on notice that it was made by some manufacturing process I never heard of, I am going to move away from this microphone real fast. I am not going to use it anymore.

Mr. MOORHEAD. We both know that this is not what is going to be enforced. There is no problem there whatsoever. That is not where the fact comes into play. It is when there are hundreds of thousands of dollars that are involved that people go to the Trade Commission or they go to court.

Those things do not have any effect—something like that does not have any effect on it.

Mr. ENGELBERG. Congressman, in the only recent process patent case in the drug field, after a lot of wrangling and a lot of litigation, it turned out that there were two processes—at least two commercial processes and a great deal of uncertainty as to which one

was being used when and by whom, and the threat of litigation and the cost of litigation is bad enough on an innocent party who is not engaged in the infringement, but there is a possibility that maybe there is infringement, maybe there is not infringement and maybe the innocent buyer of these raw materials from abroad will never find out.

What you are doing is creating a gun at somebody's head and saying, "You know that vitamin C you bring in. It may be infringing my patent, but of course, it may not because there are six other ways to make it."

Why should liability attach at that point? Why should someone have to make the decision to either defend and go forward or risk perhaps a multimillion dollar damage suit that will put them out of business? Everyone here is interested in speed and quick results and quick enforcement of intellectual property.

The ITC does that and has the default rules that Dr. Stern talked about and you get an answer by compelling an answer for a foreign manufacturer within about 3 months under current ITC law. Why should a damage clock be running under those 3 months just because someone claims there may be infringement, but that someone does not know whether, in fact, there is?

Mr. MOORHEAD. You always have to have a basis for going to court, you always have to have a basis to go before a commission, and unless there was pretty certain information along that line by the plaintiff, he would never bring the suit.

Mr. ENGELBERG. I wish that were true.

Mr. MOORHEAD. But this is true in every lawsuit we ever get in this country. There are two sides to the lawsuit. There are always two sides. The person who feels that they have damaged can take you to court any day that they can show a probable cause.

Mr. ENGELBERG. That is absolutely true, but we are changing a basic ground rule here, which is why there has never been process patent enforcement in this country against foreign-made goods and that is, we are now making someone liable who purchased the goods in interstate commerce or international commerce without any more knowledge as to how they were made than the patent owner.

Now, if there is a case of willful infringement, I do not think anybody is going to object to writing a law that says in cases of willful and knowledgeable infringement, there ought to be some Draconian remedies.

But we are talking here about a situation where the generic drug company buying these raw materials is really not the culprit. What this bill is trying to do is make that person the vehicle and the surrogate for the culprit because we have not been able to figure out a way to get at the culprit that we have been talking about all morning here. Now, we are saying, we are not only going to use this innocent purchaser as the surrogate, but we are going to hold him liable for something that he really does not know about and really cannot defend and we are going to do it based on a suggestion, not on any proof.

What that does is it unbalances the system and creates the opportunity for a lot of coercive lawsuits that really have no merit

but will scare the hell out of the potential defendants and make them run before they ever get to the merits.

Mr. MOORHEAD. A U.S. inventor or U.S. company, after many years of research and millions of dollars invested, discovers a new process for developing a medicine that is a cure for cancer. Under the present patent law, the new process which is patented in the United States can be taken overseas, reproduced, shipped back to the United States and sold much cheaper than the original brand-name. You see nothing wrong with this?

Mr. ENGELBERG. It cannot be done under current law because under the Drug Price Competition Act of 1984, if there is a patent on a new drug, that new patent would not only be subject to patent extension, but there could not be any approval granted for——

Mr. MOORHEAD. But it is on the process, not on the——

Mr. ENGELBERG. It does not really matter because the—from an FDA point of view because of the nonpatent exclusivities that are built into title I, there is at least some period of exclusivity for the first person who gets approval for this new chemical entity and if all that is left is process patent protection after everything else has run out, that person still has the ITC. We are still liable for that, and we are not even arguing that we should not be liable or should not be prevented in the case that there is process patent infringement.

What we are saying is that the rules have to be adjusted and the legislation has to be adjusted so we can honestly find out whether or not there is infringement or somebody is at risk of paying big dollars, and we ought to do that quickly and in an efficient forum. We are not objecting to that, either.

Mr. MOORHEAD. I understand your position. You are fighting to get products that are patented. You want to get your products on the market as fast as you can because it helps you with competition, but I think that it is to the interest of our company that we give the people who have invented these things, that have come up with the process, that have spent the money, some protection.

I think that the position you are advocating is one that would not give them that protection that they need.

Mr. ENGELBERG. I think we are only disagreeing about when and how much and not whether there should be protection, frankly, and I really think that that needs to be adjusted.

Also, one other point that really has not been emphasized this morning, and that is that without the domestic industry requirements that are built into current law, in opening this thing up, we are really taking a patent law which is neutral as to nationality and creating a circumstance where a Japanese auto maker can go into the ITC and shut down a Detroit assembly line within 90 days because that assembly line happens to be bringing in a filter or a chip or some other patented part from Australia or Germany or some other part of the world.

I am not sure that that kind of possibility meets the objectives that this bill really has in mind.

Mr. MOORHEAD. That is never going to happen.

I have no further questions. The meeting is adjourned.

[Whereupon, at 12:35 p.m., the subcommittee was adjourned, to reconvene subject to the call of the Chair.]

INTELLECTUAL PROPERTY AND TRADE

WEDNESDAY, APRIL 23, 1986

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The subcommittee met, pursuant to call, at 10:50 a.m., in room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Schroeder, Frank, Moorehead, and Kindness.

Staff present: Michael J. Remington, chief counsel; David W. Beier, assistant counsel; Thomas E. Mooney, associate counsel; and Audrey K. Marcus, clerk.

Mr. KASTENMEIER. The subcommittee will come to order.

We will be joined shortly by several of my colleagues.

This morning the subcommittee will be conducting our second day of hearings on intellectual property and trade. During our first hearing we heard from the U.S. Trade Representative, the International Trade Commission, Allied-Signal, Genentech, and the generic drug industry. This morning we will hear from an academic expert on international law and trade as well as witnesses with expertise on the operation of section 337 of the Tariff Act of 1930.

We want a level playing field for our intellectual property exports as well as adequate protection against counterfeited imports. Therefore, we must be sensitive to international law issues as we change our domestic laws. That is not to say we should not act. I readily acknowledge there appears to be a broad consensus about eliminating the injury requirement in section 337. I am not unalterably opposed to such a move, but rather I think we should be cautious before we leap to that change. Hopefully, this hearing will assist in our effort to understand the ramifications of such a change.

Our first witness this morning is Prof. Robert E. Hudec, University of Minnesota Law School. Professor Hudec is known over the world as an expert on international law and trade. He has written and lectured on GATT and other trade issues since he left the general counsel's office of the U. S. Trade Representative.

Professor Hudec, we have received a copy of your statement. It will be made part of the record. You may proceed any way you wish.

STATEMENT OF ROBERT E. HUDEC, PROFESSOR, UNIVERSITY OF MINNESOTA LAW SCHOOL

Mr. HUDEC. Thank you very much, Mr. Chairman. I am very happy to be here today.

My purpose is to discuss the issues of GATT law presented by two groups of bills presently before the subcommittee on intellectual property matters. First are those proposals in H.R. 1069 and title I of H.R. 4539, among others, to establish infringement liability for the sale or importation of goods made by processes patented in the United States; second are those proposals to which you just referred, Mr. Chairman, having to do with the industry and injury requirements of section 337.

I do not think that it would be appropriate for me to repeat those parts of my statement which have to do with the general background of GATT except to add one thought. Why should we be interested in the GATT consistency of these proposals? I think there are three reasons one could cite.

First, violation of GATT law can be costly in an immediate sense because a violation of GATT law does authorize those governments injured by a GATT violation to retaliate. While retaliation has not been over the history of GATT a very common remedy, it has in the last 5 years become fairly common, particularly in relations between the United States and the EEC. So I think one does have to worry in passing almost any trade legislation these days about the possibility of triggering retaliation and possibly even counter-retaliation.

The second reason, on a somewhat broader level, is the effect of GATT violations on the U.S. ability to enforce the GATT rights that it has. The United States has been over the entire history of GATT the single country most interested in enforcing GATT rules against others. I am now doing a study, for example, in which I have been counting complaints and I find the United States itself is responsible for about 40 percent of all GATT legal complaints filed since the history of the organization began in 1947. Each time that we violate the GATT ourselves we impair our ability to enforce our own GATT rights against others.

Third—and we are straying somewhat from the precise field of law and legal remedies—the United States is about to embark on a negotiation in GATT in which intellectual property will be, we hope, one of the issues on which we will be making important progress. The actions that we take with regard to intellectual property will, I think, set a framework for those negotiations and for our ability to achieve the kind of protection that we want in the negotiations. This is not the only issue currently before the Congress that may have an impact on the course of those negotiations. There are issues pertaining to the manufacturing clause. There are issues pertaining to the deductibility of the tax on tariffs paid by imports. But the area of international property legislation is, I think, certainly one of the important areas that will have an impact on the course of those negotiations.

So with that introduction, let me turn to the two groups of statutory proposals and their GATT impact. I think I can dispose of the first rather quickly. Those statutes pertaining to the new infringe-

ment remedy for process patents, H.R. 1069 and title I of H.R. 4539, seem to me not to have a GATT problem as presently drafted.

There was 2 years ago a proposal to create an infringement remedy for process patents that would have been, in my mind, a clear GATT violation because it applied only to goods made abroad under processes currently patented. The current proposals, as I read them, deal equally with goods made in the United States and goods made abroad. The relevant GATT requirements here are basically that you can regulate trade in your internal commerce as much as you want, but you must treat foreign-made goods the same as you treat domestic goods. You may prohibit counterfeit goods, you may prohibit sales of goods that infringe patents, but the prohibitions must apply equally to foreign and domestic goods.

Now, I would make one reservation as to that conclusion: I am not myself an expert in the details of intellectual property law. Therefore, while I can see no distinction between the treatment of foreign goods and the treatment of U.S.-made goods in these bills that is ultimately a question for specialists in intellectual property.

Turning to the current bills concerning section 337, we encounter a much more difficult area as far as GATT law is concerned. We have had in the GATT litigation on the GATT consistency of section 337. In 1981, the Canadian Government filed a complaint in a case that is known as the *Spring Assemblies* case. A decision was reached by the GATT panel in 1982, and the GATT council, acting for the contracting parties of GATT, adopted or accepted that decision in 1983.

The decision found that section 337 as applied in the particular case was not a violation of GATT. However, both the Canadian Government, and I must say several other leading GATT governments, including the European Community and Japan, objected to the GATT report and asked the contracting parties not to adopt it because it was wrong and also incomplete. I would agree with the view that the report is that it was rather poorly reasoned. A compromise was reached in which the contracting parties did accept the panel report, but with so many qualifications and reservations that I am afraid we have to say the panel report did not settle very much.

I would like to give my own views of what the GATT problems are with regard to the present section 337 and the proposed reforms. My comments break down into four headings.

First, there have been a number of statements to the committee in the past concerning the question of whether or not the present section 337 is protected by GATT's grandfather clause for pre-1947 legislation. It is true that all of the substantive provisions of section 337 were passed prior to 1947. However, the grandfather clause in GATT excepting pre-1947 legislation from the obligations of GATT is limited to what is called mandatory legislation, legislation which leaves no discretion on the part of the Executive as to whether or not the mandate of the law must be complied with.

The reason for this mandatory requirement goes back to the reason for the grandfather clause in the first place. The grandfather clause was put into the GATT protocol in order to enable governments to sign the GATT without having to go back to their legislatures and change legislation. It was meant to excuse govern-

ments from violations then required by law. If the Government was required to do something in violation of the law in 1947, then it could sign the GATT, go ahead and obey its law and it would not be acting inconsistently with GATT.

Where, however, the Executive did have discretion not to apply an inconsistent GATT law, the protocol did not excuse the Executive. The Executive was required to use its discretion to avoid GATT violations. The mandatory requirement has been litigated in the GATT, and there have been decisions finding governments in violation under claimed grandfather rights because, in fact, the legislation was not mandatory.

Now, section 337 is not mandatory legislation. The President does have the authority not to apply section 337 remedies for policy reasons. I think this is clear. The grandfather clause is irrelevant. If section 337 is in violation of GATT, it is not protected by the grandfather clause.

Now, the second point. There has also been argument before the committee about the industry and injury requirements of the present section 337, suggesting that these requirements show that section 337 is not GATT conforming. Now, I am going to have to back up for just a minute on that issue to explain the underlying requirement.

Section 337 authorizes exclusion orders, orders excluding goods. Orders excluding goods are prohibited by GATT article XI, flatly prohibited. GATT prohibits all import prohibitions not in the form of a tariff. The question of whether or not an exclusion order under section 337 is a GATT violation depends, therefore, on whether or not there is an express exception in the GATT for these exclusion orders. I think everyone discussing the issue agrees that that pertains in this case is article XX(d) which states in general terms that laws which are "necessary to secure the enforcement of * * * patent laws" are permitted to violate the GATT to the extent necessary.

Now, the question then is really whether exclusion orders under section 337 are necessary to the enforcement of U.S. patent laws. Do we need to have this remedy in order to be able to enforce U.S. patent laws and other intellectual property laws at the same time?

Now, let me amplify on the standard of necessity first. I believe it is settled that when the GATT says necessary to secure the enforcement, the GATT means necessary to secure the same level of enforcement that we have against goods made in the United States. As an example, if you have a civil remedy for patent infringement against goods made in the United States, you could not, against foreign goods, provide for a criminal remedy. It is true that a criminal sanction would help you enforce your patent laws, but it would be enforcement that went well beyond what you do to domestic goods. The standard here is an equal treatment standard.

It is possible that a government may need a special remedy against foreign-made goods in order to enforce the patent laws against them to the same extent that the patent laws are being enforced against U.S.-made products. Article XX(d) permits such a remedy.

The question then is: Is section 337 necessary to achieve the same kind of patent law enforcement against foreign-made goods as we have against U.S.-made goods?

The argument involving the injury and industry standards on this goes something like this. If section 337 were really necessary to secure adequate enforcement against foreign-made goods, then why don't all patent holders have a right to use section 337? Why is it that we only apply section 337 remedies on behalf of those patent holders who have a U.S. industry and, furthermore, who are injured by virtue of the alleged infringing act?

We do not ask those conditions of our own basic infringement laws. You do not need to show injury in order to bring an infringement action in a U.S. district court. You do not need to show that you have a U.S. industry to bring an infringement action in the U.S. district court.

Well, the argument runs, that shows, doesn't it, that section 337 is not really about intellectual property rights at all; it is just an extra remedy being given to U.S. industries in the guise of protecting their patents. This is an argument, I must confess, that kept my mind spinning for quite a while.

Ultimately, however, I concluded it is a red herring. It is true that we have a distinction being made between two groups of patent holders. Let's call them domestic, those that have a domestic presence in any event, and foreign patent holders. Domestic patent holders get section 337 rights. The foreign ones do not.

It is equally possible that what we are doing under section 337 is giving adequate protection to the domestic patent holders, people who have an investment in the United States, and denying adequate protection to foreign patent holders, that we are not giving adequate protection to foreign patent holders. Now, that also would be a violation of U.S. obligations, but it is not a violation of GATT. It would be a violation of the Paris Convention. It would be a patent problem, not a trade problem.

Which is it? Are we giving American industries extra protection in the guise of protecting their patent rights or are we just giving American industries basically equal protection against foreign goods but denying that protection to foreigners?

We cannot decide that issue by looking at the industry or the injury requirements. We have got to look at the basic structure of 337 itself. That is what is going to tell us whether or not section 337 is or is not necessary to enforcement. If section 337 rights as they now exist are necessary to the adequate enforcement of the patent rights, then it does not make any difference whether we have an injury requirement or not. Our law is GATT consistent. We may have trouble with the Paris Convention, but that is a patent problem.

If section 337 is necessary to secure adequate enforcement, subtracting the injury requirement and the industry requirement, making section 337 available to everyone, is not going to change its GATT characterization. It will still be GATT consistent. Foreign patentholders also have a right under GATT to adequate minimum enforcement.

On the other hand, if section 337 is not necessary to the adequate minimum enforcement of the U.S. patent rights, then adding or

subtracting the industry and injury requirements is not going to make any difference. It is not going to make it any more GATT-conforming if we strip away the injury requirement. It is not going to make it any more GATT-conforming if we strip away the industry requirement. It may make the GATT violations strike a few more people than it would have stricken before, but otherwise it will not affect the GATT requirements.

So I think there is a policy issue about whether or not you want to have an industry requirement, and there is a policy issue about whether or not you want to have an injury requirement. I do not believe, however, that the way you answer those questions will affect the GATT consistency of section 337.

The question of GATT consistency then boils down to two issues. They are issues that apply to the present section 337, and they would apply to the amended section 337 essentially in the same fashion. Those issues are, first, are the exclusion orders now authorized by section 337 really necessary to secure adequate enforcement? That is issue one. Second, is the separate administrative proceeding that exists in section 337 really necessary? Both of those have been cited by our trading partners as GATT violations. Those are where the issues are.

What is the issue with regard to exclusion orders? Our trading partners agree that an exclusion order directed to a named party in a section 337 proceeding and a cease and desist order which has to be directed to a named party create no GATT problem because those are just the functional equivalents of what happens in an infringement proceeding against a domestic infringer. The patentholder can get injunctions in a domestic court proceeding. The exclusion orders in a section 337 proceeding are simply an analog. They are not identical, but they are certainly no less favorable.

The issue is the so-called general exclusion orders, the order that can issue in a section 337 proceeding not only against goods coming from named infringers whose infringement has been proved in the proceeding but against all goods, from whatever foreign source, found to infringe the patent in question.

The Canadian Government pointed out in the *Spring Assemblies* case that there is no analog of that kind of remedy when we enforce patents against domestic infringers. Their argument was, "You are doing more against foreign infringers than against domestic infringers. That is not necessary. You are overenforcing against foreign infringers and, therefore, in violation of GATT."

The GATT panel in the *Spring Assemblies* case said, "Not necessarily." The standard in this area, as I would put it, is this: You can have remedies against foreign goods which are not the same as those you use against domestic infringing goods if the different remedy is necessary because of the different position of the foreign goods. The example that is used to justify the general exclusion remedy is the question of jurisdiction. The general exclusion order is used as a way of helping to deter others, those not named in the proceeding from infringing the patent. The U.S. Government has argued and the panel in this case agreed that there is a distinction here between domestic goods and foreign goods. In a domestic situation other potential infringers are going to be subject to a damages remedy because they are within the jurisdiction of the United

States, U.S. district courts. Jurisdiction in the U.S. district court case can easily be gotten over them, and that jurisdiction acts as a fairly powerful deterrent against strangers who might be thinking about infringing the patent. That jurisdiction is by no means certain in the case of other foreign infringers and, therefore, an additional deterrent, something like a general exclusion order, may be needed.

In theory I think that is a correct answer. The panel went on to say it is a case-by-case problem. It depends on the nature of the good, the nature of the domestic commerce in the product. I think that is also correct. I think the issue for the subcommittee, the issue for the Congress here in terms of passing GATT consistent legislation is that the general exclusion order may be authorized. The question is: Has the legal agency, whether court or ITC, been given enough discretion to apply it only in cases where it is really necessary? Do they have the freedom not to employ it where it is not necessary?

I think the answer to that question is yes; but, again, I would defer to experts in ITC procedure.

In sum, I do not think that the general exclusion order presents a serious GATT problem provided that the law allows the administering agency to limit the use of that order to cases where it is practically necessary.

Now, the second and last major issue. What about the separate procedure of section 337? The argument of the Canadians and the EEC and several other GATT countries runs like this: A domestic producer in the United States infringing a patent has one procedure to fear. That is a domestic infringement action in a U.S. district court. A foreign producer accused of infringing a U.S. patent gets hit twice: It can be hit by a section 337 proceeding and can also be hit again simultaneously by a U.S. district court proceeding. I am told by representatives of foreign governments and, indeed, by some patent attorneys in this country that it is not at all uncommon for the owner of a U.S. patent to use both remedies at the same time. This, the foreign government says, is clearly extra enforcement. You are doing something against us more burdensome than you do against your own people.

Now, the U.S. Government has argued, "Gee, fellows, the section 337 proceeding is no worse than a U.S. district court case." In fact, in some ways it may be better, easier, quicker, faster. The procedure is less formal. I do not think that is a relevant argument. The fact of the matter is that even if section 337 is no worse than a district court proceeding, it is different, and there are two of them, and two is bigger than one.

Now, if that is the case, then the issue shifts. OK, so you are imposing a greater burden on producers of foreign goods than on domestic producers. Is that justified? I think it would be justified if under our Constitution we had no other way of dealing with foreign goods than in a separate administrative proceeding. And so the issue really comes down to this. Could you do what you have to do in section 337 in a district court action? Could you give the district court, a U.S. district court in an infringement action the powers that the ITC has in a 337? Could you package it all in one place?

The U.S. Government has replied we cannot do that now because Federal district courts need personal jurisdiction and they cannot always get personal jurisdiction over foreign infringers. It seems to me that is something the Congress could change immediately. This is not a constitutional problem. The Federal district courts may not have in rem jurisdiction now, but they can certainly be given it. They could be given jurisdiction to do everything that the ITC does.

Second, and more seriously, there is an article III problem lurking here. Ever since section 337 was enacted, there has been an article III problem. Section 337 actions are subject to veto by the President. Could you give a Federal district court power in a section 337 case and still provide for the Presidential override for policy reasons?

I am not an expert on Federal jurisdiction. This committee is. This committee will ultimately decide that issue regardless of what I tell you. I can tell you that I have asked my colleagues at the University of Minnesota and they are in serious dispute about the issue.

The bottom line is you probably could do it if you wanted to, but it might not be a very good idea. And this is, I think, what the GATT problem really comes down to in the end.

We have imposed on foreign producers under section 337 a separate remedy which is more burdensome, when added to the infringement remedy, than enforcement mechanisms we use against our own producers. We have, it seems to me, a constitutional justification only to the extent we choose to have a Presidential override here. We do not really have to do it this way.

Now, some say, well, the Presidential override is really for the benefit of the foreign producer after all. In order to do you a favor, we subject you to a separate proceeding. I am always a little suspicious about those kinds of gifts.

Thank you very much, Mr. Chairman.

[The statement of Robert E. Hudec follows:]

Revision, 4/28/86

TESTIMONY OF ROBERT E. HUDEC

PROFESSOR OF LAW, UNIVERSITY OF MINNESOTA LAW SCHOOL

BEFORE THE

COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE

ADMINISTRATION OF JUSTICE

WEDNESDAY, APRIL 23, 1986

10:00 AM

ROOM 2226 RAYBURN HOUSE OFFICE BUILDING

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Mr. Chairman and Members of the Subcommittee:

My name is Robert E. Hudec. I am a professor of law at the University of Minnesota Law School. I have been a student of the General Agreement on Tariffs and Trade (GATT) for over twenty years, first as one of the original members of the Office of the U.S. Trade Representative, and later as a law teacher, legal scholar and legal consultant to USTR and to the GATT Secretariat. I am appearing today in my personal capacity, and not as a representative of the University of Minnesota.

I am pleased to be here today to discuss the issues of GATT law presented by several bills on intellectual property matters currently being considered by the Subcommittee. My testimony will focus on two principal proposals -- (1) the proposals in H.R. 1069 and in Title I of H.R. 4539, among others, to establish infringement liability for the sale or importation within the United States of goods made by processes patented in the United States, and (2) various proposals, similar but not identical, to relax or eliminate certain of Section 337's "industry" and "injury" requirements, such as the proposals in Title II of H.R. 3776 and in Title II of H.R. 4539.

I would like to begin by reviewing briefly the nature of GATT, and the content of the basic GATT obligations in question. I will then address the main issues of GATT law specifically presented by the proposed legislation.

1.What is GATT?

GATT is an international agreement, concluded in 1947. It deals with tariffs, quotas and all other measures that governments use to influence or control foreign trade. The legal obligations of GATT involve contractual undertakings by governments not to use certain kinds of trade measures, and to limit the use of others. The 1947 GATT agreement has been amended several times, chiefly in 1955, 1964 and 1979. The total package of GATT legal texts, including side agreements, would come to several hundred pages.

In addition to being a legal agreement, GATT is also an international organization. Although it is not a formal member of the U.N. family of international organizations, GATT is far and away the world's most important organization in the area of foreign trade. GATT currently has 90 full members, and about 30-35 more who participate as observers and who claim to apply and observe GATT rules on a de facto basis. Its importance can be measured by the fact that, even though it is based on free market principles, it counts four Soviet bloc countries as full members, as well as the Peoples Republic of China as an observer and possible candidate for membership.

2. What is the Status of GATT under International Law?

The GATT agreement was put into force by a separate legal instrument called the Protocol of Provisional Application. Although the Protocol merely states a commitment to apply the GATT "provisionally," and only to the fullest extent not inconsistent with existing legislation, GATT is nonetheless a valid and binding international obligation. GATT has an adjudicatory procedure under which complaints of legal violation can be litigated, leading to formal legal rulings by the organization. The primary sanction for legal violations is the normative pressure of the legal ruling itself. GATT law also provides for retaliation by the injured government, and retaliation has become considerably more frequent within the past five years.

3. What is the Status of GATT under U.S. Law?

GATT is an Executive Agreement, authorized by act of Congress. This means that GATT obligations are part of U.S. domestic law. Although GATT law is subordinate to federal legislation, GATT obligations have frequently been incorporated into federal law by statute, and, by their own force, take precedence over conflicting state law.

4. What Are the Basic Rules of GATT

The current legal text of the General Agreement is 76 pages long. This text can be divided into two parts. First, there are a few baseline rules -- clear, simple and quite strict. These are scattered about, but in total they take up only about a page. Second, there are exceptions, exceptions to exceptions, and procedures for establishing and controlling these exceptions. These take up the remaining 75 pages. What follows is an outline of the one-page basic rules; please remember that 75 pages of qualifications are being omitted.

The GATT rules begin by dividing government regulatory measures into two kinds:

(1) Measures imposed at the border, before goods leave Customs. These include tariffs, quantitative restrictions, and things like sanitary controls.

(2) Measures that apply to goods once they leave Customs and enter internal commerce. This category includes every form of government regulation -- sales taxes, licenses or permits, and anything else that can affect the sale or use of a product.

The basic GATT rule regarding this second class of government measure (so-called "internal measures") is found in Article III:2 and III:4. It says that once foreign goods enter internal commerce they must be treated no less favorably than domestic goods. This is what is known as the "national

treatment" obligation -- treatment no less favorable than that given to goods produced by the country's own nationals. The national treatment obligation does not in any way limit the extent to which governments may restrict or control internal commerce; governments remain free to tax, license, or prohibit whatever they wish, as much as they wish. But, they can only tax, license or prohibit foreign goods to the same degree as national goods.

The basic rule concerning border measures is that protection at the border should be collected in one place -- the tariff. Article XI prohibits, in one simple sentence, all nontariff restrictions on trade imposed at the border. GATT goes on to provide a number of exceptions to this flat prohibition, primarily for trade restrictions that serve widely accepted public policy objectives such as health, safety and national security. But, because of the flat prohibition in Article XI, every such exception has to be specifically enumerated.

The GATT agreement places no general limit on tariffs. The only legal controls on tariffs are those that individual governments agree to in negotiation. Since 1947, the major industrial powers in GATT have reduced their tariffs, by negotiation, from an average range of 30-60 percent ad valorem to an average range of 4-8 percent.

There is one more baseline rule in GATT that applies to both border measure and internal measures. This is the rule against

discrimination between one foreign country and another -- the so-called unconditional Most Favored Nation obligation (MFN). To the extent that governments do use protective measures, they must grant the most favorable treatment given to any country under those measures, equally and without precondition, to all GATT member countries.

5. What Are GATT Obligations Re Infringement Remedies?

a. Article III Obligations

An infringement law such as the one provided in H.R. 1069 or H.R. 4539 is, as to everyone except the importer, an internal trade measure covered by GATT Article III:4. It is a prohibition against the internal sale (and, in H.R. 1069, also the use) of the infringing product. The GATT obligation is very simple. The first step is the Article III requirement that law must treat domestic and foreign products equally. If this is done, there will be no GATT problem. If this is not done, a second step will be needed. The differential treatment, being a prima facie violation of Article III, will have to be justified under one of GATT's express exceptions.

Whether the bills before the subcommittee make any distinction between foreign and domestic goods is a question that should properly be addressed to specialists in intellectual property law. As far as I am able to tell from reading these bills, no such distinction is made in any of these proposals.

All appear to be consistent with Article III:4, and thus with GATT obligations. No question of special justification under GATT exemptions needs to be considered.

Article III:1 also states a further principle, though not an obligation, condemning nondiscriminatory internal measures that have a protective effect -- for example, a nondiscriminatory prohibition against all sales of bananas in a country which has no domestic production of bananas. The principle would apply to any legal requirement which, even though nondiscriminatory in form, was in fact prejudicial only to someone dealing in foreign goods. I am not aware of any such requirement in the bills before the committee, but, once again, this is really a question for specialists.

b. Article XI and Article XX (d)

The fact that the new infringement remedy also makes importation an act of infringement places this aspect of the new infringement remedy into a gray area which arguably falls under GATT Article XI. The legal and injunctive remedies all aim at the import transaction per se. Article XI prohibits, without qualification, any and all import prohibitions, as well as all other measures that exclude goods at the border. To be permitted under GATT, therefore, remedies involving import prohibitions must qualify under one of GATT's express exceptions.

There is an express exception for laws relating to the protection of intellectual property. Article XX (d) sets aside GATT prohibitions in the case of laws enforcing intellectual property rights such as patents, copyrights and trademarks if certain conditions are met. The underlines are meant to stress the fact that Article XX (d) is not a carte blanche exception for intellectual property laws. GATT does apply to such laws to the extent they affect trade, and it does set conditions on what they can and cannot do.

The conditions for an Article XX (d) exemption are as follows:

(1) the measure must not be applied "in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail,"

(2) it must not be applied in a manner which would constitute "a disguised restriction on international trade," and

(3) it must be "necessary to secure compliance with laws or regulations which are not [otherwise] inconsistent with the provisions of this Agreement."

The first condition is not at issue in the present infringement bills, because the remedies being proposed do not involve any country-specific discrimination. The second condition, in the my view, is essentially a more general version

of the third condition -- namely, that the restriction must in fact be necessary to the ostensible objective of the law, and not merely a protectionist measure parading under some other public purpose justification. The idea represented by the second and third conditions -- the idea of "necessity" -- will require some added explanation.

In my view, and, I think, the view that GATT itself would take, the words "necessary to secure compliance" must be read to mean "necessary to secure the same level of compliance expected of the country's own nationals." Article XX does not permit a government to put foreign infringers in jail while imposing only civil remedies for domestic infringers. One sometimes hears a contrary view expressed in connection with intellectual property matters, particularly in statements like the following: "Just because we hobble ourselves with horse-and-buggy remedies against domestic infringers doesn't mean we have to accept the same ineffective and inadequate remedies against foreign infringers." In my view, such statements are dead wrong as a matter of GATT law. That is exactly what GATT means to require. That is the only kind of international obligation there is that can be effective in keeping valid social legislation from being used for protectionist purposes.

"Necessary" does not mean "identical," however. Import transactions do not have the same legal or economic aspects as domestic transactions. Consequently, it may well be necessary to use different legal measures in order to arrive at the same

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enforcement outcome. This is a potentially dangerous loophole, because it introduces an issue of judgment that can be abused. But such judgment is not completely exempt from legal control. The GATT has been willing and able to adjudicate the issue of necessity, and in one case it has ruled against a government's claim of necessity.

How does this GATT obligation apply, then, to the present bills making importation an infringement? In my view such bills can safely be said to be GATT conforming. The existing law already provides a way to keep infringing goods produced by domestic producers from entering the U.S. market -- an infringement action against the domestic producer. An infringement remedy prohibiting importation of infringing goods is merely the functional equivalent of that remedy.

6. GATT Obligations Re Section 337 Reforms

The GATT legal issues raised by Section 337 are very difficult. In 1981, the GATT entertained a legal complaint against Section 337 in the Spring Assemblies case, but the decision did not settle very much. The complaint led to a panel decision in 1982, finding that the application of Section 337 in the case in question was not in violation of GATT, but expressing doubts about other possible applications. The panel decision was not very well reasoned, and, when the GATT Council finally accepted the decision in 1983, objections of other governments led to so many qualifications and reservations that the Council decision cannot be viewed as having affirmed any legal conclusions at all.

The GATT legal arguments that have been raised concerning the proposed changes in Section 337 mirror this general state of legal uncertainty. Some witnesses take the view that Section 337 is currently GATT-conforming, and that eliminating "injury" and "industry" requirements will make it even more GATT conforming. Others say that Section 337 is already inconsistent with GATT and that the proposed amendments will make it worse. It is hard to think of a legal position that wouldn't fit somewhere between these two positions.

What follows is my own view of the debate. I shall take up the issues in a somewhat unusual order, seeking first to dispose of some confusing collateral issues in order to be able to focus on the main issues more clearly.

a. Is Section 337 protected by GATT's 'grandfather clause' for pre-1947 legislation?

The Protocol giving legal effect to GATT contains a reservation for mandatory legislation in force on the date of signature -- in the case of the United States, October 30, 1947. If Section 337 qualifies under this reservation, then its present form is technically consistent with GATT legal obligations even if it does not comform in substance. This issue has to be cleared up at the outset, so that we can know what possibilities of GATT violation we ought to be concerned about.

In my view, Section 337 does not qualify under the grandfather clause. Even though its relevant substantive provisions were all enacted prior to 1947, it does not, and never did, qualify as "mandatory" legislation. The limitation of the grandfather clause to mandatory legislation was an early gloss on the words of the Protocol, adopted by all GATT member governments in the Belgian Family Allowances decision of 1951. The "mandatory" requirement is based on the fact that the Protocol reservation was designed solely to permit governments to sign the General Agreement immediately, without having to seek further legislation. The reservation was designed to excuse only those cases where the Executive Branch did not have legal authority to comply with the obligations of the Agreement -- in other words, where the law required government actions in violation. Section

337 has always permitted the President to deny or overturn relief for policy reasons. If some aspects of Section 337 had violated GATT, the President clearly had (and still has) the power to avoid the GATT violation by ruling that no action be taken. In brief, the possibility that the United States may have some grandfather rights under Section 337 can be put aside as unfounded. All of Section 337 is exposed to GATT obligations.

(As a footnote, the subcommittee might be interested to know that, according to research done by former U.S. Tariff Commissioner Bruce Clubb, there was not a single case in which Section 337 remedies were granted between 1936 and 1968. Clubb has found only three cases during that period in which the Tariff Commission decided in favor of granting relief, and in each case the actual granting of a remedy was vetoed by the President.)

b. Do the 'industry' and 'injury' requirements of Section 337 prove that Section 337 is not really 'necessary' to the enforcement of the U.S. intellectual property laws?

Section 337 exclusion orders, as well as Section 337 cease and desist orders prohibiting importation, fall under the GATT Article XI rule against import prohibitions. Thus, in order to conform to GATT obligations, they must be justified under the Article XX (d) exception described above. The question is the same: Are these remedies necessary to secure the same level of enforcement that is provided against domestic infringers?

One argument of GATT violation that is sometimes raised, though almost never by our trading partners, is one that rests on the "industry" and "injury" requirements of Section 337 as it is presently written. Although the argument turns out to be a red herring, it is worth going through the steps to see why. The argument runs like this: The only enforcement remedies that apply to domestic infringers are the formal infringement remedies of Titles 15, 17 and 35. These remedies are not conditioned on any industry or injury requirements. All patent, trademark and copyright holders, foreign or domestic, have a right to an infringement remedy just by virtue of their intellectual property rights. If Section 337 were <u>really</u> an intellectual property remedy, one that was "necessary" to give owners of these rights equivalent enforcement remedies against foreign infringers, the remedies of Section 337 would also be available to <u>all</u> owners of these rights, and would not be qualified by any further requirements of industry or injury. (Just between us, this argument gains further credibility each time we hear someone in authority arguing that the International Trade Commission (ITC) is a "trade" agency not an intellectual property agency, and that Section 337 is a "trade" remedy, not an intellectual property remedy.)

Persuasive as it may look, this argument really takes us nowhere. The problem is that Section 337's distinction between domestic and foreign patent holders (that's basically what it is,

after all) does not necessarily mean that domestic patent holders are getting some extra trade protection disguised as a patent remedy. It can just as easily be viewed as discrimination against the foreign side -- a refusal to grant foreign patent holders the minimum adequate protection of patent rights that is being given to other patent holders who invest in the United States. This type of discrimination would probably still be an act inconsistent with international obligations, but not GATT obligations. The person injured by such discrimination would be the foreign patent holder, and the nature of his injury would be a violation of the Paris Convention obligations pertaining to the enforcement of patents issued to foreign applicants.

The only way to know which way the discrimination runs is to look at central issue that would be there with or without the discrimination -- i.e., are these Section 337 remedies really needed to provide the same degree of enforcement that the infringement law provides against domestic infringers? If they are necessary, then Section 337 rights will not violate GATT no matter how widely or narrowly they are granted. If, on the other hand, Section 337 remedies are not necessary, then broadening the statute will not make them any more or less conforming; it will only increase the number of possible victims who could complain.

This conclusion has an important bearing on the present legislative proposals to amend Section 337's industry and injury

requirements. The conclusion tells us that such amendments would not affect the GATT conformity of Section 337, in either direction. If the present Section 337 meets the "necessity" test of Article XX (d), so would Section 337 as amended. If the present section does not, the proposed amendments are not going help it.

The real GATT issue in this area is whether the basic law of Section 337, as it now stands, is or is not "necessary" in the GATT sense. There are two main issues:

Is the remedy of a general exclusion order necessary?

Is the existence of a separate administrative procedure necessary?

The final two sections take up these two issues.

c. Are the GENERAL EXCLUSION ORDERS authorized by Section 337 really 'necessary'?

The Canadian GATT complaint in the Spring Assemblies case of 1981-1983 conceded that some Section 337 remedies would meet the test of Article XX (d). Canada had no problem with Section 337 exclusion orders directed against specific infringers named in the action. The same conclusion, presumably, applied to cease and desist orders as well. Canada agreed with the point made above -- that such actions are functional equivalents of what happens in an infringement suit against a domestic infringer.

Canada argued, however, that the general exclusion orders authorized by Section 337 did not meet the test of Article XX (d). A general exclusion order is an order prohibiting the entry into the United States of infringing goods from any source whatever. Canada argumed that there was no analogue to such orders in a domestic infringement action, and thus that such orders amounted to excessive enforcement against foreign products.

The United States replied that extra remedies were justified because of the jurisdictional difficulties in obtaining effective damage remedies against foreign producers. While the prospect of damage liability was a fairly effective deterrent against copying by other, unnamed producers located within the United States, these jurisdictional difficulties made the same threat ineffective as a deterrent against other, unnamed foreign producers who might want to try their hand. The general exclusion order was thus needed to make up for the fact that infringement damage remedies were a less effective deterrent in the case of imports.

The GATT panel in the Spring Assemblies case decided that a general exclusion order was justified under Article XX (d) on the facts of the specific case before it. The decision is somewhat unclear, but it appears to rest on the ground that the specific product in question was easy to copy, that infringement by other foreign suppliers was thus a substantial danger, and that, in

this case, the danger could not effectively be deterred or controlled by domestic infringement actions against either foreign producers or domestic users. Canada objected to the panel's legal conclusion. Other governments supported Canada's position, and the GATT Council decision adopting the panel report reserved Canada's right to make that argument in the future.

In my view, the panel's standard of decision was certainly correct as a matter of theory. This is exactly the kind of extra remedy that may well be needed because of the different enforcement problems presented by imports. I believe the panel was also correct in saying that the need for particular remedies a matter of judgment based on all facts and circumstances and thus will vary from case to case. I think the panel was wrong, however, to suggest that GATT itself should take a case-by-case approach to this problem, because governments cannot afford to wait and see what GATT thinks case-by-case. The proper answer, I believe, is that GATT law requires governments wishing to employ such "extra" remedies to instruct their legal authorities (whether courts or agencies) as to the correct standard of "necessity," and to give them the discretion needed to limit the use of such extra remedies to such "necessary" cases.

My conclusion, then, is that the general exclusion remedy of Section 337 is not inconsistent with GATT obligation <u>if</u> the law expressly provides the correct standard to govern its application and provides the administering legal authority with sufficient

discretion to apply that standard. My own understanding of Section 337 is that it conforms to this requirement, but this is a judgment that should be made by those most expert with the detailed operation of the current law, as it has been defined by the ITC and by its reviewing courts. It goes without saying, likewise, that any revision of Section 337 should include a careful review of the above issue to make certain that the law contains both the discretion and the standards needed to make it comply with this GATT obligation.

d. Is the SEPARATE PROCEDURE of Section 337 really 'necessary'?

The other major ground of complaint against Section 337 is the fact that it subjects imports to a second, separate legal procedure that does not apply to domestic products. This was perhaps the primary ground of the Canadian GATT complaint in the Spring Assemblies case, and it appears likely to be the primary ground of a forthcoming GATT complaint being prepared by the EEC. The complaint can be summarized most easily by stating the solution being sought: The complainants are asking that the remedial powers now contained in Section 337 be given to federal district courts, as part of the remedies available in ordinary infringement actions. Imports, like domestic products, would then be subject to only one action, in exactly the same forum.

The argument of GATT violation here consists of two steps: (1) Being subject to two complaint procedures (Section 337 and an

infringement action) is a greater burden for those who deal in imported goods than is the exposure to one procedure (an infringement action) for those who deal in domestic goods. Technically, this is a violation of Article III -- the same internal procedures not being applied to imports and domestic products alike. (2) This extra burden cannot be justified under Article XX (d), because it is not really necessary; all the remedial powers of Section 337 could be given to and and administered by a federal district court.

It is fair to say that the panel decision in the Spring Assemblies case never addressed this issue explicitly. Canada repeated its complaint in the review that followed, and several other governments supported Canada's position. It was claimed that the United States is the only country (in the world, or in GATT, anyway) that has a double procedure like this.

The United States has made several responses to this charge, some of which are not very persuasive. One is the argument that Section 337 is no more burdensome than a district court action, and may even be less burdensome on balance. This might be a relevant answer if Section 337 were the only procedure applicable to foreign goods. Article III does not require exact parity -- only treatment no less favorable. But such equivalence simply does not meet the complaint that foreign goods are subject to two procedures whereas U.S. goods are subject to only one. This is not merely a theoretical burden, either, for foreign producers accused of infringement are in fact often sued under both

procedures at the same time. It borders on alchemy for the United States to keep arguing that two is equal to one.

The United States also argues, sometimes, that a special ITC procedure is needed because federal district courts do not have the power to grant all the special remedies contained in Section 337. In other words, even if exposure to a second, Section 337 procedure does constitute a greater burden, this is the only way the United States can provide adequate protection against infringement by foreign goods, and so the extra burden meets the 'necessity' test of Article XX (d).

I believe the extra burden could, if not excessive, be justified as a matter of GATT law <u>if</u> there were in fact some basic constitutional impediment to empowering district courts with the kind of remedial powers needed. Is there? This is really a question the subcommittee and its staff can answer better than I. For what it is worth, however, my thoughts, based on a Federal Jurisdiction course of twenty-five years ago, are these:

(1) There is surely no problem of jurisdiction. United States officials have sometimes pointed to the fact that federal courts do not now have the <u>in rem</u> jurisdiction needed to grant the kind of remedies provided for in Section 337. This is not a constitutional impediment, however. Congress could pass a statute awarding such jurisdiction, and the grant of power would

certainly be constitutional. Federal courts can exercise as much in rem power as the ITC or any other federal instrumentality.

(2) There has been a serious question of whether Section 337 involved a case or controversy for Article III purposes. The source of the problem has been the statute's grant of power to the President to deny relief after an affirmative finding has been made, by means of an unreviewable decision on "policy" grounds. The very first Section 337 case ever brought went all the way to the Supreme Court of the United States over the question of whether the proceeding could be reviewed by the Court of Customs and Patent Appeals, it being argued that the CCPA was an Article III court and thus could not hear the matter because the proceeding was not a "case or controversy" in the Article III sense, but was merely an advisory opinion to the President over whether to restrict trade. The Court held that the CCPA was not an Article III court, and so did not have to answer the question directly, but it's reasoning strongly suggested that section a 337 proceeding was not a case or controversy. Ex Parte Bakelite Corp., 279 U.S. 438 (1929) (Section 337 was called Section 316 at this time). It is my understanding that the 1974 amendments to Section 337 were in part intended to remove this unanswered problem, making the ITC decision a final order so that it could be reviewed by an Article III court. Whether this change also removed the Article III problem for the district court, prior to Presidential policy review, is a question about which there is a difference of opinion among my Minnesota colleagues who are expert in these matters.

Even if the Article III problem is real, it is still self-imposed. The Congress could remove the problem by removing the President's override power. It is sometimes argued that this would be a perverse thing for GATT to require, because the override power is meant to make the law operate more favorably to foreign trade interests. But if the price of this "favor" is subjection to an entirely separate administrative proceeding, it is hard to believe that the favor is worth the price paid for it. I do not believe a GATT panel, given a second chance, would find this extra burden "necessary" on this ground.

The ultimate issue of GATT law here is clouded by the fact that the administrative proceeding in question is certainly the typical or traditional way in which the United States legal system goes about administering the type of remedy found in Section 337. Would Article XX (d) authorize a government to employ a procedure that imposes an extra burden on foreign goods, not because it is constitutionally required, but merely because it is more consistent with the legal traditions of the country involved? Stated more succinctly, how much does a government have to put itself out? I do not know of a general answer to that question. I believe it would turn on balancing the relative inconveniences.

A final thought: If (1) the Congress does wish to remove the industry and injury requirements of Section 337, and if (2)

the ITC does not wish to become (and does not regard itself as qualified to become) a full time patent court, and if (3) there really is no constitutional barrier to assigning Section 337 powers to a federal district court, why, after all, are we keeping Section 337 as a separate procedure?

END

Mr. KASTENMEIER. Thank you very much, Professor Hudec, for that very informative, constructive presentation.

I am just trying to understand what you were saying toward the end. Are you saying that theoretically we could abolish the ITC, put all the jurisdictional power to deal with these matters in the district court? We still have the problem of what to do about the Presidential veto or Presidential action with respect to these matters. If we could reconcile that could we do away with the ITC?

Mr. HUDEC. I think we could do away with ITC jurisdiction over patents and trademarks. I think except for the Presidential veto my understanding is there would not be any Federal jurisdiction or constitutional problem in doing that, and that would eliminate what is the major GATT problem.

Mr. KASTENMEIER. The other issues—such as changing section 337, matters of domestic industry or injury—are largely policy issues which you have, I suppose, two or three interfaces here. You have importers, that is, foreign goods, and domestic versus domestic. You have proprietary rights and user rights dealing with patent problems, which the balancing of these issues may be different depending on which of these conflicts people consider important and what ought to derive from those conflicts in terms of public policy.

Mr. HUDEC. As you said, Mr. Chairman, in some of your recent remarks before the Ways and Means Committee, the degree to which we enforce our own patent laws against our own people is a bargain, the term you used. It represents a balancing of interests. Now, the GATT standards that I think we should employ—and they are also the kind of commercial policy standards I think we would want to write if we had the power to write the foreign regulation that was going to affect our own exporters—is one which simply strikes the same balance.

Our infringement remedies within the country are by no means draconian, by no means guarantee 100 percent of the market for every patent owner no matter what. They are not about to be made so. That issue is also presented when you approach the question of enforcing against foreigners. The question of how much to enforce is really a question that the committee in its judgment has to deal with. I think the only standard of GATT law is a standard that asks you to make that same judgment for foreign and domestic infringers alike. The judgment of where to draw the line is separate, and that judgment is really the most important thing that has to be done.

Mr. KASTENMEIER. In terms of what a GATT panel would likely do to section 337 as you make these changes, I take it you feel that on balance they would not find our changes to be illegal.

Mr. HUDEC. Not the changes themselves. If, for example, you eliminated the injury requirement, and/or the industry requirement, I believe that you would not change the outcome of the GATT panel case by having done that. I suspect that a second GATT challenge to section 337, whichever way these amendments come out, is going to succeed. The panel the last time said that it was not saying that the separate section 337 procedure was the way things should be. They said they found it troublesome. I think they frankly lost their nerve, but they certainly did not bless sec-

tion 337. So I think that the existence of a separate section 337 procedure could well result in a finding of GATT violation in the next GATT case that comes up. But, I do not think that the finding in that case would be affected one way or another by the way the Congress resolves these questions of industry and injury.

Mr. KASTENMEIER. As I recall, last Congress the House passed a process patent which limited infringement liability to the imported infringing products. Wouldn't such a statute on the face of it likely violate GATT?

Mr. HUDEC. I think it would flatly violate GATT, yes. Without knowing very much about patent law, I can tell you that even on the basis of most superficial knowledge of patent law that proposal would have violated the GATT, yes.

Mr. KASTENMEIER. Before I yield to my colleague, I would like to go afield to another aspect of the intellectual property protection which vexes this committee and has for some time. There may be an analog with your discussion of exclusion orders, whether they are general or not, and that aspect is the manufacturing clause. You indicated the problems of the general exclusionary orders would normally have, in terms of copyright law, had a protective trade policy imbedded in from a couple generations ago which is called the manufacturing clause. It comes up again. We have tried to encourage the parties to seek other, if any, relief through trade. However, we are likely to confront legislation again very shortly on that score.

I would like to solicit your judgment about what would happen if we contemplate extending the manufacturing clause or what we might consider in resorting of foreign countries in terms of trade institutions if we did extend the manufacturing clause again.

Mr. HUDEC. Well, as I think this committee knows, the manufacturing clause has already been taken before the GATT and found in violation. The substantive violation was clear. The exclusionary barrier of the manufacturing clause is prohibited by article XI and not authorized by any other exception in GATT. The panel was unanimous. The panel ruling was approved unanimously. There was no doubt expressed by any member of the GATT membership that this was in violation. The case was brought by the EEC. So we have already been found in violation and that was several years ago now.

The EEC and the rest of GATT have been waiting for the natural expiration of this statute in the summer of this year, sensibly enough, rather than trying to go to war earlier over it.

The question of consequences if that act is extended come down to two, I believe. First of all, the European Community has committed itself, as I see it, to retaliation. They have announced that they are going to withdraw trade concessions, and my experience with the way the EEC behaves is that in order to make a public announcement like that their internal proceedings have to be carried far enough forward that it becomes extremely difficult for them to reverse the announcement when it comes to acting. They are a little more rigid than we are in terms of making threats. So I think their threats have to be taken a little more seriously than the threats of the U.S. Executive.

Second, I think the European Community would use our failure to abide by the manufacturing clause decision to block a substantial number of efforts that the U.S. Government has been making over the years to enforce GATT obligations against them. I privately never believed that the commercial importance of the manufacturing clause was all that great to the European Community. I believe it has been mainly a defensive device to stop us from pressing them so hard. This, if you recall, was also the strategy of the EEC'S other major complaint against us over the last decade in the DISC case. The DISC case—a tax deduction for our exporters which was frankly a subsidy—turned out to be a rather insignificant commercial instrument. I doubt it affected EEC trade at all, but they used that case at every opportunity. Every time we were pressing the EEC, the answer would be, all right, and what are you doing in the DISC case. It took us about 10 years to correct that. Now, as soon as we corrected the DISC case, up came the manufacturing clause case.

So, yes, there will be retaliation. Some districts are going to find that exporters are being affected by new restrictions in the European Community. The community has plenty of places where they would like a little added protection. But the more serious consequence, I think, is going to be the second one. I think it is going to make it much harder for us to enforce our own legal claims against the European Community.

Mr. KASTENMEIER. Thank you.

As you perhaps know, there has been a variance of extension floating around which, as I understand, targets country by country to get at several countries. Ostensibly, Europeans do not tend to be offenders as far as domestic publishing is concerned.

Some reformulation still maintained in general as manufacturing clause, is predicated on typical levels. Would that be equally offensive to them?

Mr. HUDEC. There are many permutations in the newspapers, and one cannot judge by reading newspaper reports what they are, so that it is impossible to make any kind of direct comment about this. The U.S. Government does have—and this brings us back pretty much to the area where we are today—the right to exclude from this country counterfeit, pirated infringing goods. If the concerns being expressed are those directed against parts of the world where U.S. copyrights are simply ignored by local printing houses, we would have considerable opportunity to keep those infringing goods out of the United States. It would seem to me to be almost a needless violation, or trouble, however, to try to have that remedy carry forward under the manufacturing clause. It would be, from a GATT point of view, much better to write separate legislation.

Now, there is one other possibility, however, that ought to be considered. I have heard as part of this package of compromises a possibility of doing the following: keeping out all printed matter, whether infringing or not, from countries that do not respect our intellectual property rights, that do not have sufficient copyright laws and so forth of their own. This would be a GATT violation. GATT says that you can keep out goods to the same extent you restrict trade in infringing goods within your own country; but what you cannot do is use trade restrictions to reflect displeasure with

other aspects of a government policy. You cannot use trade restrictions because you do not like the way they deal with the Soviets. You cannot use trade restrictions because of how they protect your tourists when they go there. I think that is fairly clear.

