INFORMAL DISCUSSION

With Greg Glover's presentation stimulating questions regarding the Bayh-Dole Act and proposed legislative changes, the rest of the luncheon was devoted to an exchange of viewpoints among all participants regarding areas of mutual and exclusive interest. Participants also engaged in self introductions and described their respective organizations.

John Kelly opened the discussion by acknowledging that in today's political climate the issue of prescription drug "cost" weighs heavily on the minds of PhRMA and its member companies. Though university representatives recognized the importance of cost discussions to the political debate, they stated in general terms that "cost" issues were not their primary concern. However, to the extent that universities engage in less collaborative research, that is of concern to them.

Shelley Steinbach noted the importance of personal relationships in Washington, D.C., and sounded a refrain that meetings of this sort are extremely valuable. Shelley also recognized that joint meetings stimulated mutual understanding with the possibility of achieving joint positions.

As the discussion continued, Richard Turman made the point that the issue of "tech transfer" is important to his organization as it involves both research and government relations aspects. However, Richard cautioned that universities are "reluctant to get political."

Valerie Volpe argued that universities should be considering cost issues by noting that pharmaceutical companies will be reluctant to invest in research of drugs tailored for "boutique" diseases when there is a good chance that the companies will not recoup their investments.

Rich Harpel stated that the Bayh-Dole Act means different things to universities, but most importantly the Act provides an "environment of cooperation" between universities and pharmaceutical companies. It is for this reason that universities have an interest in preserving Bayh-Dole, according to Rich. Rich further stated that he has found that current Hill staff don't know much about the legislative intent of Bayh-Dole and that a lot of his time is spent "tutoring" Hill staff to some extent.

Kate Phillips also recognized the benefits of Bayh-Dole, but stated that the Council on Government Relations, is agency-focused, not Hill-focused. Nonetheless, she noted that she perceives "hostility" toward Bayh-Dole in many directions and that this hostility is troublesome. She made special mention of a "challenge" coming from Sen. Ron Wyden. Robert Hardy echoed Kate's statement and further added that it is essential from COGR's perspective to "preserve the central integrity of Bayh-Dole."

Andy Cohn mentioned three areas of concern for WARF that he hoped others will find common interest in: 1) collaborative research patent reform (a bill will soon be introduced in the U.S. House of Representatives); 2) sovereign immunity reform (which should not unnecessarily destroy state university patent rights); and 3) growing legal concerns regarding patent infringement issues and a broad research exception.

Rich Harpel noted that he and representatives from the NASULGC had "conversations" with Sen. Patrick Leahy and his staff regarding S. 2031, the sovereign immunity legislation. Rich found the dividing lines to be between the university community and the entertainment community. Further, he stated that he found the issue to be a conflict between state government and the federal government, thus it is a constitutional issue. According to Rich, the bill is on hold indefinitely, and that is good.

Upon hearing the concerns raised by participants, John Kelly acknowledged that there is "no lack of attacks" going on with regards to patent law and pharmaceutical research. He stated that "periodic" ongoing discussions could be helpful as it is in everyone's interest to weigh in with their concerns for all to hear. Attendees agreed.

In light of John's statement, Richard Turman stated two areas of common interest between universities and PhRMA, notably the doubling of funding for NIH and the use of animals for research.

Robert Hardy followed up by noting that he sees an "erosion" in NIH's commitment to Bayh-Dole and that NIH managers view Bayh-Dole as "more of an option" than before.

Mike Remington said that reorganization of the U.S. Patent and Trademark Office, especially with regards to fees, should also be a mutual concern for both universities and PhRMA. According to Mike, good government should be a shared goal. Attendees seemingly agreed.

Richard Turman stated that the university community is very concerned with "bias and patient safety issues." Further, he noted that presidents and chancellors are "keenly" aware and interested in human subject issues, another issue of mutual concern between universities and PhRMA companies.

Stephen Heinig said his primary interest is keeping information in the public domain. John Kelly agreed that that is an important concern, especially with regards to clinical trials. He then referenced a pamphlet handed out at the luncheon entitled " Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results."

Andy Cohn voiced a plea for mutual cooperation in the stem cell research debate. Valerie Volpe said that PhRMA is "not involved publicly yet" in the debate. However, she mentioned that PhRMA is supporting and funding individual member companies in their advocacy of the issue.

Aware of everyone's areas of interest, John Kelly acknowledged his amazement at how much commonality there was. He suggested that all parties should come together and celebrate the upcoming birthday of the Bayh-Dole Act amendments on December 12. All parties agreed that would be a beneficial thing.

Further, Mike Remington offered a suggestion that there should be an additional grass-roots approach to the celebration whereby individual companies and universities work together at the state and congressional district level in acknowledging the importance of the Bayh-Dole Act. That suggestion also received favorable acceptance.

In closing, it was agreed by all that patent law is necessary for the development of collaborative research between universities and pharmaceutical companies, to the betterment of the public. All attendees agreed that further meetings should occur, and that parties could approach each other directly on pressing issues of concern.