So, legislation which goes to that extent, using trade restrictions on ordinary and otherwise legitimate trade to express displeasure with the kind of protection you are getting in the home market of another country, would be GATT violative.

Mr. KASTENMEIER. One thing I must say that I have been interested in, at least regarding the intellectual property laws, is the domestic laws of essentially a trade issue. But I see no easy way of achieving that, at least no one else has. However, in terms of the orderliness of U.S. laws, I would like that to happen.

I gather, in terms of the protection sought, it would be very difficult to achieve, through laws other than the intellectual property laws and in this case the copyright laws.

Does my colleague have any comment?

Mr. MOORHEAD. I wish to thank you for the very learned treatise that you presented to us. It is going to be very helpful and I know that the question of the effect of this legislation on GATT has been raised superficially at least by a number of people as a boogieman back there in the distance. I think that you have pretty well clarified that question, and I want to thank you.

Mr. HUDEC. Thank you, Congressman.

Mr. KASTENMEIER. Yes. We will encourage all members of our committee to read your prepared statement which I regard as superior and necessary for an understanding of these issues. I want to compliment you again and thank you very much for your appearance.

Mr. HUDEC. It has been my pleasure. Thank you very much.

Mr. KASTENMEIER. I would like to call two witnesses who are actually on different sides of the issue, but they are good enough to constitute a panel. Our second witness will be David Foster, representing the International Trade Commission Trial Lawyers Association. Mr. Foster is currently in private practice after Government service with the ITC, and I should probably note Mr. Foster represents Sumitomo in a section 337 case brought by Corning. We will also hear subsequently from Mr. Michael Stein.

Mr. Foster, we have, of course, a copy of your statement which we will put in the record. You may proceed as you wish. Do you have a colleague you would like to introduce to us.

STATEMENT OF DAVID FOSTER, ESQ., ON BEHALF OF THE INTERNATIONAL TRADE COMMISSION TRIAL LAWYERS ASSOCIATION, ACCOMPANIED BY THOMAS V. HEYMAN, ESQ.

Mr. FOSTER. Thank you, Mr. Chairman. I have with me Mr. Tom Heyman who has been a practicing patent lawyer for 25 years and is also a member of the association; Mr. Heyman will help me respond to any questions that the committee may have.

We are here on behalf of the International Trade Commission Trial Lawyers Association. The association appreciates very much the opportunity to appear and discuss the issues with the committee today.

Before addressing the substance of some of the amendments to section 337 which are being considered, I would like to provide a little background information about the Trial Lawyers Association. It is a national professional organization of more than 300 lawyers who practice before the U.S. International Trade Commission. The main purpose of the association is to improve the operation of the United States international trade laws and, in particular, section 337 of the Tariff Act of 1930. The association's members are attorneys, probably a majority of whom are intellectual property attorneys, and the members represent U.S. manufacturers and industries as well as foreign manufacturers and importers of foreign articles, and include outside counsel to corporations as well as in-house counsel. For example, I have represented both domestic industries and foreign industries under 337 practice and many of our members do the same. Some exclusively represent domestic industries, others exclusively represent importers.

We believe that the association represents the full spectrum of business interests which use section 337, those who prosecute section 337 cases and those who are required to defend themselves under section 337.

The association agrees with the objective of many of the proposed amendments to section 337, the objective being to make section 337 more effective and more efficient. But the association believes that some of the specific amendments would not accomplish this objective. The basic position of the association is that section 337 has been an effective remedy, an effective tool for defending U.S. intellectual property rights; and the primary purpose of the association is to ensure that that remedy remains available and remains effective.

The association specifically opposes, however, the elimination of the requirement in section 337 that some economic harm be demonstrated to a U.S. industry in patent, trademark, copyright, trade secret and maskwork cases. I want to make three points with respect to this.

First of all, section 337 has worked well in protecting U.S. intellectual property interests in its present form with the injury test and we do not believe needs to be amended. The injury requirement has rarely been dispositive of any case under section 337. In fact, according to the International Trade Commission it has been dispositive in only one case and that happened to be the case where my firm represented Sumitomo Electric against Corning Glass Works; but as far as we know that is the only case where it has been the dispositive issue under section 337.

Second, eliminating the injury requirement would subject section 337 in our opinion to needless opposition because of its asserted inconsistency with U.S. international trade obligations. I want to make the point here that the association certainly hopes that if section 337 is ever challenged internationally it will be found to be consistent with U.S. international obligations under the GATT. What we would like to avoid is the precipitation of numerous challenges to section 337, and we think this is likely the result if the injury requirement is eliminated or the industry requirement is eliminated. We also think the result of these challenges will be retaliation against U.S. exports, and increased disapprovals by the

President of affirmative ITC decisions. This would make relief under section 337 far less predictable than it is today, and less useful.

Also we think that elimination of the injury requirement would interject section 337 into the upcoming multilateral trade negotiations and likely interfere with or prevent accomplishment of U.S. intellectual property goals for such negotiations, such as the conclusion of an anticounterfeiting code. I think this really is the same point that Professor Hudec was making with respect to the copyright clause. We do not want to give our trading partners issues, whether they are legitimate or not, which they can use in a defensive way to keep from taking actions which are otherwise in the interests of the United States. We are concerned that if you interject section 337 into the upcoming trade negotiations it will be used to deflect attention from other issues, other intellectual property issues in the negotiations.

Finally, we note that Chairwoman Stern of the U.S. International Trade Commission in recent testimony before this subcommittee indicated that removal of the injury test and the industry test would expand the jurisdiction of the ITC far beyond international trade matters and, in effect, turn it into a patent court.

Finally, with respect to the injury requirement, it is the belief of the Trial Lawyers Association that you cannot eliminate injury as a consideration under section 337 investigations. Under present law injury is considered in a due process proceeding under the Administrative Procedures Act by a judge and the Commission itself and findings on injury are subject to judicial review at the Court of Appeals for the Federal Circuit. If injury is removed from the criteria for violation of the statute, this will no longer be the case. However, injury will still be considered by the Commission in its public interest considerations. Lack of injury will clearly have a bearing on whether the public interest is served by an order excluding imports.

Further, the President in his review of section 337 findings by the Commission will have to consider injury questions. There is no doubt that foreign governments and manufacturers and U.S. importers and users of the imported product will argue that the President should reject an action of the Commission because there is no injury and the intellectual property owner has relief available in district court, and that if the United States takes action, it will be faced with an international challenge under GATT and subject to retaliation.

These arguments will be particularly persuasive when action under 337 would precipitate challenges which may interfere with general trade relations without benefiting any industry in the United States because none is being injured. These are powerful arguments and can be made behind closed doors with no review of the President's decision possible. Thus injury will be moved from the present posture of being examined as a criteria for relief under due process proceedings by the Commission with judicial review, to a behind-the-scenes consideration by both the Commission and the President with no due process requirement and no judicial review available. The result, again, will be increased uncertainty of wheth-

er relief will be provided under section 337, and we believe this ultimately will greatly diminish section 337's effectiveness.

Besides the elimination of the injury test, the association also opposes the elimination of the need to demonstrate the existence of a domestic industry under section 337. Section 337 was enacted to protect an established or about to be established U.S. industry from unfair trade practices. Removal of the domestic industry requirement would have the anomalous result of permitting foreign companies with no economic investment or equipment in the United States to petition the ITC to prevent U.S. companies from importing a component of a product for assembly in the United States. Indeed, it would also permit a foreign company with no economic presence in the United States to use the ITC to prevent another foreign country which also has no economic presence in the United States from importing an article.

Since foreign companies have expressed an interest in using section 337 in the past, an influx of complaints on behalf of the foreign interests could be expected. Foreign concerns will not only have an incentive to burden the U.S. administrative process to their economic advantage, but they would be given the tools to do so. For example, of the 11 companies having the most U.S. patents granted in 1984, seven were foreign. In addition, 42 percent of all U.S. patents issued in 1984 were issued to foreign companies.

In closing, I would just like to point out that some people have argued that the section 337 amendments are appropriate because all you are really doing is removing criteria under section 337 which are not required under the domestic intellectual property laws. While it is true that an industry and economic harm are not required by domestic law, domestic law proceedings are of a fundamentally different nature than section 337 proceedings. Domestic law proceedings are on a party-by-party basis involving private rights and are not part of the international trade laws of the United States. They are proceedings which require the establishment of personal jurisdiction and subjecting your patent in each case to arguments on infringement and validity.

Persons who now choose to proceed against foreign producers and U.S. importers under section 337 and the ITC do so because of the extraordinary remedy that can be obtained under this law, which is not available under domestic law. The ITC can issue an order that bars not only goods of the defendant before it but also of those who never participated in the proceeding and even of those that first produced the goods long after the decision is rendered. This extraordinary jurisdiction is much broader than that which can be obtained in Federal district court under domestic law, where you must prove your case against each party. The amendments on industry and injury would change this fundamental nature of the section 337 proceeding.

To argue that by removing these criteria you are merely equalizing requirements in domestic law and under section 337 ignores the fact that the laws and remedies are totally different. The injury and industry criteria are appropriate under section 337 because they justify the broad relief available under 337 and not under domestic law and justify the different form and procedures.

They make section 337 a trade statute and justify the trade statute remedy.

Mr. Chairman, we thank you for the opportunity to comment today, and we would be happy to answer any questions.

[The statement of David Foster follows:]

BEFORE THE HOUSE COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON COURTS, CIVIL

LIBERTIES AND THE ADMINISTRATION

OF JUSTICE

TESTIMONY OF THE ITC TRIAL LAWYERS ASSOCIATION ON AMENDMENTS TO SECTION 337

APRIL 23, 1986

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APRIL, 1986

COMMENTS OF THE ITC TRIAL LAWYERS ASSOCIATION* ON PROPOSED AMENDMENTS TO SECTION 337 INVOLVING UNFAIRLY TRADED IMPORTS

SUMMARY OF ASSOCIATION POSITION

A number of bills** have been introduced in the House which would radically amend the provisions of Section 337. The Subcommittee on Trade of the Ways and Means Committee has also issued a discussion draft trade bill amending Section 337. The Association has studied and

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* The ITC Trial Lawyers Association ("Association") is a professional organization of more than 340 lawyers who practice before the U.S. International Trade Commission. The Association has as its purpose the advancement and improvement of the operation of the international trade laws, and, in particular, Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) ("Section 337"), a law which permits the exclusion from entry into the United States of articles which are unfairly traded and which injure a U.S. industry. The Association is a national professional association whose members are attorneys, including a large number of patent attorneys, representing U.S. manufacturers and industries, as well as foreign manufacturers and importers of foreign articles, and which includes outside counsel to corporations as well as in-house counsel.

** Among such bills are H.R. 3776 introduced by Congressman Moorhead (R-CA), and H.R. 3777 introduced by Congressman Dingel (D-MI).

analyzed the amendments proposed in these bills and opposes enactment of certain of their key provisions as now drafted.

While the Association agrees with the apparent objective of these bills to make Section 337 more effective and efficient, and indeed agrees with many of the specific provisions, the Association believes that the bills as a whole do not accomplish their objective. To the contrary, some of the amendments proposed in the bills, if adopted, would severely interfere with the effectiveness of Section 337 and make it less useful in protecting U.S. intellectual property interests. The Association believes strongly that before any amendments are made to Section 337 affecting its use for years to come, the appropriate legislative committees of the Congress should thoroughly consider whether the purported gain from certain proposed amendments is worth risking the future effectiveness of the statute as well as other adverse effects on U.S. intellectual property rights.

The Association specifically opposes the elimination of the requirement in Section 337 that some economic harm be demonstrated to a U.S. industry in patent, trademark, copyright, trade secret and maskwork cases.

The injury requirement has rarely been determinative of whether relief will be provided under Section 337 (in only 1 contested case in 221 investigations instituted and completed). Eliminating the injury requirement:

1. would subject Section 337 to needless opposition because of its inconsistency with our international trade obligations (particularly the General Agreement on Tariffs and Trade ("GATT")), resulting in increased challenges to Section 337 actions, retaliation against U.S. exports, and increased disapproval of relief by the President following affirmative ITC decisions; thus making relief under Section 337 unpredictable and less useful;

2. would interject Section 337 into the upcoming multilateral trade negotiations and interfere with or prevent accomplishment of U.S. intellectual property goals for such negotiations, such as conclusion of an anticounterfeiting code;

3. would increase duplicating litigation by encouraging unsuccessful parties before the ITC to retry the issues in the federal courts or, having failed in the courts, retry the issues at the ITC.

4. and, as noted by Chairwoman Stern of the U.S. International Trade Commission (ITC) in her recent

> testimony before the House Judiciary Committee, would (along with the elimination of the domestic industry requirement as proposed in the bill) expand the jurisdiction of the ITC far beyond international trade matters and turn the ITC into an international patent court.

Based on the foregoing, the Association believes the adverse effects of eliminating the injury requirements in Section 337 outweigh the supposed benefits.

The Association also opposes the elimination of the need to demonstrate the existence of a domestic industry under Section 337 in patent, trademark, copyright, trade secret and maskwork cases. Section 337 was enacted to protect an established, or about to be established, United States industry from unfair trade practices. Removal of the domestic industry requirement in patent, trademark and copyright cases would have the anomalous result of permitting foreign companies with no economic stake in plants or equipment in the United States to petition the ITC to prevent U.S. companies from importing a component of a product for assembly in the United States. Indeed, the proposed amendments would also permit a foreign company with no economic presence in the United States to use the ITC to prevent another foreign company which also has no economic presence in the United States from importing an article.

The Association also opposes any change in the parity that now exists under Section 337 with respect to the treatment of process and product patents. While the bills are not intended to change the protection afforded process patents under Section 337a, the language is unclear and may well be interpreted as changing this important right.

The Association supports the apparent intent of the bills to amend the temporary relief provisions of Section 337, but notes that the time limit provided in the bills for decisions on temporary relief may be too brief to accomplish the objective of providing more effective and timely relief for complainants.

The Association supports the default provisions of the bills, which permit the U.S. International Trade Commission (ITC) to presume facts alleged in the complaint without further evidence, for the purpose of issuing relief limited to a defaulting party after consideration of the public interest.

The Association endorses the provisions of the bills which place the burden of proof upon a petitioner seeking an advisory opinion from the ITC or a modification or rescission of an existing order issued under Section 337, but opposes the provision which attempts to legislate the standard of evidence which may be considered by the ITC in connection with such an

advisory opinion, modification or rescission action.

Finally, the Association opposes the enactment of the provisions providing for forfeiture of imported products covered by an exclusion order. It is an unnecessary and overreaching penalty. These provisions would treat importers differently from domestic producers who infringe intellectual property rights, and create an application of the U.S. patent and intellectual property laws beyond the intended scope of such laws.

OVERVIEW OF THE CURRENT LAW

Section 337 of the Tariff Act of 1930 has not changed in substance since its enactment. It declares unlawful unfair methods of competition and unfair acts in the importation of articles into the United States, or in the sale of an imported article in the United States, the effect or tendency of which is substantially to injure an efficiently and economically operated United States industry, or to restrain or monopolize trade or commerce in the United States. A violation of this law usually leads to exclusion from entry into the United States of the articles connected with the unfair trade practice. Such an exclusion order normally covers not only articles of persons over whom personal jurisdiction existed and who participated in the proceedings to determine violations, but also articles of importers and foreign manufacturers who never participated in the proceedings and over whom no personal jurisdiction existed in the United States. Such an order can apply to the articles of persons who did not start to produce the articles until well after the order was issued. As such, it is an extraordinary remedy which allows extremely broad relief to a holder of intellectual property rights or some other individual harmed by an unfair trade practice.

Section 337 is administered by the ITC which, by virtue of procedural amendments to the statute in 1974, conducts an investigation under the adjudicatory provisions of the Administrative Procedure Act. The determination of violation is made initially by an administrative law judge of the ITC, whose decision is subject to review by the Commission. Final ITC decisions are subject to review by the President only for "policy reasons." If the President disapproves an ITC decision, the order of the ITC is not effective. A final effective exclusion order of the ITC is administered by the U.S. Customs Service, which determines if an import is covered by the exclusion order.

Section 337 has operated satisfactorily in the past decade to accomplish the intent of Congress. There have been over 240 cases instituted under Section 337 since its amendment in 1974. The vast majority of these cases have been based on allegations of infringement by imports of U.S. intellectual property rights, i.e., patents, trademarks or copyrights.

Seventy percent of the completed cases were resolved in favor of the domestic complaining party by virtue of the entry of an exclusion order, a consent order or a settlement agreement. The foregoing is the case despite the fact that the law now requires injury to a U.S. industry by the offending importations. In fact, this requirement has existed in Section 337 since the adoption of its precursor statute in 1922. In only one (1) contested case out of 221 completed cases under Section 337 since the 1974 amendments has the complaining party been unsuccessful by reason of the injury requirement. This is not an indication of a major impediment to relief.

THE PROPOSED AMENDMENTS

I. THE INDUSTRY REQUIREMENT

The bills seek to amend Section 337 by eliminating the requirement that an industry seeking relief for unfair trade practices involving infringement of a patent, trademark, copyright, trade secret or maskwork be "efficiently and economically operated" in the United States. Under the amendments the existence of the domestic industry would be established simply by ownership of a valid United States patent, copyright, trademark, trade secret or maskwork. The Association opposes this provision.

These amendments, along with the amendment discussed below provide that all one would have to show to establish a violation of Section 337 is that the unauthorized imported article infringes an intellectual property right. This must be viewed against the fact that exclusive jurisdiction for the determination of patent and copyright cases resides in the United States District Courts pursuant to 28 U.S.C. § 1338(a). Legislation which amended Section 337 in 1974 clarified the ITC's jurisdictional position in its consideration of unfair trade practices involving infringement of a U.S. patent. The legislative history makes it clear that patent validity determinations of the ITC are properly not accorded res judicata effect because the ITC has no jurisdiction to determine patent validity, except to the limited extent necessary to decide a case otherwise properly before it. See S.Rep. No. 93-1298, supra, 1974 U.S. Code Cong. & Ad. News at 7329.

Under current law in order for a case to be properly before the ITC it is necessary to establish that there is an "efficiently and economically operated" domestic industry facing unfair acts of importation which have the effect or tendency to substantially injure that industry. The proposed amendments, by removing this requirement, will effectively destroy the exclusive jurisdiction of the United States District Courts to determine

matters affecting patent and copyright infringement and validity and turn the ITC into an international patent court where the only requirement for jurisdiction will be ownership of a United States patent or copyright and an act of importation which is an infringement thereof.

The proposed amendments will open the floodgates of litigation before the ITC by, inter alia, foreign companies. Elimination of the requirement of an "efficiently and economically operated" industry in the United States would mean that an investigation by the ITC could be initiated upon receipt of an allegation that a valid United States patent, trademark, copyright, trade secret or maskwork has been infringed. The ITC would become available not only to substantially injured or threatened United States industries but to any owner of United States intellectual property rights without regard to whether it has an established industry in the United States or is about to establish an industry in the United States. Accordingly, a foreign company whose only nexus to the United States is ownership of a valid U.S. intellectual property right could sue a United States company which was importing a component of a product for assembly in the United States or the complete product itself. For example, a Japanese company which owns a United States patent could complain of unfair trade practices before the ITC if a U.S. company manufactures products in Hong Kong and then imports them into the United States, even though that Japanese company has no established industry in the United States. Consider the even more anomalous situation in which a Japanese company with no economic presence in the United States seeks to have the products of a German company, which also has no economic presence in the United States, excluded.

Since foreign companies have expressed an interest in using Section 337 in the past, an influx of complaints on behalf of foreign interests can be expected. With these changes in Section 337, foreign concerns would not only have an incentive to burden the U.S. administrative process to their economic advantage, but they would be given the tools to do so. Consider that, of the eleven companies having the most U.S. patents granted in 1984, seven were foreign. In addition, forty-two percent of all U.S. patents issued in 1984 were issued to foreign companies. (USA Today, Money, p. 1, Sept. 14, 1985; N.Y. Times, Sept. 24, 1985).

If the proposed amendments were to become law, investigations would no longer involve the economic expertise of the ITC which is central to its present jurisdiction over trade cases. There would no longer be a need to determine whether an industry is "efficiently and economically operated," and no longer be a need to determine whether the acts of importation have an effect or tendency to cause harm to a domestic industry. The only issues to be decided by the ITC would be

validity and infringement of the intellectual property right owned by the complainant. The ITC has no special expertise to handle such judicial issues. In fact, only one of the present Commissioners is a lawyer, and in recent history the Commission has been comprised of a majority of non-lawyers. The increased case load will require major increases in the staff of the ITC and larger appropriations. The case load in the federal courts will not be reduced by reason of the proposed amendment to Section 337.

Persons who now choose to proceed against foreign importers in the ITC do so because of the extraordinary remedy which can be obtained. The ITC can issue an order that bars not only the goods of a respondent, but of those who never participated in the proceedings and even those who first produce the goods long after the decision was rendered. This in rem jurisdiction is much broader than that which can be obtained in a Federal District Court.

One important effect of the proposed amendments will be to deny respondents access to an Article III court which currently have exclusive jurisdiction over issues involving patent and copyright pursuant to 28 U.S.C. § 1338(a). Respondents before the Commission are denied the right to a jury trial and may not counterclaim for infringement of any of their patents which are being infringed by the complainant. Thus the respondent whose patent is being infringed by a complainant can seek relief only in a federal district court while the complainant obtains an exclusion order on an abbreviated time schedule, removing the respondent as a competitor in the United States market. The inequality of this situation needs no further elaboration.

In conclusion, there is serious doubt concerning the value of having the ITC -- an administrative agency not equipped with any specific expertise in the area of intellectual property rights -- invest valuable time and resources into investigations whose sole purpose will be determination of intellectual property issues. By proposing to eliminate the requirement of injury to an operating industry in the United States, the amendments seek to fundamentally alter the purpose for which Section 337 was enacted, namely, as an international trade statute to protect an established or about to be established United States industry from harm.

II. THE INJURY REQUIREMENT

A. General

The proposed amendments would eliminate the injury requirement from Section 337 in patent, trademark, copyright,

trade secret and maskwork cases. The Association opposes such amendments. It is the Association's position that a test of economic harm should remain in Section 337.

This proposed change in the statute would raise anew questions of whether Section 337 is consistent with United States obligations under international agreements, and in particular the GATT. The status of Section 337 under the GATT is not secure as it now stands. Little comfort can be derived from any past consideration of Section 337 by the GATT contracting parties. The recently instituted Aramid Fiber investigation by the European Communities shows that our trading partners are concerned about Section 337. Further, these renewed questions would occur in the context of the United States no longer enjoying "Grandfather" immunity.

Any renewed focus on Section 337 actions taken against other countries' exports to the United States will likely result in demands for retaliation against U.S. exports. This is indeed the crux of the Aramid Fiber investigation now before the European Communities. Borrowing on U.S. practice under Section 301 of the Trade Act of 1974, if countries find Section 337 inconsistent with U.S. GATT obligations, retaliation against the United States is certainly a real alternative.

Renewed consideration of Section 337 resulting from the proposed amendment will also interject Section 337 into the upcoming trade negotiations, which are likely to include serious consideration of important intellectual property issues. Countries not interested in achieving positive results will use the amendments to Section 337 to delay and obfuscate. Particularly vulnerable to this sort of tactic will be the anticounterfeiting code. Developing countries can be expected to use an amendment to Section 337 as a foil against consideration of the code and use it to influence even developed countries to postpone consideration. The chances for an anticounterfeiting code would accordingly be substantially diminished.

Further, it is appropriate for an injury test to be applied in Section 337 cases even if the ITC does not consider injury in its investigation. There is no doubt that the extent of injury being experienced by those persons, firms or industries included in the amendment will become an important factor in the Commission's determination of whether it is in the U.S. public interest to grant relief. This mandated consideration is not subject to adjudicatory proceedings, so the opportunity will exist for relatively untested arguments on injury to be made; arguments which now are made subject to cross-examination and discovery. Further, there is no doubt that foreign governments and companies will argue that the President should disapprove an action of the Commission because the intellectual property owner has relief available in the district courts and that, if the

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United States takes action, it will be faced with an international challenge under GATT and be subject to retaliation. Such challenges may interfere with general trade relations without benefiting any industry in the United States. These are powerful arguments which can be made behind closed doors, with no review of the President's decision possible under existing law. The result will be increased uncertainty as to whether relief will be provided under Section 337 and greatly diminish its effectiveness.

B. International Agreements

As set forth above, Section 337 substantive jurisdiction has remained unchanged for over fifty-five years. In 1973 the Congress considered the elimination of the injury requirement from Section 337. However, the Trade Act of 1974 retained the historical injury requirement. The requirement was retained for two important reasons:

(1) To leave the substance of Section 337 unchanged and therefore not disturb the "Grandfather" status of the section under GATT; and

(2) To make sure that Section 337 remained a trade statute as intended and not be injected into the then pending Multilateral Trade Negotiations by disturbing the uneasy acceptance accorded Section 337 internationally.

In the half century since its enactment, the only changes in Section 337 were procedural. Indeed, the Senate Report on the 1974 Act, in addressing the amendments to Section 337, stated:

> "No change has been made in the substance of the jurisdiction conferred under Section 337(a) with respect to unfair methods of competition or unfair acts in the import trade." (S.Rept. No. 93-1298, 93rd Cong., 2nd Sess., p.194 (Nov. 26, 1974)).

By preserving its substance, the section continued to be consistent with GATT by virtue of the "Grandfather Clause" of the Protocol of Provisional Application (¶ 1(b)). The Protocol insulates legislation in existence on October 30, 1947, which is inconsistent with GATT obligations, from the requirement that it conform to such obligations and in effect permits amendments to such legislation only if such amendments do not change the substance of the existing statute. It was in recognition of the necessity of insuring that the proposed amendments were substantively the same as the provisions existing on October 30, 1947, that the injury requirement was retained. Such a precaution was responsive to the Interim Commission for

the International Trade Organization's statement that the Contracting Parties to GATT are " . . . expected not to enact any new legislation that is inconsistent with it." (GATT Reports 8 (Jan. 1948-Aug. 1949)).

C. The Spring Assemblies Case

Some proponents of the elimination of the injury criterion argue that Section 337 is safe from attacks as inconsistent with U.S. GATT obligations based upon the GATT panel decision referred to as the Spring Assemblies case. They assert that Spring Assemblies held that Article XX(d) of the GATT exempted Section 337 actions from the requirement that it be consistent with the provisions of GATT. Such assertions are ill-founded.

The panel decision in Spring Assemblies was referred to the GATT Council for consideration. Absent adoption of a panel report by the Council, the report does not constitute GATT precedent. In the initial consideration of this decision, Canada, the European Communities and the Nordic countries all expressed disapproval of the panel report and urged its rejection, and were joined in part by Japan. The only countries supporting approval of the report were the United States and Australia. No final action was taken at the first consideration.

The panel report was again considered by the Council at its May 1983 meeting. A decision was made to adopt the panel report, but only after it was agreed that the report would, in effect, not be a precedent. As described by the official publication on GATT affairs,

> When the Council adopted the report it did so on the understanding that it did not foreclose future examination of the use of Section 337 to deal with patent infringement cases from the point of view of consistency with Article III and XX of the General Agreement. GATT Activities in 1984, at 44-45 (1984).

Based upon the foregoing, if a vote were held in the Council today, it appears likely that Section 337, as it now stands, may be considered inconsistent with the GATT, given the positions of the Council members on their first consideration and their acquiescence in the report only when it was rendered meaningless as a precedent.

D. National Treatment

If Section 337 is not exempted under Article XX(d) (GATT) as necessary to the protection of U.S. intellectual

property rights, then consideration of national treatment obligations would occur. The GATT's National Treatment clause prohibits application to imported products laws and regulations which are less favorable than those applied to domestic products. Thus, because of the greater difficulties that would be encountered by foreign parties in Section 337 proceedings than in federal district court proceedings, a violation of the National Treatment clause would arise.

Many of thoses who rely inappropriately on the GATT panel report in Spring Assemblies also assert that even if the Article XX(d) exemption were not available, there is nothing inconsistent within the operation of Section 337 and with the requirement under Article III of the GATT for "national treatment." The Association believes there is at least serious doubt as to the correctness of this assertion, and certainly many of our major trading partners do not agree with this proposition.

Those who argue that Section 337 provides no less favorable treatment to imports assert that the injury test is irrelevant, yet extensively cite the injury requirement as demonstrating that Section 337 is no less favorable because the injury test must be met. It is difficult to reconcile all the attention given to the injury test in light of this assertion of irrelevancy. Indeed it is clear that the injury test is relevant and that its removal would weaken substantially any defense of Section 337 while irrevocably destroying any "Grandfather" rights.

E. Equal Treatment Under The Intellectual Property Laws

Proponents of the amendment have developed questionable arguments to overcome the obvious differences between Section 337 actions and actions in the federal courts. U.S. district court actions are the only actions which U.S. manufactured products must face. Proponents speciously argue that to the extent there are any differences between Section 337 actions and district court actions, such differences operate to the advantage of foreign interests. A quick consideration of some basic differences demonstrates the lack of credibility such arguments should be accorded:

1. It has been asserted that the one year deadline which exists under Section 337 for completion of an action (federal court actions against U.S. products have no such deadline) operates as an advantage to importers, especially importers not infringing. This, of course, assumes that an importer will be able to prove in one year (actually, the evidence taking must be concluded within seven (7) months) that a patent, for instance, is either invalid or not infringed. In fact,

the deadline most often operates in favor of the U.S. complainant, which before the time limit begins can completely prepare its case while respondents are burdened with discovery and motions during much of the seven (7) month period.

2. While importers can be subject to actions in two different systems (one under Section 337 and the other in the federal courts), domestic producers are subject only to actions in the federal courts. Some argue that this does not represent less favorable treatment because a domestic party may be involved in more than one federal court action. This overlooks the fact that an importer is subject to litigation in a forum in which a domestic party is never subject to litigation. It is further argued that any financial burden on an importer due to multiple actions is offset by the heavy financial burden on the party bringing suit. The argument ignores the fact that the party bringing suit can control its costs by deciding whether to bring action in multiple fora; the importer does not have this luxury. In fact, many litigated cases under Section 337 also involve concurrent federal court litigation.

3. Proponents of the amendments have also argued that there is no unequal treatment of imports because there are "safeguards" which prevent Section 337 from being used as an harrassment. Among the safeguards asserted are motions to dismiss in the federal courts. Of course, such a motion in a Section 337 action will be successful in all likelihood only if the underlying federal court action can also be dismissed, so as such it does not operate to prevent multiple litigation. This will particularly be the case with the removal of the injury criterion, which has operated as a separate basis for a motion to dismiss a Section 337 action. (In fact, a motion to dismiss an entire Section 337 case on the basis of no injury has never been granted.) Further, perhaps the best response to harrassment, a counterclaim, is simply not available in Section 337 actions.

4. While proponents admit that the rules of evidence differ between Section 337 investigations and federal court cases, they assert that the differences are not significant. This is a highly questionable assertion. Under Section 337 administrative proceedings, hearsay evidence is admissible, while it is not under federal court rules, except for instances in which its use is limited.

5. Proponents who assert that Section 337 is not discriminatory against imports claim that it operates more as an advantage to a foreign respondent than a disadvantage since a determination by the Commission under Section 337 on patent validity and infringement is not binding on the federal courts. It is doubtful that following affirmance of the validity of an intellectual property right by the CAFC based upon a Section 337 record that it would reach an opposite finding upon later review of a district court finding regarding the same intellectual property right.

Further, an assertion that U.S. intellectual property holders are reluctant to bring a federal court action when Section 337 relief has not been granted is without foundation. Many Section 337 actions involve concurrent federal court litigation initiated in most cases by the complainant in the Section 337 action.

6. Finally, it is asserted that the remedy available under Section 337, a general exclusion order, applying to persons not even before the Commission, which is admittedly unavailable in the district courts, is not unequal treatment because it applies only to goods which the Customs Service determines to be infringing, and an advisory opinion is available from the ITC. This argument ignores the fact that the effect of the exclusion order is to shift the burden of proof to all persons wishing to import a product which may be covered by an outstanding order, including persons never before the ITC. While in the federal courts a plaintiff would have the burden of proving infringement against each party against whom it wanted relief; however, under a Section 337 exclusion order, the importer has the burden of showing he does not infringe.

F. Conclusion

The Association opposes the provisions of the bills which would eliminate the injury requirements in patent, trademark, copyright, trade secret and maskwork cases. The risk of likely negative impacts of the amendment far outweigh gains from it, if any, particularly since the statute works well now.

III. PROCESS PATENTS, Section 337a

The Association supports the current parity that exists between process and product patents as embodied in Section 337a and Section 337. However, the Association cannot support the provisions of the bills relating to process patents because, as currently drafted, the bills do not clearly maintain that parity.

While the bills are not intended to change the process patent protection of Section 337a, the language of proposed § 1337(a)(2)(B) may well change this important right.

Presently, Section 337a gives the product of a process performed outside the United States, which if performed in the United States would infringe a United States process patent, the same status for purposes of Section 337 as a product that is covered by the claims of a United States patent. That section is necessary because the U.S. patent laws, as they now exist, do not provide coverage to holders of U.S. process patents when such processes are used abroad. Practice of a process abroad cannot constitute patent infringement, nor can importation or use in the U.S. of a product made by a process abroad constitute a violation of U.S. patent laws. Thus, Section 337a provides a process patent holder with protection otherwise unavailable under the patent laws. However, there is legislation pending to amend the patent laws to fill this void, namely S.1543 and H.R. 1069. Until such legislation is enacted, however, it is incorrect to amend Section 337 by using the term "infringe" or "covered by a patent." As such, use of this incorrect terminology does not provide adequate coverage to the process patent holder.

The language of Section (a)(2)(B) of the bills is not only different from Section 337a, but is also ambiguous. Since infringement of a United States patent currently covers only acts in the United States (assuming that the Mathias bill S.1543 or the Moorhead bill H.R.1069 have not been enacted), it is inaccurate to refer to foreign acts as "covered by" a U.S. patent. To avoid this problem, Section 337a refers to these foreign acts as "covered by the claims of" a U.S. patent. The bills, on the other hand, uses the terms "covered by a" patent in subsection (i) and "would infringe" in subsection (ii). It could be argued that the choice of different language was intentional, and therefore the drafters intended a different effect. If it is deemed necessary to include Section 1337a in the bills, to avoid any ambiguity, subsection (B) should be amended as follows:

> (B) Unauthorized importations of an article made, processed, or mined under or by means of a process covered by the claims of a valid United States patent.

IV. TEMPORARY EXCLUSION ORDERS

The bills would amend the temporary exclusion order ("TEO") provision in two respects: (1) the ITC would be required to make a determination within 90 days after the date of the filing of a petition for a TEO; and (2) the ITC would have the

option of requiring the petitioner to post a bond as a prerequisite to the issuance of a TEO. While the intent of the bills is to provide more effective relief for complainants, as the comments below show, this intent will not be effectuated. Thus, while the Association supports the thrust of the bills in that they would impose time limits for ITC determinations regarding temporary relief, the Association believes that the 90-day time frame proposed is too short.

The 90-day deadline from date of filing would prove unworkable for several procedural and practical reasons. While there has been some lowering of the high standard for issuance of preliminary injunctions in patent cases, a complainant would rarely have sufficient time to meet that burden in 90 days. Discovery is also generally needed for a showing of infringement, and 90 days would be too short a period to obtain the necessary discovery. The short time period would also work a substantial hardship on respondents, as respondents would be unable to prepare a defense to validity and infringement in such a short period of time. Consideration should be given to lengthening the time period, at least for patent cases.

Moreover, it should be recognized that a Section 337 investigation is a multi-tiered process. The Commissioners must first vote to institute an investigation. Following that, an administrative law judge reaches an initial determination. Then, the case goes back to the Commissioners for a final decision. These procedures make a 90-day time limit virtually unworkable.

Trademark and copyright cases are more amenable to a fair resolution in a short time period, provided appropriate procedures are implemented. One possibility is to have the ITC handle preliminary relief for trademark and copyright cases in the same manner as do district courts.

V. DEFAULT PROVISION OF H.R. 3776

The Association favors the addition of the new subsection "(h) Default" to 19 U.S.C. 1337, as proposed in H.R. 3776. The new subsection allows the ITC to presume the facts alleged in the complaint, without a further showing of prima facie evidence, for the purpose of issuing relief limited to a defaulting party and upon consideration of the public interest.

Addition of this provision would change the ITC's current practice, set forth at 19 C.F.R. § 210.25, which requires the complainant to establish a prima facie case of violation of the statute to obtain a remedy against a defaulting party. This subsection would deter respondents from making a decision to default in the hope that complainant will not obtain sufficient evidence from other sources and be denied relief. The new

subsection would make it easier for the complainant to obtain a remedy when there are defaulting respondents, but at the same time protect participating respondents against an all-inclusive exclusion order absent establishment of a prima facie case.

The Association presumes that a limited exclusion order, which would be based upon the facts set forth in the complaint, would be unnecessary if the complainant were able to make a prima facie showing of violation sufficient to justify issuance of a general exclusion order.

VI. ADVISORY OPINIONS

H.R. 3776, at section (b)(15), would add to the present subsection (h) (redesignated as (j) in H.R. 3776) of 19 U.S.C. § 1337 a new paragraph which deals with the circumstances under which parties previously found to be in violation of Section 337 may petition the ITC for a determination that they are no longer in violation of the section (hereinafter an "advisory opinion") or for the modification or rescission of an order entered by the ITC. The new language states that the burden of proof in any such proceeding is upon the petitioner and that relief may be granted by the ITC only on the basis of "new evidence or evidence that could not have been presented at the prior proceeding."

The Association endorses that portion of the amendment (proposed subsection (j)(2)(A)) which places the burden of proof upon the petitioner seeking an advisory opinion or a modification or rescission of an existing order. However, as discussed below, establishing by legislation the standards as to what evidence may be considered by the ITC in connection with such a petition is fraught with problems. Therefore, the Association opposes proposed section (j)(2)(B) of H.R. 3776.

To the extent it reflects the current law, the amendment is salutary. However, by adding the provision that the ITC in connection with such a petition can consider only "new evidence or evidence that could not have been presented at the prior proceeding," the legislation opens up the possibility of a plethora of litigation over what is or is not "new evidence or evidence that could not have been presented at the prior proceeding."

First, a petition for an advisory opinion as to whether certain activities on the part of the petitioner will not be violative of an existing order or a petition requesting modification or rescission of an order will, in almost every instance, be a totally new proceeding in which the issues are different from those before the ITC in the prior Section 337 proceeding. However, it is entirely possible that evidence presented to the ITC in the prior Section 337 proceeding may be

relevant for wholly different purposes in the later petition proceeding.

Next, the question arises as to what is the meaning of the words "evidence which could not have been presented at the prior proceeding." Does it mean that it did not exist? Does it mean that it could not have been presented because it was irrelevant to the issues before the ITC in that proceeding? If it could have been presented in the prior proceeding but is now being used on different issues from those in the prior proceeding, is its use now barred? Any proposed legislation which raises so many questions as to its meaning is best eliminated if it has little to commend it.

The question of what evidence can be used to enable the petitioner to carry its burden when seeking an advisory opinion or rescission or modification of an existing order should be developed on a case-by-case basis by the ITC and should not be legislated by Congress. Accordingly, the Association does not endorse that portion of the proposed amendment which legislates what evidence may be considered by the ITC in connection with a petition for an advisory opinion or modification or rescission of an existing order.

VII. FORFEITURE

H.R. 3776 would add a subsection (g) to 19 U.S.C. § 1337 to make available to the ITC the remedy of seizure and forfeiture. The remedy of seizure and forfeiture would be enforced by the Secretary of the Treasury, presumably by the Customs Service.

The Association opposes the forfeiture provisions of H.R. 3776. They are objectionable for trade policy reasons, as well as for their questionable value for copyrights and trademarks in light of the existing seizure and forfeiture authority of Customs, and for their drastic effect in connection with patent infringement. The forfeiture proposal, if enacted, would be targeted by U.S. trading partners as an unnecessary penalty for patent infringement which treats imports differently from domestic products which infringe patent rights. The remedy of forfeiture is not currently available in domestic patent infringement cases. Under the forfeiture provision, an importer would not only be enjoined from producing and selling in the U.S., but would be further punished by having his goods destroyed. This would amount to an extraterritorial application of the U.S. patent laws expanding them far beyond their intended scope. Its use would lead to demands for retaliation and compensation as being inconsistent with the GATT, and no "Grandfather" rights under Section 337 would be available as a defense. It would probably result in the President denying

Section 337 relief in some cases. This would increase uncertainty of relief under the statute, and possibly result in less use of Section 337.

The remedy of seizure and forfeiture is presently available under the Customs regulations for trademark and tradename violations, and for copyright violations. See 19 C.F.R. § 133.52.

The Customs law also specifically sets forth at 19 U.S.C. § 1526 provisions for the treatment of goods which are in violation of the trademark laws.

The Customs regulations provide a number of different mechanisms for the treatment of goods subject to seizure and forfeiture, including, depending on particular circumstances, sale, destruction, and gift to charity. See, generally, 19 C.F.R. Part 162. The Customs regulations also provide, under certain circumstances, for the exportation, or in lieu of exportation, destruction of prohibited merchandise. See 19 C.F.R. §§ 18.25-18.27 and 158.41-158.45.

The Customs regulations also provide for petitions for relief from forfeiture for violation of the trademark or copyright laws (19 C.F.R. § 133.51) and have general provisions for relief from forfeiture. See generally, 19 C.F.R. Part 171. Goods which have been imported in violation of the law may be seized and forfeited under 18 U.S.C. § 545. The statute of limitations for action under 18 U.S.C. § 545 is 5 years.

In summary, the Association opposes the forfeiture provisions of the bill for the following reasons:

1) The "forfeiture" provision of proposed subsection (g) does not specify how the goods which are seized and forfeited are to be disposed. Other laws which have seizure and forfeiture provisions, e.g., copyright and trademark laws, specifically provide for the nature of the disposal.

2) Subsection (g) does not clearly identify the goods which could be subject to its provisions. A literal reading of subsection (g) appears to make it applicable to goods which have been imported before the ITC has found a violation of Section 337, or even to goods which were imported before the bringing of the complaint.

3) In view of the existing seizure and forfeiture provisions of Customs and 18 U.S.C. § 545 for trademarks and copyrights, subsection (g) would appear to be redundant and not to provide any meaningful new relief. With respect to patents, forfeiture would provide a draconian measure not available in domestic patent infringement cases.

The Association would be pleased to provide any additional information which may be requested.

Executive Committee
ITC Trial Lawyers Association

Mr. KASTENMEIER. Thank you, Mr. Foster. I have just a question or two and then we will proceed and possibly get back to my questions.

Mr. FOSTER. Certainly.

Mr. KASTENMEIER. The trade aspects of this area are largely new to this committee, so we are still attempting to learn. You cited Professor Hudec favorably with respect to the injury and industry requirements, but I recall that he said the panel would not on those grounds render section 337 illegal so long as we basically subjected foreign and domestic goods to the same test. Would you agree with that?

Mr. FOSTER. Mr. Chairman, our basic concern in the association is that we believe section 337 is a rather fragile statute, if you will, in terms of its consistency with GATT obligations. We certainly hope that it is GATT consistent, and what we would like to avoid is raising challenges to it and giving the opportunity for GATT panels to consider it and for the contracting parties to consider it and perhaps determine it to be inconsistent; our concern with the injury and industry requirements is that we feel by removing these you will, in effect, provoke additional challenges against section 337.

A challenge against 337 is not just a legal exercise, of course. It is a political exercise. It is a very political decision to decide to bring an international challenge under GATT against another trading party's practices; and in making that decision a number of factors are taken into account. We think that removing industry and injury would have a tendency to make it more likely for our trading partners to be willing to bring a challenge against section 337 and, therefore, increase the number of exposures of section 337 to litigation, if you will, or adjudication before the GATT. And that is our primary concern.

I think a number of our members believe, contrary to what Professor Hudec said, that the grandfather clause is an important aspect of our GATT defense. We are not aware that even the administration has indicated they do not believe that there is a GATT grandfather defense. They did not assert it in the *Canadian Spring Assemblies* decision. But I do not believe they have abandoned it, and I believe a number of people feel if you remove injury and industry from section 337 you are just going to encourage challenges to section 337, and that is what we seek to avoid, if there is no legitimate need to do so.

And that is the second point. We think section 337 has worked well and the injury requirement and the industry requirement have not been a major impediment, indeed, hardly an impediment at all, to receiving relief under section 337 and certainly have not prevented intellectual property owners from achieving relief under the domestic laws in the alternative.

Mr. KASTENMEIER. It is your comment that a plausible complaint of those in terms of equal treatment is that they are subject to two complaint procedures. Is it not adequate to say that one of the procedures, if you represent the foreign goods—the section 337 and the Presidential review—is, in fact, more generous in terms of practice than the other? It isn't enough to say that. The fact is by virtue of being subjected to two complaining procedures that that is inher-

ently unequal in a sense. This tends to suggest perhaps in time the U.S. district court might be vested with respect to intellectual properties with the sole jurisdictional authority, subject to disposition of the Presidential rule.

What is your response to that?

Mr. FOSTER. Well, we think if section 337 is attacked internationally under the GATT the issues that Professor Hudec pointed out are going to be probably the decisive issues, and one of these issues will be the perhaps inherently unequal treatment of having to go through potentially two proceedings as opposed to an entirely domestic dispute being handled under one proceeding.

This is exactly the sort of challenge we want to avoid, and we really want to avoid, I think, having the remedy and the benefits of section 337 moved to a district court setting.

Section 337 now provides an effective, relatively rapid adjudication of patent, trademark, and other intellectual property claims in a forum that we think is basically fair and open and subject to due process, and we would like to see it kept there and we do not want it moved to the district courts exclusively, and that really is our concern. We are concerned that if section 337 is challenged repeatedly, and repeatedly held to be a violation in particular cases of our international obligations then the pressure will mount, as indeed it did in the *DISC* case, to do something about it because we will be repeatedly subject to retaliation. We also will be repeatedly subject to the same sort of things that Professor Hudec mentioned with respect to the manufacturing clause, where our repeated asserted violations are thrown back to us as reasons for not dealing with other issues internationally. That is what we would like to avoid.

Mr. KASTENMEIER. Would it be unfair for me to infer that there may be a corollary in terms of where ITC trial lawyers end up and, let's say, the American Trial Lawyers Association would end up; that is to say, that you would prefer to maintain as many forums as possible as they do in adversity cases, that they do not look necessarily for simplicity or limitations on the ability of plaintiffs. As you know, ATLA is opposed to product liability limitations. As I say, would it be unfair to assume that in the more limited context of trade your association would have sort of parallel interests?

Mr. FOSTER. I think that is fair to say, Mr. Chairman. We see section 337 as being an effective tool in certain situations and in other situations approach to a district court is perhaps the more effective tool, and we would like to have multiplicity of remedies and, indeed, that is what section 337 is all about, and section 337, subsection (a), says it is a remedy in addition to other law, and that is the basic concept behind it, that it is an additional remedy that is useful in certain situations but not necessarily all situations.

Mr. KASTENMEIER. Thank you.

I yield to my colleague.

Mr. MOORHEAD. Thank you.

You know, it is quite evident to a lot of people we are getting eaten up alive in foreign trade and have been for a few years by countries that are very aggressive in their policies and they are not particularly concerned about what we might do or what international organization we might go to. But we seem to stand back and

say they might take this up in an international organization or they might think we are violating GATT to protect our own rights. Aren't we always going to get eaten up if we have that kind of cowardly position, that we are afraid of what happens? Every time a bill comes before Congress someone said that might be unconstitutional, they might take that to the courts and it might not get through. There is always that danger. But sometimes you have to get it litigated and find out, and the professor told us this morning that there are things there they could bring up with GATT and he did not think it was going to matter what we did about this injury test or efficiency in economically operated businesses, that he did not think it would change it that much.

It does seem some place as a nation we have got to take a stand. We cannot always stand back and say hit me on the chin again. We are afraid to fight. Isn't that a concern?

Mr. FOSTER. Of course it is a concern, and I think that really gets to the root of our concern. Our concern here is that we do not want section 337 challenged, and I think that the testimony of Professor Hudec raises some of the issues that we are concerned about, because section 337 has never been given a stamp of approval internationally and there are arguments to be made that it may be inconsistent with GATT. We are concerned that if it is found to be that way that the reaction will be exactly as you say, that the administration, when it is found to be inconsistent with GATT and is repeatedly found to be inconsistent with GATT, will decide in the Presidential review of section 337 orders that, well, maybe we should not approve this order because all we are doing is throwing fuel onto the fire, and if the domestic indicator has an adequate remedy under the U.S. patent laws domestically, let them proceed under that. That is the concern that we have.

Mr. MOORHEAD. Is that adequate? There is a different test in the courts. You do not need to prove damage. You have to prove violation and should there be an entirely different test? You quoted a few figures or made some comments about this not being a deciding question in court, but how many thousands of potential cases have not been filed because companies do not want to disclose all of the data they have to their competitors on their business and economic feasibility? And they do not want to spend the perhaps millions of dollars that might be required in proving total economic loss.

Mr. FOSTER. As a practitioner under the statute who has represented both domestic and foreign interests and in my discussion with other practitioners, I do not think a real violation of confidential business information of the sort that you have asserted——

Mr. MOORHEAD. I was going by the testimony that has been given to us.

Mr. FOSTER. I do not think that in my experience that has never been cited by a client or a potential client as a reason for not going forward under section 337. Again, Representative Moorhead, we are concerned in that we want to keep section 337 an effective tool and our belief is that the amendments that are being discussed with respect to industry and injury really won't change proceedings under section 337 enough to warrant their enactment and to warrant the risk that we would subject ourselves to international-

ly. Our concern is that if we make the amendments and are found to be in violation of GATT, then that is a political decision and it has political consequences. What we like as lawyers is to be able to advise our clients that, "Look, if you bring a section 337 case and you win, then you have a fairly reasonable certainty of being able to get relief." The President is not going to overturn you. In order to do that, we need to tell our clients and we need to believe that the political decisions to be made at the Presidential level are, first of all, limited, and are not increased. Every time we get a finding from a GATT panel, internationally that section 337 may be inconsistent, that puts pressure on the President to do something; it increases the political decisions to be made.

Mr. MOORHEAD. You understand the administration supports this change.

Mr. FOSTER. I understand that.

Mr. MOORHEAD. And they seem to take exactly the opposite of the position you are afraid they might take. They are saying it is necessary.

Mr. FOSTER. I do not think they have taken a position on what they would do if section 337 is found to be in violation of our obligations. They have never taken that position.

Mr. MOORHEAD. They have taken the position that it is not in violation of our obligations.

Mr. FOSTER. That is right. But, again, we are faced with a situation that we do not have the deciding vote, if you will, on whether it is in violation or not. It is both a legal and a political judgment that will be made, and we would just as soon not have that judgment made if we can avoid it, if section 337 is working satisfactorily now.

Mr. MOORHEAD. The Japanese do everything they can to protect their very small citrus industry, and any industry it has until it gets strong and healthy and able to compete on the open market. Their automobile industry was the same for a long period of time and many others. How are we going to protect our small industries before they become economically strong in matters such as this if they are being eaten by foreign competitors that are violating the patents that might be available or might be held by our people?

Mr. FOSTER. I think section 337 now is an effective tool for that very issue. There is a prevention of establishment of industry grounds under section 337 for getting relief. So you do not have to have an industry now; but if you demonstrate to the ITC that you intend legitimately to start an industry, but you are being prevented or seriously hampered in starting an industry because of infringing imports of some product, then you can get relief under section 337 and it has been granted in several cases on that ground. I think that is a very legitimate interest, and our association agrees with you 100 percent. We want that sort of relief to be available under section 337, and we think it is now and we want it to continue to be available.

Mr. MOORHEAD. How about our schools and colleges that are not a business, nonprofit?

Mr. FOSTER. Well, I am not familiar with any particular case and what we have opposed is the total elimination of any industry requirement. There may be a need and there may be some concern to

amend the industry requirement, to broaden it, to take care of specific types of issues; and if that is the concern and that is the case and language is proposed to that effect, our association would be happy to take a look at it and give some comments. But what we are worried about is the total elimination of an industry requirement altogether.

Mr. MOORHEAD. I have no further questions.

Mr. FOSTER. Thank you.

Mr. KASTENMEIER. Now I would like to call on our other witness today. He is Mr. Michael Stein, a distinguished lawyer who specializes in this area. Mr. Stein is a former general counsel of the ITC and his firm, I gather, represents not only the Sumitomo-Corning issue, both parties, but Mr. Stein personally represents Corning on this trade issue. In any event, Mr. Stein, we would like to have your views. We have your statement and if you desire to, your statement can be made part of the record in full. You may summarize it if you wish.

STATEMENT OF MICHAEL STEIN, ESQ., ON BEHALF OF CORNING GLASS WORKS

Mr. STEIN. Thank you, Mr. Chairman. I do desire that my statement be made part of the record.

For the record, my name is Michael Stein, a partner in the law firm of Dewey, Ballantine, Bushby, Palmer & Wood. I am appearing today on behalf of the Corning Glass Works and the views that I am expressing in my testimony are based on my 7 years as the general counsel of the International Trade Commission and are not intended to reflect the views of Dewey, Ballantine or other clients of the firm.

In 1922 when the predecessor statute of section 337 was passed, Senator Smoot, its sponsor, called it a dumping law with teeth. The notion that section 337 was going to be used to protect intellectual property rights is one that grew up slowly over the course of the next few decades. The statute was not drafted with intellectual property rights particularly in mind, and there are requirements in the statute that may not fit very well with the enforcement of intellectual property rights.

One of these requirements, we submit, is the injury test. If one has a right to exclude one's competitors from the field of economic combat, then their mere entry into the field of combat could be considered injurious because it derogates from the right to exclude. This being the case, we think a very strong argument can be made that the showing of infringement of an intellectual property right is itself a finding that there is injury. And I think if we analyze the arguments that are being made in favor of retaining the injury requirement you may be able to see this.

Mr. Foster essentially made three arguments in favor of retaining the injury requirement, and they may not be consistent. The first is really it does not work, that the ITC rarely, if ever, finds negatively.

He suggested there has been one case where the injury requirement was dispositive. There is a recent GAO report that notes that

injury was solely responsible for the denial of relief in 6 cases and that there were no injury determinations in 11 cases.

If the injury requirement, in fact, does not result in much of a change, then there really is no reason to have it. It is extremely expensive to litigate these issues. Section 337 cases are adversary proceedings with full discovery and a trial in a very short period of time. Discovery on the injury requirement and on the efficient and economic operation requirement, which has not been mentioned here, can be and often is very expensive—very expensive—and the risk of arbitrary Commission determinations, especially on the injury requirement, is an ever present one.

In light of those factors, it is not clear that retention of the requirement is terribly meaningful. I would like to point out also that the injury requirement, I think, is in the statute and in our trade laws not so much to protect the exporters to the United States but to protect the U.S. public interest in that if there is an overall economic interest in expanded trade and we do not want to limit trade except in those cases where it makes sense to do so, where it is in the public interest to do so and at least with respect to the trade statutes, countervailing duty laws, escape clause and so forth, there is this injury requirement to make sure that any derogations from free trade are ones that are in our public interest, which gets to the second point.

The injury requirement will come in through the back door in the ITC public interest proceeding and in the President's policy determination regarding whether to disapprove ITC judgments. I think the answer to that, at least with respect to the ITC, is clear. Public interest requirements are that the ITC is to deny relief in cases where the relief would injure the public health, safety or welfare and might have an adverse effect on U.S. consumers.

In two cases where there have been affirmative determinations, the ITC has found negative on public interest grounds. Again, I think they are instructive. In one case the issue involved particle accelerator tubes for atomic accelerators that are used in university research. Universities came to the Commission and made a showing that, in fact, the imported infringing tubes were necessary for their continued nuclear research and the Commission denied relief on public interest grounds.

The other case is the case involving the machines that are used to make crankpins for automobile engines and this case came to the Commission in the early 1980's, and the domestic industry that made these machines was found to be injured notwithstanding the fact that they were back ordered for about a 2-year period, the Commission finding that because they had a right to exclude others they might ultimately lose sales to foreign infringers, even though they could not make these sales for quite some time. However, on representations of American automobile companies that these machines were necessary to help them meet fuel economy standards, the Commission found that it would not be in the public interest to exclude these machines.

The point I want to make is that it is not easy to fit the ordinary injury requirements into the Commission's public interest determinations.

With respect to the President's policy determination, it is not likely that the President, whose U.S. Trade Representative is arguing so strenuously for abolition of the injury requirement as being unnecessary, would put back into the law this injury requirement that he wishes to take out. In fact, the policy arguments to date that have generated controversy have generally involved the question of whether Commission relief went beyond what the GATT authorized and the disapproval of Commission actions has almost exclusively focused on the question of whether such actions would be in conformity with the United States GATT obligations.

And, finally, the argument has been made that elimination of the injury requirement would somehow increase our exposure to an adverse GATT panel ruling or might foment such a ruling. With respect to the second issue, the question of the legality under GATT of present section 337 is now the subject of a complaint in the GATT by the European Community. So I would say that issue is essentially moot since it is likely that in the course of the next year or so we will have another GATT ruling.

With respect to the former issue, I think, as Congressman Moorhead had noted, the administration is anything but reticent in objecting to proposed amendments to our trade laws on the basis that they may violate the general agreement. It is noteworthy that in this case the administration is of the view that it is quite comfortable defending the present section 337 and does not believe that the changes that have been suggested would make this defense more difficult.

Professor Hudec agrees with the position that, in fact, the injury and industry requirements will not be dispositive. And I would suggest also that it is highly unlikely that the injury and industry requirements would matter that much to those challenging section 377 in the GATT for, I think, one major reason, which is I do not think right now that substantively exporters to the United States think of the injury requirement as much protection. I do not think they are prepared to rely on this protection. In any individual case the injury requirement can be quite important because it increases the cost of litigation in many cases to the point where the game is not worth the candle, and I think the cases may not be brought.

With respect to the industry requirement, I agree with my colleague that elimination of the industry requirement would be unfortunate. The injury requirement increases expense, increases uncertainty and increases the trouble that litigants have at the ITC.

The industry requirement, however, is really the gate. When I was general counsel I had any number of potential claimants come through my office, tell me their sad stories, and I would say, geez, it sounds like you have a case, you might have a case. You do manufacture this product in the United States, don't you? And they would slink out of the office.

The opening of the industry requirement to the point where the bare holding of an intellectual property right is sufficient to grant standing would substantially increase the reach of section 337, and it could be that you would be turning the International Trade Commission into an intellectual property court, which I do not think is in the interests of the Nation or of the jurisdiction. What keeps section 337 a trade statute is the notion that it is being used by do-

mestic industry to protect their rights against imports. That being the case, we would suggest that the industry requirement be retained. We urge that the injury requirement be eliminated.

I would like to direct myself briefly to the provisions of the bill that is before us today, H.R. 4539, simply to note that bill would create a rebuttable presumption of injury. The problem with the presumption of injury is that it really does not change very much. A presumption shifts the burden of going forward with evidence. I think there is a debate among legal scholars whether it has an effect on the ultimate burden of persuasion, but I have been led to believe the better view is it does not, which means that a respondent who wishes to can place injury in issue in any given case and the domestic industry would then, again, have to show all of what it has to show now. It would not eliminate what I see as the principal vice of the injury requirement, which is the additional trouble and expense and putting of confidential business information at risk, and you would gain really very little because, in fact, the burden of persuasion would remain where it is now. So for this reason we think that this is not a change that would be sufficient to remedy the problems that are caused by the injury requirement.

Those are the major points that I wanted to make, Mr. Chairman.

[The statement of Michael Stein follows:]

TESTIMONY OF
MICHAEL H. STEIN,
PARTNER,
DEWEY, BALLANTINE, BUSHBY, PALMER & WOOD,

ON BEHALF OF
CORNING GLASS WORKS

BEFORE THE
HOUSE JUDICIARY COMMITTEE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES
AND THE ADMINISTRATION OF JUSTICE

APRIL 23, 1986

TESTIMONY OF MICHAEL H. STEIN, APPEARING ON BEHALF OF CORNING GLASS WORKS BEFORE THE HOUSE JUDICIARY SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE ADMINISTRATION OF JUSTICE

Introduction and Summary

Mr. Chairman, my name is Michael Stein. I am a partner in the law firm of Dewey, Ballantine, Bushby, Palmer & Wood, and am appearing before you today on behalf of Corning Glass Works. The views expressed in this testimony are based upon my seven years as General Counsel of the International Trade Commission. They are not intended to reflect the views of Dewey Ballantine or of other clients of the firm. I would like to thank you and the other members of the Subcommittee for giving me the opportunity to appear before you today to testify on proposed amendments to section 337 of the Tariff Act of 1930.

Corning Glass Works and other high technology U.S. corporations employ many thousands of persons. They have invested billions of dollars in research that has yielded inventions which have contributed significantly to making the United States a key competitor in high-technology markets around the world. Meaningful enforcement of U.S. patent, maskwork, and other intellectual property laws is extremely important to Corning and other high technology U.S. corporations, because it goes to the heart of their ability not only to recoup the hundreds of millions of dollars already invested, but to their ability to continue to make the

huge investments necessary for continued participation in these markets in the future.

Section 337 is a valuable tool in the enforcement of U.S. intellectual property rights against infringing imports. However, with the rapidly increasing volume of imports that enter the United States each year, amendments are needed to strengthen the effectiveness of section 337 in enforcing these rights. Many of the amendments proposed in H.R. 4539 are useful and welcome changes. Corning urges this Committee to make some changes in the draft bill, however. Particularly, we favor eliminating the need to prove that the U.S. industry is "efficiently and economically operated," and the need to show injury beyond that shown by infringement, while retaining the domestic industry requirement. H.R. 4539 as now drafted would retain the "efficiently and economically operated" requirement as a public interest factor, and would still require the petitioner to prove injury to the domestic industry in contested cases.

The infringement of intellectual property, without exception, injures the U.S. industries that own such property. Not only is the owner deprived of the return due it on the infringing sales, but the presence of infringers often makes licensing more difficult, and the owner must incur substantial costs to enforce its rights against an infringer. Because infringement is always injurious to the company that owns the property, proof of infringement in

section 337 investigations should constitute "substantial injury" within the meaning of the statute.

While it makes sense to eliminate the need to prove injury beyond that shown by infringement, the requirement that a complainant establish that there is a U.S. industry exploiting the intellectual property should remain. The purpose of the ITC is to adjudicate trade disputes between U.S. industries and those that seek to import. Moreover, the issuance of an exclusion order makes little sense if it does not protect an industry within U.S. borders. H.R. 4539 retains the requirement, but expands dramatically the definition of domestic industry. The Committee should consider carefully whether sales and marketing, standing alone, should be considered sufficient to satisfy the domestic industry requirement.

Section 337 should also be amended to eliminate the requirement that a complainant prove that the U.S. industry is "efficiently and economically operated." This element is vague, highly subjective, and to its credit, the U.S. International Trade Commission has never denied relief on this basis. This element adds additional, needless cost to the already high price of section 337 relief, and subject U.S. industries to extensive discovery by counsel for foreign respondents.

These changes will not affect the GATT legality of section 337.

The Need For Change

High-technology inventions are the result of years of research by highly educated individuals with advanced equipment and adequate financial resources at their disposal. It takes millions of dollars of high-risk investment, year after year, not only in research that ultimately yields a commercially useful invention, but in much research that ultimately fails and must be abandoned, to be competitive in high technology industries.

U.S. companies cannot afford to continue to take these large risks if there is not some meaningful assurance that when the years of research do bear fruit, the inventors will be financially rewarded for their willingness to invest in America's future.

Corning applauds the efforts to improve the effectiveness of section 337 as a tool for the enforcement of U.S. intellectual property rights. With U.S. industries competing in an increasingly global marketplace, the need for effective tools for the enforcement of U.S. intellectual property against infringing imports has grown, and can be expected to continue to grow in the years to come.

Currently, to secure relief under section 337 against infringing imports, a complainant must establish, in addition to infringement: (1) that an industry in the United States is exploiting the patent; (2) that the U.S. industry is "efficiently and economically operated;" (3) that the infringing imports have the effect or tendency of substan-

tially injuring or destroying the U.S. industry; and (4) that the beneficial effect of any contemplated relief is not outweighed by any adverse impact on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers. While some of these elements make sense in the context of other unfair methods of competition, they do not make sense when the unfair act involved is the infringement of U.S. intellectual property.

Infringing imports were not the primary concern of Congress when the predecessor to section 337 was initially enacted in 1922. As indicated by the scope of its language, section 337 was designed to cover a broad range of unfair acts not then covered by other unfair import laws. Senator Smoot called it a "dumping law with teeth." However, over the years, patent, copyright, and trademark infringement were recognized as unfair practices within the meaning of the section 337, and today, of course, section 337 is predominantly used to enforce U.S. intellectual property rights. The injury and efficient and economic operation requirements of section 337, designed for the antidumping context originally intended in the statute, make no sense in the intellectual property arena.

A Finding of Infringement Should
Satisfy The Injury Requirement.

The reason why the injury test makes no sense in the intellectual property context is that, unlike dumping or countervailing duties, or even other unfair trade practices such as false advertising or other business torts, the owner of intellectual property has been granted a temporary statutory monopoly for the purpose of encouraging innovation. Any sale in the United States of an infringing product is a sale that rightfully belongs only to the holder or licensee of that property. The importation of any infringing merchandise derogates from the rightful monopoly and diminishes the value of the intellectual property. Under such circumstances, requiring proof of injury, beyond that shown by proof of the infringement of a valid intellectual property right, should not be necessary.

In antidumping, countervailing duty, and escape clause cases, as well as section 337 cases involving unfair acts which are not based on intellectual property rights, an injury test is necessary because the U.S. producers have no right to prohibit sale in the United States of competing products. Thus, the U.S. industry is not necessarily harmed by such sales. However, as explained above, this is not the case with imports which infringe U.S. intellectual property, because any infringement has the effect or tendency of substantially injuring the U.S. industry involved.

The ITC and its reviewing court have generally recognized that lost sales alone may be sufficient to require an

affirmative injury determination. For example, in Bally/Midway Mfg. Co. v. USITC, 714 F.2d 1117, 1124 (Fed. Cir. 1983), the court stated:

> Where the unfair practice is the importation of products that infringe a domestic industry's copyright, trademark, or patent right, even a relatively small loss of sales may establish, under section 337(a), the requisite injury to the portion of the complainant's business devoted to the exploitation of those intellectual property rights.

However, despite this direction from its reviewing court, the Commission has not always found injury in cases where there were substantial infringing sales. Opponents of this change in the statute assert that denials of relief on the basis of a no injury finding are rare, and therefore no amendment of the statute is necessary. Unfortunately, such denials are not rare. In any event, the rarity of a no-injury finding is, contrary to opponents' arguments, an excellent reason to establish the requisite injury by statute in intellectual property cases. If in fact the injury test does not provide significant protection for importers, there is no reason to retain it.

Establishing injury by statute would not only eliminate the present inconsistency in the way the Commission administers the injury test, it also would save substantial amounts of money and energy. Section 337 litigation is extremely costly. The substantial expense of the injury portion of a section 337 adjudication is an additional reason to establish by statute that infringement is a sufficient showing of

injury, especially if the outcome in any case is a foregone conclusion as opponents of the legislation argue. During my time at the ITC, I was appalled by the waste of resources occasioned by the injury test in intellectual property cases. The existence of the test raises the costs of litigation to the point where the case itself can often cost more than the relief is worth.

H.R. 4539 attempts to deal with the problems of the present injury test by establishing a statutory presumption that infringement constitutes injury. A rebuttable presumption will simply not remedy the current problems. A rebuttable presumption shifts the burden of going forward with evidence. It does not shift the ultimate burden of persuasion. The domestic industry would still have to prove injury, if respondents choose to litigate the issue. The same risk that infringers will be allowed to import in blatant disregard of U.S. intellectual property rights would remain. In addition, the burdensome costs of litigating the issue will remain the same.

In summary, the injury test is vestigial, left over from a time the statute was expected to have a much different function. Section 337 should be amended to conform to modern business reality. Proof of infringement of valid intellectual property rights should satisfy the substantial injury requirement.

The Industry Requirement Should Be Retained.

While it does not make sense to require a showing of injury beyond that shown by infringement, it does make sense to retain the requirement that a complainant show that it is an "industry in the United States." Section 337 is, by its terms, a supplementary remedy. Its procedures are "in addition to any other provisions of law. . ." 19 U.S.C. 1337(a). The United States District Courts have primary jurisdiction to adjudicate intellectual property disputes. Allowing holders of intellectual property rights who have no contact with the United States other than those bare intellectual property rights to utilize section 337 would increase its reach dramatically, and would fundamentally alter the balance between the courts and the Commission. The purpose of the Commission is to adjudicate trade disputes between U.S. industries and those who seek to import goods from abroad. Retention of the requirement that the statute be utilized on behalf of an industry in the United States would retain that essential nexus. The ITC ought not become a patent court. H.R. 4539 would find a domestic industry to exist on the basis of marketing and sales organizations in the U.S. alone. The Committee should consider carefully what it means by "domestic industry." If it decides to retain the requirement, it makes sense to have a good idea of the reach of the provision. At present, some manufacturing presence in the U.S. is necessary. The bill would eliminate that requirement.

The "Efficiently and Economically Operated" Element of the Statute Should Be Eliminated, At Least With Respect to Intellectual Property Cases.

The requirement that a section 337 complainant prove that the U.S. industry is "efficiently and economically operated" is extremely vague and highly subjective. In fact, in this era of intense competition and rapid change, any company that is not efficiently and economically operated simply cannot stay in business, with or without the aid of section 337. Nor does the requirement make sense in many situations. For example, how does one establish that a new, emerging industry is efficiently and economically operated? Understandably, and to its credit, the ITC has never denied section 337 relief on the basis that an industry was not efficiently and economically operated.

The test is not only superfluous, but also mischievous. The ITC rules of discovery provide in pertinent part:

> [A] party may obtain discovery regarding any matter, not privileged, which is relevant to the claim or defense of any other party, including the existence, description, nature, custody, condition and location of any books, documents, or or other tangible things, and the identity and location of persons having knowledge of any discoverable matter. It is not ground for objection that the information sought will be inadmissible at hearings if the information sought appears reasonably calculated to lead to the discovery of admissible evidence.

19 C.F.R. section 210.30. Because almost every aspect of a company's business bears on its efficient and economic operation, almost every document in a company's possession becomes a possible target of discovery on this issue. (A

foreign respondent, of course, is not subject to discovery on this issue.) Companies view this as a substantial risk because so much confidential information must be disclosed to counsel for one's foreign competitors. In addition, the extensive discovery on this superfluous issue contributes significantly to the already high price tag for securing section 337 relief.

In sum, the added burden of establishing that the U.S. industry is efficiently and economically operated is a highly intrusive element which adds significantly to the cost of bringing and defending a section 337 case, although it provides little protection for section 337 defendants, and has little relevance in the context of intellectual property-based cases.

We are aware of little or no opposition to the removal of this requirement. However, H.R. 4539 would, rather than eliminating this element entirely, merely change the point in the investigation at which it is considered by the Commission. Rather than making it an element of the basic violation of section 337, the bill proposes that it should be made a public interest factor which must be considered before the ITC issues any relief. This would avoid the problem of burdensome discovery, but would retain the uncertainty created by having the provision in the statute.

Corning opposes this suggestion. It appears to eliminate the test from the investigation with one hand, but it reintroduces it with the other. The inappropriateness of

making the efficient and economic operation of a U.S. industry a public interest factor can be seen by comparing it to the public interest factors currently enumerated in the statute. All current public interest factors are broad-based national policy considerations distinct from the case at hand -- the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers.

The introduction of "the efficient and economic operation" of the industry as a public interest factor might have the ironic result of affording the factor greater weight than it has now, as any action by Congress is presumed to have significance. We urge you to eliminate the requirement.

Mr. Chairman, I would like to thank you and the other members of the Subcommittee again for having given me this opportunity to appear before you today. I would also like to thank the Subcommittee for the attention it has given to this legislation of great importance to the competitive strength of U.S. industries.

I would be happy to answer any questions that the Subcommittee may have at this time.

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Mr. KASTENMEIER. Thank you very much, Mr. Stein.

On the latter point, there are a lot of cases in the ITC that are not really fully litigated or contested. Wouldn't the presumption on injury issue have some beneficial effect there?

Mr. STEIN. Yes, it would in cases where a respondent defaults because it would eliminate the need for the complainant at that point to make a showing. But that is, again, a minority of cases and it still leaves the option with the respondent to force the complainant to his proof in a given case.

Mr. KASTENMEIER. Well, that is a good question. One does not really know. It could very well be as you say. In that respect it might have little effect, but we really do not know. I think this would be somewhat more difficult for a respondent to show, in fact, the complainant has suffered no injury whatsoever or whatever. It may lead to that issue dropping out in some case, but I honestly do not know.

Mr. FOSTER. Mr. Chairman, may I comment on that just a moment?

Mr. KASTENMEIER. Mr. Foster.

Mr. FOSTER. I would tend to agree with Mike and the chairman, of course, certainly in default cases that would eliminate that issue altogether. But I perhaps am a little more sanguine than Mr. Stein is about the effect on the other cases. I think that what the burden shifting does really is force respondents in these cases to almost prove the negative, that they have not injured a domestic injury, which is a considerably different standard than a domestic industry having to demonstrate that they have been injured. In order to prove a negative, you essentially have to show that any sale that you may have or anything that you intended to do in the future simply would not amount to anything more than de minimus injury to that industry, and I think that is a very difficult standard to meet and I personally believe the effect of this would mean that in cases where you have a demonstrated number of sales by a respondent in the U.S. market that are clearly, at least on their surface, in competition with the domestic patent holder's or intellectual property holder's sales, that that sort of case would essentially stop being contested after a period of time.

I believe the Commission is likely to interpret that sort of case by establishing that respondents have an almost overwhelming burden in demonstrating no injury. The case that would be left for contesting would be the case that probably should be left, and that is the case where there really is an issue as to whether there is any cognizable injury to the U.S. industry. On that case then it may be justifiable for a respondent to spend rather significant resources to prove no injury. I think if respondents, who have had a substantial quantity of U.S. sales and market penetration of 3 or 4 percent, believe they have to try to prove that they have not been injuring a complainant, as then having represented a number of respondents I know that would be considered an extremely difficult and expensive task, and I think most counsel would just advise their parties in those situations that it is not worth the candle. However, if you are in a closer situation, then it is a legitimate issue at that point.

Mr. KASTENMEIER. Mr. Stein, on another point about the test of litigation or difficulty of litigation, frequently the issue being

raised is not the sole test of whether certain language is good policy or not. However, I do note that the number of cases, as you indicated at the outset, in which relief was denied solely on the basis of no injury was shown are very, very rare. According to the GAO there were 3 cases out of 221, but it depends on what sort of analysis you make of the various cases that you use to contrast. Yet you feel injury should be eliminated; but you say on the other hand that the domestic industry requirement should be retained. According to GAO and ITC definition, the ITC definitional problems with the domestic industry requirement are frequent and that this is more of a problem for them in some respects than the injury requirement.

Do you think the law in this area is settled, that is, what constitutes domestic industry?

Mr. STEIN. No; I do not think it is settled. I think that it is an area where the Commission has, in fact, made some forays into expanding the industry requirement and then has of late pulled back rather a good deal. The two limits are very different. It is the rare holder of intellectual property who does not believe that the infringement of that property is causing injury and it is with a great deal of surprise that after a contested proceeding the complainant learns that, in fact, he was not injured. I do not think that the injury requirement stops too many cases from going forward. I think that it does in the marginal case where the trade volume is not sufficient to warrant the litigation expense, and I think one reason for considering eliminating the injury requirement is the fact that it is expensive in every contested case and it is dispositive in not that many, but a significant portion.

There have been more than 200 cases filed. My recollection when I was at the ITC was about half of the cases filed actually got as far as the final judgment. If we use the GAO statistics, there were 11 no injury findings, so it is something about 10 percent. Now, it is true that in half of those 11 cases there was some other reason, the no injury finding was in addition to some other finding that would have denied relief. So, it is difficult to determine exactly how many cases the injury test was responsible for domestic industry not getting relief.

But it cannot be disputed that in every contested case litigation expense is quite high and it also cannot be disputed that where one is entitled to exclude all others from competition the existence of that competition is harmful. That being the case, it is not unreasonable simply to say for this particular class of cases that we will simply find that infringement constitutes injury. That is the point.

But the industry requirement does limit the reach of section 337. I think there is no doubt that if that requirement were expanded or eliminated there would be a very dramatic increase in the volume of section 337 litigation, to the point where it would be difficult for the ITC to cope with the volume and to the point where our trading partners would mount an even more vigorous attack on the legality under GATT of section 337.

Mr. KASTENMEIER. Couple other questions. If a bill is enacted which eliminates injury, will that have any effect on existing litigation or, for example, on the *Sumitomo* case? Would that be either in district court or otherwise?

Mr. STEIN. That case is now in the district court, and is likely to be decided—it is being held up at the moment while the district court awaits a decision by the Court of Appeals for the Federal Circuit on an appeal from the *ITC* case. Incidentally, just for the record neither I nor my law firm is representing Corning in any of that litigation.

Mr. KASTENMEIER. I appreciate that.

Mr. STEIN. The litigation was pending while I was general counsel, but I was not general counsel when the case was decided.

Right now if Corning wished to, it could bring another section 337 action and attempt to show injury again. If the injury requirement were eliminated and there were still time remaining on the patent, I think that Corning could bring a new section 337 case. The patent issues would likely be considered collateral estoppel in the *ITC*. And then there would be the question of injury.

Mr. KASTENMEIER. Let me ask you both in a nutshell, without dealing in particulars, whether or not you support Commissioner Paula Stern's recommendations for procedural changes with respect to the ITC dealing with consent orders, public interest factors, standards of review, et cetera. There are quite a number of them, and I may be unfair to ask you to comment in a general sense on a number of specifics. However, Mr. Foster and Mr. Stein, in general are you supportive of those or do you think they pose some major problems?

Mr. STEIN. In general I am supportive of the changes. The one change that we might want to look at is the one involving what information can be brought to the Commission to challenge an order that already exists. There has been litigation on this point, and I guess the Court of Customs and Patent Appeals, as it then was, seemed to indicate that even though the information could have been brought to the Commission, the fact that it was not would allow the Commission to look at it again in a case called *Tong Seae* v. *USITC*.

The troubling aspect of this is that respondents may not understand the clear implications of an ITC decision and they get something in the mail in a different language and do not respond and then suddenly find that a year later that their access to the U.S. market has been cut off. Should the fact that they could have defended be dispositive in all cases? I do not know the answer to that, and I am not suggesting that it is wrong. I am suggesting that it is one issue the committee might want to look at. Otherwise, I think the changes are salutory.

Mr. KASTENMEIER. Mr. Foster.

Mr. FOSTER. I would agree with Mr. Stein on that, and I think our committee of the association rather generally would support those sort of changes that go to making the operation of the statute a little more effective and efficient generally without changing standards of decisions and that sort of thing.

I would like the opportunity perhaps to just submit something for the record on that, if the Chair would like.

Mr. KASTENMEIER. Yes, indeed. I am glad you mentioned that. You are both invited to comment further on that or other matters raised this morning by letter with the committee and we would like to put it as an addendum on the record.

The gentleman from California.

Mr. MOORHEAD. We have a quorum call and 5-minute vote on the floor, so I have two very fast questions I wish to ask. The first is this. You commented about the percent of the cases that come to the ITC that are thrown out because of the failure to meet the injury requirement. But if you had 200 such cases that went to the ITC, how many similar cases would there be where the injury has taken place but rather than try to meet that requirement and spending the money or whether it has just been a violation, they have decided, well, we would not be able to prove the injury; yet they have stayed away from ITC. That is the broader field and that is the area where there has been damage to our country. How far does that go?

Mr. STEIN. Congressman, I think there would be more cases brought if the requirement was not there. It is very difficult to know just how many cases would be brought. Again, you get back to the question of litigation expense. You get back to the question of putting information at risk. Just the difficulty of the case itself I think is at least as important as the ability to meet the injury requirement which really, if you look at Commission precedent, is not in many cases that hard to meet.

Mr. MOORHEAD. The second question. You recommended the retention of the U.S. industry requirement which my bill eliminates. What concerns me is the present practice excludes from U.S. industry colleges and universities. Would you support expanding the present definition of U.S. industry to include colleges and universities?

Mr. STEIN. I think that in appropriate cases colleges and universities could be included. Right now colleges and universities who own intellectual property and license that property have not had difficulty in having that property protected at the ITC. Stanford owns the basic gene splicing patent and has used the prospect of the section 337 litigation to underpin its successful efforts to require people who use that technology to license it, to pay them royalties and, in fact, it has been a very successful program. And if it were not for the process patent section of section 337, in fact, they would not have been able to enforce that patent.

Mr. MOORHEAD. Where they have really gone into business themselves.

Mr. STEIN. Yes; in those cases it works now. I am not sure about the cases you are concerned about. What we are suggesting is the industry requirement should not be eliminated altogether and any changes that should be made should be carefully considered.

Mr. MOORHEAD. Thank you very much.

Mr. KASTENMEIER. On behalf of the committee, we thank both witnesses. You were very thoughtful and helpful this morning. As I indicated, any additional comments on these issues we will be pleased to entertain by letter.

I regret that more of my colleagues did not join us. We also apologize to you for the late start this morning, but activity on the floor did prevent us from a more timely commencement of these proceedings. You were very good to stay over for them. We thank you and commend you for your testimony.

The committee stands adjourned.

[Whereupon, at 12:40 p.m., the subcommittee was adjourned.]

INTELLECTUAL PROPERTY AND TRADE

WEDNESDAY, MAY 21, 1986

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The subcommittee met, pursuant to call, at 10 a.m., in room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

present: Representatives Kastenmeier, Mazzoli, Synar, Schroeder, Berman, Moorhead, Hyde, DeWine, Coble.

Staff Present: Michael J. Remington, chief counsel; David W. Beier, assistant counsel; and Audrey Marcus, clerk.

Mr. KASTENMEIER. The subcommittee will come to order.

This morning the subcommittee is conducting its second and final hearing on process patent reform. It is the intention of the Chair that the hearing will be immediately followed by a markup of the bills before us.

This morning we will be hearing from opponents of the reform in this area. It had earlier been my hope that we would have both proponents and either opponents or those with reservations this morning. The two prospective witnesses which would have had reservations about the bill elected not to make a presentation to this committee.

It is my hope that this hearing, in combination with the one earlier in this Congress and 4 days of hearings in the last Congress on the subject, will enable members of this committee to have a full range of information and views on the subject.

The testimony presented to the subcommittee thus far indicates that very considerable support for some form of process patent reform, not only as the House previously passed a bill on this subject but also action in this area, is widely perceived as being the appropriate response to the trade deficit problem. The bill on the subject has the support of the administration, certainly most business groups, and numerous corporations.

There do remain, however, some vexing issues which I believe we will need to address.

For example, should patent infringement attach to persons who merely use an article made by a process protected by a U.S. patent? Should patent infringement apply only when an article is directly made by the patented process? Should there be a presumption that an article is made in violation of a process patent when certain circumstances are met, and should such a presumption

apply only to new products? What should be the elements of knowledge which are the prerequisites of liability? Should notice alone be sufficient? If so, how specific must the notice be and what should be the effective date of the legislation? These are reasonable questions which I think any legislation must address.

I am pleased to be joined this morning by the principal sponsor of the bill, the gentleman from California, Mr. Moorhead, as well as the gentleman from Illinois, Mr. Hyde.

If there are no other statements, I would like to call on our first witness this morning. He is Mr. David Mallino, legislative director, Industrial Union Department, AFL–CIO.

Actually, we would like to invite our two witnesses this morning to come up together. Mr. Richard Witte, on behalf of the National Association of Manufacturers also represents Procter & Gamble.

Mr. Mallino, you have a brief statement. We will call on you at this time.

STATEMENTS OF DAVID MALLINO, LEGISLATIVE DIRECTOR, INDUSTRIAL UNION DEPARTMENT, AFL-CIO; AND RICHARD WITTE, PROCTER & GAMBLE, NATIONAL ASSOCIATION OF MANUFACTURERS

Mr. MALLINO. Yes, Mr. Chairman. It is a brief statement and if you don't mind, I will just read it.

My name is David Mallino and I am the legislative director for the AFL–CIO's Industrial Union Department. My department represents 55 industrial unions in the United States, with a total of 5.5 million workers.

At the outset, let me say that we support H.R. 1069, a bill that would protect patent owners from importation into the United States of goods made abroad in violation of U.S. process patents.

Current law prohibits the manufacture, use or sale of a product in the United States in violation of a U.S. patent. It does not, however, prohibit the importation of a product made in a foreign country in violation of an American process patent. The exception to this is section 337 of the International Trade Commission Act, which we believe to be inadequate.

H.R. 1069 would eliminate this anomaly in the U.S. law by giving American process owners the right to bring a suit for patent infringement against a party who uses, sells, or imports a product made abroad using a U.S. patent process. It is the intent of this legislation to stop foreign processing of material in violation of U.S. patents, and not aimed at pharmacists or other retailers.

We believe that U.S. law should not foster and support the manufacture and importation of foreign made goods utilizing cheaper labor in industries subsidized by foreign governments in direct competition with the same products made in the United States, which if made here by a competitor, would violate the law. This is simply not fair.

As you are well aware, thousands of American manufacturing jobs are lost every year, jobs which probably will never return to the United States. Among the many reasons for this job loss is inadequate U.S. patent law protection process technology against for-

eign firms that engage in pirating the patents of the U.S. manufacturers.

Inventions and processes resulting in new U.S. technology patents of not only the creation of a few scientists and technicians hidden away in small laboratories. They are also the result of knowledge and dedication of American workers and craftsmen working with the scientists to create entirely new processes that will improve American competitiveness.

Such U.S. patent processes are stolen and infringed upon by foreign entrepreneurs. The American worker and his community are both cheated and robbed. Lack of effective patent protection processes is a giant loophole in U.S. patent law which currently allows foreign manufacturers to circumvent our patents when they cover a process rather than a product. This happens because a product patent is infringed upon whenever the product is made and sold or used in the United States. The process is infringed only if the manufacturing occurs in the United States.

We need legislation to protect U.S. companies from unfair competition by foreign manufacturers who are in effect taking a ride on American research and development expenditures. If the rights of U.S. patent owners are protected, these owners are more likely to invest in manufacturing facilities located in the United States, thus preserving jobs for American workers.

In addition, effective protection for owners of U.S. process patents is important to foster a climate to encourage U.S. companies to invest in additional research. Such legislation is important for two other reasons. First, it will benefit the emerging biotechnology industry in America, whose only protection lies often in a process patent.

Second, it would provide an adequate remedy for damages to process patent owners against foreign infringers. At the present time, the only remedy for preventing goods manufactured in a foreign country by a process protected by U.S. patent entering the United States is the inadequate and complex remedy under section 337 of the International Trade Commission Act.

This legislation would allow domestic parties to bring actions in U.S. district court in order to block importation of such products. We understand that America's major trading partners, including Japan, West Germany, France, and the United Kingdom already have similar provisions to H.R. 1069 in their laws. Therefore, we are not suggesting anything new or different from the way others deal with this problem.

American inventiveness, if given adequate legal protection, can help us recover some of the manufacturing jobs lost in this country. The industries in which our members are employed, such as pharmaceutical and petrochemical industries, rely heavily on patented technology. America will continue to have an advantage in these technologies only if its intellectual property is effectively protected.

Thank you, Mr. Chairman.

[The statement of Mr. Mallino follows:]

STATEMENT OF DAVID MALLINO

LEGISLATIVE DIRECTOR, INDUSTRIAL UNION DEPARTMENT, AFL-CIO

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE ADMINISTRATION OF JUSTICE

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

ON

H.R 1069

A BILL TO PROTECT PATENT OWNERS FROM IMPORTATION
INTO THE UNITED STATES OF GOODS MADE OVERSEAS
BY THE USE OF A U.S. PATENTED PROCESS

May 21, 1986

Mr. Chairman and members of the Subcommittee, my name is David Mallino and I am the Legislative Director for the AFL-CIO's Industrial Union Department.

At the outset, let me say that we support H.R. 1069, a bill that would protect patent owners from importation into the United States of goods made abroad in violation of U.S. process patents.

Current law prohibits the manufacture, use or sale of a product in the U.S. in violation of a U.S. patent. It does not, however, prohibit the importation of a product made in a foreign country in violation of an American process patent. The exception to this is Section 337 of the International Trade Commission Act. H.R. 1069 would eliminate this anomoly in the U.S. law by giving American process owners the right to bring a suit for patent infringement against a party who uses, sells or imports a product made abroad using a U.S. patent process. It is the intent of this legislation to stop foreign processing of material in violation of U.S. patents, and not aimed at pharmacists or other retailers.

We believe that U.S. law should not foster and support the manufacture and importation of foreign made goods utilizing cheaper labor in industries subsidized by foreign governments in direct competition with the same products made in the U.S., which if made here by a competitor, would violate the law. This is simply not fair.

As you are well aware, thousands of American manufacturing jobs are lost every year — jobs which will probably never return to the U.S. Among the many reasons for this job loss is inadequate U.S. patent law protection for process technology against foreign firms that engage in pirating the patents of U.S. manufacturers.

Inventions and processes resulting in new U.S. technology patents are not only the creation of a few scientists and technicians hidden away in small laboratories. They also result from the knowledge and dedication of American workers and craftsmen working with the scientists to create entirely new processes that will improve American competitiveness. When such U.S. patent processes are stolen and infringed upon by foreign entrepreneurs, the American worker and his community are both cheated and robbed.

The lack of effective patent protection for processes is a giant loophole in the U.S. patent law which currently allows foreign manufacturers to circumvent U.S. patents when they cover a process rather than a product. This happens because a product patent is infringed upon whenever the product is made, sold or used in the U.S., but a process is infringed only if the manufacturing occurs in the U.S.

We need legislation to protect U.S. companies from unfair competition by foreign manufacturers who are in effect taking a free ride on U.S. research and development expenditures. If the rights of U.S. patent owners are protected, these owners are more likely to invest in manufacturing facilities located in the United States, thus preserving jobs for American workers. In addition, effective protection for owners of U.S. process patents is important to foster a climate to encourage U.S. companies to invest in additional research and development.

Such legislation is important in two other respects. First, it will benefit the emerging biotechnology industry in America whose only protection lies often in a process patent, and secondly, it would provide an adequate remedy for damages to process patent owners against the foreign infringers. At the present time, the only remedy for preventing goods manufactured in a foreign country by a process protected by a U.S. patent from entering the U.S. is the inadequate and complex remedy under Section 337 of the International Trade Commission Act.

This legislation would allow domestic parties to bring actions in U.S. District Court in order to block the importation of such products. As we understand it, America's major trading partners — including Japan, West Germany, France and the United Kingdom — already have provisions similar to H.R. 1069 in their patent laws, and therefore we are not suggesting anything new or different from the way others deal with this problem.

America's inventiveness, if given adequate legal protection, can help us recover some of the manufacturing jobs lost in this country. The industries in which our members are employed, such as the pharmaceutical and petrochemical industries, rely heavily on patented technology. America will continue to have an advantage in these technologies only if its intellectual property is effectively protected.

Thank you.

Mr. KASTENMEIER. Thank you, Mr. Mallino, for your statement. Now we would like to call on Mr. Witte.

Mr. WITTE. Mr. Chairman, thank you for this opportunity to discuss process patent legislation. I have a summary of the prepared remarks for the record.

Mr. KASTENMEIER. Without objection your statement in its entirety will be received and made part of the record and you may proceed from your summary.

Mr. WITTE. Thank you. I am appearing here today on behalf of the National Association of Manufacturers. I am chairman of the NAM's Intellectual Property Task Force. I am also vice president of Intellectual Property Owners and I am chief patent counsel for the Procter & Gamble Co.

These organizations support legislation to improve process patent protection. If U.S. corporations believe their competitors, particularly foreigners, can take a free ride on their process research and development, they will have less incentive to invest in such R&D, or they may be tempted to resort to secrecy rather than publish their R&D result for the stimulation of all.

But if U.S. patent owners can be protected against foreign free riders, who have no R&D expenses, but sell infringing products in the United States, thousands of U.S. jobs can be preserved. NAM strongly endorses legislation to improve the protection provided by process patents.

The patent statute should be amended to provide the owner of a U.S. process patent the right to enforce it against someone who uses, sells, or imports a product produced by the patented process. This would eliminate a deficiency in our laws and put the U.S. laws on equal footing with the patent laws of our major trading partners, including West Germany, France, United Kingdom, and Japan.

There is no reason for U.S. manufacturers to be prevented from exporting products made by processes patented in foreign countries, while at the same time permitting the import of products made by processes patented in the United States.

Several provisions of the proposed law are appropriate to deal with some of the important practical problems of its implementation. First, the law would not be retroactive to cover past infringement. That is, products already imported.

Second, the law should, however, cover future infringement of all unexpired process patents. This important remedy is needed now. Even though the basic R&D has been done for existing patents, the stimulus provided by the extra patent protection to scale up and to commercialize is needed through the proposed legislation.

Of course, U.S. companies can and do get foreign process patents, but U.S. companies should get protection against U.S. imports under U.S. laws and U.S. courts and with U.S. remedies.

Third, in order to make the proposed changes meaningful, however, the U.S. patentee should have a procedural advantage. The patentee should have a rebuttable presumption of infringement, but in order to get this presumption, however, the patentee must demonstrate a substantial likelihood of infringement and have made a substantial effort to find out what the importer is doing in the foreign country.

This presumption is needed because the fact that the process is being practiced abroad provides great potential for stonewalling and making facts difficult to obtain.

If the accused infringer wants to do business in the United States by importing products made by patented processes, or the customers want to take advantage of foreign-made products, none should complain if the accused infringer must tell our courts how the imported products are made, or at least, tell us how they are not made.

The presumption should apply to all types of products, whether new or old or whatever category. If the presumption is limited to new products or to particular technical areas such as biotechnology, it is much too restrictive.

To illustrate this point, there are two examples which come to mind involving old, well-known products like insulin and penicillin, both great benefits to mankind, both bases for creation of new industries. But until a new process was developed to make these old products, they weren't benefiting mankind, so this presumption is needed to provide a proper stimulus for the creation of a new industry, which may turn on whether or not patent rights are enforceable.

Fourth, the infringement remedy for imported products made by a patented process should be of the full range; importation, sale, and use. A limitation only to the importation or sale could limit the remedy only to elusive sales agents who may be unavailable and/or judgment proof.

Fifth, the remedy should include actions against use by the U.S. purchaser, from whom damages and injunctive relief can be obtained, but without any preconditions. Knowledge and notice should be carefully treated in the proposed law. Innocent infringers without knowledge of how the imported products were made should be protected, of course.

But once the importer, seller, or user of the products knows how they were made, whether by actual knowledge or being put on notice, liability should obtain.

Sixth, the imported product should be defined as infringing if it was made by a patented process whether directly or whether it was given some subsequent nonmaterial treatment. This drafting problem is best dealt with in the law by not using the word directly, which is much too limiting and which would make the law too easy to evade.

This legislation is necessary even if section 337 of the Tariff Act is changed to eliminate the injury requirement. Infringement by importation is so important and so complex that the complementary procedures and remedies of 337 and an amended patent statute are required.

Thank you, Mr. Chairman.

[The statement of Mr. Witte follows:]

TESTIMONY OF

NATIONAL ASSOCIATION OF MANUFACTURERS

BY

RICHARD C. WITTE

CHIEF PATENT COUNSEL

THE PROCTER & GAMBLE COMPANY

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES

AND THE ADMINISTRATION OF JUSTICE

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

May 21, 1986

Good morning. My name is Richard C. Witte. I am Chief Patent Counsel of the Procter and Gamble Company. Today, I am representing the National Association of Manufacturers as chairman of its Task Force on Intellectual Property.

NAM is a voluntary business association of more than 13,000 corporations, large and small, located in every state. NAM membership ranges in size from very large to more than 9,000 smaller manufacturing firms, each with an employee base of fewer than 500. NAM member companies employ 85 percent of all workers in manufacturing and produce more than 80 percent of the nation's goods. NAM is affiliated with an additional 158,000 businesses through its Associations Council and the National Industrial Council.

We note that a considerable number of bills have been introduced in this Congress that seek to provide protection for U.S. intellectual property--be they patents, trademarks, copyrights, trade secrets, or the very newest forms of intellectual property--semi-conductor chip mask works. We also note that much of this legislation seeks to give such protection through amending Section 337 of the Tariff Act of 1930. We applaud such efforts to strengthen our trade laws, particularly as they apply to the intellectual property content of our international trade problems. We are especially appreciative of the promptness with which this Subcommittee marked up and reported the Section 337 provisions of H.R. 4539. It is an indication of how seriously the members of this Subcommittee view the importance of protecting intellectual property rights in the conduct of our trade.

But notwithstanding the importance of amendments to the Tariff Act, the manufacturing community views as a most important, if not the most important priority, the earliest passage of legislation that would protect U.S. process patents. As you may be aware, already more than 70 U.S. manufacturing companies and thirteen trade associations have indicated support for legislation to protect U.S. process patents. The NAM supports legislation to protect U.S. process patents because it in effect is protecting U.S. developed technology. Process technology has become so fundamental to modern products and thus to modern commerce that some developed and many developing countries seek to obtain it--both by legitimate and, unfortunately, illicit means.

At a time when the United States is spending some $122 billion (an estimate for 1986 by the National Science Foundation) on research and development, we cannot continue to neglect the protection of such an enormous investment. U.S. industry will invest somewhat more than 50 percent of that $122 billion, and we are most anxious that our laws be strong enough to protect that level of investment--particularly against abuses of our system for safeguarding the products of such outlays.

While our patents system does a generally good job of providing some protection against pirates and infringers of our process patents in the U.S., it provides absolutely no protection for those patents outside the U.S. Individual U.S. companies do have remedies against use of their process patents by taking legal action against pirates in their own countries, provided the U.S. company is fortunate enough to have obtained a patent on the process in the offending country. But, it is an expensive, time-consuming and often fruitless effort, as many U.S. companies have discovered to their chagrin.

The courts of foreign countries, particularly developing ones, are unlikely to be sympathetic to complaints from foreign litigants, more especially when the intellectual property laws of those countries provide less comprehensive or sophisticated remedies for domestic abuse of foreign-owned intellectual property rights.

If one has a process patent in the United States, one can prevent the illegal use of that process in this country. However, since one

cannot prevent the use of that process abroad, manufacturing by competitors abroad is thus encouraged. The movement of manufacturing to foreign countries does nothing for the creation of jobs in the U.S. In fact, as we well know, it results in job losses. That is why the NAM strongly urges this subcommittee to report out legislation that would make it an infringement of a U.S. process patent to import, use or sell the product of that process patent in the United States. Most of our major trading partners, including most European countries, provide similar protection for process patents.

In today's climate of fierce competition in high technology products and processes, requiring huge expenditures on R&D and swift marketing of the results of that R&D, the United States has become increasingly vulnerable to piracy and counterfeiting of our products and processes. In such a high-technology environment, the short life of many products establishes a need for the strongest protection so that investments can yield some return. Pirates, who frequently engage in fly-by-night production, have no need to make costly R&D outlays.

In considering legislative remedies to address these problems, we believe that four major provisions should be considered. They are simply--effective date, presumption, use and knowledge.

Effective Date

It is extremely important that process patents already in force should be protected against foreign misuse. We favor having a law that will apply only to products produced or imported after date of enactment.

But to limit the law's application to U.S. patents granted on or after date of enactment would put all patents in force before enactment at great peril. It would open up those patents to free pirating by manufacturers abroad, who you can be sure, would note the benefits of such a limitation. Giving foreign pirates carte blanche to use U.S. process patents, which would be totally unprotected by an effective date limitation, would create a loss of jobs in this country and would certainly provide no protection to investments already made in R&D, in building plants, and in manufacturing and marketing. The NAM is not seeking in this legislation any provision for retroactivity for infringements before enactment. But U.S. patents in force at the time of enactment and thereafter must be equally protected.

It is also important to give protection to patents already issued but not yet commercialized, thus encouraging such commercialization.

Presumption

One of the most difficult problems facing U.S. companies in protecting their process patents is to establish through the legal process of discovery that a foreign pirate is actually using a U.S. patented process. A U.S. company may hire a number of lawyers and/or experts in a foreign country to attempt to determine whether an alleged infringer is actually using a U.S. patented process. But for one reason or another, discovery can be a most difficult process. A foreign nation's concern for national security, protection of indigenous industry, its own concern for protecting jobs, etc., can thwart efforts at discovery. It too can be expensive, time-consuming

and often fruitless.

That is why the NAM believes that this legislation must contain a provision that allows the U.S. courts--given certain conditions--to direct that there is a presumption that a product was made by a U.S. patented process abroad.

Those certain conditions that the claimant must meet would be that a substantial likelihood exists that the product was produced by the patented process, and that the claimant has made a reasonable good-faith effort to determine what process was actually used in the production of the product and was unable to do so. Of course, the defendant would still have the right to rebut that presumption but his burden would be to establish that the product was not produced by the process in question.

Use

There has been a suggestion that the legislation only cover imports and sales and not cover uses. We feel that it is important that uses be included. Let me give you an example to make the point. Assume that an innovative breakthrough consists of a process for making chemical X, which is an intermediate. Further assume that a competitor takes that innovation abroad and manufactures X. He then has X imported into the United States through some agent whose sole assets in this country are a warehouse and articles of incorporation. The competitor buys X from the importer and uses X to make a final product Y. He then sells Y in competition with the U.S. company. But

the costly part of producing Y was in the making of X. Thus the competitor of the U.S. company that originated the process for making X is able to undersell the originator because he doesn't have to recoup any of the R&D expenses that resulted in product X. If "uses" is not included in the legislation, the U.S. company that developed the process for making X is without any remedy against the competitor. Suing the importer would be fruitless in this kind of situation. Without the inclusion of "uses", we are leaving a huge loophole in the protection this legislation is intended to provide.

It is not adequate for the patent owner to be able to sue the user only after having sued a seller or importer and failed to obtain a sufficient remedy. Multiple suits mean extra expense and delay in enforcing patent rights. Patent owners need to be able to seek relief initially from an infringer who has financial resources to satisfy a judgment.

Knowledge

A problem facing an importer of products made abroad using a U.S. patented process is that he may not know that the product he is importing was made by that process. We feel that such a person or company should not be culpable until he or his company has knowledge that the product is in fact produced by a process used illegally abroad. But he or his company is given sufficient legal notice of an alleged infringement, he or his company should then be responsible for continued import, sale or use of the infringing product.

Requiring proof of actual knowledge is an unreasonable burden because essentially one would have to go into a person's mind to establish such proof. We believe that a notice of infringement must be sufficiently clear so that the alleged infringer understands that the product he or his company is importing, selling or using is clearly the product of a U.S. patented process being used illegally overseas.

Let me turn to consideration of limitations which we feel should not be included in legislation to protect process patents:

Products Directly Produced

Limiting the reach of the legislation to "products directly produced" by a patented process threaten the very purpose of this legislation. Some examples may be helpful: A metal strip with unique properties is covered by a U.S. patented process. A foreign competitor takes that strip, makes it into a core, puts the core in a transformer and imports the transformer. Most agree that that should be infringement. But, how will the courts read "directly"?
A chemical intermediate is made abroad by a patented process. It is then subjected to a common chemical reaction and becomes a salt or an amino-derivative. That product is then imported. Direct or not direct?

I believe we need and want to cover those types of examples. On the other hand, suppose a process covers the mining of ore, which ore is mined abroad, made into steel, then into a car. Should the U.S. patent owner be able to sue the car salesman? Probably not.

Our solution is to make it clear that the legislation is not intended to cover infringements which are too far removed from the patented process; but including the word directly could be too dangerous. Instead, let the bill or report language suggest that this does not apply to products materially changed chemically by subsequent steps or processes from the product resulting from the patented process. It would not exclude from the scope of the legislation a product which was subjected to an immaterial physical change or altered in shape or configuration.

"New" Products

Limiting a rebuttable presumption to new products surely creates an enormous hurdle for those companies that may have new processes that produce old products.

For example, the U.S. biotechnology industry is now unquestionably in the world lead in research and development, in developing new processes, and in making products of immense importance to people's health, to agricultural production, and to the quality of life.

But the biotechnology industry is not exclusively in the business of making "new" products. Insulin is not a new product, but the process by which the biotechnology industry makes it is new. Here we have a U.S. industry which leads the world, but it could be seriously at risk if this legislation were to limit infringement to new products made by a patented process.

Japan and Europe are already catching up in their efforts to compete with the U.S. biotechnology industry. For example, the Japanese view biotechnology as the last major technological revolution of the 20th century. According to the Congressional Office of Technology Assessment, a broad range of Japanese companies have extensive experience in traditional bioprocess engineering. Further, the Japanese government has targeted biotechnology as a key technology of the future and is financing cooperative inter-industry biotechnology projects.

If among the foreign companies involved in biotechnology in Europe or Asia there are potential pirates of our processes, then the limitation of a rebuttable presumption to new products would mean that we are making it too difficult to prevent potential foreign pirates from stealing biotechnology processes which do not produce "new" products. For the thousands and thousands of products on the marketplace someone, somewhere is always looking to come up with better, more efficient, more economical processes for making them. The limitation of this presumption provision to new products could relegate these creative, innovative people to the fate of the dodo--extinction. Do we want to repress the inventive and innovative genius of our scientists and researchers so that only those who come up with new products--and not new processes--are protected against piracy and infringement of their patents?

The NAM considers the passage of legislation in this session of

Congress incorporating our four basic provisions to protect our process patents to be of the utmost importance to U.S. manufacturing industry. It will close a loophole in our patent laws that has existed for too long. If the U.S. is to advance our industrial competitiveness, then our inventiveness, our investments in research and development, and our jobs must be protected by all the legal means we can muster.