SUMMARY OF CONSENSUS ITEMS

- Dr. Glover's Power Point presentation would be distributed electronically to all participants.
- Informal meetings to discuss legislative proposals that impact on the pharmaceutical industry and universities are productive and should occur periodically.
- The "success" of the Bayh-Dole Act is critical to the future of collaborative research and the ability of universities and pharmaceutical companies to engage in inventive activities and to bring new products and processes to the market. However, because the Bayh-Dole is under criticism, its success should not be taken for granted.
- The parties should consider a 22nd birthday celebration on December 12 for the Bayh-Dole Act, as enacted on December 12, 1980.
- The parties should consider a grass-roots approach to Bayh-Dole programs to occur at a handful of universities where successful collaborative research and technology transfer have occurred.
- Patent law is necessary not only for inventive activities on university campuses and in pharmaceutical companies but also for collaborative activities between and amongst these entities. As a general proposition, legislative efforts to decrease patent protections should be seriously scrutinized by the respective parties which, based on their own priorities, should express opposition.

D

Protection of Collaborative Research – A PhRMA Perspective:

The Importance of Patents to the Discovery and Development of New Treatments and Cures

Gregory J. Glover, M.D., J.D.
Ropes & Gray
September 26, 2002

Overview

- Development of New Treatments and Cures
- Important Role of Patents
- The Relevance of the Hatch-Waxman Act to Patent Protection for New Treatments and Cures
- S.812/HR 5311: Recent Proposed Legislative Changes to the Hatch-Waxman Act
- Effects of Proposed Legislative Changes for Research Institutions

Development of New Treatments and Cures

- Development of new treatments and cures depends upon the work of both academic research institutions and commercial entities.
- Both have critical roles to play.
- Each depends upon the other.

Role of Research Institutions

- Research institutions play an essential role, particularly with regard to basic research.
- Universities, private foundations and charities fund and perform research that identifies potential new treatments and cures.
- This work is an essential prerequisite to the developmental work of commercial entities.

Role of Commercial Entities

- Commercial entities continue the development process by
  - performing the R&D necessary to evaluate the viability of drugs for human use,
  - conducting the Phase I-III trials necessary to assess safety and efficacy, and
  - helping to support the work of research institutions, through grants, licensing agreements and other arrangements.

Important Role of Patents

- Patents are an essential reward for the inventor of a new product.
- Patents can be obtained for any new and useful process, machine, article of manufacture, composition of matter (*e.g.* chemical compositions), and any new and useful improvement to any of these.
- The invention must be useful, novel, and non-obvious.

The Patentee's Exclusive Rights

- The patentee can exclude others from making, using, selling, offering for sale in the United States or importing the claimed subject matter into the United States. 35 USC 271(a).
- Use, sale, or importation of an article made by a patented method is infringement irrespective of where the invention was made. 35 USC 271(g).

The Patentee's Remedies

- Injunction to prevent infringement until the patent expires; and
- Damages for lost profits/sales due to infringement; or
- Damages set at a reasonable royalty.

Importance of Patents to Research Institutions

- The indirect importance of patents to academic research institutions is, at least, as important as their direct benefits.
- Patents have important direct benefits for academic research institutions, enabling them both to recoup the costs of their basic research and to fund further research.
- Patents also indirectly support this research by enabling commercial entities to make the enormous investments essential for the R&D needed to bring new treatments and cures to market.

Importance of Patents to Commercial Pharmaceutical Innovation

- Existing patent protections are critical to commercial development of new treatments and cures because of the enormous risks and costs and the many years of R&D and regulatory review required.
- Estimated average cost for a commercial entity to develop a new pharmaceutical treatment or cure is over $800 million.
- Only 20 in 5,000 compounds that are screened enter preclinical testing, and only 1 drug in 5 that enters human clinical trials is approved by the FDA as being both safe and effective.
- Effective patent life is unusually short relative to other research-intensive fields both because commercial entities must seek patents early due to the high degree of competition within therapeutic classes, and because of lengthy regulatory review periods.
- Patents enable the full range of innovation, including sequential innovation, essential to refinement and to discovery of entirely new treatments and cures.

The Hatch-Waxman Act

- In the Drug Price Competition & Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act"), Congress attempted to pursue two goals:
  - Making low cost generic drugs more rapidly available;
  - Maintaining incentives for pioneering pharmaceutical research.

Approval of Generic Drugs

- To speed and reduce the cost of generic drug approval, the Hatch-Waxman Act allowed generic companies to rely upon the safety and efficacy data submitted in support of the branded drugs they wish to copy, so long as the generic can show that its product is bioequivalent to the branded original.
- To enable generic companies to perform the required bioequivalence testing, the Act grants generic companies an exception from patent infringement so that they can use approved branded drugs to test the bioequivalence of their copies.

Patent Protection for Pioneer Companies

- To maintain incentives for pioneer companies to innovate, Congress had to ensure that they could still protect their patent rights.
- The Hatch-Waxman Act requires generic drug applicants to certify for patents listed in the "Orange Book": (1) that patent information has not been filed; (2) that the original patent has expired; (3) the date on which the patent will expire; or (4) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug (Paragraph IV Certification).
- If the generic applicant files a paragraph IV certification, and the patent owner brings suit for patent infringement within 45 day of receipt of notice of the certification, FDA will stay final approval of the ANDA for 30 months.

Operation of the Hatch-Waxman Act

- Since 1984, the generic industry's share of the prescription-drug market has jumped from less than 20 percent to almost 50 percent.
- Pioneer R & D investment has increased from $3.6 billion in 1984 to more than $30 billion in 2001.
- Few patent disputes have arisen.

Yet, changes have been contemplated through legislation in response to lobbying efforts by the generic drug industry.