Thank you.

* * *

Mr. KASTENMEIER. Thank you, Mr. Witte, for your statement.

Briefly, Mr. Mallino, you said that one of the reasons for the necessity of this bill was that the only remedy currently was the inadequate complex remedy under section 337. However, you are well aware that on the floor today is a trade bill which contains substantial changes in section 337 with the purpose of making it more effective. So the likelihood is that at some point we will have an amended section 337 which will no longer, hopefully, constitute an inadequate complex remedy.

Would that lessen your sense of urgency about passing this bill?

Mr. MALLINO. Unfortunately, Mr. Chairman, even if you passed the trade bill today, even if the Senate takes up the trade bill later on in the summer, and even if the President of the United States then finally signs the bill, even if all that comes about, you are still going to have to go through the ITC procedure. Assuming they change the injury test so that the infringement of the process patent constitutes injury, and I am not sure that is going to happen, but if they do, you still have to go through the whole panoply of filing petitions with the ITC. And, as we all know, even when the ITC hands down a recommendation for relief, that relief is often subject to various political pressures that swirl around the White House.

We have a whole litany of cases from a lot of industrial unions and industries that we represent where we have gotten affirmative decisions on the part of the ITC and the President has seen not to implement them.

We think that 337 needs reform, primarily so that the injury test is merely that you can prove infringement. However, we also think that if this infringement occurs and there is a violation of a process patent, that the owners of those patents also ought to have the right to go into district court to prove their case and get damages. It is probably a much faster test, and we don't see any conflicts. We think one supplements the other.

Mr. KASTENMEIER. Another point you made was that you are not suggesting anything new or different with the way others deal with the problem, including talking about our trading partners, Japan, West Germany, the United Kingdom, et cetera. How important is it for us to harmonize our laws with theirs?

For example, a number of these countries, most of them limit liability to products directly made by the protected process. Have you any objection to that being the test?

Mr. MALLINO. Mr. Chairman, I have to admit to you I am not familiar with all the laws of other countries. It is our understanding that the laws that they have on the books in those countries are very similar to what has been suggested in 1069. I might refer to my colleague from NAM as to what directly or indirectly means.

Mr. KASTENMEIER. But as a general test, you would agree that our laws ought to generally conform to those of our trading partners?

Mr. MALLINO. I would agree with that.

Mr. KASTENMEIER. Mr. Witte, what do you think about the term "directly," which has been recommended by the Justice Department and the Commerce Department, as conforming our bill to those of our trading partners?

Mr. WITTE. Well, I agree with the concept that the law should be limited to processes which essentially make the material that is imported into the United States, but the word "directly" is too limiting. I would prefer that it be stated a different way. Instead of saying, "directly made by the process," I would prefer to say something like, "not materially changed after it has been made by the patented process."

What you have here is a problem as to whether or not directly means that nothing can be done with it. It has to be exactly the way it comes out at the end of the pipe in the foreign country or whether you can still grind it up or change it into another form or make a simple chemical change to it or put it in some component of a further manufactured article and still be—I think the sense is that it still infringes if it hasn't been materially changed, and I think that would be a much better definition.

Mr. MALLINO. Mr. Chairman, if I might, I think words like this, the reason we being so hesitant, words like these take on not only certain political connotations but legal connotations. As you well know, the definition of injury across the board in American trade law means "significant" injury.

The word "significant " has had a massive amount of impact on filing successful trade cases. In 1981, an unfair trade practice was filed on automobiles and the whole thing was thrown out over the fact that we couldn't prove that the injury being done by imports was more significant than the injury that was being done by the recession at the time. I just raise that as a point when we get involved in some of these words like significant and directly. They can take on a much greater meaning than even what the Congress might intend.

Mr. KASTENMEIER. As a matter of fact, we have added quite a few words to this bill. We passed, in the last Congress, the process patent bill. We had no presumption, you remember, but there is one in this bill. What was wrong with the one we passed 2 years ago?

Mr. WITTE. I would prefer that it had presumption in it then, but a bill without presumption was better than no bill.

Mr. KASTENMEIER. This is sort of a bill with a wish list in it.

Mr. WITTE. There must have been a lot of additional debate to help fully understand it as to how it would work in practice.

Mr. KASTENMEIER. One last question, Mr. Mallino. What will be the effect of this legislation on consumer drug prices in the United States?

Mr. MALLINO. Well, Mr. Chairman, I can't give you a definite answer on consumer drug prices in the United States. There is an issue swirling around as to whether this will somehow eliminate the impact on so-called generic drugs in the United States.

Mr. KASTENMEIER. May I say to you, sir, it may be somewhat similar to the bill extending patent term restoration, which the AFL–CIO opposed, I remember, for this reason.

Mr. MALLINO. The short answer is that we think that generic drugs are a good idea. We think generic drugs ought to be available. We also think generic drugs ought to be made in the United States, as the same way we feel about a whole host of other products that come in from foreign countries made by cheap labor,

made by pirated patents and pirated technology and we are not about to take the position that just because it is cheaper that it is good for the United States or the people we represent, including the senior citizens.

Mr. KASTENMEIER. In other words, you concede it may be cheaper to import——

Mr. MALLINO. Absolutely.

Mr. KASTENMEIER. But it is not worth the price?

Mr. MALLINO. It may be cheaper at the counter but we think when you start adding the cost of unemployment compensation, that the loss of revenue to the Treasury, and the other social costs involved and what we are seeing in a whole host of industries, including the chemical industry basically being wiped out in this country that those costs are simply too much to bear for a few pennies or few dollars.

Mr. KASTENMEIER. Thank you. I yield to my colleague and author of one of the principal bills before us, the gentleman from California.

Mr. MOORHEAD. What you are saying basically is that if you are unemployed and don't have a job you may not be able to pay the few pennies less that you might have saved to get a somewhat better item.

Mr. MALLINO. That is correct, sir.

Mr. MOORHEAD. In mid-1984, when we were considering the process patent legislation, we received a letter from the American Flint & Glass Workers Union, AFL-CIO. They stated that in the American glass industry alone, more than 50,000 jobs had been lost. Most of these jobs will never be recovered. The International Trade Commission estimated back in 1902 that infringement of U.S. intellectual property cost Americans 131,000 jobs in five select industrial sectors.

My suspicions are that this has gotten worse. Would you comment on these figures and tell us what you see happening?

Mr. MALLINO. Mr. Moorhead, I can't confirm or deny the specific figures that you have. However, those figures do not surprise me in terms of the actual numbers of jobs lost. The Flint Glass Workers Union would know better than I do as to what the impact on their union and their industry has been, but we have just seen tens of thousands, hundreds of thousands of jobs lost in not only basic industries but in high-technology industries across the spectrum of the economy. And those numbers do not surprise me.

I understand that the Oil, Chemical, and Atomic Workers have lost up to 50,000 jobs in the basic chemical industries. A large part of it is due to what we consider to be very unfair trading practices.

There are a lot of other reasons why these jobs are being lost in American industry, but one of the principal and major factors is the kind of competition we are experiencing from foreigners in a market literally unregulated and the whole idea of pirating patents and stealing process technology, all to add substantially to the overall job loss.

Mr. MOORHEAD. I appreciate your comments. You know, Mr. Berman and I both come from an area where our people are losing their jobs because of stolen copyrights and people copying our

motion pictures and our records that are made in California, and it is hurting our balance of trade. It is hurting everything else.

So I know in our area this is a very, very serious problem, the process patent. The patent situation is right down the same alley, and is of great concern to us as we see our people that should be working that don't have jobs.

One of the questions that comes up is whether the process patent legislation should apply to existing process patents that are already in existence. I think the representative from the National Association of Manufacturers has already expressed his position on that. I wondered whether you feel it should only apply on those patents that may be someday be applied for or whether it should apply to those that are being ripped off today?

Mr. MALLINO. We think they should apply to existing patents.

Mr. MOORHEAD. Assuming that the amendments which have been approved by the House to section 337 relating to the enforcement of intellectual property rights become law, what effects should that have on our deliberations?

Mr. MALLINO. The chairman asked a similar question. We think that your bill is a necessary compliment and supplement to whatever reforms occur to section 337, again because of a procedure that one goes through with the ITC, even if we change the law, even if one wins his case at the ITC, one is still subject to determinations by the White House, the State Department, the Treasury Department and who knows who else gets involved in these decisions as to whether the President is even going to grant the relief that the ITC has recommended. We think access to the district courts is a necessary supplement to any reform to section 337.

Mr. MOORHEAD. One other thing. This could be the only major trade bill that passes the Congress this year and actually becomes law, so it is vitally important.

Mr. MALLINO. If we can convince enough members on this side and enough members on the other side to do that, which we are going to be engaged in the rest of the summer, hopefully the President will sign it. We think it is a good trade bill that will be on the floor and hopefully we can get some of our bill passed——

Mr. MOORHEAD. I am talking about this being a trade bill we are considering here also.

Mr. MALLINO. Mr. Moorhead, I am going to make any suggestions as to how you might want to offer this as an amendment to the trade bill and then we could get a final vote on the overall bill, but I guess you are going to mark this thing up after the hearing this morning, and it will be on its own track.

Mr. MOORHEAD. Did you have any comments you would like to make?

Mr. WITTE. Yes, I think this is vitally important even if section 337 is improved. Even if section 337 isn't improved, it still deals with process patents. The changes would make it a little bit easier to deal with process patents, but the remedies are complementary. For example, damages are not available at ITC. That could be very important to a U.S. process patent holder.

The ITC is in rem proceedings after things, not individuals. This whole business of importation is so complex and takes so many different forms, intermediates or manufacturers, elusive individuals, I

think you have to have both remedies to get the full benefit from U.S. process patents.

Mr. MOORHEAD. Thank you both very much.

Mr. KASTENMEIER. The gentleman from Kentucky.

Mr. MAZZOLI. No questions.

Mr. KASTENMEIER. The gentleman from California, Mr. Berman.

Mr. BERMAN. Thank you, Mr. Chairman. I have a couple of questions for Mr. Mallino.

In reading your testimony, would it be fair to say that the thrust of your position can be summed up in your statement that we believe that U.S. law should not foster and support the manufacturer and importation of foreign-made goods utilizing cheaper labor in industry subsidized by foreign governments in direct competition with the same products made in the United States, which if made here by a competitor would violate the law. This is simply not fair.

Given that the legislation before us is trying to deal with that, what would be wrong with adding a requirement to that legislation in a sense that gives this action, this remedy that you think would help strengthen the domestic industry adding to it a requirement that the remedies apply where the patented processes are not being used by the patentee or its licensee to produce the product in the United States?

In other words, basically, that the remedy would only apply where there is a domestic industry in the United States and the correlary of that is otherwise we are simply protecting foreign process patent owners who are not manufacturing in the United States or U.S. process patent owners who are seeking to manufacture outside the United States.

Would you be adverse to, in effect, that kind of domestic industry requirement?

Mr. MALLINO. I think the labor movement would be supporting that. Our principal concern not only in this legislation but with all the other legislation is that we protect, preserve, and promote employment in the United States.

Mr. BERMAN. The tradeoff. The fact is there is a major campaign going on on a lot of different fronts, and I understand it. I am not trying to place any kind of pejorative values on it, by pharmaceutical manufacturers vis-a-vis the generic drug industry.

Balancing the interest in U.S. jobs and a vibrant U.S. pharmaceutical manufacturing industry against the price advantages of generic drugs, would not the domestic industry requirement to trigger the remedies that this legislation would provide be consistent with both values where there was no domestic industry requirements still allow the price advantages and at the same time where there was protect infringing uses of patent process from taking away those jobs?

Mr. MALLINO. We are representing 55 industrial unions and have spent a lot of time trying to get a domestic content requirement on automobiles, we would be hard pressed not to support that kind of concept.

Mr. BERMAN. I have no further questions, Mr. Chairman.

Mr. KASTENMEIER. You have no further questions?

Mr. BERMAN. That is right.

Mr. KASTENMEIER. The gentleman from North Carolina.

Mr. COBLE. No questions, Mr. Chairman.

Mr. KASTENMEIER. The gentleman from Ohio, Mr. DeWine.

Mr. DEWINE. No questions, Mr. Chairman.

Mr. KASTENMEIER. If there are no further questions, we thank you both, Mr. Mallino and Mr. Witte, for your appearance this morning. It has been very helpful in this brief but concluding hearing on process patent reform.

As I said at the outset, I am sorry, we were also hoping to have representatives of retailers and a representative of one of the senior citizen groups appear, but they will not be appearing.

We did, the committee will recall, have a representative of the generic industry testify earlier expressing reservations about the bill. I say that because I think hearings should be as balanced as possible. The hearing record will be open and certain statements made for the record will be accepted and made part of the record.

That, therefore, concludes this morning's hearing, and the hearings on process patents. We will recess for about 2 minutes, at which time we will reconvene for the purposes of markup.

[Whereupon, at 10:44 a.m. the subcommittee was adjourned subject to the call of the Chair.]

ADDITIONAL MATERIALS

99TH CONGRESS
1ST SESSION

H. R. 1069

To protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 7, 1985

Mr. MOORHEAD introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To protect patent owners from importation into the United States of goods made overseas by use of a United States patented process.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 2. Section 154 of title 35, United States Code, is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling products produced thereby or importing products produced thereby into, the United States.".

SEC. 3. Section 271 of title 35, United States Code, is amended by—

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(1) inserting "(1)" after "(a)"; and

(2) adding at the end of subsection (a), the following:

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product produced by such process infringes the patent.";

SEC. 4. Section 287 of title 35, United States Code, is amended by—

(1) inserting "(a)" before "Patentees,"; and

(2) adding at the end thereof the following new subsection:

"(b) No damages shall be recovered by the patentee for infringement under section 271(a)(2) of this title from an infringer who did not use the patented process except on proof that such infringer knew of or was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such knowledge or notice. Filing of an action for infringement shall constitute such notice.".

SEC. 5. (a) Title 35, United States Code, is amended by adding the following new section 295:

"§ 295. Presumption: Product produced by patented process.

"In actions alleging infringement of a process patent based on use or sale of a product produced by the patented process, if the court finds (1) that a substantial likelihood exists that the product was produced by the patented process and (2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so produced, and the burden of establishing that the product was not produced by the process shall be on the party asserting that it was not so produced.".

(b) The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: Product produced by patented process.

SEC. 6. This Act shall apply only to products produced or imported after the date of enactment.

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99TH CONGRESS
1ST SESSION

H. R. 3776

To protect patent, trademark, and copyright owners from importation into the United States of goods made overseas in violation of United States patent, trademark, and copyright law, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 1985

Mr. MOORHEAD (for himself, Mr. FISH, Mr. HUGHES, Mr. KINDNESS, Mr. LUKEN, Mr. DEWINE, Mr. MORRISON of Connecticut, Mr. ECKART of Ohio, Mr. COBLE, and Mr. NIELSON of Utah) introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To protect patent, trademark, and copyright owners from importation into the United States of goods made overseas in violation of United States patent, trademark, and copyright law, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Intellectual Property Rights Protection and Enforcement Act of 1985".

TITLE I—PROCESS PATENTS

SEC. 101. Section 154 of title 35, United States Code, is amended by inserting after "United States," the following:

"and, if the invention is a process, of the right to exclude others from using or selling products produced thereby or importing products produced thereby into, the United States.".

SEC. 102. Section 271 of title 35, United States Code, is amended by—

(1) inserting "(1)" after "(a)"; and

(2) adding at the end of subsection (a), the following:

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product produced by such process infringes the patent.";

SEC. 103. Section 287 of title 35, United States Code, is amended by—

(1) inserting "(a)" before "Patentees,"; and

(2) adding at the end thereof the following new subsection:

"(b) No damages shall be recovered by the patentee for infringement under section 271(a)(2) of this title from an infringer who did not use the patented process except on proof that such infringer knew of or was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring

after such knowledge or notice. Filing of an action for infringement shall constitute such notice.".

SEC. 104. (a) Title 35, United States Code, is amended by adding the following new section 295:

"§ 295. Presumption: Product produced by patented process.

"In actions alleging infringement of a process patent based on use or sale of a product produced by the patented process, if the court finds (1) that a substantial likelihood exists that the product was produced by the patented process and (2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so produced, and the burden of establishing that the product was not produced by the process shall be on the party asserting that it was not so produced.".

(b) The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: Product produced by patented process.

SEC. 105. This Act shall apply only to products produced or imported after the date of enactment.

TITLE II—ENFORCEMENT OF PATENTS, COPYRIGHTS AND TRADEMARKS IN INTERNATIONAL TRADE

SEC. 201. (a) Subsection (a) of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), is amended—

(1) by striking out "(a) Unfair" and inserting in lieu thereof "(a)(1) Unfair",

(2) by striking out "efficiently and economically operated",

(3) by striking out "prevent" and inserting in lieu thereof "impair or prevent", and

(4) by adding at the end thereof the following new paragraph:

"(2) For purposes of this section, the following acts in the importation of articles into the United States or in their sale are declared to be unfair and to have the effect or tendency to destroy or substantially injure an industry or to impair the establishment of an industry:

"(A) Unauthorized importation of an article which infringes a valid United States patent or the unauthorized sale of such an imported article.

"(B) Unauthorized importation of an article which—

"(i) was made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid United States patent, and

"(ii) if made, produced, processed, or mined in the United States, would infringe a valid United States patent,

or the unauthorized sale of such an imported article.

"(C) Unauthorized importation of an article which infringes a valid United States copyright or the unauthorized sale of such an imported article.

"(D) Importation of an article which infringes a valid United States trademark, or the sale of such an imported article, if the manufacture or production of such imported article was unauthorized.".

(b) Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) is amended—

(1) by striking out "subsection (d) or (e)" in subsection (c) and inserting in lieu thereof "subsection (d), (e), (f), or (g)",

(2) by striking out "subsection (d), (e), or (f)" in subsection (c) and inserting in lieu thereof "subsection (d), (e), (f), (g), or (h)",

(3) by striking out "subsections (d), (e), and (f)" in subsection (c) and inserting in lieu thereof "subsection (d), (e), (f), (g), or (h)",

(4) by striking out "If" in the first sentence of subsection (e) and inserting in lieu thereof "(1) If",

(5) by adding at the end of subsection (e) the following new paragraph:

"(2) Any person may petition the Commission for the issuance of an order under this subsection. The Commission shall make a determination with regard to such petition by no later than the date that is 90 days after the date on which such petition is filed with the Commission. The Commission may require the petitioner to post a bond as a prerequisite to the issuance of an order under this subsection.",

(6) by striking out "In lieu of" in subsection (f)(1) and inserting in lieu thereof "In addition to, or in lieu of,",

(7) by inserting "twice" after "of $10,000 or" in subsection (f)(2),

(8) by redesignating subsections (g), (h), (i), and (j) as subsections (i), (j), (k), and (l), respectively,

(9) by inserting after subsection (f) the following new subsections:

"(g) FORFEITURE.—In addition to taking action under subsection (d) or (e), the Commission may issue an order providing that an article imported in violation of the provisions of this section be seized and forfeited to the United States. The Commission shall notify the Secretary of the Treasury of

any order issued under this subsection and, upon receipt of such notice, the Secretary shall enforce such order in accordance with the provisions of this Act.

"(h) DEFAULT.—If—

"(1) a complaint is filed against a person under this section,

"(2) such complaint and a notice of investigation are served on such person,

"(3) such person fails to respond to the complaint and notice or otherwise fails to appear to answer the complaint and notice,

"(4) such person fails to show good cause why such person should not be found in default, and

"(5) the facts alleged in the petition establish a violation of the provisions of this section, and

"(6) the complainant seeks relief affecting solely such person the Commission shall presume the facts alleged in the complaint and shall, upon request, issue relief under this section affecting solely such person, unless, after considering the effect of such an order of relief upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the Com-

mission finds that such an order or relief should not be issued.",

(10) by striking out "subsection (d), (e), or (f)" each place it appears in subsection (i), as redesignated by paragraph (8) of this subsection, and inserting in lieu thereof "subsection (d), (e), (f), (g), or (h)",

(11) by inserting "and no seizure shall be made of any article under subsection (g) until such determination becomes final if such a bond is posted" after "becomes final" in subsection (i)(3), as so redesignated,

(12) by striking out "and (g)" in subsection (j), as so redesignated, and inserting in lieu thereof "and (i)",

(13) by striking out "notifies" in subsection (j), as so redesignated, and inserting in lieu thereof ", or order to seize, notifies",

(14) by striking out "Except" in subsection (j), as so redesignated, and inserting in lieu thereof "(1) Except",

(15) by adding at the end of subsection (j), as so redesignated, the following new paragraph:

"(2) If any person who has previously been found by the Commission to be in violation of this section petitions the Commission for a determination that the petitioner is no longer in violation of this section or for a modification or recision of an order under subsection (d), (e), (f), (g), or (h)—

"(A) the burden of proof in any proceeding before the Commission regarding such petition shall be on the petitioner, and

"(B) relief may be granted by the Commission with respect to such petition only on the basis of new evidence or evidence that could not have been presented at the prior proceeding.",

(16) by striking out "subsection (d), (e), or (f)" in subsection (k), as so redesignated, and inserting in lieu thereof "subsection (d), (e), (f), (g), or (h)", and

(17) by striking out "patent" each place it appears in subsection (k) and inserting in lieu thereof "patent, copyright, or trademark".

SEC. 202. The Act of July 2, 1940 (54 Stat. 724, chapter 515; 19 U.S.C. 1337a) is hereby repealed.

TITLE III—LICENSEE CHALLENGES TO PATENT VALIDITY

SEC. 301. (a) Title 35, United States Code, is amended by adding after section 295 the following new section:

"§ 296. Licensee challenges to patent validity.

"(a) A licensee shall not be estopped from asserting in a judicial action the invalidity of any patent to which it is licensed. Any agreement between the parties to a patent license agreement which purports to bar the license from

asserting the invalidity of any licensed patent shall be unenforceable as to that provision.

"(b) Any patent license agreement may provide for a party or parties to the agreement to terminate the license if the licensee asserts in a judicial action the invalidity of the licensed patent, and, if the licensee has such a right to terminate, the agreement may further provide that the licensee's obligations under the agreement shall continue until a final and unappealable determination of invalidity is reached or until such right to terminate is exercised. Such agreement shall not be unenforceable as to such provisions on the ground that such provisions are contrary to Federal patent law or policy.".

(b) The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 295 the following:

"296. Licensee challenges to patent validity.".

TITLE IV—INDUSTRIAL DESIGN PROTECTION

SEC. 401. Title 17, United States Code, is amended by adding at the end thereof the following new chapter:

"CHAPTER 10—PROTECTION OF INDUSTRIAL DESIGNS OF USEFUL ARTICLES

"Sec.
"1001. Designs protected.
"1002. Designs not subject to protection.
"1003. Revision, adaptations, and rearrangements.
"1004. Commencement of protection.
"1005. Term of protection.
"1006. The design notice.

"1007. Effect of omission of notice.
"1008. Infringement.
"1009. Application for registration.
"1010. Benefit of earlier filing date in foreign country.
"1011. Oaths and acknowledgments.
"1012. Examination of application and issue or refusal of registration.
"1013. Certification of registration.
"1014. Publication of announcements and indexes.
"1015. Fees.
"1016. Regulations.
"1017. Copies of records.
"1018. Correction of errors in certificates.
"1019. Ownership and transfer.
"1020. Remedy for infringement.
"1021. Injunction.
"1022. Recovery for infringement, and so forth.
"1023. Power of court over registration.
"1024. Liability for action on registration fraudulently obtained.
"1025. Penalty for false marking.
"1026. Penalty for false representation.
"1027. Relation to copyright law.
"1028. Relation to patent law.
"1029. Common law and other rights unaffected.
"1030. Administrator.
"1031. Severability clause.
"1032. Amendment of other statutes.
"1033. Time of taking effect.
"1034. No retroactive effect.
"1035. Short title.

"DESIGNS PROTECTED

"SEC. 1001. (a) The author or other proprietor of an original design of a useful article, which design is intended to make the article attractive or distinct in appearance to the purchasing or using public, may secure the protection provided by this chapter upon complying with and subject to the provisions hereof.

"(b) For the purposes of this chapter—

"(1) A 'useful article' is an article which in normal use has an intrinsic utilitarian function that is not merely to portray the appearance of the article or to convey information. An article which normally is a

part of a useful article shall be deemed to be a useful article.

"(2) The 'design of a useful article', hereinafter referred to as a 'design', consists of those aspects or elements of the article, including its two-dimensional or three-dimensional features of shape and surface, which make up the appearance of the article. The design must be fixed in a useful article to be protectable under this chapter.

"(3) A design is 'original' if it is the independent creation of an author who did not copy it from another source.

"DESIGNS NOT SUBJECT TO PROTECTION

"SEC. 1002. Protection under this chapter shall not be available for a design that is—

"(a) not original;

"(b) staple or commonplace, such as a standard geometric figure, familiar symbol, emblem, or motif, or other shape, pattern, or configuration which has become common, prevalent, or ordinary;

"(c) different from a design excluded by subparagraph (b) above only in insignificant details or in elements which are variants commonly used in the relevant trades;

"(d) dictated solely by a utilitarian function of the article that embodies it;

"(e) composed of three-dimensional features of shape and surface with respect to men's, women's, and children's apparel, including undergarments and outerwear;

"(f) a semiconductor chip product which is protected under chapter 9 of this title; or

"(g) in no case does protection for a design under this chapter extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such design.

"REVISIONS, ADAPTATIONS, AND REARRANGEMENTS

"SEC. 1003. Protection for a design under this chapter shall be available notwithstanding the employment in the design of subject matter excluded from protection under section 1002 (b) through (d), if the design is a substantial revision, adaptation, or rearrangement of said subject matter: *Provided*, That such protection shall be available to a design employing subject matter protected under chapters 1 through 8 of this title, or title 35 of the United States Code or this chapter, only if such protected subject matter is employed with the consent of the proprietor thereof. Such protection shall be independent of any subsisting protection in subject matter employed in the design, and shall not be construed as securing any right to subject matter excluded from protection or as extending any subsisting protection.

"COMMENCEMENT OF PROTECTION

"SEC. 1004. The protection provided for a design under this chapter shall commence upon the date of publication of the registration pursuant to section 1012(a) or the date the design is first made public as defined by section 1009(b), whichever occurs first.

"TERM OF PROTECTION

"SEC. 1005. (a) Subject to subsection (b) and the provisions of this chapter, the protection herein provided for a design shall continue for a term of ten years from the date of the commencement of protection as provided in section 1004.

"(b) All terms of protection provided in this section shall run to the end of the calendar year in which they would otherwise expire.

"(c) Upon expiration or termination of protection in a particular design as provided in this chapter all rights under this chapter in said design shall terminate, regardless of the number of different articles in which the design may have been utilized during the term of its protection.

"THE DESIGN NOTICE

"SEC. 1006. (a) Whenever any design for which protection is sought under this chapter is made public as provided in section 1009(b), the proprietor shall, subject to the provisions of section 1007, mark it or have it marked legibly with a design notice consisting of the following three elements:

"(1) the words 'Protected Design', the abbreviation 'Prot'd Des.', or the letter 'D' with a circle thus Ⓓ or the symbol *D*;

"(2) the year of the date on which protection for the design commenced; and

"(3) the name of the proprietor, an abbreviation by which the name can be recognized, or a generally accepted alternative designation of the proprietor; any distinctive identification of the proprietor may be used if it has been approved and recorded by the Administrator before the design marked with such identification is registered.

After registration the registration number may be used instead of the elements specified in (2) and (3) hereof.

"(b) The notice shall be so located and applied as to give reasonable notice of design protection while the useful article embodying the design is passing through its normal channels of commerce. This requirement may be fulfilled, in the case of sheetlike or strip materials bearing repetitive or continuous designs, by application of the notice to each repetition, or to the margin, selvage, or reverse side of the material at reasonably frequent intervals, or to tags or labels affixed to the material at such intervals.

"(c) When the proprietor of a design has complied with the provisions of this section, protection under this chapter

shall not be affected by the removal, destruction, or obliteration by others of the design notice on an article.

"EFFECT OF OMISSION OF NOTICE

"SEC. 1007. The omission of the notice prescribed in section 1006 shall not cause loss of the protection or prevent recovery for infringement against any person who, after written notice of the design protection, begins an undertaking leading to infringement: *Provided,* That such omission shall prevent any recovery under section 1022 against a person who began an undertaking leading to infringement before receiving written notice of the design protection, and no injunction shall be had unless the proprietor of the design shall reimburse said person for any reasonable expenditure or contractual obligation in connection with such undertaking incurred before written notice of design protection, as the court in its discretion shall direct. The burden of providing written notice shall be on the proprietor.

"INFRINGEMENT

"SEC. 1008. (a) It shall be infringement of a design protection under this chapter for any person, without the consent of the proprietor of the design, within the United States or its territories or possessions and during the term of such protection, to—

"(1) make, have made, or import, for sale or for use in trade, any infringing article as defined in subsection (d) hereof; or

"(2) sell or distribute for sale or for use in trade any such infringement article: *Provided, however,* That a seller or distributor of any such article who did not make or import the same shall be deemed to be an infringer only if—

"(i) he induced or acted in collusion with a manufacturer to make, or an importer to import such article (merely purchasing or giving an order to purchase in the ordinary course of business shall not of itself constitute such inducement or collusion); or

"(ii) he refuses or fails upon the request of the proprietor of the design to make a prompt and full disclosure of his source of such article, and he orders or reorders such article after having received notice by registered or certified mail of the protection subsisting in the design.

"(b) It shall not be infringement to make, have made, import, sell, or distribute, any article embodying a design created without knowledge of, and copying from, a protected design.

"(c) A person who incorporates into his own product of manufacture an infringing article acquired from others in the ordinary course of business, or who, without knowledge of the protected design, makes or processes an infringing article

for the account of another person in the ordinary course of business, shall not be deemed an infringer except under the conditions of clauses (i) and (ii) of paragraph (a)(2) of this section. Accepting an order or reorder from the source of the infringing article shall be deemed ordering or reordering within the meaning of clause (ii) of paragraph (a)(2) of this section.

"(d) An 'infringing article' as used herein is any article, the design of which has been copied from the protected design, without the consent of the proprietor: *Provided, however,* That an illustration or picture of a protected design in an advertisement, book, periodical, newspaper, photograph, broadcast, motion picture, or similar medium shall not be deemed to be an infringing article. An article is not an infringing article if it embodies, in common with the protected design, only elements described in subsections (a) through (d) of section 1002.

"(e) The party alleging rights in a design in any action or proceeding shall have the burden of affirmatively establishing its originality whenever the opposing party introduces an earlier work which is identical to such design, or so similar as to make a prima facie showing that such design was copied from such work.

"(f) It is not an infringement of the exclusive rights of a design owner for a person to reproduce the design in a useful

article or in any other form solely for the purpose of teaching, analyzing, or evaluating the appearance, concepts, or techniques embodied in the design, or the function of the useful article embodying the design.

"APPLICATION FOR REGISTRATION

"SEC. 1009. (a) Protection under this chapter shall be lost if application for registration of the design is not made within one year after the date on which the design was first made public.

"(b) A design is made public when, by the proprietor of the design or with his consent, an existing useful article embodying the design is anywhere publicly exhibited, publicly distributed, or offered for sale or sold to the public.

"(c) Application for registration may be made by the proprietor of the design.

"(d) The application for registration shall be made to the Administrator and shall state (1) the name and address of the author or authors of the design; (2) the name and address of the proprietor if different from the author; (3) the specific name of the article, indicating its utility; (4) the date, if any, that the design was first made public, if such date was earlier than the date of application; (5) affirmation that the design has been fixed in a useful article; and (6) such other information as may be required by the Administrator. The application for registration may include a description setting forth

the salient features of the design, but the absence of such a description shall not prevent registration under this chapter.

"(e) The application for registration shall be accompanied by a statement under oath by the applicant or his duly authorized agent or representative, setting forth that, to the best of his knowledge and belief (1) the design is original and was created by the author or authors named in the application; (2) the design has not previously been registered on behalf of the applicant or his predecessor in title; and (3) the applicant is the person entitled to protection and to registration under this chapter. If the design has been made public with the design notice prescribed in section 1006, the statement shall also describe the exact form and position of the design notice.

"(f) Error in any statement or assertion as to the utility of the article named in the application, the design of which is sought to be registered shall not affect the protection secured under this chapter.

"(g) Errors in omitting a joint author or in naming an alleged joint author shall not affect the validity of the registration, or the actual ownership or the protection of the design: *Provided,* That it is shown that the error occurred without deceptive intent. Where the design was made within the regular scope of the author's employment and individual authorship of the design is difficult or impossible to ascribe

and the application so states, the name and address of the employer for whom the design was made may be stated instead of that of the individual author.

"(h) The application for registration shall be accompanied by two copies of a drawing or other pictorial representation of the useful article having one or more views, adequate to show the design, in a form and style suitable for reproduction, which shall be deemed a part of the application.

"(i) Where the distinguishing elements of a design are in substantially the same form in a number of different useful articles, the design shall be protected as to all such articles when protected as to one of them, but not more than one registration shall be required.

"(j) More than one design may be included in the same application under such conditions as may be prescribed by the Administrator. For each design included in an application the fee prescribed for a single design shall be paid.

"BENEFIT OF EARLIER FILING DATE IN FOREIGN COUNTRY

"SEC. 1010. An application for registration of a design filed in this country by any person who has, or whose legal representative or predecessor or successor in title has previously regularly filed an application for registration of the same design in a foreign country which affords similar privileges in the case of application filed in the United States or to citizens of the United States shall have the same effect as if

filed in this country on the date on which the application was first filed in any such foreign country, if the application in this country is filed within six months from the earliest date on which any such foreign application was filed.

"OATHS AND ACKNOWLEDGMENTS

"SEC. 1011. (a) Oaths and acknowledgments required by this chapter may be made before any person in the United States authorized by law to administer oaths, or, when made in a foreign country, before any diplomatic or consular officer of the United States authorized to administer oaths, or before any official authorized to administer oaths in the foreign country concerned, whose authority shall be proved by a certificate of a diplomatic or consular officer of the United States, and shall be valid if they comply with the laws of the state or country where made.

"(b) The Administrator may by rule prescribe that any document to be filed in the Office of the Administrator and which is required by any law, rule, or other regulation to be under oath may be subscribed to by a written declaration in such form as the Administrator may prescribe, such declaration to be in lieu of the oath otherwise required.

"(c) Whenever a written declaration as permitted in subsection (b) is used, the document must warn the declarant that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may

jeopardize the validity of the application or document or a registration resulting therefrom.

"EXAMINATION OF APPLICATION AND ISSUE OR REFUSAL OF REGISTRATION

"SEC. 1012. (a) Upon the filing of an application for registration in proper form as provided in section 1009, and upon payment of the fee provided in section 1015, the Administrator shall determine whether or not the application relates to a design which on its face appears to be subject to protection under this chapter, and if so the Administrator shall register the design. Registration under this subsection shall be announced by publication. The date of registration shall be the date of publication.

"(b) If, in the judgment of the Administrator, the application for registration relates to a design which on its face is not subject to protection under this chapter, the Administrator shall send the applicant a notice of refusal to register and the grounds therefor. Within three months from the date the notice of refusal is sent, the applicant may request, in writing, reconsideration of his application. After consideration of such a request, the Administrator shall either register the design or send the applicant a notice of final refusal to register.

"(c) Any person who believes he is or will be damaged by a registration under this chapter may, upon payment of

the prescribed fee, apply to the Administrator at any time to cancel the registration on the ground that the design is not subject to protection under the provisions of this chapter, stating the reasons therefor. Upon receipt of an application for cancellation, the Administrator shall send the proprietor of the design, as shown in the records of the Office of the Administrator, a notice of said application, and the proprietor shall have a period of three months from the date such notice was mailed in which to present arguments in support of the validity of the registration. It shall also be within the authority of the Administrator to establish, by regulation, conditions under which the opposing parties may appear and be heard in support of their arguments. If, after the periods provided for the presentation of arguments have expired, the Administrator determines that the applicant for cancellation has established that the design is not subject to protection under the provisions of this chapter, he shall order the registration stricken from the record. Cancellation under this subsection shall be announced by publication, and notice of the Administrator's final determination with respect to any application for cancellation shall be sent to the applicant and to the proprietor of record.

"(d) When a design has been registered under this section, the lack of utility of any article in which it has been embodied shall be no defense to an infringement action under

section 1020, and no ground for cancellation under subsection (c) of this section or under section 1023.

"CERTIFICATION OF REGISTRATION

"SEC. 1013. Certificates of registration shall be issued in the name of the United States under the seal of the Office of the Administrator and shall be recorded in the official records of that office. The certificate shall state the name of the useful article, the date of filing of the application, the date of registration, the date the design was made public, if earlier than the date of filing of the application, and shall contain a reproduction of the drawing or other pictorial representation showing the design. Where a description of the salient features of the design appears in the application, this description shall also appear in the certificate. A certificate of registration shall be admitted in any court as prima facie evidence of the facts stated therein.

"PUBLICATION OF ANNOUNCEMENTS AND INDEXES

"SEC. 1014. (a) The Administrator shall publish lists and indexes of registered designs and cancellations thereof and may also publish the drawing or other pictorial representations of registered designs for sale or other distribution.

"(b) The Administrator shall establish and maintain a file of the drawings or other pictorial representations of registered designs, which file shall be available for use by the

public under such conditions as the Administrator may prescribe.

"FEES

"SEC. 1015. (a) There shall be paid to the Administrator the following fees:

"(1) On filing each application for registration or for renewal of registration of a design, $15.

"(2) For each additional related article included in one application, $15.

"(3) For recording an assignment, $3 for the first six pages, and for each additional two pages or less, $1.

"(4) For a certificate of correction of an error not the fault of the Office, $10.

"(5) For a certification of copies of records, $1.

"(6) On filing each application for cancellation of a registration, $15.

"(b) The Administrator may establish charges for materials or services furnished by the Office, not specified above, reasonably related to the cost thereof.

"REGULATIONS

"SEC. 1016. The Administrator may establish regulations not inconsistent with law for the administration of this chapter.

"COPIES OF RECORDS

"SEC. 1017. Upon payment of the prescribed fee, any person may obtain a certified copy of any official record of the Office of the Administrator, which copy shall be admissible in evidence with the same effect as the original.

"CORRECTION OF ERRORS IN CERTIFICATES

"SEC. 1018. The Administrator may correct any error in a registration incurred through the fault of the Office, or, upon payment of the required fee, any error of a clerical or typographical nature not the fault of the Office occurring in good faith, by a certificate of correction under seal. Such registration, together with the certificate, shall thereafter have the same effect as if the same had been originally issued in such corrected form.

"OWNERSHIP AND TRANSFER

"SEC. 1019. (a) The property right in a design subject to protection under this chapter shall vest in the author, the legal representatives of a deceased author or of one under legal incapacity, the employer for whom the author created the design in the case of a design made within the regular scope of the author's employment, or a person to whom the rights of the author or of such employer have been transferred. The person or persons in whom the property right is vested shall be considered the proprietor of the design.

"(b) The property right in a registered design, or a design for which an application for registration has been or

may be filed, may be assigned, granted, conveyed, or mortgaged by an instrument in writing, signed by the proprietor, or may be bequeathed by will.

"(c) An acknowledgment as provided in section 1011 shall be prima facie evidence of the execution of an assignment, grant, conveyance, or mortgage.

"(d) An assignment, grant, conveyance, or mortgage shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Office of the Administrator within three months from its date of execution or prior to the date of such subsequent purchase or mortgage.

"REMEDY FOR INFRINGEMENT

"SEC. 1020. (a) The proprietor of a design shall have remedy for infringement by civil action instituted after issuance of a certificate of registration of the design.

"(b) The proprietor of a design may have judicial review of a final refusal of the Administrator to register the design, by a civil action brought as for infringement and shall have remedy for infringement by the same action if the court adjudges the design subject to protection under this chapter: *Provided,* That (1) he has previously duly filed and duly prosecuted to such final refusal an application in proper form for registration of the design, and (2) he causes a copy of the complaint in action to be delivered to the Administrator within ten days after the commencement of the action, and

(3) the defendant has committed acts in respect to the design which would constitute infringement with respect to a design protected under this chapter.

"(c) The Administrator may, at his or her option, become a party to the action with respect to the issue of registrability of the design claim by entering an appearance within sixty days after such service, but the Administrator's failure to become a party shall not deprive the court of jurisdiction to determine that issue.

"(d) The parties to an infringement dispute under this law, within such time as may be specified by the Administrator by regulation, may determine such contest or any aspect thereof by arbitration. Such arbitration shall be governed by the provision of title 9 to the extent such title is not inconsistent with this section. The parties shall give notice of any arbitration award to the Administrator, and such award shall, as between the parties to the arbitration be dispositive of the issues to which it relates. The arbitration award shall be unenforceable until such notice is given. Nothing in this subsection shall preclude the Administrator from determining whether a design is subject to registration in a cancellation proceeding under section 1012(c).

"INJUNCTION

"SEC. 1021. The several courts having jurisdiction of actions under this chapter may grant injunctions in accord-

ance with the principles of equity to prevent infringement, including, in their discretion, prompt relief by temporary restraining orders and preliminary injunctions.

"RECOVERY FOR INFRINGEMENT, AND SO FORTH

"SEC. 1022. (a) Upon finding for the claimant, the court shall award such claimant damages adequate to compensate for the infringement, but in no event less than the reasonable value the court shall assess them. In addition, the court may increase the damages to such amount, not exceeding $50,000 or $1 per copy, whichever is greater, as to the court shall appear to be just. The damages awarded in any of the above circumstances shall constitute compensation and not a penalty. The court may receive expert testimony as an aid to the determination of damages.

"(b) Alternatively, the court may award the claimant the infringer's profits resulting from the sale of the copies if it finds that the infringer's sales are reasonably related to the use of the claimant's design. In such a case, the claimant shall be required to prove only the infringer's sales and the infringer shall be required to prove its expenses against such sales.

"(c) No recovery under paragraph (a) shall be had for any infringement committed more than three years prior to the filing of the complaint.

"(d) The court may award reasonable attorney's fees to the prevailing party. The court may also award other expenses of suit to a defendant prevailing in an action brought under section 1020(b).

"(e) The court may order that all infringing articles, and any plates, molds, patterns, models, or other means specifically adapted for making the same be delivered up for destruction or other disposition as the court may direct.

"POWER OF COURT OVER REGISTRATION

"SEC. 1023. In any action involving a design for which protection is sought under this chapter, the court when appropriate may order registration of a design or the cancellation of a registration. Any such order shall be certified by the court to the Administrator, who shall make an appropriate entry upon the record.

"LIABILITY FOR ACTION ON REGISTRATION FRAUDULENTLY OBTAINED

"SEC. 1024. Any person who shall bring an action for infringement knowing that registration of the design was obtained by a false or fraudulent representation materially affecting the rights under this chapter, shall be liable in the sum of $1,000, or such part thereof as the court may determine, as compensation to the defendant, to be charged against the plaintiff and paid to the defendant, in addition to

such costs and attorney's fees of the defendant as may be assessed by the court.

"PENALTY FOR FALSE MARKING

"SEC. 1025. (a) Whoever, for the purpose of deceiving the public, marks upon, or applies to, or uses in advertising in connection with any article made, used, distributed, or sold, the design of which is not protected under this chapter, a design notice as specified in section 1006 or any other words or symbols importing that the design is protected under this chapter, knowing that the design is not so protected, shall be fined not more than $500 for every such offense.

"(b) Any person may sue for the penalty, in which event, one-half shall go to the person suing and the other to the use of the United States.

"PENALTY FOR FALSE REPRESENTATION

"SEC. 1026. Whoever knowingly makes a false representation materially affecting the rights obtainable under this chapter for the purpose of obtaining registration of a design under this chapter shall be fined not less than $500 and not more than $1,000, and any rights or privileges he may have in the design under this chapter shall be forfeited.

"RELATION TO COPYRIGHT LAW

"SEC. 1027. (a) Nothing in this chapter shall affect any right or remedy now or hereafter held by any person under

chapters 1 through 8 of this title, subject to the provisions of section 113 of this title.

"(b) When a pictorial, graphic, or sculptural work in which copyright subsists under chapters 1 through 8 of this title is utilized in an original ornamental design of a useful article, by the copyright proprietor or under an express license from such proprietor, the design shall be eligible for protection under the provisions of this chapter.

"RELATION TO PATENT LAW

"SEC. 1028. (a) Nothing in this chapter shall affect any right or remedy available to or held by any person under title 35 of the United States Code.

"(b) The issuance of a design patent for an ornamental design for an article of manufacture under said title 35 shall terminate any protection of the design under this chapter.

"COMMON LAW AND OTHER RIGHTS UNAFFECTED

"SEC. 1029. Nothing in this chapter shall annul or limit (1) common law or other rights or remedies, if any, available to or held by any person with respect to a design which has not been registered under this chapter, or (2) any trademark rights or right to be protected against unfair competition.

"ADMINISTRATOR

"SEC. 1030. The Administrator and Office of the Administrator referred to in this chapter shall be the Register of Copyrights and Library of Congress, respectively.

"SEVERABILITY CLAUSE

"SEC. 1031. If any provisions of this chapter or the application of such provision to any person or circumstance is held invalid, the remainder of the chapter or the application to other persons or circumstances shall not be affected thereby.

"AMENDMENT OF OTHER STATUTES

"SEC. 1032. Title 28 of the United States Code is amended—

"(a) by inserting 'designs,' after 'patents,' in the first sentence of section 1338(a);

"(b) by inserting ', design,' after 'patent' in the second sentence of section 1338(a);

"(c) by inserting 'design,' after 'copyright,' in section 1338(b);

"(d) by inserting 'and registered designs' after 'copyrights' in section 1400; and

"(e) by revising section 1498(a) to read as follows:

"'(a) Whenever a registered design or invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the Court of Claims for the re-

covery of his reasonable and entire compensation for such use and manufacture.

"'For the purposes of this section, the use or manufacture of a registered design or an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

"'The court shall not award compensation under this section if the claim is based on the use or manufacture by or for the United States of any article owned, leased, used by, or in the possession of the United States, prior to, in the case of an invention, July 1, 1918, and in the case of a registered design, the date of enactment of this Act.

"'A Government employee shall have the right to bring suit against the Government under this section except where he was in a position to order, influence, or induce use of the registered design or invention by the Government. This section shall not confer a right of action on any design registrant or patentee or any assignee of such design registrant or patentee with respect to any design created by or invention discovered or invented by a person while in the employment or service of the United States, where the design or invention was related to the official functions of the employee, in cases

in which such functions included research and development, or in the making of which Government time, materials, or facilities were used.'.

"TIME OF TAKING EFFECT

"SEC. 1033. This chapter shall take effect one year after enactment of this Act.

"NO RETROACTIVE EFFECT

"SEC. 1034. Protection under this chapter shall not be available for any design that has been made public as provided in section 1009(b) prior to the effective date of this chapter.

"SHORT TITLE

"SEC. 1035. This chapter may be cited as the 'Design Protection Act of 1985'.".

SEC. 402. Title 17, United States Code, section 113, is amended by adding at the end thereof the following new subparagraph:

"(d) Protection under chapters 1 through 8 of this title of a work in which copyright subsists shall not terminate with respect to its utilization in useful articles whenever the copyright proprietor or its authorized person has obtained registration of a design of a useful article embodying said work under the provisions of chapter 10 of this title.".

I

99TH CONGRESS
2D SESSION

H. R. 4585

To encourage innovation, promote research and development, and stimulate trade by strengthening the protection given intellectual property rights by making necessary and appropriate amendments to the intellectual property rights laws.

IN THE HOUSE OF REPRESENTATIVES

APRIL 15, 1986

Mr. ERDREICH introduced the following bill; which was referred jointly to the Committees on the Judiciary, Ways and Means, and Energy and Commerce

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A BILL

To encourage innovation, promote research and development, and stimulate trade by strengthening the protection given intellectual property rights by making necessary and appropriate amendments to the intellectual property rights laws.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Trade Counterfeiting and Piracy Prevention Act of 1986".

TITLE II—TECHNOLOGY LICENSING UNDER THE ANTITRUST LAWS

SEC. 201. The Clayton Act, as amended (15 U.S.C. 12 et seq.) is amended by renumbering section 27 as section 28 and by adding the following new section 27:

"SEC. 27. Agreements to convey rights to use, practice, or sublicense patented inventions, trade secrets, or know-how, or rights in a mask work subject to protection under chapter 9 of title 17, United States Code, shall not be deemed illegal per se in actions under the antitrust laws.".

TITLE III—ELIMINATION, IN CERTAIN SECTION 337 CASES, OF REQUIREMENT OF INJURY TO A UNITED STATES INDUSTRY

SEC. 301. Subsection (a) of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) is amended by—

(1) striking out "(a) Unfair" and inserting in lieu thereof "(a)(1) Unfair", and

(2) adding at the end thereof the following new paragraph:

"(2) The lawfulness under this section of the following acts shall be determined without regard to whether such acts have the effect or tendency to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to impair the establishment of such an industry:

"(A) Importation of an article into the United States which infringes a valid and enforceable United States patent or the sale of such an imported article;

"(B) Importation of an article into the United States which—

"(i) was made, produced, processed, or mined under, or by means of, a process covered by a valid and enforceable United States patent, and

"(ii) if made, produced, processed, or mined in the United States, would infringe a valid and enforceable United States patent,

or the sale of such an imported article;

"(C) Importation of an article into the United States which infringes a valid and enforceable United States copyright, or the sale of such an imported article;

"(D) Importation of an article into the United States which infringes a valid and enforceable United States registered trademark, or the sale of such an imported article; and

"(E) Importation of an article into the United States which infringes a valid and enforceable United States mask work right protected under chapter 9 of title 17, United States Code, or the sale of such an imported article.".

SEC. 302. Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) is amended—

(1) by striking out "If" in the first sentence of subsection (e) and inserting in lieu thereof "(1) If",

(2) by adding at the end of subsection (e) the following new paragraph:

"(2) Any person may petition the Commission for the issuance of an order under this subsection. When such petition is filed prior to the date on which the Commission's notice of investigation is published in the Federal Register, the Commission shall make a determination with regard to such petition by no later than the date that is 90 days, or 135 days in cases declared more complicated, after the date on which the Commission published its notice of investigation in the Federal Register. The Commission may require the petitioner to post a bond as a prerequisite to the issuance of an order under this subsection. When such petition is filed after publication of the Commission's notice of investigation in the Federal Register, the Commission shall make a determination with regard to such petition no later than the day which is 90 days, or 135 days in cases declared more complicated, after the date on which the petition is filed. Any petition filed under this subsection must be filed within 30 days after the date on which the Commission's notice of investigation is published in the Federal Register.",

(3) by striking out "In lieu of" in subsection (f)(1) and inserting in lieu thereof "In addition to, or in lieu of,",

(4) by inserting "twice" after "of $10,000 or" in subsection (f)(2),

(5) by striking out "Except" in subsection (h), and inserting in lieu thereof "(1) Except",

(6) by adding at the end of subsection (h) the following new paragraph:

"(2) If any person who has previously been found by the Commission to be in violation of this section petitions the Commission for a determination that the petitioner is no longer in violation of this section, or for a modification or recission of an order under subsection (d), (e), or (f), the burden of proof in any proceeding before the Commission regarding such petition shall be on the petitioner.",

(7) by striking out "patent" each place it appears in subsection (i) and inserting in lieu thereof "patent, copyright, registered trademark or mask work right".

SEC. 303. The Act of July 2, 1940 (54 Stat. 724, chapter 515; 19 U.S.C. 1337a) is hereby repealed.

TITLE IV—PROCESS PATENTS

SEC. 401. Section 154 of title 35, United States Code (35 U.S.C. 154), is amended by inserting after "United States," the words "and, if the invention is a process, of the

right to exclude others from using or selling products directly produced thereby throughout, or importing products directly produced thereby into, the United States,".

SEC. 402. Section 271 of title 35, United States Code (35 U.S.C. 271), is amended by—

(1) redesignating subsection (a) as paragraph (a)(1); and

(2) inserting the following new paragraph (a)(2):

"(2) If the patented invention is a process, whoever without authority uses or sells within, or imports into, the United States during the term of the patent therefor a product directly produced by such process infringes the patent.".

SEC. 403. Section 287 of title 35, United States Code (35 U.S.C. 287), is amended by—

(1) designating the existing language as subsection (a); and

(2) adding the following new subsection (b):

"(b) No damages shall be recovered by the patentee for infringement under section 271(a)(2) of this title from an infringer who did not use the patented process except on proof that such infringer knew of or was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring

after such knowledge or notice. Filing of an action for infringement shall constitute such notice.".

SEC. 404. (a) Title 35, United States Code, is amended by adding the following new section 295:

"§ 295. Presumption: Product directly produced by patented process

"In actions alleging infringement of a process patent based on use, sale, or importation of a product directly produced by the patented process, if the court finds (1) that a substantial likelihood exists that the product was directly produced by the patented process and (2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so produced, and the burden of establishing that the product was not produced by the patented process shall be on the party asserting that it was not so produced.".

(b) The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: Product directly produced by patented process.".