Contemplated Legislative Changes to Hatch-Waxman that Affect the Rights of Patent Holders

- Essentially identical legislation has been proposed in the Senate and House, S. 812 / HR 5311/HR 1862 (McCain-Schumer/Thune-Emerson-Gutknecht/Brown).
- If enacted, this legislation would undermine intellectual property rights, threatening economic incentives for commercial entities to develop new treatments and cures, and adversely effecting the value of research institution developments and opportunities for research support.

Undermining Intellectual Property Rights
Limitations on Enforcement of Patent Rights

- Bar on Infringement Actions for Unlisted Patents:
  - Under the proposed legislation, if the NDA applicant fails to file patent information with FDA before the required date, then the owner of the patent is ***barred*** from bringing an infringement action against a generic applicant or any person that makes, uses, or sells an approved generic product.
- Bar on Infringement Actions After 45 Days:
  - If the patent owner fails to bring an infringement action with 45 days of receiving a Paragraph IV certification notice, the patent owner is ***barred*** from bringing an infringement case "in connection with the development, manufacture, use, offer to sell, or sale of the [generic] drug.
- Limitations on Scope of the 30-Month Stay:
  - The proposed legislation would limit the 30-month stay to only those patents filed with FDA within 30 days of NDA approval.

Effects of Potential Hatch-Waxman Legislative Changes for Research Institutions

- By weakening patent rights, the proposed legislation would undermine the certainty of investments made by commercial entities.
- Loss of rights to bring patent infringement claims for failure to meet an arbitrary, short filing deadline could jeopardize the patents of research institutions that license rights to these patents to pharmaceutical companies.
- The benefits of patents obtained by research institutions under the Bayh-Dole Act would be reduced, because the economic incentives of commercial entities to license the rights to these patents would be diminished.
- Limitation of 30-month stay rights would reduce incentives for commercial entities to perform and support sequential innovation to develop improved treatments and cures.
- The proposals will jeopardize the economic incentives necessary for commercial entities to develop the technologies of research institutions for patients.

E

F

107TH CONGRESS
2D SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

Mr. COBLE introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title 35, United States Code, to promote collaborative research among universities, the public sector, and private enterprise.

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 "University Research Promotion Act of 2002".

SEC. 2. LIMITATION ON NONPUBLIC INFORMATION IN OBVIOUSNESS DETERMINATIONS.

(a) CONDITIONS FOR PATENTABILITY; NOVELTY.—Section 102(f) of title 35, United States Code, is amended

by inserting after "patented," the following: "except that subject matter under this subsection shall not be considered prior art under section 103 of this title;".

(b) CONDITIONS FOR PATENTABILITY; NONOBVIOUSNESS.—Paragraph (c) of section 103 of title 35, United States Code, is amended to read as follows:

"(c) Subject matter developed by another person, which qualifies as prior art only under one or both of subsections (e) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, ~~at the time the application claiming the invention was filed,~~ owned by the same person or subject to an obligation of assignment to the same person.".

SEC. 3. EFFECTIVE DATE.

(a) IN GENERAL.—The amendments made by this Act shall apply to any patent granted before, on, or after the date of the enactment of this Act.

(b) SPECIAL RULE.—The amendments made by this Act shall not affect any final decision of a court or the Patent and Trademark Office rendered before the date of the enactment of this Act, and shall not affect the right of any party in any case pending before the Patent and Trademark Office or a court on the date of the enactment of this Act to have that party's rights determined on the

basis of the provisions of title 35, United States Code, in effect before the date of the enactment of this Act.



PURPOSE AND SUMMARY

In a 1997 decision, the Court of Appeals for the Federal Circuit interpreted subsection 103(c) of title 35, United States Code, which was amended in 1984 to allow free communication among research scientists in one organization regarding development of an invention, as not applying to the same free communication if made among collaborators from different organizations. This decision is having a chilling effect on research collaborations among government, university and corporate inventors. To remedy this problem, H.R. ___ amends subsection 103(c) of title 35, United States Code, to ensure that information shared among researchers engaged in scientific collaboration cannot be used to preclude patentability or invalidate a patent under subsection 103(c) where that shared information qualifies as prior art under subsections 102(e), (f) or (g). If adopted, the proposed amendment to subsection 103(c) will overturn the Federal Circuit's decision in *Oddzon Products, Inc. v. Just Toys, Inc.* [1] and will prevent the chilling effect that decision is having on public, private and non-profit research collaborations.

BACKGROUND AND NEED FOR THE LEGISLATION

Collaborative research among private, public and non-profit entities is extremely important to the U.S. economy. A 1999 report of the National Research Council's Committee on Science, Engineering, and Public Policy found that partnerships among industry, academia and governments have greatly contributed to the recent technological successes in the United States, and the report recommended even stronger partnerships in the future.[2] In addition, a 1998 report by the National Science Foundation found that there had been a major increase in the number of inter-sector collaborations since the early 1980s, including more than 3,500 new cooperative research and development agreements (CRADAs) between 1992 and 1995 among Federal laboratories and other entities.[3] Additionally, not-for-profits and universities spent a record $23.8 billion on research and development, the majority of which came from collaborations.[4] The income and positive effects on the U.S. economy from these collaborations have been substantial. Sales of products developed from inventions that were transferred from the university research centers resulted in revenues of $20.6 billion in 1996, and U.S. universities, hospitals and research institutes realized approximately $500 million in gross license income in 1996.[5]

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[1] 122 F.3d 1396, 43 U.S.P.Q.2d 1641 (Fed. Cir. 1997)

[2] "Capitalizing on Investments in Science and Technology," National Research Council, National Academy Press, 23-25; 49-51 (1999).

[3] Science and Engineering Indicators 1998, Chapter 4: U.S. and International Research and Development: Funds and Alliances, report by the National Science Foundation. http://www.nsf.gov/sbe/srs/seind98/c4/c4h.htm. ["NSF Report"].

[4] *Id.*

[5] *See* Jane A. Biddle and Thomas D. Mays, *Nonprofit-To-Industry Technology Transfers Grow*, NAT'L L. J. C30 (October 19, 1998), citing AUTM Licensing Survey FY 1996, Association of University Technology Managers Inc., Norwalk, Conn. (1998).

The Federal law aggressively promotes and expressly provides for such collaborative interactions. For instance, the Bayh-Dole Act of 1980 and the Steven-Wydler Technology Innovation Act of 1980 specifically encourage and promote interaction among the public, private and non-profit sectors. Federal laws and programs designed to promote collaborative research advance the U.S. economy and increase the rate of technological and industrial innovation. The patent laws, similarly, should promote collaboration among industry, university and government partners. The current quandary regarding section 103 began when the U.S. Court of Customs and Patent Appeals (CCPA), the precursor to the Federal Circuit, interpreted section 103 to mean that earlier inventions made by individual members of a research team would be used under section 103 to preclude the team's invention from being patented.[6] In other words, team members employed by the same entity could not freely share information in developing an invention for fear that the shared information could preclude them from patenting a resulting technology. This interpretation greatly worried entities utilizing team research.

Therefore, in 1984 Congress amended section 103 by adding the current subsection 103(c) to address the problem created by the CCPA's interpretation related to team research within an organization. The legislative history of the 1984 amendment clearly establishes that subsection 103(c) was designed to help encourage teamwork within organizations. The issue of teamwork between institutions, however, was not directly addressed as a concern, and an explanation as to why the provision should not extend to research between organizations was not provided. Given the text of subsection 103(c) and its legislative history, it is clear that the enactment of subsection 103(c) sought to encourage teamwork among researchers, rather than stifle team research. Thus, it can only be assumed that certain inter-organizational exchanges were not expressly exempted because there was a different research paradigm in place at the time of enactment.

A recent decision of the Court of Appeals for the Federal Circuit interprets 35 USC 103(c) (the 1984 amendment) to run counter to the well-designed and effective legislative system described above that promotes desirable collaborative research efforts, by holding that information communicated among research collaborators could later be used to invalidate a patent on an invention one of these collaborators developed. Specifically, in the case of *Oddzon Products, Inc., v. Just Toys, Inc.*, the Federal Circuit interpreted subsection 103(c) to hold that prior art under subsections 102(f) or (g)[7] could be used to determine the obviousness of an invention in situations where (a) there was no common ownership or assignment of the invention and information being shared among the collaborators, and (b) the information exchanged was not publicly known. Prior to the *Oddzon* decision, it was in question whether information under 102(f) and (g) that was shared among collaborators would qualify as prior art in determining whether an invention is obviousness under section 103. Thus, there was some doubt as to whether courts would interpret 103(c) to distinguish collaborations involving one entity from those involving more than one entity. The holding in *Oddzon* accurately interpreted the law, but nonetheless was a wake-up call to the patent community that information under 102(f) or (g) could invalidate a patent in the circumstances of joint research. The *Oddzon* decision creates a significant threat for the loss of intellectual property rights for inventors that engage in joint

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[6] *See, In re Bass*, 474 F.2d 1276 (CCPA 1973) and *In re Clemens*, 622 F.2d 1029 (CCPA 1980).

[7] Section 103(c) was amended by the American Inventor's Protection Act of 1999 to add section (e) to the 103(c) exclusions.

research and development projects with scientists not employed by the same company or institution.

The implications of the *Oddzon* decision are significant. Researchers that enter into a well-defined and structured research collaboration, but who do not at that time transfer their rights (not only rights in future inventions, but also the background technology on which the collaboration is based) to a single entity can create obstacles to obtaining or enforcing a patent on an invention that arises out of the research collaboration. The information exchanged under the collaboration does not have to be publicly disclosed or commonly known– instead, all that is required is that the collaborators exchange the information without first designating common ownership of the information or of any invention that may arise from the collaboration.

The *Oddzon* decision is creating significant problems due to the very nature of collaborative research and development projects among universities, government labs, and industry. The unhindered flow of information among researchers within these collaborations is essential to the conduct of research and crucial to a successful outcome. Laws and policies that have the effect of impeding the flow of information among researchers will, for obvious reasons, have a stifling effect on the progress and success of such projects. The proposed amendment to subsection 103(c) will remedy the undesirable impediments to collaborative research created by the *Oddzon* decision.

SECTION-BY-SECTION ANALYSIS

Section 1. Short Title.

This Act may be cited as the "Collaborative Research Promotion Act of 2002".

Section 2. Amendment to Subsection 103(c) Related to Non-Obvious Subject Matter.

Section 2 enlarges the exception presently provided under subsection 103(c) of title 35, United States Code. It provides that subject matter under subsection (e), (f) and (g) of section 102 shall not be considered in determinations of non-obviousness in certain circumstances. The amendment equates the treatment of information shared among researchers from different entities to that of information shared among researchers employed by a single entity, or who have commonly assigned their interests.