TITLE V—PATENT TERM RESTORATION FOR CERTAIN AGRICULTURAL AND CHEMICAL PRODUCTS

SEC. 501. (a) Title 35, United States Code, is amended by adding the following new section immediately after section 157.

"§ 158. Restoration of patent term for certain agricultural and chemical products

"(a)(1) The term of a patent which claims a product subject to a regulatory review period or a method for using such a product or a method for manufacturing such a product shall be extended, in accordance with this section, from the original expiration date of the patent if—

"(A) the product sponsor notifies the Commissioner in compliance with the provisions of subsection (b)(1);

"(B) the product has been subject to a regulatory review period before its commercial marketing or use;

"(C) the term of the patent has never been extended under this section; and

"(D) the patent to be extended has not expired prior to notification of the Commissioner under subsection (b)(1).

"(2) The rights derived from any claim of any patent extended under paragraph (1) shall be limited in scope during the period of any extension as follows:

"(A) In the case of any patent, to the scope of such claim which encompasses the product subject to regulatory review.

"(B) In the case of a patent which claims a product or a method of using a product—

"(i) which is subject to regulatory review under the Federal Food, Drug, and Cosmetic Act, to the uses of the product which may be regulated by the chapter of such Act under which the regulatory review occurred, but not including any such uses which were previously authorized under such statute, or

"(ii) which is subject to regulatory review under any other statute, to the uses of the product which may be regulated by the statue under which the regulatory review occurred, but not including any such uses which were previously authorized under such statute.

"(C) In the case of a patent which claims a method of manufacturing a product, to the method of manufacturing as used to make the approved product.

"(3)(A) Subject to subparagraph (B), the term of a patent shall be extended by the time equal to the regulatory review period which occurred after such patent was granted.

"(B)(i) In determining a regulatory review period for purposes of subparagraph (A), if an application or notice described in paragraph (4)(B)(ii) or (4)(C)(ii) of subsection (c) was rejected and returned to the product sponsor because of insufficiency of data or other required information, the period beginning on the date the application was rejected for insufficiency of data or other required information and ending on the date the application was subsequently accepted shall be excluded, except that if during such period the product sponsor conducts a major health or environmental effects test, the period during which such test is conducted shall not be excluded. In determining the regulatory review period for purposes of subparagraph (A) with respect to a new animal drug, if the Secretary of Health and Human Services refuses to approve an application submitted under section 512 of the Federal Food, Drug, and Cosmetic Act on the grounds that the application contains insufficient information, the period beginning on the date the Secretary issues an order under subsection (d)(1) of such section refusing to approve such application and ending on the date a subsequent application is approved shall be excluded.

"(ii) In no event shall the term of any patent be extended for more than five years. No term of any extended patent may exceed twenty-five years from the date of filing of the earliest United States patent application which provides support under section 120 of this title for any claim of the patent to be extended. If the regulatory review period for a product began before the date of enactment of this section and if on such date the regulatory review period had not ended, it shall be measured from the date of enactment and the period of extension for the patent shall not exceed three years. If the regulatory review period for a product began before the date of enactment of this section and if on such date the regulatory review period had been completed, there shall be no extension of the patent.

"(C) In no event shall more than one patent be extended for the same regulatory review period for any product.

"(b)(1) To obtain an extension of the term of a patent under subsection (a), the product sponsor shall notify the Commissioner within sixty days after the termination of the regulatory review period for the product to which the patent relates, that the regulatory review period has ended. If the product sponsor is not the owner of record of the patent, the notification shall include the written consent of the owner of record of the patent. Such notification shall be in writing and shall—

"(A) identify the Federal statute under which regulation review occurred and, if the regulatory review occurred under the Federal Food, Drug, and Cosmetic Act, the chapter of the Act under which the review occurred;

"(B) state the dates on which the regulatory review period commenced and ended, and identify the event which caused such period to commence;

"(C) identify the product for which regulatory review was required;

"(D) state that the requirements of the statute under which the regulatory review referred to in subsection (a)(1)(B) occurred have been satisfied and commercial marketing or use of the product is not prohibited under the Federal statute identified in accordance with subparagraph (A);

"(E) identify the patent and any claim thereof to which the extension is applicable; identify any uses previously authorized; identify the filing date of the earliest United States application referred to in subsection (a)(3)(B)(ii); and state that the term of the patent has never been extended under this section and that no other patent has been extended for the regulatory review period for the product; and

"(F) include such patent or other information as the Commissioner may require.

"(2)(A) Within sixty days of the submittal of the extension notification under paragraph (1), the Commissioner shall notify—

"(i) the Secretary of Agriculture if the patent claims a veterinary biological product subject to the Virus-Serum-Toxin Act or a method of using or manufacturing such a product,

"(ii) the Secretary of Health and Human Services if the patent claims an animal drug product or animal antibiotic product subject to the Federal Food, Drug, and Cosmetic Act or a method of using or manufacturing such a product,

"(iii) the Administrator of the Environmental Protection Agency if the patent claims a pesticide subject to the Federal Insecticide, Fungicide, and Rodenticide Act, a chemical substance or mixture subject to the Toxic Substances Control Act, or a method of using or manufacturing such a pesticide, substance, or mixture,

of the extension notification and shall submit to the Secretary or Administrator who is so notified a copy of the extension notification. Not later than thirty days after the receipt of the extension notification from the Commissioner, the Secretary or Administrator receiving the extension notification shall

review the dates contained therein pursuant to paragraph (1)(B), shall determine the applicable regulatory review period, and shall notify the Commissioner of the determination.

"(B) The Secretary, the Administrator, and the Commissioner may establish such fees as appropriate to cover the costs of carrying out their respective duties and functions under this section.

"(3)(A) The Commissioner shall determine that a patent is eligible for extension under subsection (a) and that the requirements of subsection (b)(1) have been complied with. A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the notification under subsection (b)(1). If the Commissioner determines that the patent is eligible for extension and upon receipt of a determination of the applicable regulatory review period under paragraph (2), he shall issue to the owner of record of the patent a certificate of extension, under seal, stating the length of the extension, identifying the product and the statute under which regulatory review occurred, and specifying any claim to which such extension is applicable. Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent. The Commissioner shall publish in the

Official Gazette of the Patent and Trademark Office a notice of such extension.

"(B) If the term of a patent for which a notification has been submitted under subsection (b)(1) would expire before a certificate of extension is issued or denied under subparagraph (A) respecting the notification, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension. Such periods shall not exceed the period calculated from the information provided in the notification submitted under paragraph (1).

"(4) If information submitted by a product sponsor during a regulatory review period is considered a trade secret or confidential commercial or financial information under the law under which such regulatory review occurred, such information may only be disclosed under this section in accordance with such law. This paragraph does not prohibit the Commissioner, the Secretary, and the Administrator from identifying the patent owner, the product sponsor, the product, the patent, and any other information necessary to identify, describe, and calculate the regulatory review period in any notification, publication, or public record required by this section.

"(c) As used in this section:

"(1) The term 'product' means any machine, manufacture, or composition of matter for which a patent may be obtained and is limited to the following:

"(A) Any new animal drug or animal antibiotic subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(B) Any veterinary biological product subject to regulation under the Virus-Serum-Toxin Act.

"(C) Any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act.

"(D) Any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(2) The term 'major health or environmental effects test' means an experiment or study to determine or evaluate health or environmental effects which requires at least six months to conduct, not including any period for analysis or conclusions, and the data from which is submitted to receive permission for commercial marketing or use.

"(3) The term 'product sponsor' means any person who, with the consent of the patent owner, initiates testing or investigations, claims an exemption, or sub-

mits an application, petition, protocol, request, or notice described in paragraph (4) of this subsection.

"(4) The term 'regulatory review period' has the following meaning:

"(A) With respect to a product which is a new animal drug, animal antibiotic, or veterinary biological product, the regulatory review period is the sum of—

"(i) the period beginning on the date—

"(I) an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act, or

"(II) the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act,

became effective for the approved product and ending on the date an application was submitted for such product under section 512 of the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act, and

"(ii) the period beginning on the date the application was submitted for the approved product under section 512 of the Federal Food, Drug, and Cosmetic Act or

the Virus-Serum-Toxin Act and ending on the date such an application was approved.

"(B) With respect to a product which is a pesticide, the term means the sum of—

"(i) the period beginning on the earlier of the date the product sponsor (I) initiates a major health or environmental effects test on such pesticide, or (II) requests, in accordance with regulations issued by the Administrator, the grant of an experimental use permit for the pesticide under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act, and ending on the date an application is submitted for registration of such pesticide pursuant to section 3 of such Act, and

"(ii) the period beginning on the date an application is submitted, in accordance with regulations issued by the Administrator, for registration of such pesticide pursuant to section 3 of such Act and ending on the date such pesticide is first registered, either conditionally or fully, under such section.

"(C) With respect to a product which is a chemical substance for which notice is required under section 5 of the Toxic Substances Control

Act or which is a mixture which contains a substance for which such notice is required and—

"(i) which is subject to a rule requiring testing under section 4(a) of such Act, the term means a period commencing on the date the product sponsor has initiated the testing required in such rule and ending on the expiration of the notice period for such chemical substance under section 5 of such Act, or if an order or injunction is issued under section 5(e) or 5(f) of such Act which prohibits the use of the product, the date on which such order or injunction is dissolved or set aside; or

"(ii) which is not subject to a testing rule under section 4 of such Act, the term means a period commencing on the earlier of the date the product sponsor—

"(I) submits, in accordance with regulations issued by the Administrator, a notice under section 5 of such Act, or

"(II) initiates a major health or environmental effects test on such chemical substance or mixture,

and ending on the expiration of the notice period for such substance under section 5 of such Act, or if an order or injunction is issued under section 5(e) or 5(f) of such Act which prohibits the use of the product, the date on which such order or injunction is dissolved or set aside.

"(5) The term 'Virus-Serum-Toxin Act' means the Act of March 4, 1913 (21 U.S.C. 151–158).".

(b) The analysis for chapter 14 of title 35 of the United States Code is amended by adding at the end the following:

"158. Restoration of patent term for certain agricultural and chemical products.".

SEC. 502. Section 512(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)) is amended by adding at the end the following new sentence: "Clause (1) of the previous sentence shall not apply in the case of an application for a drug for which a previous application has been approved in accordance with subsection (c), if the drug for which such subsequent application is filed meets appropriate standards of identity, strength, quality, purity, stability, and bioequivalence in relation to the drug approved in the previous application, except that in the case of an application for a drug for which a previous application was approved in accordance with subsection (c) within three years prior to enactment of this sentence, clause (1) of the previous sentence shall apply for ten years following enactment of this sentence.".

TITLE VI—PATENT MISUSE

SEC. 601. Section 282 of title 35, United States Code (35 U.S.C. 282), is amended by—

(a) designating the existing language as subsection (a); and

(b) adding the following new subsection (b):

"(b) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following, unless such conduct, in view of the circumstances in which it is employed, violates the antitrust laws: (1) licensed the patent under terms that affect commerce outside the scope of the patent's claims, (2) restricted a licensee of the patent in the sale of the patented product or in the sale of a product made by the patented process, (3) obligated a licensee of the patent to pay royalties that differ from those paid by another licensee or that are allegedly excessive, (4) obligated a licensee of the patent to pay royalties in amounts not related to the lecensee's sales of the patented product or a product made by the patented process, (5) refused to license the patent to any person, or (6) otherwise used the patent allegedly to suppress competition.".

TITLE VII—LICENSEE CHALLENGES TO PATENT VALIDITY

SEC. 701. (a) Title 35, United States Code, is amended by adding the following new section 296:

§ 296. Licensee challenges to patent validity

"(a) A licensee shall not be estopped from asserting in a judicial action the invalidity of any patent to which it is licensed. Any agreement between the parties to a patent license agreement which purports to bar the licensee from asserting the invalidity of any licensed patent shall be unenforceable as to that provision.

"(b) Any patent license agreement may provide for a party or parties to the agreement to terminate the license if the licensee asserts in a judicial action the invalidity of the licensed patent, and, if the licensee has such a right to terminate, the agreement may further provide that the licensee's obligations under the agreement shall continue until a final and unappealable determination of invalidity is reached or until the license is terminated. Such agreement shall not be unenforceable as to such provisions on the grounds that such provisions are contrary to Federal patent law or policy.".

(b) The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 295 the following:

"296. Licensee challenges to patent validity.".

EFFECTIVE DATE

Titles II, III, IV, V, VI, and VII shall take effect on the date of enactment. Titles II, III, VI, and VII shall apply to all actions commenced on or after the date of enactment. Title IV shall not apply to any product imported into or made in the United States before the date of enactment.

I

99TH CONGRESS
2D SESSION

H. R. 4539

To amend the patent and trademark laws of the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 9, 1986

Mr. KASTENMEIER introduced the following bill; which was referred jointly to the Committees on the Judiciary and Ways and Means

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A BILL

To amend the patent and trademark laws of the United States, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Intellectual Property and Trade Act".

TITLE I—PATENT AND TRADEMARK AMENDMENTS

SEC. 101. USE OF PATENTED PROCESSES.

(a) INFRINGEMENT FOR IMPORTATION OR SALE.—Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(e) Whoever without authority imports into the United States or sells within the United States a product which is directly made by a process patented in the United States shall be liable as an infringer, if the importation or sale of the product occurs during the term of such process patent.".

(b) DAMAGES FOR INFRINGEMENT.—Section 287 of title 35, United States Code, is amended by adding at the end the following: "No damages may be recovered for an infringement under section 271(e) of this title unless the infringer knew that the product was made by a process patented in the United States. Damages may be recovered only for infringement occurring after such knowledge.".

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall apply only to United States patents granted on or after the date of the enactment of this Act.

SEC. 102. PATENT AND TRADEMARK LAWS AMENDMENTS.

(a) LATE FEE PAYMENT ALLOWED.—Section 8(c) of the Trademark Act of 1946 (commonly known as the Lanham Act) (15 U.S.C. 1058(c)) is amended by adding at

the end the following: "Fees for filing the affidavits, together with fees for late payment, may be accepted by the Commissioner after the filing of the affidavits.".

(b) RENEWAL OF REGISTRATION.—Section 9(a) of the Trademark Act of 1946 (15 U.S.C. 1059(a)) is amended—

(1) in the first sentence by striking "payment of the prescribed fee and";

(2) by inserting after the first sentence the following: "The fee required for renewal, the time of payment, and any fee for late payment shall be prescribed by the Commissioner."; and

(3) in the second sentence by striking "the additional fee herein prescribed" and inserting "a surcharge".

(c) PERIOD FOR RESPONSE.—Section 12(b) of the Trademark Act of 1946 (15 U.S.C. 1062(b)) is amended—

(1) in the second sentence by striking "six months" and inserting "3 months, or longer as may be prescribed by the Commissioner,";

(2) in the third sentence by striking "six months" and inserting "3 months, or longer as may be prescribed by the Commissioner,"; and

(3) by adding after the third sentence the following: "The Commissioner shall prescribe fees for extending any time for response.".

(d) EXTENSION OF PERIOD FOR OPPOSING MARK.—Section 13 of the Trademark Act of 1946 (15 U.S.C. 1063) is amended—

(1) in the second sentence by striking "thirty days" and inserting "60 days"; and

(2) by inserting after the second sentence the following: "The Commissioner shall prescribe conditions, including the payment of fees, for the further extensions.".

(e) CHAIRMAN OF BOARD ADDED TO TRADEMARK TRIAL AND APPEAL BOARD.—Section 17 of the Trademark Act of 1946 (15 U.S.C. 1067) is amended in the second paragraph by striking "and members" and inserting "and a chairman and members".

(f) VERIFICATION REQUIREMENT FOR CANCELLATION PETITION DELETED.—Section 24 of the Trademark Act of 1946 (15 U.S.C. 1092) is amended by striking "verified" in the second sentence.

(g) CHAIRMAN AND VICE-CHAIRMAN ADDED TO BOARD OF PATENT APPEALS AND INTERFERENCES.—Section 7(a) of title 35, United States Code, is amended in the second sentence by inserting "a chairman and a vice-chairman appointed by the Commissioner," after "Assistant Commissioners,".

(h) ATTESTATION REQUIREMENT FOR ISSUANCE OF PATENT DELETED.—Section 153 of title 35, United States Code, is amended by striking "and attested by an officer of the Patent and Trademark Office designated by the Commissioner".

(i) PLANT PATENTS.—Section 163 of title 35, United States Code, is amended by inserting "or any part thereof" after "reproduced".

(j) EFFECTIVE DATE.—Subsection (i) shall apply only to acts of infringement committed on or after the date of the enactment of this Act. Subsections (a) through (h) shall take effect 6 months after the date of the enactment of this Act.

SEC. 103. ENFORCEMENT BY THE UNITED STATES ALLOWED IN CERTAIN PATENT APPLICATION CASES.

Section 135(c) of title 35, United States Code, is amended by adding at the end the following: "The United States may bring an action for equitable or declaratory relief to enforce the provisions of this section.".

TITLE II—ENFORCEMENT OF PATENTS, COPYRIGHTS, TRADEMARKS, AND MASK WORKS IN INTERNATIONAL TRADE

SEC. 201. REFERENCE TO TARIFF ACT OF 1930.

Except as otherwise expressly provided, whenever in this title an amendment is expressed in terms of an amend-

ment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Tariff Act of 1930.

SEC. 202. UNFAIR PRACTICES IN IMPORT TRADE.

(a) UNFAIR METHODS OF COMPETITION.—Subsection (a) of section 337 (19 U.S.C. 1337) is amended—

(1) by inserting "(1)" before the first sentence;

(2) by striking "or tendency";

(3) by striking ", efficiently and economically operated,";

(4) by inserting "or to be a threat thereof," after "in the United States,";

(5) by inserting "or substantially impair" after "prevent"; and

(6) by adding at the end the following:

"For purposes of this section, an 'industry in the United States' includes a substantial investment in facilities or activities related to the exploitation of patents, copyrights, trademarks, or mask works described in paragraph (2), including research, development, licensing, sales, and marketing.

"(2) For purposes of this section, there is a rebuttable presumption that the following acts have the effect to destroy or substantially injure an industry, or to be a threat thereof,

or to prevent or substantially impair the establishment of an industry:

"(A) Unauthorized importation of an article which infringes a valid and enforceable patent issued under title 35, United States Code, or the unauthorized sale of such an imported article.

"(B) Unauthorized importation of an article which—

"(i) was made, produced, processed, or mined under, or by means of, a process covered by a claim of a valid and enforceable patent issued under title 35, United States Code, and

"(ii) if made, produced, processed, or mined in the United States, would infringe a valid and enforceable patent issued under title 35, United States Code,

or the unauthorized sale of such an imported article.

"(C) Unauthorized importation of an article which infringes a copyright registered under title 17, United States Code, or the unauthorized sale of such an imported article.

"(D) Importation of an article which infringes a valid and enforceable trademark registered under the Trademark Act of 1946, or the sale of such an import-

ed article, if the manufacture or production of such imported article was unauthorized.

"(E) The importation of a semiconductor chip product in a manner that constitutes infringement of a mask work registered under chapter 9 of title 17, United States Code.".

(b) DETERMINATIONS; REVIEW.—Subsection (c) of section 337 is amended—

(1) in the first sentence by inserting before the period the following: ", except that the Commission may, by issuing a consent order or on the basis of a settlement agreement, terminate any such investigation, in whole or in part, without making such a determination"; and

(2) in the fifth sentence by inserting after "its findings" the following: "on whether the adversely affected industry is efficiently and economically operated and its findings".

(c) EXCLUSION OF ARTICLES FROM ENTRY.—Subsection (d) of section 337 is amended in the first sentence by inserting after "considering" the following: "whether the adversely affected industry is efficiently and economically operated, and after considering".

(d) EXCLUSION OF ARTICLES FROM ENTRY DURING INVESTIGATION EXCEPT UNDER BOND.—Subsection (e) of section 337 is amended—

(1) in the first sentence—

(A) by striking "If" and inserting "(1) If"; and

(B) by inserting after "considering" the following: "whether the adversely affected industry is efficiently and economically operated, and after considering"; and

(2) by adding at the end the following:

"(2) A complainant may petition the Commission for the issuance of an exclusion from entry under this subsection. The Commission shall, within 90 days after receipt of the petition, make a determination with regard to the petition. The Commission may extend that 90-day period for an additional 60 days in a more complicated case. The Commission shall publish in the Federal Register its reasons for designating any case as a more complicated case. The Commission may require the petitioner to post a bond as a prerequisite to the issuance of an exclusion from entry under this subsection.

"(3) The Commission may grant preliminary relief under this subsection with respect to a violation involving a registered trademark, copyright, or mask work or a patent, to the same extent as preliminary injunctions and temporary re-

straining orders may be granted under the Federal Rules of Civil Procedure.".

(e) CEASE AND DESIST ORDERS.—Subsection (f) of section 337 is amended—

(1) in paragraph (1)—

(A) by striking "In lieu of" and inserting "In addition to, or in lieu of,"; and

(B) by inserting after "considering" the following: "whether the adversely affected industry is efficiently and economically operated, and after considering"; and

(2) in paragraph (2) by striking "$10,000" and inserting "$100,000".

(f) DEFAULT.—Section 337 is amended—

(1) by redesignating subsections (g), (h), (i), and (j) as subsections (i), (j), (k), and (l), respectively; and

(2) by inserting after subsection (f) the following new subsections:

"(g) DEFAULT.—(1) If—

"(A) a complaint is filed against a person under this section;

"(B) the complaint and a notice of investigation are served on the person;

"(C) the person fails to respond to the complaint and notice or otherwise fails to appear to answer the complaint and notice;

"(D) the person fails to show good cause why the person should not be found in default; and

"(E) the person seeks relief affecting solely that person,

the Commission shall presume the facts alleged in the complaint to be true and shall, upon request, issue an exclusion from entry or order, or both, which affects only that person unless, after considering whether the adversely affected industry is efficiently and economically operated and after considering the effect of such exclusion or order upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the Commission finds that such exclusion or order should not be issued.

"(2) An in rem exclusion from entry of the articles concerned, regardless of the source or importer of the articles, may not be issued under paragraph (1) unless a violation of the provisions of this section is established by substantial, reliable, and probative evidence.

"(h) ABUSE OF PROCESS.—The Commission may by rule prescribe sanctions for abuse of discovery and abuse of

process to the extent authorized by Rule 11 and Rule 37 of the Federal Rules of Civil Procedure.".

(g) PERIOD OF EFFECTIVENESS.—Subsection (j) of section 337, as redesignated by subsection (f)(1) of this section, is amended—

(1) by inserting "(1)" before the first sentence; and

(2) by adding at the end the following:

"(2) If any person who has previously been found by the Commission, on the basis of a contested proceeding, to be in violation of this section petitions the Commission for a determination that the petitioner is no longer in violation of this section or for a modification or recission of an exclusion from entry or order under subsection (d), (e), (f), or (g)—

"(A) the burden of proof in any proceeding before the Commission regarding such petition shall be on the petitioner; and

"(B) relief may be granted by the Commission with respect to such petition only on the basis of new evidence or evidence that could not have been presented at the prior proceeding.".

(h) IMPORTATION BY OR FOR THE UNITED STATES.—Subsection (k) of section 337, as redesignated by subsection (f)(1) of this section, is amended—

(1) in the first sentence by striking "claims of United States letters patent" and inserting "any claim of a patent, copyright, trademark, or mask work"; and

(2) in the second sentence by striking "a patent owner" and inserting "an owner of the patent, copyright, trademark, or mask work".

(i) CONFIDENTIALITY OF INFORMATION.—Section 337, as amended by subsection (f) of this section, is amended by adding at the end the following:

"(m) CONFIDENTIAL INFORMATION.—(1) Information submitted to the Commission or exchanged among the parties in connection with proceedings under this section which is designated as confidential by the person submitting it may not be disclosed (except under a protective order issued under regulations of the Commission which authorizes limited disclosure of such information) to any person (other than a person described in paragraph (2)) without the consent of the person submitting it.

"(2) Notwithstanding the prohibition contained in paragraph (1), information referred to in that paragraph may be disclosed to—

"(A) an officer or employee of the Commission who is directly concerned with carrying out the investigation in connection with which the information is submitted, or

"(B) an officer or employee of the United States Customs Service who is directly involved in administering an exclusion from entry under this section resulting from the investigation in connection with which the information is submitted.".

(j) TECHNICAL AMENDMENTS.—Section 337 is amended—

(1) in subsection (c)—

(A) by striking "(d) or (e)" and inserting "(d), (e), or (f)",

(B) by striking "or (f)" and inserting "(f), or (g)", and

(C) by striking "and (f)" and inserting "(f), and (g)";

(2) in subsection (i) (as redesignated by subsection (f)(1) of this section), by striking "or (f)" each place it appears and inserting "(f), or (g)";

(3) in subsection (j) (as redesignated by subsection (f)(1) of this section), by striking "(g)" and inserting "(i)"; and

(4) in subsection (k) (as redesignated by subsection (f)(1) of this section), by striking "or (f)" and inserting "(f), or (g)".

SEC. 203. EFFECTIVE DATE.

(a) IN GENERAL.—Subject to subsection (b), the amendments made by this title shall apply with respect to findings made by the United States International Trade Commission under section 337 of the Tariff Act of 1930 on or after the date of the enactment of this Act.

(b) APPLICABILITY TO CERTAIN PRIOR FINDINGS.—Section 337(j)(2) of the Tariff Act of 1930, as added by section 202(g) of this Act, shall apply with respect to findings of the International Trade Commission made before the date of the enactment of this Act, except that with respect to any such finding regarding which the President did not take action under section 337 of the Tariff Act of 1930 before such date of enactment, the finding shall be treated as having been received by the President on such date.

TITLE III—PATENT COOPERATION TREATY AUTHORIZATION

SEC. 301. REFERENCE TO TITLE 35, UNITED STATES CODE.

Whenever in this title an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of title 35, United States Code.

SEC. 302. DEFINITIONS.

(a) TREATY.—Section 351(a) is amended by striking ", excluding chapter II thereof".

(b) REGULATIONS.—Section 351(b) is amended by striking "excluding part C thereof".

(c) INTERNATIONAL SEARCHING AUTHORITY AND INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY.—Section 351(g) is amended by striking "term 'International Searching Authority' means" and inserting "terms 'International Searching Authority' and 'International Preliminary Examining Authority, mean".

SEC. 303. TIME FOR FILING FEES.

Section 361(d) is amended to read as follows:

"(d) The international fee, and the transmittal and search fees prescribed under section 376(a) of this part, shall be paid either on filing of an international application or within such later time as the Commissioner may prescribe.".

SEC. 304. PATENT OFFICE AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY.

(a) AUTHORITY OF PATENT OFFICE.—Section 362 is amended to read as follows:

"§ 362. International Searching Authority and International Preliminary Examining Authority

"(a) The Patent and Trademark Office may act as an International Searching Authority and an International Preliminary Examining Authority with respect to international applications in accordance with the terms and conditions of an agreement which may be concluded with the International

Bureau, and may discharge all duties required of such Authorities, including the collection of handling fees and their transmittal to the International Bureau.

"(b) The handling fee, preliminary examination fee, and any additional fees due for international preliminary examination shall be paid within such time as the Commissioner may prescribe.".

(b) CONFORMING AMENDMENT.—The item relating to section 362 in the table of sections for chapter 36 is amended to read as follows:

"362. International Searching Authority and International Preliminary Examining Authority.".

SEC. 305. INTERNATIONAL STAGE: PROCEDURE.

Section 364(a) is amended by striking "or International Searching Authority, or both," and inserting ", an International Searching Authority, or an International Preliminary Examining Authority,".

SEC. 306. SECRECY OF INTERNATIONAL APPLICATIONS.

Section 368(c) is amended by striking "or International Searching Authority, or both," and inserting ", an International Searching Authority, or an International Preliminary Examining Authority".

SEC. 307. COMMENCEMENT OF NATIONAL STAGE.

(a) RECEIPT OF DOCUMENTS FROM THE INTERNATIONAL BUREAU.—Subsection (a) of section 371 is amended to read as follows:

"(a) Receipt from the International Bureau of copies of international applications with any amendments to the claims, international search reports, and international preliminary examination reports (including any annexes thereto) may be required in the case of international applications designating or electing the United States.".

(b) TIME LIMIT FOR COMMENCEMENT OF NATIONAL STAGE.—Subsection (b) of section 371 is amended to read as follows:

"(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22(1) or (2) or under article 39(1)(a) of the treaty.".

(c) FILING OF ENGLISH TRANSLATION.—Subsection (c) of section 371 is amended—

(1) in paragraph (4) by striking the period and inserting "; and"; and

(2) by adding at the end the following:

"(5) a translation into the English language of any annexes to the international preliminary examination report, if such annexes were made in another language.".

(d) TIME PERIOD FOR SUBMISSION OF ANNEXES.—Subsection (d) of section 371 is amended by adding at the end the following new sentence: "The requirement set forth in

subsection (c)(5) shall be complied with at such time as the Commissioner may prescribe, and failure to do so shall be regarded as cancellation of the amendments made under article 34(2)(b) of the treaty.".

(e) TIME PERIOD FOR PRESENTATION OF AMENDMENTS.—Subsection (e) of section 371 is amended by inserting "or article 41" after "28".

SEC. 308. FEES.

(a) HANDLING AND PRELIMINARY EXAMINATION FEES.—Subsection (a) of section 376 is amended—

(1) by striking "fee, which amount is" and inserting "fee and the handling fee, which amounts are";

(2) by redesignating paragraph (5) as paragraph (6); and

(3) by inserting after paragraph (4) the following new paragraph:

"(5) A preliminary examination fee and any additional fees (see section 362(b)); and".

(b) PRESCRIPTION AND REFUNDABILITY OF FEES.—Subsection (b) of section 376 is amended—

(1) in the first sentence by inserting "and the handling fee" after "international fee"; and

(2) in the third sentence by inserting "the preliminary examination fee, and any additional fees," after "fee,".

SEC. 309. EFFECTIVE DATE.

The amendments made by this title—

(1) shall take effect on the same day as the effective date of entry into force with respect to the United States of chapter II of the Patent Cooperation Treaty, on account of the withdrawal of the declaration under article 64(1)(a) of the Patent Cooperation Treaty; and

(2) shall apply to all international applications pending on or filed on or after the date on which the amendments made by this title take effect.

I

99TH CONGRESS
2D SESSION

H. R. 4899

To amend title 35, United States Code, with respect to patented processes and the patent cooperation treaty.

IN THE HOUSE OF REPRESENTATIVES

MAY 22, 1986

Mr. KASTENMEIER (for himself, Mr. MOORHEAD, Mr. MORRISON of Connecticut, Mr. FISH, Mr. HYDE, Mr. KINDNESS, Mr. DEWINE, Mr. COBLE, and Mr. SWINDALL) introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To amend title 35, United States Code, with respect to patented processes and the patent cooperation treaty.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Patent Equity Act".

SEC. 2. REFERENCE TO TITLE 35, UNITED STATES CODE.

Whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of title 35, United States Code.

TITLE I—PATENTED PROCESSES

SEC. 101. RIGHTS OF OWNERS OF PATENTED PROCESSES.

Section 154 is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products directly made by that process,".

SEC. 102. INFRINGEMENT FOR IMPORTATION OR SALE.

Section 271 is amended by adding at the end the following new subsection:

"(e) Whoever without authority imports into the United States or sells or uses within the United States a product which is directly made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the use of a product unless there is no adequate remedy under this title for infringement on account of the importation or sale of that product.".

SEC. 103. DAMAGES FOR INFRINGEMENT.

Section 287 is amended—

(1) by inserting "(a)" before "Patentees"; and

(2) by adding at the end the following:

"(b)(1) No damages may be recovered for an infringement under section 271(e) of this title unless the infringer knew or was on notice that the product was made by a process patented in the United States. Damages may be recovered only for such infringement occurring after such knowledge or notice and, with respect to products in the United States obtained before such knowledge or notice, shall be limited to reasonable royalties therefor.

"(2) For purposes of paragraph (1)—

"(A) a person has knowledge if that person is aware or has a firm belief that the product was made by a process patented in the United States; and

"(B) 'notice' means receipt of facts set forth in writing which are sufficient to establish that there is a reasonable likelihood that the product was made by an infringing process.".

SEC. 104. INFRINGEMENT ACTIONS.

(a) PRESUMPTION IN CERTAIN ACTIONS.—Chapter 29 is amended by adding at the end the following:

"§ 295. Presumption: Product produced by patented process.

"In actions alleging infringement of a process patent based on the importation, sale, or use of a new product or a product directly made from recombinant DNA or hybridoma technology, if the court finds—

"(1) that a substantial likelihood exists that the product was made by the patented process, and

"(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine,

the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.".

(b) CONFORMING AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: Product produced by patented process.".

SEC. 105. EFFECTIVE DATE.

The amendments made by this title shall apply to United States patents granted before, on, or after the date of the enactment of this Act, except that these amendments shall not apply to any product imported into or made in the United States before the date of the enactment of this Act.

TITLE II—PATENT COOPERATION TREATY AUTHORIZATION

SEC. 201. DEFINITIONS.

(a) TREATY.—Section 351(a) is amended by striking ", excluding chapter II thereof".

(b) REGULATIONS.—Section 351(b) is amended by striking "excluding part C thereof".

(c) INTERNATIONAL SEARCHING AUTHORITY AND INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY.—Section 351(g) is amended by striking "term 'International Searching Authority' means" and inserting "terms 'International Searching Authority' and 'International Preliminary Examining Authority' mean".

SEC. 202. TIME FOR FILING FEES.

Section 361(d) is amended to read as follows:

"(d) The international fee, and the transmittal and search fees prescribed under section 376(a) of this part, shall be paid either on filing of an international application or within such later time as the Commissioner may prescribe.".

SEC. 203. PATENT OFFICE AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY.

(a) AUTHORITY OF PATENT OFFICE.—Section 362 is amended to read as follows:

"§ 362. International Searching Authority and International Preliminary Examining Authority

"(a) The Patent and Trademark Office may act as an International Searching Authority and an International Preliminary Examining Authority with respect to international applications in accordance with the terms and conditions of an agreement which may be concluded with the International

Bureau, and may discharge all duties required of such Authorities, including the collection of handling fees and their transmittal to the International Bureau.

"(b) The handling fee, preliminary examination fee, and any additional fees due for international preliminary examination shall be paid within such time as the Commissioner may prescribe.".

(b) CONFORMING AMENDMENT.—The item relating to section 362 in the table of sections for chapter 36 is amended to read as follows:

"362. International Searching Authority and International Preliminary Examining Authority.".

SEC. 204. INTERNATIONAL STAGE: PROCEDURE.

Section 364(a) is amended by striking "or International Searching Authority, or both," and inserting ", an International Searching Authority, or an International Preliminary Examining Authority,".

SEC. 205. SECRECY OF INTERNATIONAL APPLICATIONS.

Section 368(c) is amended by striking "or International Searching Authority, or both," and inserting ", an International Searching Authority, or an International Preliminary Examining Authority".

SEC. 206. COMMENCEMENT OF NATIONAL STAGE.

(a) RECEIPT OF DOCUMENTS FROM THE INTERNATIONAL BUREAU.—Subsection (a) of section 371 is amended to read as follows:

"(a) Receipt from the International Bureau of copies of international applications with any amendments to the claims, international search reports, and international preliminary examination reports (including any annexes thereto) may be required in the case of international applications designating or electing the United States.".

(b) TIME LIMIT FOR COMMENCEMENT OF NATIONAL STAGE.—Subsection (b) of section 371 is amended to read as follows:

"(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22(1) or (2) or under article 39(1)(a) of the treaty.".

(c) FILING OF ENGLISH TRANSLATION.—Subsection (c) of section 371 is amended—

(1) in paragraph (4) by striking the period and inserting "; and"; and

(2) by adding at the end the following:

"(5) a translation into the English language of any annexes to the international preliminary examination report, if such annexes were made in another language.".

(d) TIME PERIOD FOR SUBMISSION OF ANNEXES.—Subsection (d) of section 371 is amended by adding at the end the following new sentence: "The requirement set forth in

subsection (c)(5) of this section shall be complied with at such time as the Commissioner may prescribe, and failure to do so shall be regarded as cancellation of the amendments made under article 34(2)(b) of the treaty.".

(e) TIME PERIOD FOR PRESENTATION OF AMENDMENTS.—Subsection (e) of section 371 is amended by inserting "or article 41" after "28".

SEC. 207. FEES.

(a) HANDLING AND PRELIMINARY EXAMINATION FEES.—Subsection (a) of section 376 is amended—

(1) by striking "fee, which amount is" and inserting "fee and the handling fee, which amounts are";

(2) by redesignating paragraph (5) as paragraph (6); and

(3) by inserting after paragraph (4) the following new paragraph:

"(5) A preliminary examination fee and any additional fees (see section 362(b)); and".

(b) PRESCRIPTION AND REFUNDABILITY OF FEES.—Subsection (b) of section 376 is amended—

(1) in the first sentence by inserting "and the handling fee" after "international fee"; and

(2) in the third sentence by inserting "the preliminary examination fee, and any additional fees," after "fee,".

SEC. 208. EFFECTIVE DATE.

The amendments made by this title—

(1) shall take effect on the same day as the effective date of entry into force with respect to the United States of chapter II of the Patent Cooperation Treaty, on account of the withdrawal of the declaration under article 64(1)(a) of the Patent Cooperation Treaty; and

(2) shall apply to all international applications pending on or filed on or after the date on which the amendments made by this title take effect.

University Patents, Inc.

May 1, 1986

The Honorable Robert W. Kastenmeier
Judiciary Subcommittee on Courts, Civil
Liberties, and the Administration of Justice
The United States House of Representatives
Washington, D. C. 20515

Dear Congressman Kastenmeier:

We understand that H. R. 1069 sponsored by Rep. Moorhead is before your subcommittee for action following a hearing last February.

University Patents, Inc. is carefully watching the progress of this and other bills that would right some of the existing wrongs in the area of process patent protection for American manufacturers and inventors. As the exclusive technology transfer representative for a number of American universities (including Princeton, New York University and the Universities of Pennsylvania, Arizona, Colorado and Illinois), we move university generated technology into industry. Our licensees include IBM for electronics, Becton-Dickinson for assay kits, Applied Biosystems, Inc., for genetic engineering, to name a few. As a result of our activities, millions of dollars have been returned to the universities and used to support further research.

We feel strongly that there is one immediate remedial action which can be taken to stop the drain of U. S. technological innovation by foreign companies: mandatory Preliminary Relief for the infringed patent holder. The enclosed proposed modification to Title 35 United States Code would provide that relief. Our reasons for seeking this change are threefold:

(1) As it now stands, a patent owner of an infringed patent, if lucky, gets a decision on his "presumptively valid" patent some five years after the enforcement of his rights commences. Thus, his suit against an infringer need not be treated as a contingency in the infringer's current budget, and possibly not even in its five year plan.

(2) Preliminary injunctive relief is non-existent. A non-litigated patent never (that we can find) receives preliminary relief, and

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(3) When the patentee does finally prevail, he is usually held to "a reasonable royalty" by law. The law says that "reasonable" is the license fee that the patentee has been charging others. Thus, the infringer's worst-case scenario essentially becomes his best case. Even interest on past due royalties, which only recently became available due to a Supreme Court decision, is charged only at the going rate.

As one knowledgeable in this field, I stand ready to be of any help that I can to your Committee and staff members.

Sincerely yours,

A. SIDNEY ALPERT, ESQ.
President

ASA/rg
enclosure: Amendment

35 USC 283. INJUNCTION (AMENDED)

The several courts having jurisdiction of cases under this title shall grant injunctions to prevent the violation of any right secured by patent, in accordance with the following principles:

(1) at any time after the filing of an infringement action pursuant to 35 USC 281, and if the patent in suit has previously been litigated in a district court and not been found to be invalid or unenforceable under 35 USC 282, the patentee or party claiming under such patentee (hereinafter "patentee") shall be entitled to a preliminary injunction against the adverse party effective until such time as the court in the instant action renders its decision;

(2) upon the filing of an infringement action pursuant to 35 USC 281 with respect to a patent that has not been previously litigated in a district court, the patentee shall be entitled to a hearing regarding a preliminary injunction against the adverse party and the court in the instant action shall grant such preliminary injunction against the adverse party unless such party adequately shows that the patent in suit is likely to be held invalid, non-infringed or unenforceable under 35 USC 282;

(3) upon the finding of infringement of a patent pursuant to 35 USC 271 by a court in a civil action under 35 USC 281, and if such court did not find such patent invalid or unenforceable under 35 USC 283, the patentee shall be entitled to a permanent injunction against the adverse party in such suit including, without limitation, any non-party that provides monetary support of such adverse party.

SOHIO THE STANDARD OIL COMPANY
1001 TWENTY-SECOND STREET N.W., SUITE 600
WASHINGTON, D.C. 20037
TELEPHONE: (202) 785-4888

September 9, 1985

Michael Remington, Counsel
Subcommittee on Courts, Civil Liberties,
and the Administration of Justice
Committee on the Judiciary
U.S. House of Representatives
2137 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Remington:

On August 22, Sohio Engineered Materials Company, a unit of The Standard Oil Company (Ohio), was pleased to testify on the unfairness of the Japanese patent system before the Subcommittee on Economic Goals and Intergovernmental Policy of the Joint Economic Committee in Binghamton, New York. Attached for your information is a copy of our testimony.

We conclude that the Japanese patent system can be--and is--used by Japanese business to effectively deny patent protection to important U.S. high technology inventions, even in cases where the Japanese Patent Office concludes that a patent should be issued.

This ability of Japanese firms to legally copy U.S. invented high technology in Japan not only prevents U.S. manufacturers from effectively penetrating the Japanese market, but encourages Japanese firms to use U.S. invented technology to establish a platform for marketing those goods in the world market.

Worse, if the invention is protected by a U.S. patent on the process of making a product, rather than on the product itself, U.S. patent law does not prevent foreign firms from using that process abroad and exporting the product into the U.S. market--directly competing with the U.S. inventor! Meanwhile, Japanese law strictly protects Japanese process patents from foreign exporters.

We believe U.S. process patent holders should be protected in the same way that U.S. patent law protects product patent holders.

We hope the House Judiciary Committee will promptly give U.S. companies a level playing field with the Japanese in the U.S. high technology market by reporting out legislation that amends U.S. patent law to provide protections for U.S. process patent holders from international copiers. Congressman Moorhead has introduced such a bill, H.R. 1069.

If I can provide any further information on the Japanese patent system or on the need to bolster U.S. patent law, please call me at 785-4888.

Sincerely,

Marshall E. Whitenton
Associate Director, Federal
Government Affairs

MEW/amh
Attachment

TESTIMONY OF

JOHNATHAN W. HINTON
VICE PRESIDENT AND GENERAL MANAGER
STRUCTURAL CERAMICS DIVISION
SOHIO ENGINEERED MATERIALS COMPANY

BEFORE THE
SUBCOMMITTEE ON ECONOMIC GOALS AND
INTERGOVERNMENTAL POLICY
OF THE
JOINT ECONOMIC COMMITTEE
ON
THE CASE OF JAPAN: BARRIERS TO U.S. EXPORTS

AUGUST 22, 1985

Senator D'Amato:

My name is Jonathan Hinton. I am Vice President & General Manager, Structural Ceramics Division, Sohio Engineered Materials Company. We are an operating division of The Standard Oil Company of Ohio. With me this afternoon are Lewis Koppel, who serves as Director, Strategy Development, Sohio Engineered Materials Company, and R. Lawrence Sahr, Senior Patent Attorney for Sohio. I would like to summarize my remarks and I request that my full statement, which will be sent to your Washington office this week, also be included in the hearing record.

Sohio Engineered Materials Company is headquartered in Niagara Falls, NY and employs nearly 1200 people in New York State. Our most exciting new industrial product is a patented advanced ceramic material which is extremely hard, strong, corrosion, abrasion, and heat resistant. It has many applications for machinery components in severe environments, where even exotic metal alloys cannot do the job.

We appreciate this opportunity to appear before you today. Our Company has had extensive experience with direct investments in Japan. We have been partners with various Japanese firms going back as far as the 1950's. Our experience there has taught us that there are a great many areas in which Japanese practices make it difficult for U.S. companies to succeed. Today, I would like to focus on one critical area of difficulty, namely patents.

As generally covered by Mr. Mu's and Mr. Suwinski's testimony, commerce in Japan is quite unique. Personal and corporate relationships are so strong that a Japanese firm will purchase from another Japanese firm rather than buy a less expensive equivalent product from an American firm. In addition, Japanese firms have a proven track record of copying the inventions of others. The Japanese patent system should be one of the tools which an American firm can use to minimize the inherent disadvantage we have in attempting to penetrate the complex Japanese market. Unfortunately, it isn't.

Both the U.S. and Japanese Constitutions support, in similar language, the rights of inventors to patents. Society strikes a bargain. In exchange for inventors' placing their inventions into the public domain to advance the state of technology, the government grants the inventor a monopoly for a limited time. This gives society the benefit of advanced technology upon which even newer technology can be developed, while providing the opportunity for the inventors to enjoy the financial rewards of their work.

This bargain works in the U.S. -- for both U.S. and foreign inventors -- because the U.S. patent system is set up in a way that protects the rights of all patentees equally. In Japan, this simply is not so. The practices of the Japanese patent system, industry and society operate to keep foreign inventors from participating equally with Japanese firms in the bargain.

The beginning of the patent process in Japan is to file an application in the Japanese Patent Office. From that point, it generally takes five (5) to seven (7) years for the application to be declared allowable, compared to two (2) to three (3) years in the U.S. Unlike U.S. patent applications, Japanese patent applications are published after 18 months, allowing competitors several years to study and copy new inventions.

The difficulties experienced by U.S. businesses in this initial stage of filing and prosecution of Japanese patent applications have been well documented. Both the American Chamber of Commerce in Japan and the U.S. Embassy, as well as several professional patent associations, have lodged multiple protests with the Japanese regarding these problems. The response has generally been limited to actions designed to publicly placate, without resulting in any significant changes. To use your earlier analogy, Senator, "the undisciplined child has apologized -- but still has neither walked the dog or taken out the garbage."

But what happens next? Once a patent application is found to be allowable, after this 5 to 7 year period, it is republished for opposition. Japanese opposers, who can be anyone from a corporation to a person with no economic interest, have three (3) months from the date of publication to file their oppositions arguing why the patent application should not become a granted patent. We have had extensive experience with this opposition process, which we would like to share with you.

To begin with, there are several unfair, but ultimately surmountable, procedures in the opposition process. The opposition documents are not required to be served by the opposers on the applicant. They are merely filed in the Patent Office which, in turn, immediately sends those opposition documents, plus patent application files, into what is termed "processing." This bureaucratic processing can take anywhere from one (1) to six (6) months depending upon the number of oppositions filed and the overall workload of the Patent Office. However, during this period, all of these opposition documents, which are, in the words of the Japanese law, "public records available to the public" are not in fact available to the public or the applicant. The applicant does not know the basis for any of the oppositions. He does not even know how many opposers there are or their names.

When the "processing" is completed, the opposition documents are formally served on the applicant's patent attorney. From that date, the applicant has three (3) months -- including the time needed for translation -- to reply to <u>all</u> of the oppositions.

It has been our experience, as well as that of other U.S. firms, that the arguments of the opposition documents are very well thought through and polished. We have been told by Japanese patent attorneys that this is no accident: the opposers have had access to the Patent Office application files since the original publication of the application, in most cases from five (5) to seven (7) years before publication for opposition. Thus, the opposers have had many years to develop their arguments and polish them.

If the patent application technology covers a basic invention, or is considered significant to an important Japanese market, or falls into an area of technology targeted by MITI (the Japanese Ministry of International Trade & Industry) -- such as advanced ceramics -- there will be a surprisingly large number of oppositions. In most of these cases there will be more than ten (10) oppositions and in a few recent cases, in excess of one hundred (100) -- all of which must be effectively answered in three months. Each opposition brief will contain several reasons why the opposer believes the patent should not be issued. If the applicant fails adequately to answer only one of these arguments, in only one of these briefs -- he loses his patent.

Some of the arguments in some of the briefs will be identical -- not merely similar, but exactly and literally identical. The applicant will notice, if there are many opposers, that certain phraseology is repeated in several of the opposition briefs, each of which has supposedly been developed by a separate and independent opposer. The arguments used and the order of their arrangement will also be repeated in several opposition briefs. In addition, certain support documents are used by all or a majority of the opposers, and those support documents will bear duplicated tell-tale markings, such as photocopy machine imperfections, marginal notes and underlining, indicating that each was copied from a single master copy. It appears that all of the opposers have met to collectively define the issues, distribute the support documents, develop the arguments and divide those issues and arguments among themselves, all by way of mutual agreement. In fact, this collusion is exactly what has happened,

as has been verified privately by many Japanese patent attorneys who have attended such meetings. Yet, those same attorneys do not report engaging in such meetings where the applicant is Japanese.

After the applicant files his reply briefs, each opposer may request rebuttal. The Patent Office frequently allows opposers to file rebuttals where the applicant is foreign, especially if there are a large number of opposers or if the arguments and issues are complex. The Patent Office usually takes one (1) or two (2) years to decide to allow the rebuttals. After it does so, there is no set time limit to file those rebuttals. The applicant, on the other hand, has only forty (40) days to respond to the rebuttals after another bout of bureaucratic "processing" in the Patent Office, as mentioned before. Beyond this, the Patent Office can then decide to allow yet another round of opposer rebuttals, necessitating further responses by the applicant. Finally, if the applicant is successful in persuading the Patent Office that he still has a patentable invention in spite of the oppositions, the Patent Office will issue a decision to grant a patent.

Having survived this ordeal, however, the U.S. firm still does not have an enforceable patent. There are problems that follow the opposition process which go beyond being merely "unfair." Once the patent is actually granted, it can be subjected to a revocation proceeding. Statistics show that a very high percentage of opposed and appealed patent applications, which finally result in granted patents, are subjected to revocation proceedings. Anyone can file a revocation proceeding. A revocation proceeding can be filed even

though no oppositions were filed. And, finally, there is no time limitation for the filing of a revocation proceeding; it can even be used as a defense to an infringement suit. The revocation proceeding starts in the Patent Office and, for all intents and purposes, follows the same procedure, and takes the same amount of time as an opposition proceeding. The revocation proceeding is also subject to a two-tiered appellate procedure, taking about two (2) years for each appeal. The net result is a patent which may never reach an enforceable stage.

The terms of a Japanese patent cannot extend for more than twenty (20) years from the date of original filing of the application. The initial application, you will recall, takes between five (5) and seven (7) years. This leaves a potential useful patent life of between thirteen (13) to fifteen (15) years, provided no oppositions are filed. If oppositions are filed, as much as five (5) more years can be cut from the life of that patent, leaving a potential life of only from eight (8) to ten (10) years. An additional nine (9) years can be cut from the life of the granted patent through revocation proceedings. This means that the possible twenty (20) year patent term can expire before a U.S. applicant has an enforceable Japanese patent.

Thus, the Japanese government has established a system which can be manipulated to ensure that an enforceable patent will never be issued to a U.S. firm until the patent period has expired. U.S. firms have, of course, complained to the Japanese government. The response of the Japanese Patent Office is that an applicant can assert his

patent against an infringer by filing suit as of the date that the patent application is published for opposition. A review of those patent infringement law suits filed in the Tokyo District Court, from 1975 to 1985, where the suit was filed under an opposed patent application and/or a granted patent which was subjected to a revocation proceeding, has shown, in every single instance, that the litigation was stayed until all of the oppositions, revocation proceedings and their respective appeals were completely and finally exhausted. Not a single instance was found where a prohibitive order was issued by the Tokyo District Court, to prevent the infringing practice from continuing during the oppositions, revocation proceedings and their respective appeals. Thus, the right to file a patent infringement action, based on a patent application published for opposition, seems to be a hollow right.

The net result of these provisions of the Japanese patent system is that the Japanese are provided with all of the tools necessary to deny the foreign applicant any effective patent rights in Japan. The use of these tools, in combination with the collusion among interested domestic competitors, can and in many cases, does effectively destroy the exclusive rights that a U.S. inventor otherwise should have under Japanese patent law, and which a Japanese inventor does have in the U.S.

Without a level playing field for patent rights, Japanese industry can continue to blatantly copy the newest U.S. products and, through industry collusion, keep the U.S. patent holder from selling any of his products in Japan. This costs U.S. workers more than just production jobs. Profits from sales to the large Japanese market for advanced ceramics, for example, could be a major source of funding for our R&D efforts in Niagara Falls.

The availability of Japanese-made copies not only prevents U.S. firms from penetrating the Japanese market, but the copies also are shipped to the United States where they compete directly with the U.S. patent holder's products. In cases where the Japanese export products infringing U.S. product patents, U.S. law permits the U.S. patent holder to sue the Japanese firm and force it to stop exporting. However, if the Japanese firm exports products which infringe only U.S. process patents, then U.S. law does not authorize the U.S. process patent holder to force the Japanese firm to stop.

Unlike U.S. law, Japanese patent law fully protects Japanese process patent holders. Section 104 of the Japanese Patent Law reads, in essence:

> "In the case of a patent for an invention of a process of manufacturing a product, ... any identical product shall be presumed to have been manufactured by that process."