The ability to exclude information pursuant to the amendment would require proof that a research collaboration existed among the parties sharing information, and that the collaboration existed prior to the time the invention was made. A research collaboration, as envisioned in the legislation, could include formal arrangements between the institutions employing the researchers (e.g., defining the scope, objectives and other parameters of a research project), as well as more limited arrangements (e.g., material transfer agreements, non-disclosure agreements) between researchers in different institutions. The collaboration requirement also ensures that the information exchanges being exempted by the subsection were consensual (i.e., that the inventor did not "derive" the information without the consent of the holder of the information).

A party wishing to use this exception would have to provide evidence that a qualifying collaboration existed prior to the time the invention was made. Conventional rules of evidence would govern whether a party seeking to prove the existence of a research collaboration has met his burden in establishing the existence of a research collaboration. The most effective means of proving the existence of a research collaboration would be through use of documentary evidence (e.g., a contract, an exchange of letters) that identifies the date the collaboration was established, and the parties involved in the collaboration. Thus, a material transfer agreement executed prior to or concurrent with the exchange of a biological sample would be sufficient to demonstrate the existence of a research collaboration within the meaning of this section.

The requirement that the information shared in the research collaboration not have been disclosed or claimed in an earlier filed patent application serves to protect the public. It does so by preventing the possibility of two patents being granted on closely related inventions to different entities of a qualifying research collaboration. Thus, pursuant to the section, a party filing an application directed to an invention that is obvious in view of the contents of an earlier filed application could not use this exemption. Without the exemption, the second filed application would have to be directed to a nonobvious—and therefore independently patentable – invention.

Section 3. Effective date

Section 3 sets the effective date of the amendment. Subsection (a) set out the general applicability of the amendment and states it applies to all U.S. patents granted before, on or after the date of enactment, as well as all patent applications pending at the U.S. Patent and Trademark Office on the date of enactment or filed with the U.S. Patent and Trademark Office after the date of enactment. Subsection (b) defines exceptions to the general applicability of subsection (a). According to subsection (b), the amendment will not affect any final decision that has been rendered by a court or the Patent and Trademark Office regarding a patent or patent application. Subsection (b) also establishes that the amendment shall not affect the rights of parties engaged in litigation or administrative proceedings before the Patent and Trademark Office prior to the date of enactment of the Act.

Statement of

Carl E. Gulbrandsen

Before the
House Judiciary Subcommittee on
Courts, the Internet and Intellectual Property

On

Patent Law and Non-Profit Research Collaboration

March 14, 2002

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March 14, 2002

RE: Testimony to the Judiciary Subcommittee on Courts, the Internet and Intellectual Property Hearing on Patent Law and Non-Profit Research Collaboration

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the important topic of "patent law and non-profit research collaboration."

My name is Carl E. Gulbrandsen. I am the Managing Director of the Wisconsin Alumni Research Foundation, known as WARF. WARF is the patent management organization for the University of Wisconsin-Madison. My statement today is being made on behalf of WARF and the Council on Governmental Relations known as COGR. COGR is an association of 145 research-intensive universities in the United States. They promote policies and practices in research administration that balance accountability and recognition of the interests of all parties in achieving the maximum scientific benefit from both federal and institutional investments in research. Neither WARF nor COGR have received any federal grants, or engaged in any federal contracts or subcontracts that require reporting under House rules.

I. Background

WARF was founded in 1925 and is one of the earliest organizations engaged in university technology transfer. WARF exists to support scientific research at the University of Wisconsin-Madison. This mission is carried out by transferring university technology to the marketplace for the benefit of the university, the inventors and the public. Licensing income is returned to the university to fund further scientific research.

Over its 76-year existence, WARF has contributed over $600 million of licensing income to UW-Madison scientific research; but of greater significance is the fact that WARF's technology transfer successes have had a profound and positive effect upon the welfare, health and safety of humankind. Included among university inventions patented and licensed by WARF are: Professor Harry Steenbock's Vitamin-D invention which essentially eradicated rickets as a childhood disease; Professor Karl Elvehjem's copper-iron complexes which improved the physiological assimilation of iron in humans; Professor Karl-Paul Link's discovery of Coumadin®, the most widely used blood-thinner for treatment of cardiovascular disease, and its counterpart Warfarin, still the most widely used rodenticide world-wide; Professor Charles Mistretta's digital vascular imaging technology which enabled accurate diagnosis of blockage of the vessels of the heart; Professor Hector DeLuca's Vitamin-D derivatives which are widely used to treat osteoporosis, renal disease and other diseases; and currently, Professor James Thompson's human embryonic stem cell lines which have unprecedented potential for research and clinical application of presently untreatable diseases such as Parkinson's disease and diabetes. In total, the benefit to the public derived from these and other inventions is incalculable.

The success of bringing these and countless university inventions to the marketplace has depended on rich collaborations among scientists within the university; collaborations among scientists at different universities and collaborations among university and industry scientists. Collaboration among scientists in husbanding research dollars makes good sense with the cost and complexity of research today especially with various institutions engaged in essentially the same technological areas. Moreover, the evolution of science has made interdisciplinary research

more and more common and, in fact essential, if solutions to complex problems are to be found. A very recent stunning example of this is the sequencing of the human genome.

Collaborative research among, private, public and non-profit entities is quantifiably important to the U.S. economy. In 2000, non-profits and universities spent a record $28.1 billion on research and development much of which involved collaborations among private, public and non-profit entities. The positive effects of these collaborations on the U.S. economy are substantial. For example, in 2000, sales from products developed from inventions that were transferred from university research centers resulted in revenues of about $42 billion, [1] and U.S. universities, hospitals and research institutes realized almost $1.2 billion in gross license income much of which was used to fund additional research.[2]

Public funding of university research and the encouragement of collaborations among scientists at public, private and non-profit entities has been a keystone of the United States strength and leadership in high technology and biotechnology. With the bulk of university research being supported through federal grants and contracts, to be prudent with the taxpayer's money, it again makes good policy sense to encourage collaboration among scientists for the public interest. And actually, there has been an increase in the number of collaborations. Today WARF has over 70 inter-institutional agreements reflecting such collaborations. In these inter-institutional agreements, there is joint ownership of the results of the research by the

[1] Calculated on the realized gross license income applying an average of 3% as the royalty charge.

[2] Citing AUTM Licensing Survey 2000, Association of University Technology Managers, Inc., Norwalk, CN (2000).

collaborating scientists since most institutions operate under the Bayh-Dole Act[3] that gives the institution the right to retain title to any invention made with federal funds. That is the applicable rule even where the institution is in a sub-contracting situation where the prime contractor is the recipient of federal funds. Thus, in collaboration on an invention, each party may hold ownership rights.

II. University Patent Licensing (the Bayh-Dole Act)

The Bayh-Dole Act had its roots in enactment in 1980 of Pub. L. No. 96-517, the Patent and Trademark Law Amendments Act, and amendments included in Pub. L. No. 98-628, enacted into law in 1984. *See* 35 U.S.C. §§ 200-212. This Subcommittee played an instrumental role in the crafting of Bayh-Dole, and its cardinal principle that the public benefits from a policy that permits universities and small businesses to elect ownership of inventions made under federal funding and to become participants in the commercialization process. After passage of the Bayh-Dole Act, universities and colleges developed and strengthened the internal expertise needed to engage effectively in the patenting and licensing of inventions. A measure of the success of Bayh-Dole is the growth of the Association of University Technology Managers ("AUTM") from 113 members in 1979 to over 1800 today. The Bayh-Dole Act, so successful in the transfer of university technology to industry, encourages collaborations between industry and university scientists. It is well known that industry depends heavily on collaborations with universities for basic research. In the pharmaceutical, biotech and hi-technology areas, America's universities are the engines of cutting-edge ideas that have kept this country's industries the world leader in

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[3] Codified at 35 U.S.C. §§ 200-212.

new technology. These collaborations between scientists at separate universities and between industrial and university scientists often result in joint inventions.

III. A Threat to Collaborative Research

In spite of the trend toward scientific collaboration and the economic and practical necessity for such collaborations, a recent decision of the U.S. Court of Appeals for the Federal Circuit threatens to chill such collaborative activity. This decision, which cries for correction, is *Oddzon Products, Inc. v. Just Toys, Inc*[4]. Oddzon interpreted subsection 103(c) of the Patent Act to hold that prior art under subsections 102 (f) and (g)[5] could be used to determine the obviousness of an invention where:

a. there was no common ownership or assignment of the invention and information being shared among collaborators; and

b. the information exchanged was not publicly known.

That holding made it clear that information under 102 (f) or (g) could invalidate a patent in the circumstances of joint collaborative research. The *Oddzon* decision has been viewed as creating a significant threat for the loss of intellectual property rights for inventors who engage in joint research and development projects with scientists not employed by the same entity, be it a university or corporation. Thus, while the need for collaborative research in the public interest is becoming more and more evident, the *Oddzon* decision exerts a substantial chilling effect on collaborative efforts among universities, the private sector and the government.

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[4] 122 F.3d 1396, 43 U.S. P.Q. 2d 1641 (Fed. Cir. 1997).

[5] Section 103(c) was amended by the American Inventors Protection Act of 1999 to add Section (e) to the 103(c) exclusions.

This is clearly not what Congress, and this Subcommittee, intended when it amended section 103(c) in 1984 in the Patent Law Act of 1984 [6] in order to encourage open communication among members of research teams working in corporations, universities or other organizations. *See* Remarks of Robert W. Kastenmeier, 129 Cong. Rec. E5777 (daily ed. Nov. 18, 1983). It was considered at that time important to the economic interests of our country to encourage collaborative research. This provision of the patent law was particularly important for large corporations that rely on open communication and collaboration among various research teams within the corporation and has succeeded in encouraging free communication among the employees of large corporations and within universities.

A bit of legislative and judicial background is in order. The current quandary regarding section 103 had its roots in a decision of the caselaw of the U.S. Court of Customs and Patent Appeals, the forerunner of the Federal Circuit, which interpreted section 103 to mean that earlier inventions made by individual members of a research team would be used under section 103 to preclude the team's invention from being patented.[7] This caselaw was a significant concern to entities, both public and private, that utilize team research. Seeking reform, they approached this Subcommittee. And the Subcommittee responded, producing a legislative proposal that was enacted into law. *See* P.L. No. 98-622, 98th Cong., 2d Sess. (1984), 98 Stat. 3383. Section 103 was amended by adding the current subsection 103(c) to address the problem created by the CCPA's interpretation related to team research within an organization. The legislative history of the 1984 amendment clearly establishes that subsection 103(c) was designed to help encourage