Similar protection must be provided to U.S. process patent holders. We urge your support for corrective legislation in the Senate this Congress.

We are currently engaged in litigation with a major Japanese ceramics company, Kyocera, to stop them from selling infringing products in the U.S. Kyocera's Director of Research & Development has publicly admitted in a newspaper interview that Kyocera has infringed our U.S. patents. But, such litigation is both time consuming (5 years, so far) and costly, robbing precious resources for our Niagara Falls-based activities. Counterparts to these U.S. patents are still pending in Japan because they are mired in opposition proceedings. And all the while, Japanese customers which should be ours continue to buy infringing Japanese products, with blatant disregard for our patents. These lost revenues will never be recaptured.

In conclusion, Mr. Chairman, we believe we have amply demonstrated that the Japanese patent system provides a significant non-tariff barrier to the penetration of the Japanese high-technology market by U.S. firms.

We agree with you, Senator D'Amato; free trade must be fair trade -- and demanding that the Japanese correct their patent system is one important step forward.

We appreciate your interest and attention, and would be pleased to answer any questions you may have regarding this testimony.

American Chemical Society

OFFICE OF THE
PRESIDENT

George C. Pimentel
President-Elect, 1985
President, 1986
Immediate Past President, 1987

1155 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4600

March 18, 1986

The Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts, Civil Liberties, and the
Administration of Justice
Committee on the Judiciary
U. S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The American Chemical Society (ACS) supports passage of H.R.1069 and S.1543, the "Process Patent Amendment of 1985." These bills would establish a U.S. patent owner's infringement rights against imported goods manufactured by a U.S. patented process.

H.R.1069 and S.1543 would eliminate a longstanding loophole in U.S. patent law by broadening the definition of patent infringement to cover the acts of importing into the United States, or using or selling in the United States, a product produced in another country by a process patented in this country. This change would prevent U.S. competitors from avoiding a patent merely by moving offshore to do their manufacturing. The ACS believes that when U.S. process patent owners are protected from offshore competition, they will have more incentive to invest in research and development. Also, they will be more likely to manufacture in the U.S., thus creating jobs and stimulating the economy. To be competitive in world markets, the U.S. must provide greater incentives for American firms to invest in research, development, and commercialization of its own technology.

Though in support of the legislation, the Society does wish to comment on the following specific provisions of the proposed bills:

PRESUMPTION PROVISION

The "presumption" provision, Section 5 of H.R.1069, is necessary to provide adequate protection for process patents. A process patent owner may not be able to satisfy the burden of proof requirement if forced to prove, by a preponderance of the evidence, that an imported article was manufactured by the patented process.

An example of an industry that is particularly in need of the presumption protection is the biotechnology industry. Often the only protection available to this emerging industry is a process patent. In a typical infringement case, if a U.S. court is to disclose information concerning the process by which a product is made, in certain countries it is illegal for

the foreign manufacturer to disclose this information because it is classified as a "trade secret." When such information falls under the country's trade secret laws, according to the traditional conflict of laws' provision that a potential criminal sanction will prevail against any civil interest, the U.S. biotechnology process patent owner will be unable to obtain the necessary information to satisfy the burden of proof requirement and probably will lose the case.

The American Chemical Society believes that the process patent owner should be protected by including a provision in the law that the product will be presumed to have been made by a patented process if the patent owner has tried without success to determine the process actually used was the patented process, and the court finds a substantial likelihood that the product was produced by the patented process. The foreign manufacturer then would have the burden of proving that the product was not produced by the process patent.

GRANDFATHER PROVISION

The "grandfather" provision, Section 3 of S.1543, which exempts certain existing supply arrangements from the coverage of the bill, is equitable. The intent of this legislation is to provide protection for new ventures in the U.S., not to interfere with old or existing commercial production.

REPORTING PROVISION

The annual reporting requirement, in Section 4 of S.1543, is administratively burdensome and unnecessary. This provision appears incompatible with current interest in federal agency paperwork and budget reduction considerations.

In conclusion, the American Chemical Society, a nonprofit, scientific and educational organization with a membership of over 135,000 chemists and chemical engineers, supports both process patent protection bills. The ACS strongly favors passage of legislation embodying the provisions of H.R.1069 in combination with Section 3 of S.1543. The Society appreciates the opportunity to express support for this legislation and wishes to provide whatever assistance possible to Congress in consideration of this important issue.

Sincerely yours,

George C. Pimentel

cc: Members, House Subcommittee on Courts,
Civil Liberties, and the Administration of Justice

USG Corporation

101 South Wacker Drive
Chicago, Illinois 60606-4385

Telephone 312/321-4000

MAR 10 1986

March 4, 1986

Honorable Robert W. Kastenmeier
2328 Rayburn House Office Building
Washington, D.C. 20510

Re: House Bill No. 1069 - The Process Patent Amendment of 1985
House Bill No. 3776 - Section 337 of The Tariff Act of 1930

Dear Congressman Kastenmeier:

The House Subcommitte on Courts, Civil Liberties and Administration of Justice is currently studying H.R. 1069 - The Process Patent Amendment of 1985 and H.R. 3776 - Amendment of Section 337 of the Tariff Act of 1930. I am requesting your support for this legislation and your best efforts in convincing your colleagues on the Subcommittee that the passage of H.R. 1069 and H.R. 3776 is important to the welfare of innovation and the development of technology in the United States.

The patent system is essential to our Nation's economic and technological progress, and it needs to be strengthened by the passage of the proposed legislation enabling owners of process patents to enforce their rights against infringers who practice the process outside of the jurisdiction (United States) but sell products made by the infringing process in the jurisdiction. Much of the technology developed by our United States Gypsum Company subsidiary relates to improvements in processes, particularly methods for energy conservation, and we are faced with the difficult decision as to whether we should seek a United States patent covering the process or try to retain the technology as a trade secret. I am sure that if the judicial protection afforded patented processes were stronger, we would not hesitate to seek patent protection, and this would encourage us to increase our investment in developing improved processes.

Several years ago, the United States Gypsum Company licensed a process to make ceiling products to a manufacturer in South Africa, believing that it would not be economically feasible for this manufacturer to export product to the United States. However, as a result of the recent strength of the U.S. dollar, this South African manufacturer is seeking to market its products made by U.S. Gypsum technology in the United States. The proposed amendment to Section 337 of the Tariff Act of 1930, whereby only proof of patent infringement is required to establish against the importer an unfair method of competition, would be of substantial assistance to U.S. Gypsum in protecting its rights against such unfair acts.

For these reasons, I urge your support for H.R. 1069 and H.R. 3776.

Sincerely,

Robert H. Robinson

Robert H. Robinson
Patent Counsel

RHR:dmg

National Retail Merchants Association

TELEX—INT'L. 220 - 883 - TAUR
TWX—DOMESTIC 710 - 581 - 5380 TPNYK
ATTN: NRMA

NRMA

1000 Connecticut Avenue, N.W.
Washington, D.C. 20036
202/223-8250

75th Anniversary
1911—1986

May 15, 1986

The Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
Committee on the Judiciary
United States House of Representatives
2137B Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

I am writing on behalf of the National Retail Merchants Association to provide testimony on the process patent legislation on which your subcommittee has recently held hearings. We request that this letter and enclosed statement be included as part of the official record of that hearing.

Thank you for the consideration of this request.

Sincerely,

Tracy Mullin
Senior Vice President
Governmental Affairs

TM:jml
Enclosure

EXECUTIVE OFFICERS

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President
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NRMA
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Home Office: 100 West 31st Street, New York, N. Y. 10001

STATEMENT OF THE NATIONAL RETAIL MERCHANTS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE ADMINISTRATION OF JUSTICE

COMMITTEE ON THE JUDICIARY

UNITED STATES HOUSE OF REPRESENTATIVES

May 15, 1986

The National Retail Merchants Association ("NRMA") respectfully submits this statement in opposition to H.R. 1069.[1] NRMA is the nation's largest trade association for the general merchandise retail industry. Our members operate 45,000 leading department, chain, independent and specialty stores in all 50 states, employ more than 3 million people and have annual aggregate sales in excess of $150 billion. If enacted in its current form, H.R. 1069 will impose unmanageable and inequitable burdens upon U.S. retail merchants, the costs of which will be borne directly by consumers of every conceivable type of retail product. Such a result is particularly troubling to NRMA.

H.R. 1069 attempts to strengthen intellectual property protection in the United States in order to encourage technological innovation of both products and processes. The bill is meant to protect holders of United States process patents from those who use the patented process overseas and then sell the resulting goods in the United States. While the goal is laudable, NRMA cannot support the means by which this bill would attempt to achieve it. H.R. 1069 attempts to stop this practice by making the retailer responsible for the infringer's violation. As

1. Title 1 of H.R. 3776 is identical to H.R. 1069, and NRMA's statement applies equally to it.

drafted, H.R. 1069 would expose U.S. retailers to significant monetary damages unless they can successfully undertake an enormously burdensome factfinding trek around the world, to overcome an unwarranted presumption based solely on the patent holder's unsubstantiated assertion that the products in question infringe a U.S. process patent.

H.R. 1069 provides that the holder of a process patent may recover monetary damages against those who use, sell or import into the United States -- but not those who manufacture overseas -- a product made pursuant to the patented process. The patent holder need only show that it is substantially likely that the product was made by means of his patented process, and that he has made a reasonable effort, but was unable to ascertain, the process used. The user, seller or importer, each of which could be a retailer, then has the almost impossible burden of proving a negative: that the product was not made by use of the patented process. Thus, the bill as currently drafted relieves the patent holder from any obligation to make a reasonable factual investigation before asserting his claim, while putting the entire factfinding burden on the retailer.[2]

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2. This is contrary to the policy and letter of Rule 11 of the Federal Rules of Civil Procedures which requires that a reasonable factual basis for a lawsuit be ascertained before a lawsuit is brought.

Imposing liability for process patent infringement upon a retailer -- who has no part in, and ordinarily no knowledge of, the processes with which products on his shelves are made -- is not only burdensome and unfair, it will be enormously costly. Retailers buy and sell thousands of different products. For the most part, these are finished products, any one of which may have hundreds of components. Retailers have no way of knowing the source of these many components, particularly for complex products. Generally, the merchandise has passed through several steps in the chain of distribution; from the manufacturer, to a wholesaler, then possibly to a distributor, and only then to the retailer.

Under these circumstances, to force a retailer to prove that a certain process was not used far up the distribution chain is inequitable and inefficient. In doing so by creating a presumption of infringement, H.R. 1069 merely adds insult to injury. There is no way that a typical store owner can meet this burden for the hundreds of different items on its shelves without spending a fortune in time and money, conducting investigations, paying lawyers, etc., both here and abroad.

A major justification for the presumption advanced by proponents of the legislation is that a patent holder may have difficulties in obtaining jurisdiction over foreign

infringers, or information concerning the process used, and should be entitled to a presumption of infringement against more readily accessible defendants. Such a justification is unpersuasive on at least two grounds. First, all that would be needed to obtain jurisdiction over a purportedly infringing foreign manufacturer, if Congress created such a cause of action, would be for the manufacturer to have "minimum contacts" with the United States.[3] To satisfy this standard, it would only be necessary for the patent owner to show that the foreign manufacturer introduced products into the stream of commerce of the forum state.[4] Second, the owner of a patent has a decided advantage over a retailer in obtaining proof on the question of infringement. The patent holder starts out with the necessary technical expertise, which the retailer does not have. The patent owner also could, in a suit against a purportedly infringing foreign manufacturer, avail itself of the time-tested and already existing rights to discovery provided by the Federal Rules of

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3. See World-Wide Volkswagen Corporation v. Woodson, 444 U.S. 286 (1980).

4. Id.; Asahi Metal Industry Co., Ltd. v. Superior Court of Salano County, 39 Cal.3d 35, 216 Cal. Rptr. 385 (1985), cert. granted, 106 S. Ct. 1258 (1986) (holding exercise of personal jurisdiction over foreign manufacturer of component parts fair where manufacturer introduced the products into the stream of commerce of the forum state).

Civil Procedure.[5] Discovery from the foreign manufacturer may also be available to the patent holder under the Hague Convention.[6] Accordingly, it would be fairer and certainly more logical to require a U.S. process patent owner to seek redress against the real infringing party (i.e., the foreign manufacturer) than it would be to create the broad presumption contained in H.R. 1069.[7]

The bill as currently drafted is also unreasonable in that it triggers a retailer's liability for damages merely upon notice from a patent owner of an alleged infringement. This provision would require a retailer either to pull allegedly infringing merchandise from the shelves during its efforts to determine whether there is an infringement, or face liability for those sales. The damages and presumption sections of the bill would also encourage patent-holding

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5. See In Re Anschuetz & Co., GmbH, 754 F.2d 602 (5th Cir. 1985); Beckman Instruments, Inc. v. LKB Produkter AB, No. R-85-3133, Slip op. (D.Md. Jan. 10, 1986).

6. Multilateral Convention on the Taking of Evidence Abroad in Civil and Commercial Matters, done 18 March 1970 [1972], 23 U.S.T. 2555, T.I.A.S. No. 7444. The Convention was adopted to provide a uniform system of discovery in foreign jurisdictions. The United States ratified the treaty in 1972.

7. Title I of H.R. 4539, at least implicitly, recognizes these inequities, and therefore is preferable to H. R. 1069 on this ground. Specifically, H.R. 4539 does not create a presumption of infringement, and does not shift the burden of proof to the person who must prove non-infringement.

suppliers to engage in coercive, anticompetitive tactics by claiming that any colorably similar imported goods were violative of their patent rights. Knowing that a retailer is likely to remove allegedly infringing products upon notice, and that most retailers cannot afford the time it takes to resolve a claim, some suppliers would simply give such notice and drive their competitors' products from retailers' shelves. Thus, in practice, the scope of the patent would be extended far beyond its legal bounds.[8]

If retailers are faced with the costs of compliance and the risks of liability created by this bill, the price of merchandise will rise. If retailers are forced to insure themselves against infringement liability (if insurance is available at all), or obtain indemnification from their suppliers, the costs will be extreme. The expense of suit, of jettisoning inventory upon notification of infringement, and of damage awards, will take their toll. All these costs will be borne by consumers.

Of course, the burdens of this legislation will extend far beyond the costs of investigating allegedly

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8. Here too, H.R. 4539 is preferable to H.R. 1069. Under H.R. 4539 a patentee will not be able to recover damages merely by providing notice of an alleged infringement. Rather, damages would be recoverable only from an infringer who "knew that the product was made by a process patented in the United States."

infringing products. Retailers will simply stop stocking whole classes of products whose methods of manufacture cannot easily be verified, and will make available to their customers fewer types of products.

If all these undesirable results were necessary to protect American innovation, H.R. 1069 might be worth the price. However, it is clear that making retailers legally responsible for the processes used to make each product on their shelves is absolutely unnecessary to protect holders of process patents.[9] Plaintiffs already have a remedy which affords redress against the infringing manufacturers themselves, who are clearly more appropriate defendants than unknowing and innocent users and sellers.[10] Retailers should not be forced to resolve international patent disputes. Yet H.R. 1069 would do just that.

For all the reasons discussed, NRMA strongly urges the Subcommittee to exclude retailers from the coverage of H.R. 1069, or to reject the bill entirely in its present form.

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9. It is even questionable whether U.S. individuals and companies will be the primary beneficiaries of H.R. 1069. Foreign nationals have sought and received an increasing percentage of U.S. patents. H.R. 1069 could result in foreign companies excluding each other from the U.S. market on the basis of U.S. process patent rights.

10. The International Trade Commission investigates claims of process patent holders and enforces process patents by preventing products made abroad by the use of patented processes from being imported into the U.S. See 19 U.S.C. §§ 1337, 1337(a). This remedy is far fairer than lawsuits against retailers. It is also more effective, because it stops the imports at their source and prevents anyone from bringing them into the country.

THE NEW YORK PATENT, TRADEMARK
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February 4, 1986

Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts,
Civil Liberties and the
Administration of Justice
Committee on the Judiciary
House of Representatives
Washington, D. C. 20515

Re: H.R. 1069

Dear Mr. Chairman:

Enclosed is the testimony of The New York Patent, Trademark and Copyright Law Association concerning the pending legislation on infringement of process patents. We respectfully request that this be inserted in the hearing record.

Our association recommends revising the proposed legislation to limit liability to the first sale in the United States of the product produced by the patented process. In our view, the proposed legislation extends liability beyond what is reasonably necessary, and we believe our proposal better balances the public interest and legitimate proprietary rights.

Since our proposal differs from those espoused by other groups, and would, we believe, resolve a number of the concerns expressed, we would very much appreciate an opportunity to explain it, if the Committee's schedule permits. We are sending our testimony prior to the hearing date in the hope that the Committee will have time to consider our proposal and question other witnesses concerning it.

Respectfully submitted,

John O. Tramontine
President

JOT/jm

Enclosure

cc (w/enc.): Congressman Hamilton Fish
Congressman Charles Schumer
Michael Remington, Esq.

TESTIMONY OF NEW YORK PATENT, TRADEMARK AND COPYRIGHT LAW ASSOCIATION ON HOUSE BILL H.R. 1069

Introduction

The New York Patent, Trademark and Copyright Law Association strongly supports the enactment of legislation granting additional, and needed, protection to holders of U. S. process patents. We make the following suggestion to improve H.R. 1069, so that it will provide an effective remedy to the patentee without placing new and unnecessary burdens on domestic manufacturers and retailers.

Summary of Suggested Improvement

We suggest that the extension of liability provided by the bill be limited to persons who import or make the first sale in the United States of the product produced by the patented process.

Background

Under our present patent law, the inventor of a new and technically advantageous process is denied exclusive enjoyment of the benefits of his invention when a person who actually practices that process is not amenable to suit, even though the product produced is ultimately introduced into commerce in the United States. This results in substantial diminution of the value of process patents and,

therefore, the incentive to make process inventions and disclose them to the public. Inventors are encouraged, instead, to keep their process technology secret to avoid its appropriation by others against whom the inventor has no redress under the patent laws.

To encourage both innovation and dissemination of technical information, process patentees should be provided more extensive remedies than they now have, as H.R. 1069 intends to do. Our association supports, and urges adoption of, legislation that will effectuate that intent.

In making our suggestion for improvements in the bill, we are mindful of the fact that the principal cause of unfairness is the use of the patented process by foreign companies, outside the reach of the present patent law, who then directly or indirectly introduce the product into United States commerce. Legislation closing that loophole may well be all that is required. The patent holder, whether U. S. or foreign, already has a direct remedy against persons who carry out the patented process in the United States. We also are mindful, however, of the consideration that the legislation should not be, or even appear to be, discriminatory against our trading partners.

Suggested Improvement

H.R. 1069 would attach liability for infringement of a process patent not only to importation of the product, but also to every sale or use of that product in the United States. While we believe that process patentees need an effective remedy against unauthorized use of their technology, our concern is that the remedy proposed goes beyond what the patentee needs. Imposition of liability on users and sellers who are several steps remote from the person who actually uses the process technology may create an unwieldy and unnecessarily burdensome system.

Our suggestion is that the acts of infringement be defined as the importation into, or the first sale in, the United States of the product produced by the patented process. Subsequent sellers and users of the product would, under our proposal, not be infringers of the process patent.

The best explanation of the reasoning underlying our proposal is by way of an illustrative example. Assume Company A holds a patent on a process for making rubber. Company B (a domestic manufacturer) makes rubber which it sells to a tire manufacturer, who sells its tires to an automobile manufacturer, who sells its cars to consumers. Under the present bill, charges of infringement of the process patent could be made against every person in that chain.

The patentee's rights normally will be adequately protected if he has a remedy against the first person who introduces the rubber into United States commerce. That person also will be the United States entity in closest proximity to the person actually carrying out the process and, therefore, the entity that can most effectively know, and control, the process technology used. Where the process is carried out by a domestic manufacturer, it normally will make the first sale. Thus, under our suggestion, there would be no expansion of the current liability of domestic manufacturers and retailers for patent infringement.

If liability for infringement is not cut off at the first sale or importation, Company B will, as a practical matter, be required to indemnify people remote from it in the chain of distribution. It will run the risk of being forced to defend a plurality of suits in inconvenient forums. Even absent a charge of infringement, it may be forced to disclose its secret process technology to a series of users and sellers to reassure them, or allow them to make their own determination, that they are not indirect infringers of any existing process patents. Furthermore, each person in the chain of distribution usually would be warranting, under Section 2-321(3) of the Uniform Commercial Code, that the product it delivers does not infringe a process patent.

Even if such a warranty were expressly excluded, those persons may be deemed joint tortfeasors (infringers) with joint and several liability. Going back to our example, if the patentee chooses to sue the tire manufacturer, and the value of the tire greatly exceeds the value of the rubber raw material, Company B may face damage liability far in excess of the revenue it derives from selling the rubber.

Because importation or first sale would become acts of direct infringement, a foreign manufacturer could be liable as an active inducer of that direct infringement, notwithstanding that the foreign manufacturer did not conduct any infringing activity in the United States, by application of existing law. See, for example, Honeywell, Inc. v. Metz Apparatewerke, 509 F.2d 1137 (7 Cir. 1965), Engineered Sports Products v. Brunswick Corp., 362 F.Supp. 722 (D.Utah 1973) and Hauni Werke Koerber & Co., K.G. v. Molins Ltd., 183 USPQ 168 (E.D.Va. 1974). Thus the holder of a U. S. process patent could have a remedy directly against the foreign manufacturer.

In summary, our Association believes that H.R. 1069 can be improved by a more careful balancing of the needs of process patentees and the burdens imposed on domestic manufacturers and retailers. That balance can be achieved

by defining, as acts of infringement, the importation into the United States, or the first sale in the United States, of a product made by a patented process.

Proposed Amendments to H.R. 1069

In the amendment to Section 154 of Title 35, delete "using or selling products produced thereby", and substitute --making the first sale in the United States of products produced thereby--; and delete the comma after "into".

In the amendment to Section 271 of Title 35, delete "uses or sells" and substitute --makes the first sale--.

In new Section 295 of Title 35, delete "use or sale" and substitute --importation or first sale--.

John O. Tramontine, President
The New York Patent, Trademark
and Copyright Law Association



CHEMICAL MANUFACTURERS ASSOCIATION

WILLIAM M. STOVER
Vice President
Government Relations

March 25, 1986

The Honorable Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
Committee on the Judiciary
United States House of Representatives
Washington, D.C. 20515

HAND-DELIVERY

Re: H.R. 1069, "To Protect Patent Owners From Importation into the United States of Goods Made Overseas by Use of a U.S. Patented Process"

Dear Chairman Kastenmeier:

This letter contains the comments of the Chemical Manufacturers Association in support of H.R. 1069, the House process patent legislation. The Chemical Manufacturers Association (CMA) is a nonprofit trade association whose company members represent more than 90 percent of the productive capacity of basic industrial chemicals in this country.

The House Judiciary Subcommittee on Courts, Civil Liberties and the Administration of Justice held a hearing on intellectual property rights legislation, including H.R. 1069, on February 19, 1986. We hereby request that these comments be included in the written record of that hearing.

Protection of processes patented in the United States from foreign infringement is extremely important to the U.S. chemical industry. CMA believes such protection is necessary to provide an incentive for continued research and development in this country and a disincentive to foreign competitors to compete unfairly in the United States market by using U.S. inventions without the need to recoup the research and development expenses associated with making such inventions. Most of the major trading partners of the United States provide such protection for processes patented in their countries, e.g., the European Community, Japan, and Korea. The proposed change in U.S. patent laws to allow such protection is supported by at least 70 individual companies and 12 major trade associations (See attached October 17, 1985, letter listing these supporters). CMA, therefore, urges you to support H.R. 1069, to correct this loophole in the U.S. patent laws, compared to the laws of other industrialized countries.

However, we also call to your attention two issues which we believe must be adequately addressed in any effective process patent legislation. CMA believes that it is very important to preserve those provisions of

H.R.1069 that provide for a realistic effective date and a presumption of infringement under appropriate circumstances.

A major aspect of any process patent legislation is the consideration of how a patentee is to prove infringement when attempts at judicial discovery abroad are thwarted, as they often are. CMA supports Section 5 of H.R. 1069, which would create a rebuttable presumption under certain circumstances. Given jurisdictional difficulties and the fact that discovery procedures are inadequate or non-existent in many other countries, this presumption is needed. It can be virtually impossible to find out the process being used outside the United States to manufacture a product in question.

Concerning the effective date of H.R. 1069, CMA believes that the legislation should apply to all patents in force at the time of enactment, as well as patents granted after the date of enactment. In addition, it is necessary to make this legislation immediately effective (as in Section 6) and make it apply to all imports thereafter. Moreover, the legislation should include an equitable grandfathering clause to ensure that existing patents are covered and that investments made in reliance of present laws are protected.

Provided these issues are adequately addressed, CMA supports early passage of H.R. 1069. We appreciate the opportunity to comment on this important subject. If you have any questions on this letter, please contact Robert B. Hill, Legislative Representative for Patents (887-1128) or Gabrielle H. Williamson, Assistant General Counsel (887-1356).

Sincerely,

William M. Stover

William M. Stover
Vice President
Government Relations

cc: Members, Subcommittee on
Courts, Civil Liberties and
the Administration of Justice

National Association
of Manufacturers

Resources and Technology Department

MAR 3 1986

February 27, 1986

The Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts, Civil Liberties,
and the Administration of Justice
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Kastenmeier:

The enclosed statement represents the views of the National Association of Manufacturers on legislation to protect U.S. process patents.

We would appreciate it if the statement could be made part of the record of the hearings conducted by your Subcommittee on February 19, 1986.

Thank you.

Sincerely,

Brendan F. Somerville

Brendan F. Somerville,
Director,
Innovation, Technology
and Science Policy

BFS:als

Enclosure

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STATEMENT OF

NATIONAL ASSOCIATION OF MANUFACTURERS

TO THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES

AND THE ADMINISTRATION OF JUSTICE

COMMITTEE ON THE JUDICIARY

UNITED STATES HOUSE OF REPRESENTATIVES

IN REFERENCE TO

H.R. 1069 AND H.R. 3776

NAM is a voluntary business association of more than 13,000 corporations, large and small, located in every state. NAM membership ranges in size from very large to over 9,000 smaller manufacturing firms, each with an employee base of less than 500. NAM member companies employ 85 percent of all workers in manufacturing and produce over 80 percent of the nation's goods. NAM is affiliated with an additional 158,000 businesses through its Associations Council and the National Industrial Council.

The NAM supports H.R. 1069 and H.R. 3776 as a means of protecting U.S. developed technology. That technology has become so fundamental to modern products and thus to modern commerce that some developed and most developing countries seek to obtain it--both by legitimate and, unfortunately, illicit means.

At a time when the United States is spending $122 billion (an estimate for 1986 by the National Science Foundation) on research and development, we cannot continue our neglect in protecting such an enormous investment. U.S. industry will invest about 50 percent of that $122 billion, and we are most anxious that our laws be strong enough to protect that level of investment--particularly against abuses of our system for safeguarding the products of such outlays.

Unfortunately, while our patents system does a generally good job of providing some protection against pirates and infringers of our products, it provides no protection against those who steal our processes.

Individual companies do have remedies against the illegal use of their process patents by taking legal action against pirates in their own countries but it is an expensive, time-consuming and often fruitless effort as many U.S. companies have discovered to their chagrin.

The courts of foreign countries particularly developing ones, are unlikely to be sympathetic to complaints from foreign litigants, more especially when the intellectual property laws of those countries provide less comprehensive or sophisticated remedies for domestic abuse of foreign-owned intellectual property rights.

Most of our major trading partners, particularly European countries, provide protection for process patents. The United States, however, does not give the holder of a process patent any right to stop the

import, use or sale in the U.S. of a product made abroad by the illegal use of a process patented in the U.S.

In the past, our patent system has been generally effective in protecting the products and processes developed by U.S. manufacturers. But in today's climate of high technology products and processes, requiring huge expenditures on R&D and swift marketing of the results of that R&D, the U.S. has become vulnerable to piracy and counterfeiting of our products and processes. In such a high-tech environment, the short life of many products requires the need for the strongest protection so that the investment can yield some return. Pirates, who frequently engage in fly-by-night production have no need to make costly R&D outlays.

Remedies under U.S. trade laws, such as those administered by the International Trade Commission, tend to be inadequate. The long lengthy time involved in applying such laws favors the pirate. By the time remedies under those laws are implemented, the pirate will have reaped his profits. There is little recompense for the injured U.S. party since he cannot recover his market losses or obtain damages from the infringer.

In the report of the President's Commission on Industrial Competitiveness, a strong point was made for protection of our intellectual property. Let me quote:

> Protection is needed for intellectual property. Since technological innovation requires large investments of both time and money, the protection of intellectual property is another task we should

> place on our competitive agenda. Research and development are always risky. If the developers of a new technology cannot be assured of gaining adequate financial benefits from its commercialization, they have few incentives to make the huge investments required.
>
> Today, the need to protect intellectual property is greater than ever. A wave of commercial counterfeiting, copyright and design infringement, technology pirating, and other erosions of intellectual property rights is seriously weakening America's comparative advantage in innovation. A recent study by the International Trade Commission estimates that American business loses almost $8 billion and 131,000 jobs annually though counterfeiting alone. In the arena of international trade, we must create safeguards against the misappropriation of intellectual property for commercial purposes, especially by the newly industrializing countries.

That quote closely echoes the following NAM policy in the area of intellectual property protection:

> Technology is one of America's greatest strengths and a major determinant of future economic growth and industrial competitiveness. For this reason, it is simply not enough to nurture the creation and application of technology; we must also provide adequate protection of this industrial knowledge known as intellectual property. Without adequate protection, the incentives for future innovation-directed R&D would be inhibited.
>
> The U.S. has a clear national interest in promoting more effective protection of intellectual property rights both at home and abroad. Unless these rights are adequately protected worldwide, the U.S. will lose whatever long-term competitive benefits it might otherwise have gained from its leadership in technological innovation. The national interest would best be served if the U.S. pursued a coordinated domestic and international policy. This policy should be based on a statement of the vital importance of intellectual property rights for U.S. industrial competitiveness; its purpose should be to strengthen protection afforded by both domestic laws and international agreements.
>
> "Accordingly, the NAM recommends that the U.S. government make the strenghtening of intellectual property rights at home and abroad a priority item

on the policy agenda and, with private sector cooperation, commit itself to implementing actions necessary to achieve this goal."

Furthermore, regarding policies that impact on domestic protection:

> The NAM believes that the U.S. cannot reasonably expect the world community to protect intellectual property rights to a greater degree than U.S. law provides. Thus, we must continually review the adequacy of our basically sound laws in light of the fast-paced technological advances by innovators and infringers. But above all, the U.S. must be strongly committed to the rights of innovators to exploit their own inventions. In particular the NAM believes public policy should:
>
> 1. Increase public awareness of the important link between intellectual property rights protection and innovation, competitiveness, improved trade performance, sound economic growth and strengthened national security.
>
> 2. Strengthen U.S. intellectual property laws to increase the system's overall protection:
>
>   - o Holders of U.S. process patents should be protected from infringement caused by the sale or use in the U.S. of goods manufacturerd abroad by an infringing process;
>
>   - o Improved mechanisms to safeguard confidential business information and trade secrets held by the government, but released under such compulsory disclosure statutes as the Freedom of Information Act, are necessary to achieve a clearer balance between the right of access and the right to confidentiality;
>
>   - o Federal and state laws concerning intellectual property laws should be revised to be more responsive to merging technologies.

With some regard to international protection, we note:

> In some developed, and many newly industrialized and less developed countries, it is difficult to establish whether "ownership rights" exist. Even when they are acknowledged, they are often flagrantly disregarded. In fact, the policies of many nations, particularly in the developing world,

are structured to acquire foreign technologies as quickly and with as little short-term expense as possible without adequate compensation or protection to the intellectual property owner. In areas such as computer software, telecommunications and biotechnology, protection and enforcement of foreign intellectual property laws, where they exist, have not kept pace with rapidly evolving technologies.

Most countries' intellectual property laws are based on the principle that foreign inventors are afforded an equivalent level of protection as domestic inventors. This principle has often failed to ensure sufficient protection because of the total absence of laws protecting intellectual rights or weaknesses in existing laws. Ultimately, adequate international protection rests with the effective enforcement of strong domestic intellectual property laws by individual countries.

The NAM believes the U.S. government must implement a strategy for negotiating adequate international protection of intellectual property rights. The primary objectives of U.S. policy should be to:

1. Exercise rights under U.S. trade statutes and resultant leverage to strengthen worldwide protection of intellectual property rights;

2. Work bilaterally to encourage changes in the laws and policies of foreign countries;

3. Under multilateral arrangements, strengthen international agreements regarding intellectual property rights and counter efforts to erode protection within those agreements; and

4. Recognize intellectual property as an important emerging trade issue and make adequate protection of such rights a priority in bilateral/multilateral trade negotiations.

As our scientists delve into new areas, the need for protection of the technology developed from their results will increase rapidly. We already face a problem in maintaining our current world leadership in one new area of advanced technology--the biotechnology industry. This young industry faces formidable challenges not only domestically--

through regulatory processes which may inhibit its growth--but from abroad. The products of the biotechnology industry may not be patentable if they are categorized as "natural" products, but its processes are patentable. Therein lies an urgent need for protecting this fledgling industry if its expensive and very advanced processing technology is not to be stolen out from under its eyes. It's a daunting prospect. It is the closest example of how important this legislation is to our manufacture's in maintaining their ability to compete.

We would like to make one other point about the importance of this legislation. In the refined area of intellectual property rights, the idea that such rights protect jobs may not often be considered. But as noted earlier in this statement, the International Trade Commission has loss of American jobs--131,000 jobs annually through counterfeiting alone. That was a 1982 estimate. It has likely increased since. Surely, we cannot sit by and allow such losses. The clear connection has been made between the growing level of foreign piracy and counterfeiting and the ravages it is causing U.S. employment. Another index is our tremendous international trade deficit.

Finally, in his September 23, 1985 trade speech, President Reagan said:

> When governments permit counterfeiting or copying of American products, it is stealing our future, and it is no longer free trade. When governments assist their exporters in ways that violate international laws, then the playing field is no longer level--and there is no longer free trade.

We couldn't agree more.

We urge this subcommittee to move swiftly on this urgently needed legislation.

* * *

December 6, 1984

Professor Bob E. Hudec
University of Minnesota Law School
Minneapolis, MN 55455

Dear Professor Hudec:

Thank you for agreeing to examine the legislative problem facing the Committee with respect to process patents.

As you know, current Federal law does not permit a patent owner to obtain damages from a foreign manufacturer who uses a process to make a product when that process is subject to a United States patent, and subsequently imports the goods into the United States. In an attempt to remedy this deficiency, the House has passed legislation (Section 101 of H.R. 6286, attached) which would provide that such acts constitute patent infringement. In response to this legislation the United States Trade Representative has argued that this bill would violate the GATT. Before proceeding further on this bill, it seemed appropriate to obtain the views of persons expert in these matters of international law.

The policy question before us is: Should the United States provide that it is an act of patent infringement for a person to import, use or sell goods within the United States when such goods are made outside the country in violation of a U.S. process patent? If so, does such legislation violate GATT? I have enclosed for your use copies of various memoranda and other materials which you may find of assistance.

Thank you in advance for agreeing to review this matter for the Committee.

Sincerely,

ROBERT W. KASTENMEIER
Chairman,
Subcommittee on Courts,
Civil Liberties and the
Administration of Justice

RWK:dbs

Enclosure

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February 7, 1985

The Hon. Robert W. Kastenmeier
Chairman, Subcommittee on Courts,
Civil Liberties and the
Administration of Justice
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Kastenmeier:

You have asked me to review for the Judiciary Committee the question whether the patent infringement provisions of H.R. 6286 in the last Congress are consistent with United States obligations in GATT.

As I understand the issue from both your letter and from the documents accompanying it, the specific provision in question is the new subsection (e) which, under section 101(a) of the bill, would be added to Section 271 of Title 35 of the U.S. Code:

> (e) Whoever without authority imports into or sells or uses within the United States a product which is made in another country by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use occurs during the term of such process patent.

It is understood that U.S. law does not now impose such infringement liability upon the sale or use of products made in the United States, and that no such parallel liability for U.S.-made products is proposed.

GATT Article III:4 requires that foreign goods be treated no less favorably than domestic goods with respect to all laws, regulations and requirements affecting their movement in internal commerce (i.e., once released from customs). The imposition of infringement liability on foreign goods in circumstances which do not create similar liability for domestic goods is clearly less favorable treatment of the kind proscribed. There is little doubt, therefore, that subsection (e) would violate GATT Article III:4 unless excused by another GATT provision.

There is a GATT excuse provision that applies expressly to patent-enforcing laws of this kind. GATT Article XX:d exempts from all GATT obligations laws which are "necessary to secure compliance with laws or regulations which are not inconsistent with [GATT], including those relating to . . . the protection of patents. . . ." In other words, GATT permits governments to treat foreign products less favorably than domestic products if it can be shown that such discriminatory treatment is "necessary" to the enforcement of the patent laws.

The key requirement of Article XX:d is requirement that the GATT-inconsistent measure be "necessary" to the enforcement of the law in question (here the patent law). Not every measure which improves enforcement is "necessary." The sense of the requirement is that governments may use a particular GATT-violative measure only where there is no GATT-consistent measure, or less severe measure, that can achieve the requisite degree of enforcement. By "requisite degree of enforcement," I mean the same degree of enforcement provided for in the case of domestic-made goods, which is presumably the degree of enforcement the government deems necessary to carry out the policy of the law; measures which impose significantly more severe enforcement against foreign-made goods could not be regarded as "necessary" under Article XX:d.

(In my view, the "necessary" requirement of Article XX:d is also stated in different language in the introductory language to Article XX, which provides that exceptions authorized by Article XX may not be a "disguised restriction on international trade.")

In 1982, the GATT concluded that the exclusion remedy of Section 337 (19 U.S.C. 1337) could be accepted as a measure "necessary" to the enforcement of the U.S. patent laws. The GATT panel investigating the dispute stated that it had considered whether there was a GATT-consistent alternative that would have given satisfactory protection to the rights of the U.S. patent holder in question. The panel agreed with the United States position that the alternative remedy—infringement actions against sellers and users in the United States—was not always fully effective against foreign-made infringing goods. The panel concluded that the special exclusion remedy of Section 337 was the only way that a U.S. patent holder could enforce his rights as effectively against foreign-made infringing goods as he was otherwise able to do, under U.S. law, against U.S.-made goods.

In my opinion, the problem of enforcing of process patents presents an even stronger case for the "necessity" of some special remedy against foreign-made products, given that the holder of a U.S. process patent has no GATT-consistent remedy

of any kind against goods made in foreign countries. That is, only manufacture is an infringement under U.S. law, and so the holder of a process patent has no remedy at all against the sale or use of foreign-made goods that enter the U.S. market. I believe that some special remedy against foreign-made goods would be upheld on this ground.

It is a separate question, however, whether any particular special remedy would be upheld as "necessary." Based on the 1982 GATT decision, I believe the exclusion remedy of Section 337a (19 U.S.C. 1337a) would be upheld. But I do not believe that the discriminatory infringement remedy proposed by subsection (e) would be considered "necessary" to cure this enforcement problem. I believe that the GATT Contracting Parties would rule that subsection (e) violates GATT, reasoning as follows:

Although perfect equality of enforcement cannot be expected, the exception in Article XX does not permit governments to impose significantly more severe enforcement sanctions against foreign goods than those which domestic law imposes upon non-complying domestic goods. More severe enforcement could not be considered "necessary" if there were any reasonable alternative that provided the appropriate level of enforcement.

United States law does not impose infringement liability upon sale or use of domestic products made in violation of a process patent. The evident reason for doing so is the considerable burden that would be placed upon commerce in those goods, where buyers have no ready way of learning or verifying the process by which goods have been made. Consequently, a law which placed such infringement liability on those who deal in foreign goods would, without question, be creating a significantly more severe enforcement sanction for foreign goods than for domestic goods.

The only conceivable situation in which a more severe enforcement remedy might be considered "necessary" would be one in which there was simply no other way to prevent foreign-made goods from causing serious failure of enforcement. As currently described, the enforcement problem of process patents does not appear to constitute such an extraordinary problem. The United States does have an alternative remedy in the exclusion and cease-and-desist remedies of Section 337a. Even if one concedes that the exclusion remedy against foreign-made goods is not as effective as the infringement action against domestic manufacturers who violate process patents, it is difficult to believe that the exclusion remedy is so much less effective, and the damage to U.S. patent policy so great, that a remedy imposing an exceptionally burdensome discrimination in the other direction could be considered necessary.

To restate my opinion succinctly, I believe that proposed subsection (e) is, and would be found to be, a violation of United States obligations under GATT. Subsection (e) discriminates against foreign goods in violation of GATT Article III:4. The violation is not excused by the patent-enforcement exception of Article XX:d, because subsection (e) fails to meet the requirement that it be "necessary" to enforce the patent laws. Subsection (e) creates a far more severe enforcement sanction against foreign goods than against domestic goods, and this degree of excess enforcement cannot be shown to be "necessary" within the meaning of Article XX:d. Although I recognize that any application of the "necessary" standard involves a judgment call, in this particular case I believe the answer is quite clear.

I hope this response will prove helpful in the Committee's work. I would be happy to elaborate further, or to answer other questions should they arise. I wish you well in your deliberations.

Cordially,

Robert E. Hudec
Professor of Law

lp

December 6, 1984

Professor John Jackson
University of Michigan Law School
Ann Arbor, MI 48109

Dear Professor Jackson:

Thank you for agreeing to examine the legislative problem facing the Committee with respect to process patents.

As you know, current Federal law does not permit a patent owner to obtain damages from a foreign manufacturer who uses a process to make a product when that process is subject to a United States patent, and subsequently imports the goods into the United States. In an attempt to remedy this deficiency, the House has passed legislation (Section 101 of H.R. 6286, attached) which would provide that such acts constitute patent infringement. In response to this legislation the United States Trade Representative has argued that this bill would violate the GATT. Before proceeding further on this bill, it seemed appropriate to obtain the views of persons expert in these matters of international law.

The policy question before us is: Should the United States provide that it is an act of patent infringement for a person to import, use or sell goods within the United States when such goods are made outside the country in violation of a U.S. process patent? If so, does such legislation violate GATT? I have enclosed for your use copies of various memoranda and other materials which you may find of assistance.

Thank you in advance for agreeing to review this matter for the Committee.

Sincerely,

ROBERT W. KASTENMEIER
Chairman,
Subcommittee on Courts,
Civil Liberties and the
Administration of Justice

RWK:dbs

Enclosures

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March 1, 1985

MAR 4 1985

Mr. Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties,
and Administration of Justice
Committee on Judiciary
United States House of Representatives
Washington, DC 20515

Re: Proposed Patent Legislation and the GATT

Dear Congressman Kastenmeier:

You have asked my opinion about proposed legislation relating to "process patents," which legislation would provide infringement liability on persons importing, selling, or using goods in the United States which were produced without permission outside the United States by processes patented in the United States (HR6286 of the last Congress). In particular, you asked me two questions:

1. Should the United States provide that it is an act of patent infringement for a person to import, use or sell goods within the United States when such goods are made outside the country in violation of a United States process patent?

2. If so, does such legislation violate GATT?

I do not have expertise about patents or patent law, so I do not find it possible to answer these questions definitively without the expenditure of considerably more time. Consequently, my comments will highlight some factual information which would be needed to make a definitive determination.

To summarize my views succinctly, however, I would say the following: It does not appear to me that the proposed legislation is automatically a violation of GATT obligations. Much would depend upon the way that the legislation was framed, and on factual circumstances turning particularly on the "necessity" of the legislation in order to "secure compliance with laws or regulations ... relating to ... the protection of patents, ..." On balance, based on what I know about the availability of a Section 337 remedy, however, it appears that the proposed legislation would likely lead to a GATT conclusion of inconsistency with GATT obligations. My reasoning follows, pursuing the following outline.

I. What is the "Law" of GATT?

II. The GATT Clauses Related to the Proposal

III. The Question of "Necessary" in GATT Article XX(d): GATT Cases and Interpretive Material

IV. Types of Factual Information Which Would Influence a Resolution of the Legal Issues

V. Conclusions

I. What is the "Law" of GATT?

There is always an initial conceptual difficulty in interpreting many international treaties, and these difficulties are somewhat more acute in connection with the GATT. The question is: How do you ascertain whether something is a violation of GATT? Most commonly, the practice seems to be to try to predict how a dispute settlement panel, if one were constituted in GATT about the issue, would decide. Another approach is to try to predict how nation members of GATT would react in practice over time, and whether through such practice they would be deemed to accept a national measure such as that proposed, as consistent with GATT. Such practice would obviously be influenced by a panel determination, but the panel determination might not be decisive in all cases.

A third question, however, is present in each case of ascertaining "GATT law." This is the question of the "negotiating cost" of a national measure, in the context of various GATT proceedings and relationships. While GATT may tolerate a national measure which has some inconsistency with the GATT obligations, nevertheless such a measure might raise sufficient hostility on the part of other GATT members, as to create negotiating problems for the United States in connection with a number of other matters. In other words, even if the United States adopted a measure that was not branded as "clearly inconsistent" with its GATT obligations, it might find that such a measure was "costly" in terms of how nations responded in a negotiating context. I sense some concern about this third consideration of "legality" in the STR memorandum. Clearly sensitivity to this third consideration should be part of a decision whether to go ahead with a proposal.

II. The GATT Clauses Related to the Proposal

The GATT clauses relating to the proposed United States legislation include Articles III and XX of GATT.

Article III is the "National Treatment" article, calling for the treatment of imported goods at least as favorably as the treatment of domestic produced goods. Since United States domestic law does not provide for patent infringement liability on sellers of domestic goode produced by a violation of a process patent, to apply such liability to the sellers of imported goods clearly is inconsistent with the obligations of Article III.

However, Article XX of GATT provides certain "general exceptions" to other articles of GATT, including Article III. Article XX(d) provides an exception for measures "necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement ..., including those relating to ... the protection of patents ..."

The introductory paragraph of Article XX adds a requirement that "such measures are not applied in a manner which would constitute a means of arbitrary of unjustifiable discrimination between countries or ... disguise restriction on international trade ..."

The legal question then boils down to whether the proposed measure fulfills the exception of Article XX, and this seems to focus on two requirements:

1. That the measure is "necessary to secure compliance" with patent protection regulations and laws; and

2. That the measure is not a "disguised restriction on international trade."

(A third issue, that the current patent law is "not inconsistent with the provisions" of GATT, does not in my view need discussion.)

Thus we see that the proposed legislation must be evaluated in the factual context in which it would operate, to see whether: first, it is necessary; and second, whether it is a

disguised restriction on international trade.

III. The Question of "Necessary" in GATT Article XX(d): GATT Cases and Interpretive Material

Unfortunately, the practice and jurisprudence of GATT is not very revealing on our subject. There are only a very few prior complaint cases in GATT which address Article XX. These cases include the following:

Uruguay's 1961 Complaint against a Number of GATT Members

Canada's 1980 Complaint against the U.S. on Tuna Restrictions

Canada's 1981 Complaint against U.S. Section 337 Procedures in the Spring Assemblies Case

U.S.'s 1982 Complaint against Canada's FIRA

Apart from these cases, I do not find nor do I recall any other useful interpretative material of the particular clauses of Article XX, relating to patents. I also note that the STR memorandum does not refer to any practice or interpretive material other than that which I have mentioned.

I do not find anything in the panel determinations listed above which would force us to a conclusion one way or another on the issue we are considering.

The 1980 Tuna Case involved an issue not relevant to the patent proposal. The 1961 Uruguayan Complaint involved some "health" measures relevant to Article XX(b). This clause has a "necessary" requirement similar to that for patent laws in XX(d), but the GATT panel report seemed to recognize the difficult factual issues and merely called on the parties to "consult" with a view to resolving differences (GATT B.I.S.D., v. 11, at p. 111, 119, 133, 141, 145-7, 148).

The panels in the two other cases, reporting in 1983 and 1984, both touched on Article XX(d) issues. The 1983 report in the Spring Assemblies Case (B.I.S.D., v. 30, p. 107) noted that it was the first to address a patent issue under XX(d). In this case the

panel agreed with the United States that its Section 337 procedure was justified despite GATT Article III, because necessity was established at least for the particular goods and under then-existing United States patent law. The panel expressed some skepticism whether all of Section 337 would be upheld in GATT in all future cases, however. Clearly, however, the "necessity" issue was decided in the context of the facts of that situation. Among other things, the panel stated (paragraph 60):

> ... Against the background of the above considerations, it was the view of the Panel that United States civil court action would not have provided a satisfactory and effective means of protecting Kuhlman's patent rights against importation of the infringing product. The Panel took the view that the only way in which, under existing United States law, Kuhlman's right to the exclusive use of its patent in the United States domestic market could be effectively protected against the importation of the infringing product would be to resort to the exclusion order procedure. For the above reasons, therefore, the Panel found that the exclusion order issued by the ITC under Section 337 of the United States Tariff Act of 1930 was "necessary" in the sense of Article XX(d) to prevent the importation and sale of automotive spring assemblies infringing the patent, thus protecting the patent holder's rights and securing compliance with United States patent law.

In the FIRA report of 1984 (B.I.S.D., v. 30, p. 140), the panel disagreed with Canada's argument that "undertakings" connected with its Foreign Investment Review Act were "necessary" within the meaning of XX(d). It said, for example, (paragraph 5.20):

> ... Since Article XX(d) is an exception to the General Agreement it is up to Canada, as the party invoking the exception, to demonstrate that the purchase undertakings are necessary to secure compliance with the Foreign Investment Review Act. On the basis of the explanations given by Canada the Panel could not, however, conclude that the purchase undertakings that were found to be inconsistent with Article III:4 are necessary for the effective administration of the Act. The Panel is in particular not convinced that, in order to achieve the

> aims of the Act, investors submitting applications under the Act had to be bound to purchasing practices having the effect of giving preference to domestic products. It was not clear to the Panel why a detailed review of investment proposals without purchasing requirements would not be sufficient to enable the Canadian government to determine whether the proposed investments were or were likely to be of significant benefit to Canada within the meaning of Section 2 of the Foreign Investment Review Act.

Thus, in both panel reports it appears that the "necessity" question of XX(d) is essentially a question of the particular factual circumstances. It will be noted that the United States, in the Spring Assemblies Case, successfully defended its Section 337 as "necessary." In addition, it will be recalled that Section 337a was enacted in 1940 precisely to address the "process patent" situation. The existence of 337 and 337a thus may make alternatives "unnecessary." Or, per contra, the existence of a future alternative legal remedy might make Section 337 and/or 337a become "unnecessary." (This could be a risk of new legislation.)

IV. Types of Factual Information Which Would Influence a Resolution of the Legal Issues

The following are several types of factual information which would bear on the legal issue. Again, let me repeat, the focus is on the two questions: "necessity" and "disguised restriction." These questions might be the focus of future hearings, or a focus of a study of the record of hearings already held and evidence received.

1. To what degree are additional legislation or legal techniques necessary, for the protection of the United States process patent? How severe are the difficulties of obtaining relief against foreign parties who abuse process patents outside the borders of the United States? Is there ever any relief possible?

2. If it is determined that some additional remedy to protect United States process patents is necessary, what are the possible alternative options to providing such additional protection? The following, I am sure, have been considered:

a) Reliance on Section 337 as it is now framed.

b) Reliance on Section 337, with some amendments.

c) New provision in United States law, such as that proposed, imposing liability on importers of goods produced by the process patent infringement.

d) Variations on (c), including a "due notice" requirement similar to that in the proposal of HR6286 in the October 1, 1984 Congressional Record.

There may be other possibilities also.

In each case, it would be necessary to evaluate the degree to which alternative proposals could furnish the desired protection, and which have the least impact in restraining imports (i.e. were the least "disguised restriction on international trade").

3. Obviously an important question is whether Section 377 is sufficient. The STR memorandum seems to think that Section 337 is adequate protection, and therefore other new legislation would not be necessary. It seems to me that they have a point, but I do not find my knowledge of patent law and patent problems adequate to determine this. Granted that the United States patent holder does not receive damages under Section 337, nevertheless it does not seem to me that the question should necessarily focus on damages. The question should be: Is the United States process patent holder adequately protected in the United States market by an exclusion order which is available under Section 337?

Section 337a, devoted to process patents, seems to have been invoked more frequently in recent years and there is some information that it can be a relatively effective remedy, despite some administrative difficulties of Customs officers applying an exclusion order. (See Herrington, "U.S. International Trade Commission: Imported Articles Made by Patented Processes," Journal of World Trade Law, V. 14, No. 6, p. 549-555 (Nov-Dec 1980).) Certainly the ITC cases would need to be examined in detail (if this has not already been

done) to see if there were any reason why the 337 or 337a remedies were inadequate so as to make new legislation "necessary."

4. To what extent is the desire for new legislation an attempt to extend the reach of United States process patent legislation into other countries which do not recognize process patents?

   If the argument against the adequacy of Section 337 is simply based on the notion that without damages, the American process patent holder will not be able to adequately inhibit foreign utilization of process patents in locations where process patents are not recognized, then such proposed legislation poses considerable questions of policy which have been encountered in a number of other contexts (antitrust, SEC, etc.). To what degree should the United States try to impose its own legal rules on activity beyond its borders?