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6 P.L. No. 98-622, 98th Cong. 2nd Session (1984), 98 Stat 3383

7 *See In re Bass*, 474 F.2d 1276 (CCPA 1973) and *In re Clemens*, 622 F.2d 1029 (CCPA 1980).

teamwork at least *within* organizations. Given the text of subsection 103(c) and its legislative history, it is clear that the enactment of subsection 103(c) sought to encourage teamwork among researchers, rather than stifle team research. In floor debate, Rep. Kastenmeier (who served as floor manager) characterized the amendment as being broader than teamwork "within" organizations, stating that the "change will be of material benefit to university and corporate research laboratories where the free exchange of ideas and concepts may have been hampered by the current state of the law with respect to what constitutes 'prior art.'" *See* 130 Cong. Rec. 10522, H10529 (daily ed. , Oct. 1, 1984), section-by-section analysis inserted in the record by Rep. Kastenmeier. Thus, it can safely be assumed that certain inter-organizational exchanges were not expressly exempted because there was a different research paradigm in place at the time of enactment.

However, after the passage of thirteen years, the *Oddzon* court held that prior art under sections 102(f) or (g) could be used to determine the obviousness of an invention in situations where (a) there was no common ownership or assignment of the invention and information being shared among the collaborators, and (b) the information exchanged was not publicly known. Effectively, the *Oddzon* decision creates a significant threat for the loss of intellectual property rights for inventors that engage in joint research projects with scientist from a different company or institution.

The solution is a legislative one. The *Oddzon* court itself invited Congress to review its decision stating that "it is sometimes more important that a close question be settled one way or another than which way it is settled. We settle the issue here (subject of course to any late intervention by Congress ...)." 122 F.3d at 1403.

Government-led initiatives to encourage the unhindered flow of information among scientists in the interest of meeting the technological needs of the country and maintain its technological leadership in the world are key elements in the consideration of the present initiative to recognize the adverse impact that the *Oddzon* decision is having on those broad goals. More immediate to the university sector is the potential loss of invaluable intellectual property rights and the delays or failure to achieve research goals where a collaborative effort would offer an opportunity to efficaciously move ahead.

The Bayh-Dole Act is of great value for universities as it provides retention of title of their intellectual property. Universities are also keenly aware of the objectives of the Bayh-Dole Act, which is to utilize the patent system to transfer technology to the private sector for development of the technology in the marketplace. The private sector is fully aware of the Bayh-Dole Act having interfaced with it for over 20 years, and appreciates that it affords a basis for protecting marketplace development and investment efforts. A significant factor in that university-private sector relationship is the willingness and opportunity to define ownership of an invention made jointly by those entities and the disposition of such jointly-owned inventions should the need arise. That opportunity under the proposed legislation should lay to rest voiced concerns about two patents directed to the same subject matter issuing to different parties in the event a collaborative arrangement is dissolved and afford a further spur to greater collaboration between the university and private sectors. This could readily result in more efficient development of products utilizing tax supported research results, and an increase in the transfer of technology for the public good.

Towards this end, we would propose a clarifying amendment to section 103 (c) that would result in:

- increasing the flow of information among scientists at different institutions;
- increasing the collaboration of scientists both within and without a given institution;
- promoting collaborations between the university and the private sector;
- promoting collaborations between government laboratories and the private sector as well as with the university sector; and
- enhancing the national pool of knowledge because of the greater unhindered flow of information among scientists.

The proposed amendment should be prospective only. Further, the amendment should not affect any final decision of a court or the Patent & Trademark Office that is rendered prior to the date of enactment and, should not affect the right of any party in any case pending before the PTO or a court on the date of enactment to have rights determined on the basis of the substantive law prior to the date of enactment.

IV. Related Issues

There is widespread recognition that the Bayh-Dole Act has been and continues to be successful beyond all expectations. It is unique in the world and is an essential component in the United States' global leadership in technology. At WARF, we receive numerous visitors each year from around the world. Invariably, our foreign visitors ask about the Bayh-Dole Act and express the wish that their own countries would adopt such forward thinking legislation. This committee can be justifiably proud of the role it played in passing such a successful, landmark legislation as the Bayh-Dole Act.

Yet, in spite of its undisputed success, there are continued attempts to alter Bayh-Dole so as to favor certain industries or groups. I trust that this Committee in its wisdom will safeguard such an important legacy of this committee and oppose any legislation that compromises the demonstrated success of the Bayh-Dole Act.

V. Conclusion

Mr. Chairman, thank you again for your time and attention. In conclusion, I leave you with three recommendations:

- an amendment to the Patent Act is necessary to promote collaborative research amongst the university and non-profit sector, the private sector and the government to achieve the promise of the 1984 amendments of this Subcommittee;
- an amendment which will, prospectively, reverse the holding in the Oddzon decision; and
- protection of the Bayh-Dole Act from amendments that compromise its demonstrated success.

If there are any questions I will be pleased to answer them.