5. What do other countries which recognize process patents do to enforce those process patents with respect to goods imported?

   If many other GATT members already have legislation similar to that which is proposed in the United States, it would seem obvious that the exposure to a GATT panel determination against the United States would be considerably less. If such facts were the case, the United States would have an additional argument that the practice of other GATT Contracting Parties suggests that the proposed legislation, HR6286, is not a violation of GATT.

6. What would be the burdens imposed on importers by the proposed legislation?

   To simply render an importer liable when he imports goods produced by infringement abroad of United States process patents, could very well impose a considerable burden on importing of any goods. The uncertainty would add an additional cost to the importing, which cost would be similar to a tariff even if the cost could be insured against by appropriate guarantees or warranties, or insurance policies. Such a burden could easily be determined by a GATT panel to be a "disguised restriction on international trade," thus establishing that the proposed legislation would not come

within the exceptions of Article XX of GATT.

However, it might be possible to shape the legislation in a way so as to minimize the burden on the importing. If such burden were minimized, and it could be established that there was necessity for legal measures other than Section 337, then there could be the possibility of legislation similar to that proposed in HR6286 which would not result in a determination of United States inconsistency with its GATT obligations.

There may be a number of different ways to minimize the burden on importing. The suggestion in HR6286 that there would be no damages "unless the infringer was on notice" might point to one way to minimize the burden. This language might be extended to require that the patent holder serve notice on an importer, and until such notice has been served there would be no liability for patent infringement as to goods either already entered at Customs, or already contracted for. It might also be possible to have a de minimus threshhold, so that small entrepreneurs would not be exposed to a liability hazard. If these various "burden minimizers" make an American process patent holder feel that he is not getting adequate relief through the proposal, he could be reminded that he also has recourse to Section 337.

Thus, the legislation might be further tailored to be aimed at the truly abusive situation, where a foreign manufacturer has rather callously utilized a United States patented process for the purpose of targeting goods for export to the United States market in substantial quantities, which would undermine the effect of the United States process patent.

V. Conclusions

To summarize, it seems to me that we can make the following conclusions.

1. The proposed legislation is inconsistent with Article III of GATT, but raises issues about Article XX exceptions.

2. It is not possible with the facts that I have available, to conclude definitively that the proposed legislation would not qualify for the Article XX(d) exception.

Mr. Robert W. Kastenmeier
U.S. House of Representatives
Re: Proposed Patent Legislation
March 1, 1985
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3. To qualify for the Article XX exception, it must be demonstrated that the proposed legislation:

   a) Is necessary "to secure compliance with" United States process patent legislation; and

   b) The proposed legislation is not a "disguised restriction on international trade."

   The evaluation of the proposal in connection with these GATT clauses, involves considerable factual analysis, and a certain weighing or balancing. The more burdensome the proposal is, the more likely a GATT finding of inconsistency. Likewise, the less "necessary" the proposal is, particularly in the light of the availability of the alternative procedure under Section 337, the more likely a finding of inconsistency could result.

   On the other hand, if the "burden" were minimized to the fullest extent possible, by due notice and de minimus provisions, and it was established that the measure was necessary even with the availability of Section 337, a GATT panel might be willing to determine that the proposal is not a violation of United States obligations. In this connection, the practice of other nations can be very influential. Even in such a case, however, there exists some risk of an adverse panel ruling, and some risk of adverse negotiating costs to the United States.

Very truly yours,

John H. Jackson

JHJ/baa



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Roy H. Massengill
General Patent Counsel

March 11, 1986

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts,
Civil Liberties and the
Administration of Justice
U.S. House of Representatives
Committee on the Judiciary
Washington, D.C. 20515

Dear Mr. Kastenmeier:

Enclosed please find Allied-Signal Inc. responses to your questions submitted to us in your letter of February 19, 1986.

Thank you for your attention.

Very truly yours,

Roy H. Massengill

Enclosures

RHM/jas

KASTENMEIER QUESTIONS & ALLIED-SIGNAL RESPONSES

1. You appear before us urging enactment of both process patent reform and modification of the Tariff Act. Which of these two measures is more urgently needed?

We strongly reiterate that meaningful process patent reform and Tariff Act reform are urgently needed to deal with the serious negative trade balance and loss of American jobs. Process patent reform would provide the most effective remedies overall to U.S. process patent owners because rights would be adjudicated in the Federal District Courts where more remedies are available, particularly if the Federal District Courts are given in rem jurisdiction. Also process patent legislation is free of GATT issues. Modification of 337 legislation is needed to protect American companies from unfair trade at the early stages of commercial development; and, thus, the injury test should be removed.

2. In a recent case before the ITC Corning Glass lost, in part, because there was finding that there was insufficient proof of injury. Part of the reasoning of the ITC involved the fact that respondents had created a manufacturing facility in North Carolina and, therefore, imports were not the only basis for harm. In addition, the ITC decision is currently on appeal in Federal court. It is further my understanding that there is a patent infringement litigation pending in Federal court concerning this same subject. Assuming that Corning wins this litigation, won't they have already obtained a full day in court?

Obviously, it would be better to ask this question of Corning Glass. However, it appears that, if Corning wins the litigation against Sumitomo, it will be true that they will have had a "full day in court." There are two problems. First, Corning will have unfortunately had two "full days in court." The first was in the ITC and the second in the District Court. (In between these two full "days in court," there will have been a time-consuming and very expensive appeal, which would not have been necessary had Section 337 not required proof of injury.) During this period Sumitomo will have had a "free ride," with no threat of damages or loss of profits ill-gained.

Second, there is the matter of delay. District Court civil litigation is plagued with delays of several years in most jurisdictions. And, here, such delays are compounded by the expenditure of 12 months before the ITC and a subsequent appeal.

In any event, Corning cannot obtain relief from the importation of products made by Sumitomo in Japan using processes claimed in Corning's process patents until process patent legislation is enacted.

3. It has been argued that the proposed amendments to Section 337 would transform the ITC into an intellectual property court. It is further argued that this change will violate GATT. Critics also claim that the bill places enforcement of rights in a trade mechanism rather than a court where it should be. What is your view?

The proposed amendments to Section 337 would retain the concept of domestic industry. It is our view that violation of an intellectual property right practiced by domestic industry is injury to the very essence of American high technology.

The GATT panel in the Automotive Spring Assemblies case found that:

> ... in the Panel's view, it could reasonably be said that in considering what were the essential elements in legislation dealing with patent related cases an injury criterion could only be considered irrelevant.

The amendments to Section 337(a) to the Tariff Act are directed to those elements which the GATT panel considered irrelevant in patent-based cases. We believe that that resolves any perceived GATT problem.

The ITC presently does hear a number of intellectual property matters. How many more this legislation would add is a matter of speculation. But, such a possibility is no reason to fail to enact legislation needed to protect industry and jobs in the U.S.

4. New York Patent Law Association and others have suggested that the process patent legislation should be limited to either imports or to imports and "first sale." What are your views on these suggestions?

There is no sound business reason for treating differently imported products based on whether they infringe a product patent or a process patent. Arguments that unsuspecting retailers will be harassed by lawsuits are not sound, as evidenced by past practice regarding product patents. Adequate notice provisions should protect those infringers who are further down the line.

99TH CONGRESS

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February 19, 1986

Mr. James Flug
Counsel, Generic Drug Manufacturers Association
c/o Lobel, Novins and Lamont
1275 K Street, N.W.
Washington, DC 20005

Dear Mr. Flug:

In order to complete the hearing record on intellectual property and trade, I submit the attached questions. It would be helpful to have a response to these inquiries by March 10, 1986.

Thank you in advance for your assistance.

With warm regards,

Sincerely,

ROBERT W. KASTENMEIER
Chairman
Subcommittee on Courts,
Civil Liberties and the
Administration of Justice

RWK:dbv

Enclosures

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U.S. House of Representatives
Committee on the Judiciary
Washington, DC 20515
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GENERAL COUNSEL
M. ELAINE MIELKE
STAFF DIRECTOR
GARNER J. CLINE
ASSOCIATE COUNSEL:
ALAN F. COFFEY, JR.

February 19, 1986

Mr. Harvey Bale
Assistant U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20506

Dear Mr. Bale:

In order to complete the hearing record on intellectual property and trade, I submit the attached questions. It would be helpful to have a response to these inquiries by March 10, 1986.

Thank you in advance for your assistance.

With warm regards,

Sincerely,

ROBERT W. KASTENMEIER
Chairman
Subcommittee on Courts,
Civil Liberties and the
Administration of Justice

RWK:dbv

Enclosures

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Washington, DC 20515
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February 19, 1986

The Honorable Paula Stern
Chairwoman
International Trade Commission
701 E Street
Washington, DC 20436

Dear Madam Chairwoman:

In order to complete the hearing record on intellectual property and trade, I submit the attached questions. It would be helpful to have a response to these inquiries by March 10, 1986.

Thank you in advance for your assistance.

With warm regards,

Sincerely,

ROBERT W. KASTENMEIER
Chairman
Subcommittee on Courts,
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February 19, 1986

Mr. Stephan Lawton
Washington Counsel, Genentech
c/o Pierson, Ball and Dowd
1200 18th Street, N.W.
Washington, DC 20036

Dear Mr. Lawton:

In order to complete the hearing record on intellectual property and trade, I submit the attached questions. It would be helpful to have a response to these inquiries by March 10, 1986.

Thank you in advance for your assistance.

With warm regards,

Sincerely,

ROBERT W. KASTENMEIER
Chairman
Subcommittee on Courts,
Civil Liberties and the
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February 19, 1986

Mr. Roy H. Massengill
General Patent Counsel
Allied Signal, Inc.
1050 Connecticut Avenue, N.W.
Suite 800
Washington, DC 20036

Dear Mr. Massengill:

In order to complete the hearing record on intellectual property and trade, I submit the attached questions. It would be helpful to have a response to these inquiries by March 10, 1986.

Thank you in advance for your assistance.

With warm regards,

Sincerely,

ROBERT W. KASTENMEIER
Chairman
Subcommittee on Courts,
Civil Liberties and the
Administration of Justice

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February 19, 1986

QUESTIONS FOR THE UNITED STATES TRADE REPRESENTATIVE

1. Please briefly describe GATT, its application to intellectual property and the consequences of a GATT violation.

2. Last Congress the staff of the USTR claimed that H.R. 6286 (relating to protection of infringing imports) violated the General Agreement on Tariff and Trade. Is this still your view? If so, please explain your position.

3. Professor John Jackson (University of Michigan) has written to Chairman Kastenmeier suggesting that creation of an alternative remedy for enforcement of process patents may make section 337a of the Tariff Act "unnecessary" and therefore violative of GATT. What is your response to this possibility?

4. In the Spring Assembly case brought by Canada in 1981 there is some indication in the panel discussion that existing ITC procedure could, in another case, run afoul of GATT (see para. 66). In light of those comments, shouldn't we be extremely cautious before we modify the Tariff Act? Don't the references in paragraphs 60 and 66 of the Panel discussion to "existing law" indicate that changes in that changes in that law -- either in title 35 or in the Tariff Act -- would produce a different result?

5. If the proponents of process patent reform are correct that the existing ITC remedy is inadequate for the protection of process patents, does this not establish that creation of a remedy for process patent infringement in Federal court is "necessary" within the terms of ARTICLE XX of GATT?

6. During the Committee deliberations last Congress the staff of the USTR presented a memorandum[1] which argued that existing ITC remedies were adequate, yet this Congress you are arguing that the remedies are insufficient. How do you reconcile these views?

7. Opponents of process patent legislation have argued that such legislation is merely a thinly disguised attempt to extend American law extraterritorially to countries which do not protect process patents. What is your view?

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[1] See Hearing before the Subcommittee on Courts, Civil Liberties and the Administration of Justice, Innovation and Patent Law Reform, Part 3, page 2424 (1984).

Con't - QUESTIONS FOR THE U.S. TRADE REPRESENTATIVE

8. The New York Patent Law Association has argued that providing for liability for the users and sellers of domestically made goods in violation of a process patent would be going too far. They have suggested that liability be limited to "first sale" or importation of the infringing goods. What is your view of this proposal?

9. Your testimony has proposed that the bill be amended to make sure that the process patent be directly involved in the infringement. Could you indicate how such an amendment would work with respect chemicals, pharmaceuticals and electronics?

10. Opponents of process patent legislation have criticized the use of presumptions. How do you respond to these claims? How important are such provisions to the effectiveness of the bill?

11. Please describe the efforts (bi-lateral and multilateral) of USTR to achieve improved intellectual property law protection abroad.

12. Opponents of amendments to section 337 of the Tariff Act have argued that these changes would transform the ITC from a trade forum to an intellectual property court. How do you view this criticism?

13. Under this legislation would respondents be able to raise defenses to alleged infringements such as antitrust violations or price gouging by the petitioners?

14. Some proponents of reform of the ITC have advocated substantial reductions in the time period within which the ITC must act. What is your view of the advisability and feasibility of these proposals?

15. What is the current status of the Aramid Fiber investigation? What GATT challenges are likely from the European Community?

16. Dr. Stern of the ITC claims in her testimony that elimination of the "domestic industry" requirement will unwisely involve the ITC in patent disputes between foreign companies who want to enter the U.S. Market. What is your view of this claim?

17. If §337 is amended as proposed, will this new law present any negotiating problems with our trading partners who already dislike §337?

February 19, 1986

QUESTIONS FOR THE CHAIRWOMAN OF THE ITC

1. Opponents of amendments to section 337 of the Tariff Act have argued that these changes would transform the ITC from a trade forum to an intellectual property court. How do you view this criticism?

2. What percentage of cases before the ITC currently involve the enforcement of intellectual property rights (copyright, patent and trademark)? How would the caseload of the ITC change if these amendments were adopted? What increase in staff would be necessary?

3. Should the Tariff Act continue to require that the petitioners establish that there is a domestic industry before they can obtain relief? Do universities currently face problems under section 337 in establishing the existence of a domestic industry?

4. In the recent Duracell battery case (which involves allegations of greymarketing or parallel importing) the President reversed the ITC on policy grounds. Subsequently the Court of Appeals for the Federal Circuit found that it had no jurisdiction to review the President's decision. Should the CAFC have jurisdiction in such cases? Should the ITC remedies be supplemented, as some suggest, to permit antitrust exemptions for industries adversely affected by unfair trade practices in section 337 cases?

5. Under this legislation would respondents be able to raise defenses to alleged infringements such as antitrust violations or price gouging by the petitioners?

6. Some proponents of reform of the ITC have advocated substantial reductions in the time period within which the ITC must act. What is your view of the advisability and feasibility of these proposals?

7. Opponents of process patent reform argue that the existing ITC remedies are adequate for the protection of process patents. Do you agree with these claims? In what ways would the existence of a District Court remedy for process patent infringement affect the caseload of the ITC?

8. Please indicate which §337 cases have raised the question of "injury" and briefly describe each case.

9. What is the current law with respect to universities (and other small entities) on the question of whether they constitute "domestic industry"?

February 19, 1986

QUESTIONS FOR ALLIED SIGNAL WITNESS

1. You appear before us urging enactment of both process patent reform an modification of the Tariff. Which if these two measures is more urgently needed?

2. In a recent case before the ITC Corning Glass lost, in part, because there was finding that there was insufficient proof of injury. Part of the reasoning of the ITC involved the fact that respondents had created a manufacturing facility in North Carolina and, there fore, imports were not the only basis for harm. In addition, the ITC decision is currently on appeal in Federal court. It is further my understanding that there is a patent infringement litigation pending in Federal court concerning this same subject. Assuming that Corning wins this litigation, won't they have already obtained a full day in court?

3. It has been argued that the proposed amendments to section 337 would transform the ITC into an intellectual property court. It is further argued that this change will violate GATT. Critics also claim that the bill places enforcement of rights in a trade mechanism rather than a court where it should be. What is your view?

4. New York Patent Law Association and others have suggested that the process patent legislation should be limited to either imports or to imports and "first sale". What are your views on these suggestions?

February 19, 1986

QUESTIONS FOR GENENTECH WITNESS

1. Would it be fair to say that the major problem which will face the biotech industry with respect to process patents is the importation of offending goods rather than the use or sale of goods domestically made?

2. Some biotech companies are currently relying on plant patents to protect their intellectual property. Does the legislation before us adequately protect this form of intellectual property, especially relative to unfair imports?

3. What are your views about limiting liability under the process patent bill to either "first sale" or importation?

4. Are any forms of statutory presumptions necessary to protect biotechnology based process patents from being infringed?

5. You seem to urge the right to a jury trial in ITC proceedings. This idea seems to run afoul of Article III of the Constitution. Do you agree?

February 19, 1986

QUESTIONS FOR GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

1. If a pharmaceutical product is made overseas (in Italy, Poland, Taiwan or South Korea) in violation of an American process patent and an American customer affirmatively knows these facts and buys the goods anyway, what penalty, if any, should be imposed on the american purchaser? Under current law the patent owner could bring a case before the ITC to exclude the goods, but could not obtain monetary damages against the importer in Federal court.

2. Is you basic objection to the process patent legislation that your cost will be increased if you are forced to purchase pharmaceutical products which are not made in violation of a process patent? Do generic drug makers purchase goods overseas to avoid U.S. process patents?

3. Mr. Engelberg, in your Senate testimony you draw attention to the testimony in 1968 of the Assistant Attorney General, Antitrust Division, in opposition to a broad process patent bill. You fail to note, however, that the President and Justice Department did support a bill which would have afforded process patent protection against infringing imported goods if the country of origin did not provide for process patent protection. What is your view of this proposal?

4. What amendments would be necessary to the process patent bill to modify or reduce your opposition?

5. What duty if any, does a purchaser have to determine whether the goods they purchase abroad have not been made in violation of a process patent? If none, then aren't such purchasers inviting disruption of their business if the patent holder obtains an exclusionary order from the ITC?

6. Should the Tariff Act be amended to permit respondents to assert counterclaims? Should the Tariff Act be amended to eliminate the requirement that the petitioner show that a domestic industry has been injured?

7. What adverse consequences to the right of generic pharmaceuticals occur if the trademark amendments to the Tariff Act were enacted?

8. What precedential value does the innocent infringement section of the Semiconductor Chip Protection Act, 17 U.S.C. 907, have for process patents?

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March 6, 1986

Hon. Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Re:Response of GPIA to Questions on Intellectual Property and International Trade

Dear Congressman Kastenmeier:

This letter sets forth the answers of the Generic Pharmaceutical Industry Association (GPIA) to the questions posed in your letter of February 19, 1986.

Question 1

The question presumes that the use of a process to produce a product under circumstances where there is no patent infringement or other violation of law in the country of origin is nevertheless a violation of U.S. law. Under current law that is not the case. A remedy exists in the ITC only when infringement cause injury to an efficiently operated domestic industry which is engaged in the exploitation of the patent rights. The current state of the law is based upon a recognition that the extension of U.S. law to extraterritorial activity is improper and that the only appropriate remedy is to prevent importation.

GPIA does not oppose a change in the current law which would create the possibility of a monetary award in cases involving a willful and deliberate violation of the current version of 19 U.S.C.1337. It must be remembered, however, that the ITC is not a court of law and does not provide a respondent with the same opportunity to develop and present defenses to a claim of willful patent infringement as is provided in cases arising in the district courts under Title 35 of the U.S.Code and the Federal Rules of Civil Procedure. For that reason the decisions of the ITC have no res judicata effect under current law.

Question 2

It is well known that the cost of the active ingredient in the typical pharmaceutical tablet or capsule is not a significant factor in the cost of producing the product. For example, in the recent ITC controversy involving indomethacin the difference in the selling price of allegedly infringing indomethacin and non-infringing indomethacin was less than $20/kilogram. Since, each kilogram of active ingredient produces almost 40,000 tablets, the difference between the price of infringing and non-infringing material was clearly meaningless as a competitive factor between the brand name and generic product in their final dosage forms. Given that fact, GPIA members would have gladly purchased indomethacin made by a non-infringing process had they known of the patent and the potential infringement problem. Indeed, the consequences of a finding of infringement are devastating because FDA approval for any product is limited to the specific material obtained from a specific source. Accordingly, an ITC Exclusion Order forces the generic manufacturer off the market for the 2 years which are normally required to formulate, test and obtain FDA approval for a new version of the same product using an active ingredient obtained from a new source. The purchase of the raw material from a non-infringing source or from the patent owner is obviously less expensive for the generic manufacturer even if those sources charge a higher price per kilogram. The payment of a reasonable royalty to the patent owner would also be a less costly and more desirable alternative than infringement.

Unfortunately, the major drug companies will not sell raw materials or grant licenses to generic companies. Their goal is to use any process patents to further delay generic competition after all product and use patents have expired. GPIA members are forced to purchase their active ingredients abroad because there are usually no other domestic sources for these ingredients. Moreover, the generic manufacturer usually has no knowledge of the process used by a foreign supplier to manufacture an active ingredient because that information is a legitimate trade secret of the manufacturer. Nor does the generic company normally have knowledge of the existence of any process patents because the brand name companies get hundreds of patents annually and the potentially relevant patents are not readily identifiable.

The foregoing combination of factors creates a risk of innocent infringement by generic companies. The brand name companies could reduce or eliminate that risk by marking their products with the relevant process patent numbers or by granting reasonable royalty licenses. In situations where more than one process is available a process patent can not serve to prevent legitimate competition and the sale of the raw material (or licensing) would generate domestic jobs and revenues. Brand name companies choose not to do this business only because they seek the windfall benefit which will result when an innocent infringement occurs and a generic competitor is forced off the market.

Question 3

GPIA members are not looking for a "free ride" on the legitimate patent rights of third parties and do not, in fact, get such a free ride under current law because of the existing ITC remedy and the previously discussed adverse economic consequences which result from an ITC Exclusion Order. Our members oppose the proposed new law only because they do not want to be put in the middle of an infringement controversy which they are unable to defend due to a lack of knowledge concerning the processes which are used to produce the products which they purchase abroad. They believe that any system which limits infringement litigation to the real parties in interest is preferable to a system which forces innocent purchasers of products to become surrogate defendants in cases which they can not defend.

The Attorney General's proposal appears to be based on the sound belief that, whenever possible, the patent owner should obtain foreign patents and sue the actual infringing manufacturer in the country where the infringement occurred. GPIA supports that approach. Moreover, ITC proceedings are available in those circumstances where there are no foreign patents or where a suit in the foreign country is impractical or unavailable. GPIA does not seek repeal of the ITC remedy.

Given the existing procedures for preventing unfair competition from infringing imports, it is unnecessary to provide for a law suit against the innocent domestic purchaser of products which may have been made by an infringing process. If patent owners are given the right to sue innocent purchasers who lack the means to defend themselves, there is a strong likelihood that infringement lawsuits will be used as coercive economic weapons to force innocent purchasers to go out of business rather than face an unknown and unquantifiable monetary risk.

Question 4

GPIA believes that pharmaceutical process patents should be exempt from the proposed legislation because of the special treatment already accorded to pharmaceutical patents in the 1984 Drug Price Competition Act. Alternatively, any legislation should include at least the following provisions:

(a) A requirement that, whenever possible, any suit for process patent infringement be brought against the actual user of the process.

(b) A requirement that the patent owner establish a substantial likelihood of success on the merits of a claim before an innocent purchaser becomes liable for any damages. Some mechanism is clearly necessary to prevent the mere self-serving and untested allegation of infringement from creating instant liability particularly in circumstances where there are several commercially viable processes for producing the same product.

(c) A limitation of damages to a reasonable royalty with no injunctive relief unless the infringement was willful or deliberate. This should be mandatory in situations where the patent owner could have marked its product with the patent number or otherwise taken steps to help avert an innocent infringement.

One way to achieve the foregoing objectives would be to leave the ITC as the principal vehicle for adjudicating process patent infringement claims but to provide for a damage suit in the district courts in those cases where the ITC makes a finding that an infringement has been willful and deliberate or that there has been some other type of conduct which demonstrates that the purchaser of a product was not an innocent infringer.

Question 5

As previously noted, there is no practical way to impose a duty on purchasers of products to determine the presence or absence of infringement because they lack knowledge of either the patents or the processes actually used by their supplier. Accordingly, purchasers are always likely to be at risk that there could be a severe disruption of their business as a result of an ITC Exclusion Order. However, it is wrong to assume that all foreign manufacturers are pirates or that U.S. manufacturers are powerless to take effective action abroad. In the majority of instances involving pharmaceuticals, the foreign suppliers of active ingredients to the U.S. generic industry are also engaged in a more significant world wide competition with the brand name companies. As a result they are aware of patents and take steps to avoid infringement. For that reason, there have been very few cases in the ITC involving pharmaceuticals.Contrary to popular belief, there is no widespread infringement problem which requires any legislative solution.

GPIA members fear that if a new law permits private law suits against individual U.S. purchasers there is no assurance that a foreign supplier will defend those suits. The decision to defend a particular case will depend on a variety of economic or world wide competitive factors rather than the merits of each case. Under the current ITC proceeding there is less likelihood of default because the entire generic industry is usually involved in a common proceeding and the entire U.S. market for a particular product is usually at stake. Moreover, independent government investigators participate in the proceeding and use the subpoena power of the government to insure that there is a reasonable basis for issuing an Exclusion Order. These factors normally combine to prevent the mere assertion of an infringement claim from coercing capitulation by innocent U.S. purchasers without regard to the merits of a claim.

Question 6

The Tariff Act was designed to protect domestic industries from unfair competition by foreign imports and to provide speedy relief via an Exclusion Order when such unfair acts are found to exist. If this rationale for the ITC's jurisdiction is eliminated then there is no reason for the continued existence of the ITC. The ITC is not a court of law and lacks many of the important

safeguards of a district court operating under the Federal Rules of Civil Procedure. There is no good reason to permit the ITC to exercise parallel jurisdiction over patent matters which, until now, have been under the exclusive jurisdiction of the federal district courts.

During the proceedings which led to the 1984 Drug Price Competition Act the brand name companies claimed that a minimum of 30 months was required to litigate a patent case. These same companies now urge that the ITC, which has no trained judges and many commissioners who are not even lawyers, can decide patent cases in 3 to 6 months. There is no credible reason to believe that the ITC can carry out such a task and do a credible job.

At most, we believe that Section 337 should be amended so as to insure that universities, individual U.S. inventors and other domestic organizations are not denied relief in cases where a patent is found to be valid and infringed provided that it is evident that the imported products will prevent the full enjoyment of the patents by a domestically operating entity.

Question 7

The proposed changes in the ITC's jurisdiction over trademark infringement has no impact on GPIA members since the transactions in which members engage are usually of an industrial nature and do not involve any advertising or promotion under circumstances where ther is likely to be confusion with respect to the source of origin of goods. In any event the ITC's jurisdiction over trademark matters will largely duplicate relief which is already available under other laws.

Question 8

The Semiconductor Chip Protection Act has precedential value because it recognizes that there should be limitations on both damages and injunctive relief awards against innocent infringers. That Act provides that there will be no damages whatsoever prior to notice of a claim of infringement and that the remedy for goods which are on hand or on order as of the date of such notice will be limited to a reasonable royalty. At a minimum, similar provisions should be incorporated into the process patent bill. Moreover, in the case of pharmaceutical process patents it is so easy for a brand name company to identify all relevant process patents in FDA labeling or product packaging that the failure to do so should result in a permanent denial of injunctive relief or damages in excess of a minimal royalty. If innocent purchasers of products are to be held liable for the manner in which those products are made they are entitled to a fair advance warning by the patent owner so that an effort can be made to avoid infringement.

Please let us know if we can be of any further assistance in your committee's further consideration of the pending legislation.

Very truly yours,

Alfred B. Engelberg

99TH CONGRESS

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U.S. House of Representatives
Committee on the Judiciary
Washington, DC 20515
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CHAIRWOMAN

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November 22, 1985

The Honorable Paula Stern
Chairwoman
International Trade Commission
701 E Street
Washington, D.C. 20436

Dear Madam Chairwoman:

The Committee on the Judiciary has jurisdiction over legislation affecting copyrights, mask works, patents and trademarks. I am writing to request information concerning section 405 of H.R. 3777, which proposes amendments to section 337 of the Tariff Act of 1930 relating to intellectual property. In order to evaluate this legislation it would be helpful to have detailed answers to the following questions:

(1) To what extent does the legislation expand or contract the rights of a person who holds a valid United States copyright, mask work right, patent or trademark?

(2) To what extent does the legislation reflect current ITC practice or precedent?

In light of the speed with which this legislation is moving, it would be helpful to have a response within 10 days. Thank you in advance for your assistance.

With best regards,

Sincerely,

// Peter W. Rodino, Jr.

PETER W. RODINO, JR.
Chairman

PWR:dbm

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The Register

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JUDICIARY COMMITTEE

December 6, 1985

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The Honorable
Peter W. Rodino, Jr.
Chairman, House Committee on Judiciary
2462 Rayburn House Office Building
Washington, D. C. 20515

Dear Mr. Chairman:

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D.C.
20540

This letter addresses the question contained in your letter of November 22, 1985. That was: "To what extent does [Section 405 of H.R. 3777] expand or contract the rights of a person who holds a valid United States copyright or mask work right?"

The short answer, I fear, is the lawyer's stock in trade, "It depends." Some think that the bill will dramatically increase the practical strength of owners of intellectual property rights by affording them a strong new presumption in proceedings before the International Trade Commission. Others think that, if it has any effect at all, it might slightly expand the rights of United States intellectual property owners. The longer answer follows.

Holders of valid U.S. copyrights or mask work rights who believe that importation of unauthorized copies of their works is harming them may seek relief in a United States District Court under sections 501, 602, or 910 of Title 17, or from the International Trade Commission under section 1337 of Title 19 (also known as section 337 of the Trade Act of 1930). The basic scope of rights and remedies, and the availability of court relief under traditional copyright and the newer mask work provisions of Title 17 is in no way affected by H.R. 3777. This bill would affect ITC proceedings only, and reasonable persons differ about the extent to which those proceedings may be affected. Its chief effect, if enacted, would be to make statutory a presumption that the importation of articles that infringe the rights of a U.S. owner is unfair and has the effect or tendency to destroy or substantially injure a U.S. industry. In essence, this would make the importation of infringing articles into a per se "337" violation. In addition, it would remove a requirement that the U.S. industry be efficiently and economically operated before it could seek relief, and would halve the time period available to the ITC in its decision-making process.

The extent to which this change would expand U.S. owners' rights is unclear and might best be explored in a hearing in the Subcommittee on Courts, Civil Liberties and the Administration of Justice. Such a hearing might compare the remedies available to copyright or mask work owners in the courts with the owners' apparently improved position before the ITC.

It appears to the Copyright Office that the most important practical difference between seeking relief from infringing imports in court and before the ITC is probably that the latter body is likely to reach a result more quickly, in part because its docket may be shorter than that found in many district courts, and in part because it will not entertain a defense predicated on the alleged invalidity of the copyright or mask work right, but will defer to court judgments on such claims. However, this latter distinction may not have much practical benefit, since a respondent-importer could put the validity of the petitioner's copyright or mask work right at issue, and the case would go to court anyway. In that case, the "speedy docket" benefit could disappear.

By making infringing importation a per se violation, rights owners would probably come to view the ITC as a more convenient forum than they do under present law. It should be noted, however, that some practitioners think that the presumption that H.R. 3777 would codify is now largely in effect as a matter of practice, at least with respect to copyrights. As a result, this advantage also is somewhat suspect.

What is clear is that while no new rights or remedies are created, nor new fora opened, section 405 of H.R. 3777 proposes a change of unknown magnitude in the burden of proof that an owner of rights must meet in the ITC. Questions concerning the impact of that proposal on owners of copyrights and mask work rights can probably best be answered at a hearing in the Subcommittee most familiar with copyright and mask work matters.

If I can be of further service to you, please let me know.

Sincerely,

Ralph Oman
Register of Copyrights

CHAIRWOMAN



UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, D.C. 20436

December 17, 1985

Honorable Peter W. Rodino, Jr.
Chairman
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This letter is in response to your letter of November 22, 1985, requesting information concerning section 405 of H.R. 3777. Section 405 proposes amendments to section 337 of the Tariff Act of 1930.

Your letter requested answers to two questions. The questions and the Commission's answers thereto are given below.

> Question 1: To what extent does the legislation expand or contract the rights of a person who holds a valid United States copyright, mask work right, patent or trademark?

Answer 1: The legislation would not expand or contract the rights of a person who holds a valid United States copyright, mask work right, patent or trademark. It would, however, make it somewhat easier for such a person to establish a violation of section 337.

Section 337 declares unlawful unfair methods of competition and unfair acts in the importation or sale of goods when the effect or tendency of such unfair methods of competition or unfair acts is to destroy or substantially injure an efficiently and economically operated domestic industry, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States. 19 U.S.C. § 1337(a). The U.S. International Trade Commission is empowered to investigate alleged violations of section 337 and, if a violation is found, issue exclusion orders and cease and desist orders. 19 U.S.C. § 1337(b)-(f). The Commission must complete section 337 investigations within 12 months of the publication of its notice of investigation in the Federal Register.

19 U.S.C. § 1337(b)(1). The Commission may take up to 18 months to complete section 337 investigations designated "more complicated." 19 U.S.C. § 1337(b)(1).

Section 405 of H.R. 3777 would make it unnecessary, in section 337 investigations based on alleged copyright, mask work right, patent, or trademark infringement, for the holder of the intellectual property in question to establish either that the domestic industry is efficiently and economically operated or that the effect or tendency of the infringement is to destroy or substantially injure the domestic industry. Elimination of the efficient/economic operation and injury requirements should make it easier for holders of intellectual property rights to establish a violation of section 337. Elimination of those requirements would not, however, expand or contract the rights of holders of intellectual property since those rights are established by Federal statutes not amended by section 405.

It should be noted that focusing on the question of the expansion or contraction of the rights of holders of intellectual property may obscure the fact that section 337 is a trade statute, not an intellectual property statute. The Commission has a public policy role in section 337 that goes beyond the adjudication of private business disputes. Therefore, more than the rights of the intellectual property holder should be assessed in considering this legislation. Such issues as the consistency of section 405 with the international obligations of the United States, the potential for friction with our trading partners, and consistency with the trade policy goals of the United States, should also be considered.

Question 2: To what extent does the legislation reflect current ITC practice or precedent?

Answer 2: Current ITC practice and precedent are based on section 337. The legislation reflects current ITC practice and precedent in that it continues the requirement that the holder of the intellectual property right establish the existence, or likely establishment, of a domestic industry. Specifically, section 405 requires that the Commission determine the existence, or likely establishment, of "an industry consisting of the United States operations of the owner of the intellectual property at issue and its licensees, devoted to the lawful exploitation of the [intellectual property] rights. . . ." H.R. 3777, p. 76, lines 5-8. This is essentially the test currently used by the Commission

to determine the existence of a domestic industry in section 337 investigations. See, e.g., ITC Inv. No. 337-TA-114, Certain Miniature Plug-In Blade Fuses, USITC Pub. 1337 (Jan. 1983) (patent); ITC Inv. No. 337-TA-105, Certain Coin-Operated Audiovisual Games and Components Thereof (viz. Rally-X and Pac Man), USITC Pub. 1267 (July 1982) (copyright); ITC Inv. No. 337-TA-152, Certain Plastic Food Storage Containers, USITC Pub. 1563 (Aug. 1984) (trademark).

The legislation does not reflect current ITC practice and precedent in that it removes the current requirements that complainant establish (1) that the domestic industry is efficiently and economically operated and (2) that, in cases based on alleged copyright, mask work right, patent, or trademark infringement, the effect or tendency of respondents' infringement is to destroy or substantially injure the domestic industry.

The legislation also does not reflect ITC current practice and precedent in that it would require the Commission to determine whether or not there is a violation of section 337 "not later than 6 months (9 months in more complicated cases) after the date of publication of notice of such investigation." H.R. 3777, p. 77, lines 16-19. As noted, the Commission currently must determine whether there is a violation of section 337 within 12 months (18 months in more complicated cases) after publication of its notice of investigation. In contrast, patent infringement actions in Federal court take substantially more time. The median length of time required to complete patent infringement actions going to trial in Federal court is about two and one-half years, and 10 percent of the patent infringement cases going to trial take 5 years to complete.

By reducing by half the time allotted to the Commission to complete section 337 investigations, the legislation would likely require major changes in the way such investigations are conducted. The time periods currently provided for respondents to answer the complaint (20 days) and for parties to respond to motions (10 days) would probably have to be shortened. The amount of discovery taken by the parties would certainly have to be curtailed. Finally, the legislation would substantially reduce the amount of time available to the Commission's administration law judges and to the Commission for reaching decisions on whether section 337 has been violated and, in the case of the Commission, on the appropriate remedy in the event a violation is found. Section 405's shortening of the statutory time limits for completion of section 337 investigations raises a serious question concerning the Commission's ability to conduct the violation phase of such investigations in conformity with the adjudicative provisions of the Administrative Procedure Act (5 U.S.C. §§ 554-557), as required by section 337(c).

Please feel free to call on us as you continue to consider this issue.

Sincerely yours,

Paula Stern
Chairwoman

GENERAL COUNSEL OF THE
UNITED STATES DEPARTMENT OF COMMERCE
Washington, D.C. 20230

6 JAN 1986

Honorable Peter W. Rodino, Jr.
Chairman
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter concerning section 405 of H.R. 3777, a bill to amend 337 of the Tariff Act of 1930 (19 U.S.C. 1337). You asked the extent to which the legislation would expand or contract the rights of a person who holds a valid U.S. patent or trademark. On balance, I believe that section 405 would slightly expand the patent and trademark owners' access to remedies under section 337 of the Tariff Act.

Section 405 would change the findings which the International Trade Commission (ITC) must make before a petitioner may be granted relief under section 337 of the Tariff Act. The bill would eliminate the requirement that an industry be "efficiently and economically operated". The bill would also eliminate the need for a patent or trademark owner to present evidence of economic injury in order to secure relief from unauthorized importation of patented and trademarked products and products made by patented processes. Section 405 would also expressly require that the ITC find that an industry consisting of U.S. operations related to exploitation of a patent or trademark existed or was likely to be established before a petitioner would be given access to remedies under section 337. Finally, the time allowed for the ITC to issue its determination would also be shortened.

By statutorily conditioning relief on an initial ITC determination that the "industry consisting of the United States operations of the owner of the intellectual property at issue and its licensees ... exists or is likely to be established," section 405 would codify ITC decisions on standing. In patent cases, the ITC considers as the industry only those operations within the United States covered by (or directly related to) the patent. If those operations are conducted offshore, relief will be denied unless the petitioner conducts sufficient related activities in the United States. This requirement is less of a problem in

trademark cases, since the ITC has taken a somewhat broader view regarding the operations of a trademark owner which are related to a trademark. For example, the ITC granted relief to a trademark owner and denied relief to a patent holder on the same general facts. Compare In re Certain Miniature, Battery Operated All Terrain, Wheeled Vehicles, Inv. No. 377-TA-122 (Oct. 1982) with In re Certain Cube Puzzles, Inv. No. 337-TA-112 (Jan. 1983).

ITC actions would be simplified by removing the requirement to show that an industry is efficiently and economically operated. While questions by respondents directed to this subject are an annoyance to patent and trademark owners, we are not aware of any cases in which this requirement has deprived a petitioner of a remedy.

Removing the injury requirement in patent and trademark cases would simplify ITC actions. This, of course, would make it easier for an intellectual property owner to exclude competing goods. For some petitioners, the difficulty showing injury is very small, but where injury is attributable to several causes, the petitioner may be unable to make the requisite showing and therefore will be denied relief. This may be particularly important for an industry facing technological change.

Finally, shortening the time permitted to complete an investigation and determination would generally benefit a patent or trademark owner. It would provide a final determination much sooner. The patent or trademark holder may particularly find this useful where the articles at issue have not been excluded during the investigation. The chief advantage is likely to be tactical, however, since a petitioner can prepare for the ITC case in advance, and the stricter time periods will limit the respondent's preparation of a defense.

This letter does not address any concerns other than the single question posed in your letter. I thank you for the opportunity to comment.

Sincerely,

Douglas A. Biggs

THE UNITED STATES TRADEMARK ASSOCIATION
6 EAST 45TH STREET • NEW YORK, N.Y. 10017
TELEPHONE: 212-986-5880

EXECUTIVE OFFICES

April 23, 1986

The Honorable Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties and
the Administration of Justice
2137 Rayburn House Office Building
Washington, D.C. 20515

Re: H.R. 4539, "Intellectual Property and Trade Act"

Dear Mr. Chairman:

USTA has reviewed H.R. 4539, the "Intellectual Property and Trade Act," and I take this opportunity to convey to you USTA's position on the Lanham Act amendments contained in section 102. At the present time, USTA has no position on the other aspects of the bill.

While the Lanham Act amendments contained in section 102 of H.R. 4539 are technical and may appear to be of a "housekeeping" nature, some of them are quite controversial and their enactment could produce negative results. For example, USTA's Board of Directors, its Patent and Trademark Office Committee and the Advisory Committee for Trademark Affairs, all of which consist of experienced trademark practitioners, overwhelmingly oppose the changes the bill would make to sections 12(b) and 13 of the Lanham Act.

Section 102(c) of H.R. 4539 would amend section 12(b) of the Lanham Act (i) to reduce from six to three months the time applicants have to respond to questions of registrability posed by the PTO and (ii) to give the Commissioner authority to charge fees for granting applicants additional time to respond. USTA opposes these changes because, in many instances, three months does not provide trademark owners sufficient time to evaluate and prepare thorough answers to the issues the PTO might raise. This is particularly true for multi-divisional companies and foreign trademark owners who must gather information from a variety of sources and contend with delays inherent in international mail delivery.

Shortening the response time and charging a fee imposes an additional burden and unfairly penalizes these applicants. For this reason and because the only apparent reasons for shortening the response time and for charging a fee if additional time is needed appear to be administrative, USTA does not believe this amendment of the Lanham Act should be enacted.

Section 102(d) of H.R. 4539 would amend section 13 of the Lanham Act to modify the timetable governing a trademark owner's decision to oppose the registration of another's mark. It would also give the Commissioner authority to prescribe conditions and impose fees on those who need more than 90 days to reach a decision. USTA opposes this modification of section 13.

There are many factors that affect the amount of time it takes a trademark owner to decide whether it should oppose the registration of a mark. Many times, it enters into lengthy, sensitive discussions with the mark's owner with the objective of avoiding a formal opposition proceeding. The spectre of fees and the need to comply with a set of PTO-established conditions would disrupt this process and could easily produce an increase in the number of formal conflicts between parties. This is not in the best interests of the system. Moreover, as it would be virtually impossible for the PTO to establish criteria for granting extensions of time that could be consistently or equitably applied, their promulgation would put the PTO in the inappropriate position of making subjective judgments about whether negotiations between private parties were proceeding in a manner that warranted their having additional time to continue discussions and possibly reach a mutually-agreeable settlement.

USTA's comment on tbe other Lanham Act amendments contained in H.R. 4539 is of s general nature and it is also relevant to the two amendments discusssed above. Last summer, USTA commissioned a "blue ribbon" panel of trademark experts, the Trademark Review Commission (TRC), to evaluate the Lanham Act on both conceptual and practical levels. While this is a comprehensive long-term project, it is one on which much progress is and has been made. Because this effort may produce an array of both substantive and technical proposals for amending the Lanham Act, USTA suggests that your Committtee may wish to defer action on the current amendments until such time as a comprehensive package of revisions can be prepared for consideration.

In closing, USTA thanks you for considering its views on the Lanham Act amendments contained in H.R. 4539 and welcomes the opportunity to answer any questions you or the other members of the Committee may have. It also requests the opportunity to testify if hearings on the proposed changes are scheduled.

Very truly yours,

William A. Finkelstein

William A. Finkelstein
President

WAF:c
Enclosure
cc: Members, Subcommittee on Courts, Civil Liberties
and the Administration of Justice
The Honorable Donald J. Quigg
Assistant Commissioner Margaret M. Laurence
Assistant Commissioenr Michael K. Kirk

PROJECT REPORT BULLETIN
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TRADEMARK REVIEW COMMISSION

STATUS REPORT, INVITATION TO SUBMIT TOPICS AND CALL FOR VOLUNTEERS

TRC had an all-day meeting in Chicago on September 27, 1985, with a lively discussion concerning purpose, committees, agenda and timetable. Dolores Hanna appointed six committees to deal with the various topics being considered in the overall review of the trademark system. They will be consulting with a group of distinguished senior counsellors, consisting of Beverly W. Pattishall, Saul Lefkowitz, Leslie D. Taggart, Julius R. Lunsford, Jr., and Nathaniel G. Sims.

The committees and their assignments are:

1. Intent-to-Use Committee

   Vito T. Giordano, Chairman
   Walter David Ganus
   Jeremiah D. McAuliffe
   Albert Robin
   Robert L. Shafter

   This Committee is actively revieving several fundamental questions of trademark law and policy. For example, does the requirement of pre-application use in interstate commerce significantly work against the objectives of a good trademark system? If so, can the system be materially improved by relaxing or clarifying that requirement without removing it? If we cannot materially improve the system by retaining the requirement, would a dual system with alternative requirements work better? If so, what type of alternative system would be best? If we adopt an intent-to-use system, how can we reduce the risk of proliferation of registrations? Can an intent-to-use system safely withstand attack on Constitutional or other legal grounds? The Committee is also considering the impact of the Crocker Bank case, equal treatment for U.S. applicants, encouraging trademark users to apply early for registration, and possible strengthening of the Section 22 constructive notice provision. For example, should the filing date of an application establish nationwide constructive notice of the earliest date of use?

2. Section 43(a) Committee

   Marie V. Driscoll, Chairman
   Donald W. Canady
   Gerard E. Murphy
   Louis T. Pirkey

   The underlying question is whether the liberal interpretation of the Section has been desirable. Some of the related questions were considered when the McClellan bill

/over pls

changes should be made. For example, do trademarks still function to identify source and to distinguish among competing products, or are there other functions which need to be added? In light of recent decisions does "abandonment" need to be redefined? Should "common descriptive name" be redefined as "generic name" in Section 15(4)?

6. Housekeeping Committee

Laurence R. Hefter, Chairman
Bert A. Collison
Ronald S. Kareken
David B. Miller

This Committee will address a variety of possible amendments to the Lanham Act. The term "housekeeping" does not imply that they will be routine, although some will be. For example, should there be a federal statute of limitations for trademark infringement actions and Section 43(a) violations? Should the Act contain a provision covering recordal of security interests in registrations? Should an application be acceptable when signed by an attorney alone? Should Section 32 expressly allow an exclusive licensee to bring a trademark infringement action? Should Section 5 be amended to provide that use by a licensee is a sufficient basis to permit an application by the licensor?

The Committees are in the process of meeting and allocating individual assignments, and beginning work on their assignments. The Intent-to-Use Committee has even held an all-day debate, with its members taking positions in favor of or against particular proposals.

As TRC moves forward we are becoming increasingly aware that the scope of the project is truly enormous, and that the twenty-nine members will need assistance. Accordingly, we would welcome and encourage participation of USTA members to handle various research, analysis and writing projects for the Committees. If you have the time to assist as a volunteer, please contact Robin A. Rolfe at the USTA offices. If you have a specific committee or topic you are interested in, please so indicate. We assure you that the rewards will be substantial, although not in the pecuniary sense.

Lastly, we are now at the stage where we would like to invite suggestions, proposals and ideas from USTA members. Almost everyone practising trademark law has an idea or two about improving the trademark system or the Lanham Act. Now is the time to speak out. We will give each suggestion full consideration. Please write Robin Rolfe.

As we move into the TRC working phase we are becoming more and more enthusiastic about the project. If you share this feeling you can make a definite contribution, and we hope you will.

Dolores K. Hanna
Chairperson

John C. McDonald
Vice Chairperson

Jerome Gilson
Reporter

Arthur J. Greenbaum
Associate Reporter

CHAIRWOMAN

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, D.C. 20436

March 10, 1986

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil
Liberties and the Administration of Justice
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I am enclosing responses to the questions adressed to me in your letter of February 19, 1986. These answers supplement my testimony of that day.

Please feel free to call on me as you continue to consider this issue.

Sincerely yours,

Paula Stern

Paula Stern
Chairwoman

Enclosure

CHAIRWOMAN'S ANSWERS TO THE QUESTIONS POSED BY
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES, AND
THE ADMINISTRATION OF JUSTICE, February 19, 1986

1. Opponents of amendments to section 337 of the Tariff Act have argued that these changes would transform the ITC from a trade forum to an intellectual property court. How do you view this criticism?

In my February 19th testimony, I stated that the amendment to section 337 being proposed in H.R. 3776 would transform "the ITC into a forum to litigate purely intellectual property rights." The proposed amendment would relieve complainants of the need to prove a domestic industry or injury to that domestic industry in a intellectual property based section 337 investigation. Thus, the only substantive issues to be resolved in a section 337 investigation would relate to the intellectual property rights, i.e. their existence, their enforceability and the infringement of them. Accordingly, a company whose only nexus to the United States is ownership of a U.S. intellectual property right could sue a U.S. company which was importing a component of a product for assembly in the United States or the complete product itself and, if successful, might have the infringing article excluded from entry into the U.S. by order of the I.T.C.

A recent case gives a concrete example of how this amendment would expand ITC jurisdiction. Certain Meat Deboning Machines, Inv. No. 337-TA-181. The case principally involved one Dutch company accusing another Dutch company of infringing its U.S. patent through the importation, use and sale in the U.S. of meat deboning machines. Because the complainant had no presence in the United States regarding the patented machine beyond sales and administrative offices and there was no prospects of establishing production related activities in the U.S., the ALJ found no violation of section 337 despite finding a valid and enforceable patent being infringed by respondents, and the Commission terminated the investigation. If this proposed amendment were in effect, the one Dutch company could have received a Commission finding of section 337 violation against the other Dutch company and a Commission exclusion order. In short, one importer could invoke the jurisdiction of the ITC to have another importer's articles excluded from entering the U.S. I fail to see the compelling special national interest and need that would prompt Congress to create a

forum at the ITC, an independent government agency, to resolve such a dispute between two foreign companies.

Even under the proposed amendment, a national interest component will remain in the statute regarding remedy, requiring any proposed remedy to pass both the Commission's test on the statutorily specified public interest factors and the President's policy review. The statute recognizes the in rem and public nature of the remedies, independent of the intellectual property rights. If those tests were not passed, the party having had its intellectual property right found to be valid, enforceable and infringed would be left without an ITC remedy and quite possibly have to relitigate these issues in federal court. Moreover, regardless of the outcome of the section 337 investigation, since section 337 is "in addition to other remedies at law" and the legislative history makes it clear that patent validity determinations of the ITC are not to be accorded res judicata effect, the prevailing party might still be required by the losing party to relitigate the issues in federal district court.

Moreover, section 337 is covered by the "Grandfather Clause" of the GATT Protocol of Provisional Application as long as its substance is preserved as it existed on October 30, 1947. A change to the injury requirement could have repercussions in the GATT. Our injury standard, while not very stringent, is perceived by our trading partners as an offset to aspects of 337 to which they object, such as time limits and different evidentiary standards.

As I stated in my testimony, I applaud and support the efforts to strengthen the protection of U.S. intellectual property rights. But, I fail to understand how the proposed amendment deleting domestic industry and injury will help our trade deficit. I further do not see why additional public funds and a public investigative agency should be made available to foreign entities to resolve their disputes over intellectual property rights. Federal courts are already available for that purpose. Finally, I do not see what role the ITC determination on public interest factors and the Presidential policy review plays in such quintessential private disputes.

The proposed amendment is, I submit, ill advised. The twin purposes of reducing the trade deficit and strengthening enforcement of intellectual property rights would be badly served by the proposed amendment. Disputes over intellectual property rights

between importers have no discernible effect on the trade deficit, and eliminating the injury and domestic industry standards would dilute our resources focused on investigations which do affect actual trade flows.

2. What percentage of cases before the ITC currently involve the enforcement of intellectual property rights (copyright, patent and trademark)? How would the caseload of the ITC change if these amendments were adopted? What increase in staff would be necessary?

All section 337 investigations currently at the ITC involve enforcement of intellectual property rights. While it is impossible to predict with any sufficient level of confidence how the caseload would increase if the amendment deleting industry and injury were adopted, I note that in the most recent twelve month period (ending June 30, 1985) 5,412 federal court civil actions were commenced involving intellectual property rights, compared to 27 section 337 investigations commenced during the same period. Thus, it is likely that the caseload would increase significantly, and would require a corresponding increase in staff. Presently, the ITC spends approximately 50 work years on section 337 investigations, and section 337 investigations consume about 30% of the Commission's resources devoted to public investigations. Based on these considerations the change being proposed would require a significant and dramatic increase of resources for the ITC.

3. Should the Tariff Act continue to require that the petitioners establish that there is a domestic industry before they can obtain relief? Do universities currently face problems under section 337 in establishing the existence of a domestic industry?

Domestic industry defines the national interest deserving of protection and warranting a public investigation. Each of the trade remedy laws administered by the Commission -- dumping and countervailing duties (19 U.S.C. §1671 et seq.), escape clause (19 U.S.C. §2251, as well as section 337 -- contains "domestic industry" as a substantive element for violation. The absence of a domestic industry does not leave owners of intellectual property rights remedy-less -- a federal district court or state court action would be available. Section 337 was created to provide an additional and special <u>in rem</u> remedy in order to protect a domestic industry against unfair methods of competition in the importation and sale therefrom. While the Commission determines whether a domestic

industry exists case by case, it limits to production related the activities that qualify in accordance with the Congressional intent expressed as long ago as 1922 with regard to section 316, the predecessor to section 337:

> Such a law as I have suggested would assure American producers that they will not be subjected to unfair competition from countries abroad. (Emphasis supplied) 62 Cong. Rec. 5879 (1922)

Most recently, the House Report accompanying the Bill that became the Trade Act of 1974 stated in relevant part:

> In cases involving the claims of U.S. patents, the patent must be exploited by production in the United States, and the industry in the United States generally consists of the domestic operations of the patent owner, his assignees and licensees devoted to such exploitation of the patent. (Emphasis supplied). H. Rep. No. 93-571, 93d Cong. 1st Sess. 78 (1973).

For example, the mere licensing activities of an intellectual property owner does not constitute a domestic industry. Miniature, Battery-Operated, All-Terrain, Wheeled Vehicles, Inv. No. 337-TA-122, aff'd sub nom, Schaper Mfg. Co. v. U.S.I.T.C., 717 F.2d 1368 (CAFC 1983) and Products with Gremlin Character Depictions, Inv. No. 337-TA-201. Thus, a university that engages in research and receives a patent would not qualify as a domestic industry under this precedent. The national interest underlying section 337 is not solely enforcement of our intellectual property right laws -- for that we have the courts -- but the productive application of the intellectual property rights in the U.S.

Section 337 offers protection of intellectual property rights in order to encourage and allow this property to be applied to commercial products and processes in the United States. As I recently stated in my Additional Views in Double-Sided Floppy Disk Drives, Inv. No. 337-TA-215:

> It is my conclusion that Congress intended the Commission to balance both the public interest served by protecting intellectual property rights and that served by the entrepreneurial activity which results from a patent's exploitation . . ..

I might add that many commentators have observed that the most glaring deficiency in our technological capabilities has been our failure to apply and commercialize that technology. It does not enhance our competitiveness nor reduce our trade deficit if we develop new technology and design state of the art products when that technology and products are either not commercially exploited or manufactured offshore. The result of deleting the domestic industry requirement from the statute entirely would be to negate the favorable effect section 337 might have on U.S. competitiveness and trade balance.

Under the present statute, universities which engage in research and patent their inventions cannot by themselves constitute a domestic industry entitled to protection under section 337. But if they get a partner which many of them do to commercialize the invention, then they may seek protection from infringing imports at the ITC. For example, in Limited-Charge Cell-Culture Microcarriers, Inv. No. 337-TA-129, the Commission instituted a section 337 investigation based upon the complaint of Massachusetts Institute of Technology and its licensee, Flow General Corporation, and upon the evidentiary record found that they constituted a domestic industry.

4. In the recent Duracell battery case (which involves allegations of grey marketing or parallel importing) the President reversed the ITC on policy grounds. Subsequently the Court of Appeals for the Federal Circuit found that it had no jurisdiction to review the President's decision. Should the CAFC have jurisdiction in such cases? Should the ITC remedies be supplemented, as some suggest, to permit antitrust exemptions for industries adversely affected by unfair trade practices in section 337 cases?

The issue of whether Presidential policy review should be reviewable by the CAFC has many aspects of which I will address two. It must be kept in mind that the President has no power to revise or change the Commission determinations. As the CAFC stated in Duracell, the effect of the Presidential disapproval is to prevent the determination of the Commission from becoming final. Duracell points out that the Presidential policy review is essentially non-reviewable. The CAFC decision suggests that the Presidential review is unreviewable by a court because the statute does not provide for review nor does it define which are the permissible policy factors for the President to consider. This

decision also makes clear that Presidential disapproval renders the underlying findings of the Commission relating to the intellectual property rights unreviewable as well. Being unreviewable, such findings would have no estoppel effect on the parties relitigating the dispute in federal or state court.

I do not believe that antitrust exemption for intellectual property rights owners is an appropriate or needed remedy. A property owner has the legal right to exclude others from using his/her property. Thus, the owner of a valid and enforceable intellectual property can already prevent anyone without authority from using that intellectual property.

5. Under this legislation would respondents be able to raise defenses to alleged infringements such as antitrust violations or price gouging by the petitioners?

Respondents presently are allowed to raise "all legal and equitable defenses." As I understand this legislation, it would make no changes in the scope of the unfair acts and defenses to them.

6. Some proponents of reform of the ITC have advocated substantial reductions in the time period within which the ITC must act. What is your view of the advisability and feasibility of these proposals?

The Commission currently must determine whether there is a violation of section 337 within 12 months (18 months in more complicated cases) after publication of its notice of investigation. In contrast, patent infringement actions in Federal court take substantially more time. The median length of time required to complete patent infringement actions going to trial in Federal court is about two and one-half years, and 10 percent of the patent infringement cases going to trial take 5 years to complete.

Substantially reducing the time allotted to the Commission to complete section 337 investigations would likely require major changes in the way such investigations are conducted. The time periods currently provided for respondents to answer the complaint (20 days) and for parties to respond to motions (10 days) would probably have to be shortened. The amount of discovery taken by the parties would certainly have to be curtailed. Finally, the amount of time available to the Commission's administrative law judges and

to the Commission for reaching decisions on whether section 337 has been violated and, in the case of the Commission, on the appropriate remedy in the event a violation is found would also have to be substantially reduced. Shortening of the statutory time limits for completion of section 337 investigations raises a serious question concerning the Commission's ability to conduct the violation phase of such investigations in conformity with the adjudicative provisions of the Administrative Procedure Act (5 U.S.C. §§ 554-557), as required by section 337(c).

7. Opponents of process patent reform argue that the existing ITC remedies are adequate for the protection of process patents. Do you agree with these claims? In what ways would the existence of a District Court remedy for process patent infringement affect the caseload of the ITC?

All owners of U.S. process patents cannot satisfy the domestic industry and injury requirements of section 337. These would be able to obtain relief from the federal courts. Furthermore, they would be able to obtain money damages. These are the two major ways that process patent reform would expand the protection of process patent owners beyond that currently provided by section 337.

The existence of a federal district court remedy for unauthorized use abroad of a process that if practiced in the U.S. would infringe a valid and enforceable process patent might reduce the ITC's section 337 caseload. I would not expect the reduction to be significant, as many owners of product patents who presently have the choice file a section 337 complaint at the ITC together with or in lieu of a federal district court action.

8. Please indicate which §337 cases have raised the question of "injury" and briefly describe each case.

The statute requires in every section 337 investigation a showing of "injury" in order to establish a violation. However, the standard of injury applied by the Commission in section 337 has been relatively low. In only one contested case has the Commission found no violation solely because the complainant had failed to establish the requisite injury. Optical Waveguide Fibers, Inv. No. 337-TA-189. In that case, the respondents had imported and sold de minimis amounts of the infringing articles, were building a U.S. production facility, and were committed to satisfy all their U.S.

sales with U.S. produced fibers. Based on those findings and others, which for reasons of confidentiality we cannot discuss here, the Commission found no substantial injury and no tendency to substantially injure the domestic industry. The exclusion order that the complainant was requesting would not have stopped respondents' sale of infringing fibers because those fibers would not have been imported.

In contrast, where there is a basis to find that imports might increase beyond de minimis amounts, the Commission has found violations of section 337 in patent-based cases under the tendency to injure standard despite respondents having imported relatively small amounts of the infringing item.

For example, in Certain Trolley Wheel Assemblies, Inv. No. 337-TA-161, Views of the Commission (1984), the Commission found a tendency to substantially injure the domestic industry, even though only one respondent imported the infringing trolley wheels on a commercial basis and that respondent accounted for less than 2 percent of the domestic industry's gross sales over a four year period. Id. at 12-14. The Commission relied on such factors as excess foreign production capacity, foreign cost advantage, a clearly demonstrated intent to penetrate the U.S. market and the resultant impact on the U.S. industry in finding the requisite tendency to injure.

Similarly, in Certain Methods for Extruding Plastic Tubing, Inv. No. 337-TA-110, Commission Opinion (1982), the Commission found a violation of section 337 even though imports were amounting to only about 2 percent of the domestic industry's production of the reclosable plastic bags at issue. Id. at 14-15. The Commission relied on evidence of substantial foreign manufacturing capacity, explicit foreign intentions to import, underselling by respondents and the resultant impact on the U.S. industry. Id. at 15.

These cases demonstrate that the Commission traditionally has not required the domestic industry necessarily to show substantial import penetration or large volumes of direct lost sales to obtain relief under section 337.

9. What is the current law with respect to universities (and other small entities) on the question of whether they constitute "domestic industry"?

Regarding universities, see my answer to question 3, above. Small entities can be domestic industries. The Commission has found an entity whose annual sales never reached $500,000 to be a domestic industry.

OFFICE OF THE UNITED STATES
TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON
20506

March 17, 1986

The Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed are answers to the Subcommittee's additional questions for the hearing record on intellectual property and trade. We appreciate the opportunity to express our views.

Sincerely,

Harvey Bale
Assistant U.S. Trade
Representative

RESPONSE TO QUESTIONS
OF THE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE
OF THE
HOUSE JUDICIARY COMMITTEE
TO THE
UNITED STATES TRADE REPRESENTATIVE

1. Please briefly describe GATT, its application to intellectual property and the consequences of a GATT violation.

The GATT is both an agreement which establishes rules for the conduct of international trade in goods and the name of the international organization which administers the General Agreement and the related agreements negotiated during the Tokyo Round of multilateral trade negotiations.

The General Agreement contains three provisions that expressly refer to patents, copyrights, and trademarks:

> Article XII provides an exception for import restrictions taken to safeguard a country's balance of payments. Subparagraph (c)(iii) says that the import restrictions imposed should not "prevent the importation of commercial samples or prevent compliance with patent, trade mark, copyright, or similar procedures.
>
> Article XVIII permits developing countries to take protective or other measures affecting imports in order promote the economic development. It contains language identical to that in Article XII, limiting the action that can be taken to promote economic development.
>
> Article XX, subparagraph (d) is a general exception from GATT obligations for actions taken to secure compliance with patent, trademark, and copyright laws which are themselves not inconsistent with the GATT.

Two GATT disputes have involved issues related to intellectual property. The United States was the "defendant" in both disputes. In the first dispute, Canada complained that a section 337 exclusion order violated the GATT. The panel found that the U.S. action was excepted from GATT obligations under Article XX(d). In the second dispute, the E.C. complained that extension of the manufacturing clause of the U.S. copyright law violated the GATT. The panel found that the extension was not "grandfathered" and, therefore, did violate the GATT.

If a contracting party acts in a way that affects adversely another contracting party's exports, the affected contracting party can challenge the action in the GATT. If the action is found to be GATT inconsistent, the responsible contracting party will be given a "reasonable time" to bring its practice into conformance with the GATT. If the practice continues, injured contracting parties can be authorized to withdraw trade concessions from the country responsible for the injury.

2. Last Congress the staff of the USTR claimed that H.R. 6286 (relating to protection of infringing imports) violated the General Agreement on Tariffs and Trade. Is this still your view? If so, please explain your position.

A. Yes. A panel likely would find inconsistent with GATT a law that made the sale or use of a product made abroad by a process patented in the United States an infringement, if sale or use of a product made in the U.S. by infringing a U.S. process patent was not. The GATT requires that imported products be treated no less favorably than domestically produced products under laws, regulations and requirements affecting their sale, offering for sale, or use.

A potential importer, purchaser (user), or seller of any foreign produced product, to be certain it could not be found liable for infringement, would have to determine the entire process used to produce the foreign product and would have to make certain that no portion of that process was covered by a U.S. patent. As an alternative, the importer, purchaser, or seller could insist on a "hold harmless" clause in its sales contract, which would increase the cost of the imported product. Either approach would create a preference for domestic products in the United States since sellers and users of foreign produced products could be sued for infringement of U.S. process patents while sellers and users of domestic products would be immune.

3. Professor John Jackson (University of Michigan) has written to Chairman Kastenmeier suggesting that creation of an alternative remedy for enforcement of process patents may make section 337a of the Tariff Act "unnecessary" and therefore violative of GATT. What is your response to this possibility?

A. We believe that a GATT panel would not conclude that the mere existence of an alternate forum would makes section 337 exclusion orders "unnecessary." The 1982 GATT panel that reviewed Canada's complaint did not. Although U.S. district courts can enjoin patent infringement, the panel accepted U.S. arguments that the difficulty of obtaining jurisdiction over foreign parties in the U.S. and the difficulty of enforcing injunctions made the spring

assemblies' exclusion order "necessary" within the meaning of GATT Article XX(d). We believe that those circumstances would apply to a section 337 exclusion order based on a process patent even if action in a U.S. district court were possible.

4. In the Spring Assembly case brought by Canada in 1981, there is some indication in the panel discussion that existing ITC procedure could, in another case, run afoul of GATT (see para. 66) In light of those comments, shouldn't we be extremely cautious before we modify the Tariff Act? Don't the references in paragraphs 60 and 66 of the Panel discussion to "existing law" indicate that changes in the law -- either in title 35 or in the Tariff Act -- would produce a different result?

A. The panel, in paragraph 54 of its report, defines "measure" in Article XX to mean the ITC's exclusion order, not section 337 itself. Then the panel analyzes whether the exclusion order was necessary and concludes that it was. It also concludes that, in similar circumstances, exclusion orders would be covered by Article XX(d). The panel does foresee, however, that there might be other circumstances in which an exclusion order would fall outside the Article XX(d) exception. A change in either section 337 or title 35 which did not conform to our obligations would be such a circumstance. Careful amendment of U.S. law and careful review by the President of ITC actions under that law should ensure that we do not violate the GATT.

5. If the proponents of process patent reform are correct that the existing ITC remedy is inadequate for the protection of process patents, does this not establish that creation of a remedy for process patent infringement in Federal court is "necessary" within the terms of Article XX of GATT?

A. The question before the Congress is whether U.S. law should do more than effectively enjoin the importer much as it would enjoin the infringer of a process patent in the United States. The ITC has no jurisdiction over imports that had entered the stream of commerce in the United States, nor can it award damages. Likewise a U.S. district court judge cannot enjoin sale or use of products that are beyond the control of the U.S. process patent infringer who made them. He also cannot ensure that the owner of an infringed process patent obtains damages if the infringer is judgment proof. The legislation under consideration would enable a U.S. process patent owner to prevent continuing injury from the goods produced using its process and would enable it to obtain damages.

6. During the Committee deliberations last Congress the staff of the USTR presented a memorandum which argued that existing ITC remedies were adequate, yet this Congress you are arguing that the remedies are insufficient. How do you reconcile these views?

A. The views are not inconsistent, since each addresses a different subject. The memorandum, which was written at the request of the Subcommittee staff, discussed a proposal which would have made it an infringement to import, use, or sell a product made abroad using a process patented in the United States. No infringement would have resulted from use or sale of a product produced in the United States by infringing the process patent. The chief argument made by supporters of the bill was that section 337 was not adequate to prevent circumvention of U.S. patent law by using the process abroad. We believe section 337 is adequate for that purpose.

The process patent bill under consideration at this hearing would strengthen the ability of a process patent owner to enforce its rights generally. We recognize that section 337 cannot achieve that objective. It cannot be used by a process patent owner to prevent sale or use of products already in the stream of commerce, nor to obtain damages. Likewise, under current U.S. patent law, a process patent owner cannot stop sale or use of products that have left the control of an infringer and has no means to obtain damages from a judgment proof infringer. The only way to strengthen process patent protection generally is to amend U.S. patent law.

7. Opponents of process patent legislation have argued that such legislation is merely a thinly disguised attempt to extend American law extraterritorially to countries which do not protect process patents. What is your view?

A. If the legislation applied only to products produced abroad, it might be challenged on the basis you suggest. The proposal discussed during the hearing, however, would apply regardless of where the products were produced. It would strengthen a process patent owner's ability to enforce its rights generally.

8. The New York Patent Law Association has argued that providing for liability for the users and sellers of domestically made goods in violation of a process patent would be going too far. They have suggested that liability be limited to "first sale" or importation of the infringing goods. What is your view of this proposal?

A. The objective of the current legislation is to strengthen a process patent owner's ability to enforce its rights generally. That objective could not be achieved by the proposed "first sale" or importation limitation.

9. Your testimony has proposed that the bill be amended to make sure that the process patent be <u>directly</u> involved in the infringement. Could you indicate how such an amendment would work with respect to chemicals, pharmaceuticals and electronics?

A. In our testimony, we suggested to the Subcommittee that only use or sale of products actually produced using a patented process be made subject to infringement actions. Sale or use of products which merely incorporate a product produced using a patented process should not be subject to infringement actions.

10. Opponents of process patent legislation have criticized the use of presumptions. How do you respond to these claims? How important are such provisions to the effectiveness of the bill?

A. A presumption would not arise until the plaintiff in an infringement action had shown that (1) there is a substantial likelihood that the process used is that covered by the claims of the patent and (2) that it has made reasonable efforts to obtain the evidence needed to make its case but has been unable to do so. This is similar to the procedure used by the USITC now. The presumption would be rebuttable and, since the defendant would have better access to information about the process used that the plaintiff, the defendant would not suffer an undue burden. U.S. law contains sufficient sanctions to discourage abuse.

11. Please describe the efforts (bi-lateral and multilateral) of USTR to achieve improved intellectual property law protection abroad.

A. The President in his September 23, 1985 statement on trade, directed USTR "to initiate and accelerate both bilateral and multilateral negotiations with countries where the counterfeiting or piracy of U.S. goods has occurred."

Following through on these directives we are now developing a strategy, in consultation with our major trading partners, to incorporate protection of intellectual property issues into the General Agreement on Tariffs and Trade. One option we are considering is negotiating an agreement or code on intellectual property in the upcoming round of trade negotiations similar to the codes negotiated in the Tokyo Round. Some of the principal elements of such an agreement or code might include: an enforcement mechanism; enhanced protection where current standards are too low; elimination of compulsory licensing (except where there is adequate compensation); and lengthening certain terms of protection. In addition, one of our top priorities is completing work on the counterfeiting code.

Complementing these efforts is a vigorous program of bilateral consultations and negotiations with some of the most problematic nations. Over the past months we have held talks with both Asian and Latin American nations, including Taiwan, Singapore, Korea, and Mexico. Some of these nations do not provide any kind of

patent, trademark or copyright protection for foreigners. Others have statutes which offer inadequate protection. Consequently our discussions with these countries cover the full range of counterfeiting and intellectual property rights problems. The Congress in re-authorizing the Generalized System of Preferences specifically directed the President to take into account a country's intellectual property laws in determining the results of the GSP general review for each beneficiary. As part of the general review we have held consultations with over twenty countries, and we expect to hold further talks in the coming months.

Korea has been a particular problem for counterfeiting, patent infringement and pirating of copyrighted works. Despite several rounds of consultations, there had been virtually no progress in Korea. As a result, the President, exercising the authority granted by Section 301 of the Trade Act of 1974 to initiate an investigations into Korea's practices. We have had two round of consultations already and made some good progress. But we still have a number of issues outstanding. The Administration is prepared to initiate additional investigations under Section 301 when appropriate.

12. Opponents of amendments to section 337 of the Tariff Act of 1930 have argued that these changes would transform the ITC from a trade forum to an intellectual property court. How do you view this criticism?

A. Section 337, amended as proposed, still would apply only to imported products. The ITC would still consider public interest factors before deciding to remedy a section 337 violation. Those factors include the effect of the remedy on human health and safety, the effect on competitive conditions in the United States economy, the effect on the production of like and directly competitive articles in the United States, and the effect on U.S. consumers. Those are not factors generally considered in intellectual property cases in court. They require economic analysis which the ITC is equipped to provide. Economic analysis of issues that now are considered in light of the industry or injury could be considered as public interest factors if the statute were amended.

13. Under this legislation would respondents be able to raise defenses to alleged infringements such as antitrust violation or price gouging by petitioners?

A. Subsection 337(c) provides that all legal and equitable defenses may be raised in all cases. Unless an amendment were drafted in a way that conflicted with this provision, the defenses available to a defendant in a district court case should be available in a section 337 investigation before the USITC.

14. Some proponents of reform of the ITC have advocated substantial reductions in the time period within which the ITC must act. What is your view of the advisability and feasibility of these proposals?

A. We believe that the time within which the ITC must act is necessary for the objectives of the Administrative Procedure Act to be achieved. Shortening the procedure would interfere with the ability of parties to complete discovery and prepare their cases. A shortened time period also would require additional staff, since current staff would have to accomplish at least the same volume of work within the shorter period. All in all, the costs of shortening the time would not appear to be countered by any benefits. Advocates of shortened time have not provided evidence to the contrary.

The Administration believes that any amendment shortening to ninety days the period within which the ITC must make its determination on temporary relief should provide for an extension of forty-five days when necessary.

15. What is the current status of the Aramid Fiber investigation? What GATT challenges are likely from the European Communities?

On Feb. 5, the European Communities initiated the investigation under its new commercial policy instrument. The United States submitted comments, suggesting that the investigation is premature, since there is an appeal pending, and that the issues raised by Enka have already been dealt with in GATT in the Spring Assemblies case. The basic allegations in the petition are that the USITC's procedures differ from those in U.S. district court, working to the disadvantage of foreign respondents. We have supplied information showing that the allegations are unfounded.

16. Dr. Stern of the ITC claims in her testimony that elimination of the "domestic industry" requirement will unwisely involve the ITC in patent disputes between foreign companies who want to enter the U.S. market. What is your view of this claim?

A. First, elimination of the industry requirement would seem to be a needed change, for some U.S. owners of U.S. intellectual property to be eligible for relief. Cases like Toy Trucks (1982) and Gremlins (in progress) illustrate that.

Second, foreign owners of U.S. patents certainly would avail themselves of section 337 for the same reason that U.S. patent owners use it. It seems appropriate to make the statute available at a time when we are asking other countries to improve the protection, including enforcement, available to U.S. owners of intellectual property rights in those countries. Allowing the foreign owner of a U.S. intellectual property right to enforce that right using section 337 is no more "unwise" than allowing

enforcement in U.S. district court. We have argued in GATT that difficulties in obtaining jurisdiction over foreign parties in U.S. courts and in enforcing judgments make section 337 actions "necessary" to enforce patents. Denying foreign patent owners access to section 337 appears inconsistent with our stated belief in the need for strong protection for intellectual property worldwide.

17. If section 337 is amended as proposed, will this new law present any negotiating problems with our trading partners who already dislike section 337?

A. It is likely that our trading partners will continue to complain about section 337 time periods, procedures, and exclusion orders when one of their products is the subject of an investigation.

The Register

March 28, 1986

The Honorable
Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil
Liberties and the Administration of Justice
U. S. House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

This letter assesses the impact of the copyright and mask work provisions of Title II of the March 18, 1986 draft of the International Property and Trade bill. The bill raises a variety of important intellectual property and trade questions. The Copyright Office is always eager to assist you and the members of your subcommittee, and I will endeavor to do so with this bill, with special emphasis in the areas where our expertise is greatest -- the fields of copyright and mask work rights.

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Of particular importance are the copyright and mask work provisions of section 202(a) of the bill. In thinking about the utility or desirability of the retention or modification of the "industry," "injury," and "efficiently and economically operated" criteria now found in 19 U.S.C. §1337(a), I must admit to some uncertainty, for these are trade concepts with which the Copyright Office has had only tangential experience.

This lack of expertise is due to the paucity of copyright decisions in the International Trade Commission. While a recent article in the Journal of the Copyright Society refers to ten copyright cases in the history of the ITC, there have really been only two decisions in which copyright law played a dispositive role: In re Certain Coin-Operated Audiovisual Games and Components Thereof, U.S.I.T.C. Pub. No. 1267 (July 1982), rev'd in part sub nom. Bally/Midway Mfg. Co. v. U.S.I.T.C., 714 F.2d 1117 (C.A.F.C. 1983), and Personal Computers and Components Thereof, 337-TA-140 (1984). The Gremlin case, 337-TA-201, is really a case concerning whether licensing activity constitutes a domestic industry (and holding that it does not).

Turning now to the question of whether or not the proposed amendment to the presumption provisions in §1337(a)(2) would change the substantive rights of copyright or mask work rights owners, the answer appears to be "probably not" with respect to copyrights and "it's hard to tell" with respect to mask works.

Proposed subsection (a)(2)(C) does little other than make the provisions of 17 U.S.C. §602 part of the new presumptions. That is, the unauthorized importation of

legitimately prepared (not pirate) copies of copyrighted works, and the domestic sale of such copies, now constitute copyright infringement. Selchow & Righter Co. v. Goldex Corp., 612 F.Supp. 19 (S.D.Fla. 1985); CBS, Inc. v. Pa. Record Outlet, Inc., 598 F.Supp. 1549 (W.D.Pa. 1984). Put another way, § 602 of the Copyright Act already more clearly restricts the "gray market" for copyrighted works than apparently is the case with respect to trademarks. On a technical point: it is unclear why the phrase "valid and enforceable" is used to modify "copyright registered under title 17." It would seem that the latter is sufficient.

Proposed subsection (a)(2)(E), the mask works provision, might better be modified to incorporate the concept of infringement, as is now the case in the copyright subsection, rather than "violation of exclusive rights," as it now provides. Given that chapter 9 of title 17 contains both exclusive rights and limitations thereon, it would be more appropriate to incorporate a complete "infringement" standard, which should take account of reverse engineering and innocent infringement, than a "violation" standard, which is somewhat ambiguous on this score. It should be noted that §910 does not make violation an infringement, as proposed subsection (a)(2)(E) suggests, but instead provides that "[e]xcept as otherwise provided in [chapter 9], any person who violates any of the exclusive rights of the owner of a mask work ... shall be liable as an infringer of such rights." It is precisely those "otherwise provisions" that the §337 amendment should recognize. This could be done by amending subsection (a)(2)(E) so that it reads, in its entirety:

> "(E) The importation of a semiconductor chip product in a manner that constitutes infringment of a mask work registered under chapter 9 of title 17, United States Code."

The line between substance and procedure is never an easy one to draw, but there would appear to be little substantive change in the rights of copyright and mask work owners if the bill were enacted with the modification suggested in the preceding paragraph. Practitioners with ITC experience observe that it is a more hospitable forum to patentees than are many District Courts, but feel that it is neither more nor less generous to copyright and trademark owners. On the very limited copyright record, it is fair to say that the ITC has followed traditional copyright doctrine in a manner very much like the courts.

For what it's worth, the trade provisions in the bill appear more modest than those in some of the bills now before the Congress. By retaining the "injury" and "industry" standards with modifications, the ITC would be required to hear cases involving the U.S. licensing "industry," but would not be required to hear disputes between foreign entrepreneurs with no direct connection with the U.S. economy. By moving the "efficiently and economically operated" criterion out of §337(a) and into the relief and review sections, more balance is maintained than if the criterion were stricken altogether. Again, at the risk of unnecessary repetition, my trade comments are necessarily made with less confidence than those with repect to copyrights and mask works.

If you have any further questions, please call me at your convenience.

Sincerely yours,

Ralph Oman
Register of Copyrights

RO/mvp

U.S. CHAMBER OF COMMERCE

Albert D. Bourland
Vice President
Congressional Relations

April 25, 1986

The Honorable Robert W. Kastenmeier
Chairman
Subcommittee on Courts,
Civil Liberties, and
Administration of Justice
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

We strongly support revision of Section 337 of the Tariff Act of 1930 to provide U.S. intellectual property holders with better protection against infringement by importers. The U.S. Chamber welcomes the attention you are giving this important subject. However, the revisions proposed in the Intellectual Property and Trade Act (H.R. 4539), in our view, do not provide sufficient protection.

Current statute provides that the International Trade Commission (ITC) may grant relief only if imports of the infringing product have the effect or tendency "to substantially injure or destroy an industry, efficiently and economically operated in the United States." The U.S. Chamber opposes the provisions requiring the petitioner to meet an "injury test" and to demonstrate the existence of an efficiently and economically operated industry. Both conditions are sources of needless uncertainty, delay, and expense for U.S. owners of intellectual property seeking to protect themselves against infringement.

H.R. 4539 does not provide for complete elimination of either of these criteria. The change in Section 337 proposed in H.R. 4539 creates a "rebutable presumption" of injury in cases where infringement is found. An intellectual property holder would be denied relief if the infringer proved to the ITC that the intellectual property owner had not suffered substantial injury by the infringement. In our view, infringement of a U.S. intellectual property right constitutes sufficient reason for exclusion of an imported article; therefore, we oppose retaining the option to demonstrate injury.

H.R. 4539 also reintroduces the "economically and efficiently operated" requirement as a public interest consideration to be examined by the ITC. The U.S. Chamber opposes retaining this unnecessary and burdensome condition in the process of protecting U.S. intellectual property rights.

The U.S. Chamber supports the provision of H.R. 4539 that would require the ITC to act promptly on requests for relief pending the final resolution of a complaint. In instances when a key shipment of infringing goods is en route or a critical selling season is approaching, the failure of the ITC to act promptly inflicts harm on the intellectual property owners that is not easily remedied.

As the subcommittee acts on H.R. 4539, we urge you to support complete elimination of the unnecessary and costly evidentiary hurtles to intellectual property protection discussed above. This would contribute significantly to combating piracy and infringement by foreign competitors.

Sincerely,

Albert D. Bourland

1615 H Street, N.W. □ Washington, D.C. 20062 □ 202/463-5600

CBEMA

April 22, 1986

The Honorable Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties and the
Administration of Justice
House Committee on Judiciary
2137 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Kastenmeier:

The Computer and Business Equipment Manufacturers Association (CBEMA) supports your proposal (H.R. 4539) to amend Section 337 of the Tariff Act of 1930. However, we encourage you to go further to remove the costly and unnecessary hurdles that intellectual property owners must now overcome in order to protect themselves from imports that infringe on their rights.

U.S. industries that invest research and development dollars and ingenuity to develop products protected under intellectual property laws should not have to contend with companies that break those laws. If the infringing company is located in the United States, the intellectual property owner has only to prove infringement to receive injunctive relief and damages. But if the infringer is a foreign company, then the owner must not only prove infringement but must also prove that the industry is "economically and efficiently operated" and that infringement is tending to destroy or substantially injure that domestic industry.

The General Accounting Office estimates that intellectual property cases against foreign infringers cost between $250,000 and $1 million to litigate, with half those costs related to proving economic harm. Thus, the total is twice what a similar suit against a domestic infringer would cost.

Both the enormous U.S. trade deficit and simple justice demand an end to this system. While your bill H.R. 4539 addresses the problem, it reintroduces the "economically and efficiently operated" requirement as an element to be considered by the International Trade Commission (ITC). In addition, it denies relief if the infringer proves to the ITC that the intellectual property owner has not suffered substantial injury.

We believe that the exact extent of injury is irrelevant in instances in which laws are clearly broken. We can think of no other case in which individuals or groups are permitted to steal property from another simply because the property owner is wealthy or does not suffer "substantially" because of the loss.

We respectfully urge you to remove the "economically and efficiently operated" test as a requirement to be considered by the USITC and the provision that creates a "rebutable presumption" of injury in cases where infringement is shown.

We hope that these views are useful to you and express our thanks for your Subcommittee's leadership in this area.

Sincerely,

Vico E. Henriques
President

cc: All Members of the Subcommittee
Mr. David Beier
Mr. Thomas Mooney

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February 18, 1986

Mr. David Beier
Assistant Counsel
Subcommittee on Courts, Civil Liberties,
and the Administration of Justice
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

RE: Questions for Hearing on
Section 337 Amendments

Dear Mr. Beier:

In accordance with our recent discussion, there follows a number of questions which may be considered appropriate to ask certain witnesses scheduled to appear at the Subcommittee hearing set for February 19, 1986, regarding amendments to Section 337 of the Tariff Act of 1930.

1. A number of persons now cite the GATT panel report in the Spring Assemblies case brought by Canada against the United States as insulating Section 337 from attack as inconsistent with the GATT. Are you aware that when this panel report was first considered by the GATT Council, which must adopt reports before they can be truly considered precedent, that the Canadians, European Communities, and the Nordics, joined in part by Japan, all expressed opposition to the report and urged its rejection? Are you aware that when the panel report was ultimately adopted in May 1983, it was adopted by the Council only with the proviso that it in effect not be precedent, i.e.,

> "When the Council adopted the report it did so on the understanding that it did not foreclose future examination of the use of Section 337 to deal with patent infringement cases from the point of view of consistency with Article III and XX of the General Agreement." GATT activities in 1983, at 44-45 (1984).

Doesn't this seem to you to be rather thin support for Section 337 as it is now written, with most of our trading partners expressing grave concern about Section 337? (Mr. Beier: See material on Aramid Fiber case, below.

2. Under the GATT, isn't Section 337 as it now stands "grandfathered," so that the United States would not have to amend Section 337 to make it consistent with GATT if it should ultimately be found to be inconsistent with GATT? Wouldn't making some of the substantive changes now contemplated (removing the industry and injury criterion from the statute) destroy U.S. "grandfather" rights?

3. In how many cases under Section 337 has the injury criteria been determinative of the outcome? (Mr. Beier: We have heard from the ITC staff that since the 1974 amendments, the answer is four (4) cases out of over 50 cases fully litigated, or four (4) compared to over 80 cases in which relief orders have been entered (including default cases), or four (4) out of over 225 cases instituted and completed since 1974.) Doesn't this indicate little or no need to amend Section 337, especially since relief is also generally available under the domestic patent laws or other domestic laws if no trade interests are being hurt?

4. We have heard that much of the push for removing the injury test from Section 337 has come from Corning Glass Works, which lost its Section 337 action on optical waveguide fiber against Sumitomo Electric of Japan because it failed to show even a tendency to injure. Didn't the ITC find that Sumitomo had imported minimal amounts of fiber, that the U.S. market was fiber short, and that Sumitomo had invested some $50 million in a U.S. facility to produce fiber and cable for the U.S. market, and would rely on that facility to supply the U.S. market, with its imports therefore expected to decline from their already de minimus level? Isn't this finding by the ITC being appealed by Corning to the CAFC (which held oral arguments on it on February 7, 1986)? Why should the law be changed for this one company? Doesn't Corning also have a federal district court action proceeding against Sumitomo in the Southern District of New York on these same patents? Why would not a decision in this action give Corning any relief to which it is entitled? (Mr. Beier: One patent is a process patent, but the key patent is the product patent. Also, Corning is suing Sumitomo's U.S. facility, which means that it can assert the process patent against that facility, which the ITC determined would be the source to supply the U.S. market.)

5. Have you heard of the Aramid Fiber investigation recently instituted by the European Communities (EC) to determine whether the recent exclusion order under Section 337 involving aramid fiber is consistent with U.S. international obligations and whether retaliation against the United States for the action

should be taken by the EC? Doesn't this indicate some concern by our trading partners with Section 337? Isn't this concern likely to increase, and more challenges be brought, if Section 337 is amended? Is the United States going to ignore the Aramid Fiber case? What will the United States do?

6. If there is no requirement for a U.S. industry under Section 337, wouldn't foreign interests, with no U.S. investment but only a U.S. intellectual property right, be able to use Section 337 to attack other foreign interests, or U.S. importing companies? Do you believe this is appropriate? What would be the impact on the number of cases brought under Section 337?

7. If there is no industry or injury criteria under Section 337, will not the ITC become, in effect, an international patent court? Is the ITC equipped for this role? How many intellectual property experts are on the ITC? (Mr. Beier: There are none.) How many lawyers? (Mr. Beier There is one out of six.) Is there not a danger that the U.S. patent law will be more determined by the ITC than the district courts? Do not the above amendments destroy, in practical terms (given CAFC review of both the ITC and district courts), the exclusive original patent jurisdiction in the federal courts? Have you considered the impact of the amendments on the district court and ITC case loads and resources?

8. What will be the impact of amendments to Section 337 on negotiation of intellectual property matters in the next multilateral trade negotiations round? Isn't it likely that Section 337 will be dragged into the negotiations? Will not our efforts on other issues, such as an anticounterfeiting code, be deflected by attention to Section 337?

9. Which companies have approached the Administration about eliminating the injury and industry issues from Section 337? Who is in charge of this issue in the Administration?

10. Isn't it likely that an industry test can not be eliminated, in practical terms, from Section 337? For example, if the ITC issued an exclusion order in a case where there was arguably no injury to any U.S. industry, is it not likely that a country would approach the President and indicate that there is no real interest of the United States at issue which cannot be protected by a domestic patent or other action, and that if the order is allowed to stand, the country will bring a case against the United States under the GATT, or ask for compensation, although small in amount? Isn't the President going to have to treat such a situation seriously? What will this President, and future Presidents, do?

We hope the above questions are useful to you. Please contact my office if you have any qustions about them; I will be out of town, but can be contacted and will try to get back to you.

Sincerely yours,

David Foster

David Foster
ITC Trial Lawyers Association

cc: Paul Plaia

Intellectual Piracy Captures the Attention Of the President and Congress

Protection of intellectual property rights has blossomed as a trade issue, not because the problem has worsened, but because the issue has become politically attractive.

BY BRUCE STOKES

On a recent business trip to Seoul, South Korea, a Washington trade lawyer stopped by a handbag shop in the Itaewon shopping district to pick up a gift for his wife. A bit wary of the cut-rate prices for what appeared to be Gucci bags, he asked the proprietor, "Are these bags okay?"

"Of course they're alright," responded the irate shopkeeper. "I made them myself."

Taken aback, but knowing a bargain, the lawyer bought a bag.

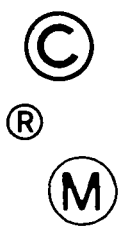
The Washington world of trade laws and regulations had run up against the multi-billion-dollar world market in counterfeit goods. Round 1 to the pirates.

U.S. trade negotiators, aware that piracy is costing U.S. companies an estimated $8 billion-$20 billion a year and convinced that America's industrial competitiveness depends on protecting its inventions and scientific discoveries, want to ensure that round 2 goes to the forces of law and order.

To that end, the protection of U.S. intellectual property rights—trademarks, patents, copyrights and mask work rights (computer chip designs)—has become one of the foundation stones of the Reagan Administration's trade policy. By championing such rights, the White House hopes to demonstrate toughness in foreign trade without appearing protectionist.

The issue of intellectual property rights has blossomed in importance in Washington even though intellectual piracy has not appreciably worsened in recent years. While few would deny the importance of protecting intellectual secrets, there are those who question the wisdom of giving intellectual property rights such a prominent role in trade policy.

These trade and intellectual property experts are concerned that the issue has become a pawn in Washington political games. They fear intellectual rights could become just another bargaining chip in trade negotiations. And they warn that with no international consensus on how to defend intellectual property rights, any attempt to impose U.S. views on others could jeopardize efforts to improve agricultural and manufacturing trade.



Piracy costs U.S. firms $8 billion-$20 billion a year. U.S. trade officials are convinced that America's industrial competitiveness depends on protecting its inventions and scientific discoveries.

Reg. U.S. Pat. Off.

A NEW AGE

In a major trade speech last Sept. 23, President Reagan pledged new efforts to protect intellectual property rights. "When governments permit counterfeiting or copying of American products, it is stealing our future and it is no longer free trade," he said. Subsequently, the White House initiated an unfair trade practices case against South Korea for a lack of safeguards against such piracy. At the same time, the Administration persuaded Taiwan to substantially improve its protection of intellectual property rights. *(See NJ, 11/30/85, p. 2696.)*

The Cabinet-level Economic Policy Council is reportedly considering a set of initiatives including legislation, an Administration policy statement, new unfair trade cases against unspecified countries and formation of an international patent office.

Congress has also jumped on the bandwagon. Recently, it has strengthened trademark protection, linked Caribbean Basin Initiative benefits and preferential treatment under the Generalized System of Preferences to protection of U.S. intellectual property rights and created new protection for computer chip designs. Major proposals now under consideration would broaden the scope of patents for manufacturing processes and make it easier to persuade the International Trade Commission (ITC) to bar imports that infringe on U.S. patents.

Much of the credit for pushing the issue to the front burner goes to the intellectual property lobby, which includes the Pharmaceutical Manufacturers Association, the National Agricultural Chemicals Association, the Semiconductor Industry Association and two coalitions—the International Intellectual Property Alliance and the Intellectual Property Owners Inc. As a result of their efforts, the Administration and Congress now see defense of intellectual property rights is critical to the future of the American economy.

"We've always had [a convincing] case," said R. Michael Gadbaw, a partner in the Washington office of the New

Worldwide Piracy Hard to Document

The world of pirated intellectual property is a nebulous one, befitting its underground nature. Concrete examples of abuse are few, and it is almost impossible to quantify the extent of the problem.

A 1985 survey by the International Intellectual Property Alliance—whose members include the Association of American Publishers, the Motion Picture Association of America and the Recording Industry Association of America—estimated that in 10 Third World countries alone, alliance members lose more than $1.3 billion annually as a result of inadequate copyright protection. The record industry was the major victim, with an estimated $600 million in annual losses, followed by book publishers, who reported losses exceeding $400 million.



Richard A. Bloom

Trade lawyer Donald E. deKieffer

A survey by Pfizer Inc. demonstrates that the losses incurred by individual U.S. firms can be substantial. In a dozen Third World countries in 1984, Pfizer sold $47.4 million worth of 12 pharmaceutical products—including Feldene, Procardia and Cefobid—for which it holds the patents. Pfizer estimates that pirates sold $41.9 million worth of these same drugs in those countries that year.

Some observers say such figures can be misleading. "There are problems with those numbers," cautioned a U.S. trade official with extensive Asian experience. The property alliance figures are "based on a highly selective survey and make some dubious assumptions about the size of the market if pirates did not exist," he said.

Whatever the volume of piracy, it is substantial. And the losses can be directly attributed to lack of protection abroad, inadequate enforcement at home and the difficulty of keeping U.S. law up to date with rapidly emerging new technologies.

In many countries where U.S. multinational companies operate, statutory protection of intellectual property rights is weak or nonexistent. In Latin America, Argentina's protection is negligible, and neither Brazil nor Mexico offers patent protection to chemical or pharmaceutical producers, although Mexico has promised to enact such legislation.

As a result, U.S. companies often market new products at their own risk. In the early 1980s, Pfizer introduced Feldene—an anti-arthritic drug—into the Argentine market. Within a year and a half, 14 competitors were selling what Pfizer contended was exactly the same drug. In 1984, Pfizer sold $1.6 million worth of Feldene, but pirates, selling the pills at 25-80 per cent of Pfizer's price, sold an estimated $17.3 million.

While Third World nations often say weak patent protection is designed to break the industrial nations' monopoly on scientific knowledge, their concerns are often more mundane. In Mexico, for example, the state-run health services buy half the drugs sold in the country. Buying from pirates saves substantial amounts of money.

Similar piracy problems exist with copyrighted materials—books, sound recordings, video tapes and computer software. Last September, the Motion Picture Association of America reported that pirated video tape copies of the films *Prizzi's Honor* and *Back to the Future* were being sold in Saudi Arabia, which has no copyright laws, before the tapes went on sale in the United States. Most illegal copies are thought to come from the Far East, where Taiwanese authorities recently uncovered a pirate assembly line—200 video tape machines wired together to reproduce the same tape.

Copyright holders also encounter market access problems that compound their piracy problems. Brazil, for example, requires that for every three copies of a foreign title distributed in the country, one copy of a Brazilian film must be distributed. This creates a demand for U.S. films that pirates are more than willing to satisfy.

Pirates are also flooding the U.S. market. "With tens of thousands of potentially patented products coming in," said Donald E. deKieffer, a partner in the Washington office of the San Francisco law firm of Pillsbury, Madison & Sutro who is also general counsel for the International Anticounterfeiting Coalition Inc., "it is extraordinarily difficult for the Customs Service to test every product to see if it is in violation of the patent laws" or, for that matter, copyright and trademark laws.

If the Reagan Administration has its way, the Customs Service's task may become even more difficult. The Administration's 1987 budget would cut 1,446 Customs jobs.

Industries that manufacture new technologies, such as computer chip makers, have another problem—their intellectual property rights are still being defined. Until 1984, no country specifically protected the design of the circuitry on computer chips. Then Congress passed the Semiconductor Chip Protection Act, which created a new intellectual property right in the design as it is embodied in the chip, not just as it is sketched out on paper.

Japan recently implemented similar legislation, and the European Community has issued a directive to member states calling for appropriate chip design protection. But such protection is still not universally accepted. Unless that changes, noted an industry observer, piracy of computer chips could outstrip in value many other violations of intellectual property rights.

York law firm of Dewey, Ballantine, Bushby, Palmer & Wood who represents the Semiconductor Industry Association. The difference is that "now we have the political clout."

But the current cachet that the issue of intellectual property rights has in Washington derives as much from shear happenstance and a variety of political and pecuniary interests as it does from the merits of the problem.

Attention was first focused on intellectual property rights after the 1983 State of the Union address in which Reagan said, "This Administration is committed to keeping America the technological leader of the world now and into the 21st century." That commitment had been conceived in haste, and the White House had no plan of action for attaining the goal. But the intellectual property lobby did have a plan, and it convinced the Administration that defense of U.S. intellectual property rights was a credible and politically expedient means of fulfilling the President's vow.

At the same time, U.S. industries were finding new value in intellectual property rights. The development of biotechnologies offered unprecedented competitive advantages if the multimillion-dollar development costs could be recouped through inviolable patents. In 1982, a new Court of Appeals for the Federal Circuit was created in Washington as the nation's highest patent court. Plaintiffs found the court responsive to the claims of patent holders. As companies won more cases, intellectual property became a more valuable asset that was worth defending in the political arena.

These firms' Washington lobbyists quickly began beating the drums for government action. "The trade associations have to justify their existence," said a U.S. trade official. These associations are "built on trying to get the government to do something. By comparison, if you talk to the guys in the field, they are much less concerned [about the violation of intellectual property rights because they have learned to deal with it]."

At the same time, free-trade-oriented Members of Congress latched onto the issue because it permitted them to portray themselves as defenders of the industries of the future rather than as patrons of industries of the past.

SELF-INTEREST

In the months ahead, the power of this issue will be tested anew on Capitol Hill and in international trade negotiations. Once again, the outcome will turn as much on politics and self-interest as it will on the merits of the problem.

For example, a number of bills in the House and the Senate would make it unlawful to import, sell or use a product made in another country using a process patented in the United States. This seemingly straightforward proposal has prompted a tug-of-war between the



Richard A. Bloom

Industry lawyer R. Michael Gadbaw

Pharmaceutical Manufacturers Association, which represents the prescription drug industry and is fearful of unfair foreign competition, and the Generic Pharmaceutical Association, which contends that the bills would restrict its members' ability to import low-cost chemicals. The generic industry until now has forestalled passage of the bill, but the prescription drug industry may show its muscle and push the bill through this spring.

Similarly, Sen. Frank R. Lautenberg, D-N.J., and others are proposing to make it easier for industries to persuade the ITC to disallow imports that infringe on intellectual property rights of the United States. Under the proposal, industries would no longer need to have any manufacturing operations in the United States or show that they were injured by the offending imports. They would merely have to prove that a foreign producer had infringed on their U.S. patents or copyrights.

This proposal has raised a howl of protest, not from foreign producers, but from the lawyers who represent U.S. industries before the ITC. In its comments on the proposal, the ITC Trial Lawyers Association said, "Eliminating the injury requirement (along with the domestic manufacturing requirement) would turn the ITC into an international patent court, would call into question the consistency of United States obligations under international agreements [such as the General Agreement on Tariffs and Trade (GATT)], could well interject [this issue] into the currently contemplated round of international trade negotiations, could undermine U.S. efforts to secure international agreement on intellectual property protection and could give rise to demands by our trading partners for compensation from the United States."

Advocates of the proposal contend that the trial lawyers—who specialize in proving injury in ITC cases—are really worried about losing work to intellectual property specialists.

There is also conflict, between patent and copyright experts and trade lawyers, over the Administration's plan to push for stronger protection of intellectual property rights under the GATT. The trade bar foresees a whole new body of lucrative GATT litigation if the proposed round of trade negotiations spells out new GATT protections. The intellectual property bar fears that its international organization—the World Intellectual Property Organization, which administers international copyright and patent codes—would be shunted aside.

Moreover, there is a concern among intellectual property experts that patents and trademarks are rights that should not be bartered like quotas or tariffs. "If intellectual property rights are folded into a trade round," said a government patent lawyer, "then at some point, the trade jocks will be trading off intellectual property rights for other issues."

Whatever the outcome of these battles, it is clear that because of the implications for the country's economic future and the strength of the intellectual property lobby, intellectual property rights will remain an important consideration in trade policy. But it is also clear, in the words of a government copyright lawyer, that "intellectual property rights are not a matter of life and death. Certainly there are people who make their livelihoods out of this, but it is not a mattter of national security."

As Congress and the Administration contemplate further action on intellectual property rights and trade, there are a small number of specialists in the field who hope they keep that in mind. □

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ANALYSIS

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Section 337

SECTION 337 AND PROPOSALS TO AMEND IT: A PRACTITIONER'S PERSPECTIVE

By: L. Peter Farkas, partner, Craig & Burns, Washington, D.C. and
T. Spence Chubb, associate, Craig & Burns, Washington, D.C.

(Ed. Note: Congress has before it a number of proposals that would fundamentally amend §337 of the Tariff Act of 1930. After reviewing the history of §337 and decisions of the U.S. International Trade Commission interpreting the statute, Mr. Farkas and Mr. Chubb review and critique the legislative proposals and offer their own recommendations for change.)

Introduction

A confluence of factors has resulted in several proposals to amend Section 337 of the Tariff Act of 1930, 19 U.S.C. Section 1337, which protects domestic industries from unfair imports which infringe intellectual property rights or violate antitrust laws.[1] First, the enormous trade deficit, $145 billion in 1985, has resulted in protectionist pressures on the Administration and Congress to do something, almost anything, to restore some balance between our imports and exports. Second, the United States International Trade Commission, the independent federal agency charged with enforcing Section 337, has been unpredictable in granting relief under the statute, particularly in the more visible cases involving high technology imports. Sponsors, who hope that streamlining Section 337 investigations will ease and speed the Commission's ability to offer import relief, propose to reduce the proof required to establish violations and shorten the time the Commission has to complete its investigations. Apart from several unobjectionable technical amendments, the common features of most of the pending proposals would eliminate or alter the domestic industry and economic injury requirements and would cut the statutory time limits by half.

For a half century prior to 1974, Section 337 was exclusively a trade law, whereby the Tariff Commission could advise the President to order the Customs Service to exclude unfair imports determined to injure domestic industries. Unfair imports were defined as those which infringe domestic intellectual property rights, such as patents, trademarks and copyrights, or which benefit from violations of antitrust and unfair competition laws. The Commission's focus was on economic issues: whether a domestic industry existed; was efficient; and was injured by imports. Validity and enforceability of intellectual property rights were presumed and the Commission made only cursory evaluations of infringement.

In 1974, Section 337 was amended to require the Commission, renamed the International Trade Commission, to consider intellectual property law issues, including defenses such as invalidity and unenforceability of the rights being asserted; to hold due process evidentiary hearings; and to complete investigations within a certain time period. The 1974 amendments also transferred to the Commission the Presidential authority to order exclusion of the offending imports. Overnight, Section 337 investigations became speedy quasi-judicial proceedings requiring determination of both economic factors and intellectual property rights. The effectiveness of the Commission's exclusion remedy, its fast track procedure, a perception of Commission sympathy to intellectual property rights and the coincidental growth of imports has substantially increased the Commission's Section 337 case load.

The Commission's recent economic determinations in several complex cases have made it harder to prove violations and have prompted a rush to strengthen the statute by eliminating some or all of the original economic issues from patent, trademark, and copyright based investigations. Some proposals pending in Congress, including S. 1860, S. 1869, H.R. 3776, and the Administration's "Intellectual Property Rights Improvement Act of 1986" would eliminate the need to prove (1) existence of a domestic industry, (2) its efficient and economic operation, (3) injury in intellectual property cases, and (4) (except for the Administration bill) would shorten the time to complete investigations by half. Other proposals (H.R. 3777 and H.R. 4800) offer less drastic changes. Of special interest is H.R. 4800, the House's omnibus trade bill which would retain, but clarify, the requirement of proving the existence of an industry in the United States and create a rebuttable presumption of injury in cases of intellectual property infringement.

The more drastic proposals may have troublesome unintended side effects, and could result in the enactment of similar measures aimed at American exports by our trading partners. First, eliminating the economic issues may undermine the statute by cutting out its historical *raison d'etre*, the prevention of injury to American industries. Second, elimination of the domestic industry requirement will hurt consumers without benefitting American firms. Third, shortening the investigation will hamper discovery and preparation of claims and defenses by all parties and jeopardize well reasoned decisions by the Commission's Administrative Law Judges (ALJs) and the Commission itself. Fourth, the amendments will discriminate against infringing importers in favor of domestic infringers, in possible violation of the General Agreement on Tariffs and Trade (GATT). The less drastic

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