G

Attachments on the
Doha / TRIPS Issue

1. Doha Declaration
2. USTR Press Release: U.S. Announces Interim Plan to Help Poor Countries fight HIV/AIDS and other Health Crises in Absence of WTO Consensus
3. PhRMA Statement (by Alan Holmer regarding the Postponement of the WTO TRIPS Negotiations)
4. Wall Street Journal Article: The Assault on Drug Patents
5. Global Humanitarian Partnerships
6. Recent HIV/AIDS Medicines Initiatives
7. Congress letter to Zoellick (11-25-02)
8. Senate letter to Zoellick (11-25-02)
9. Congress letter to Zoellick (12-06-02)
10. Biotechnology letter to Zoellick (11-27-02)
11. Iowa Biotechnology letter to Zoellick (12-02-02)
12. Pennsylvania Healthcare Technology Network letter to Zoellick (12-03-02)
13. Wisconsin Biotechnology Association letter to Zoellick (12-03-02)
14. Missouri Biotechnology Association letter to Zoellick (12-03-02)
15. Minnesota Biotechnology Industry letter to Zoellick (12-04-02)
16. Colorado Biotechnology Association (12-03-02)
17. Washington Biotechnology & Biomedical Association (12-03-02)
18. Texas Healthcare & Bioscience Institute (12-03-02)
19. Biotechnology Council of New Jersey (12-10-02)

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

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6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON, D.C.
20508

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FOR IMMEDIATE RELEASE:
DECEMBER 20, 2002

02-119
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U.S. Announces Interim Plan to Help Poor Countries fight HIV/AIDS and other Health Crises in Absence of WTO Consensus

United States Calls on Other WTO Members to Join in Individually Implementing the Doha Declaration on the TRIPS Agreement and Public Health

WASHINGTON - The United States today announced an immediate practical solution to allow African and other developing countries to gain greater access to pharmaceuticals and HIV/AIDS test kits when facing public health crises. The U.S. pledged to permit these countries to override patents on drugs produced outside their countries in order to fight HIV/AIDS, malaria, tuberculosis, and other types of infectious epidemics, including those that may arise in the future.

In the November 2001 Doha trade negotiations, Ministers affirmed that global trade rules permit compulsory licensing of drugs for such domestic health emergencies. One issue left remaining was how to enable poor countries without domestic production capacity to import under compulsory license from third countries drugs needed for HIV/AIDS, malaria, tuberculosis, and other infectious epidemics.

Negotiations in the World Trade Organization (WTO) have been unable to forge a consensus around a new multilateral rule to deal with this situation. Some WTO members and advocacy organizations sought to expand the targeted "poor country epidemic" focus of Doha to allow much wealthier countries to override a wide range of drug patents, for example, Viagra. This approach could seriously undermine the WTO rules on patents that provide incentives for development of new pharmaceutical products, including those to treat diseases of a non-epidemic nature.

The United States will continue to work with other WTO Members to try to find a solution within the WTO. In the meantime, the United States will implement the Doha Declaration by pledging not to challenge any WTO Member that breaks WTO rules to export drugs produced under compulsory license to a country in need, and called on others to join the United States in this moratorium on dispute settlement.

"The United States has worked intensively to find a solution that will provide life-saving drugs to those truly in need, and will continue to work towards that end," said U.S. Trade Representative Robert B. Zoellick. "We urge others to join us in this moratorium to help poor countries get access to emergency life-saving drugs."

Interim Measure by the United States Government

At Doha, Ministers affirmed their commitment to the TRIPS Agreement and confirmed Members' ability to use the flexibility in the Agreement, including the ability to override patents, to address public health crises.

However, many least-developed countries, for example in Africa, and some developing countries, lack sufficient manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing as currently provided by the TRIPS Agreement. The interim solution that the United States is announcing today is designed to help those countries combat HIV/AIDS, malaria, tuberculosis, and other infectious epidemics of comparable gravity and scale, including those that may arise in the future, by enabling them to treat these diseases by importing drugs from other WTO Members under the compulsory licensing rules of the TRIPS Agreement. Such infectious diseases would include, for example, ebola, African trypanosomiasis, cholera, dengue, typhoid, and typhus fevers.

The United States expects that all countries will cooperate to ensure that the drugs produced are not diverted from countries in need to wealthier markets.

The United States remains committed to finding a workable, transparent, sustainable, and legally certain solution that will fulfill the Doha Declaration directive as soon as possible. We encourage all countries to reflect on the original purpose of the Doha Declaration and to work for a solution that is consistent with it.

This special measure will not apply to developed country Members of the WTO or those developing economy Members classified by the World Bank as high income countries - Barbados, Brunei, Cyprus, Hong Kong, Israel, Kuwait, Liechtenstein, Macao, Malta, Qatar, Singapore, Slovenia, Taiwan, and the United Arab Emirates. These countries have sufficient production capacity in the pharmaceutical sector or sufficient financial resources to address such public health problems and thus do not need to import under compulsory licenses.

After a year of intensive negotiations, WTO Members have not been able to reach a consensus to implement the remaining elements of the Doha Declaration on the TRIPS Agreement and Public Health because some countries insisted that the solution cover all health problems, including non-emergencies. Further, some Members have insisted that the limited exception be available to all countries regardless of their manufacturing capacities or financial resources. This element of the Doha Declaration was intended to focus international action on the grave public health crises afflicting the poor and to assist countries lacking capacity and resources to obtain access to needed medicines for infectious epidemics. Unless WTO Members focus on infectious epidemics and truly needy countries, the solution called for at Doha will not benefit those for which it was intended.

Background:

The United States has been, and remains, committed to the Doha Declaration of the TRIPS Agreement and Public Health. Throughout the process leading up to, and following, Doha, the United States has sought to address the problems of those countries most in need:

- Prior to the Doha Ministerial last year, the United States recognized the crisis situation resulting from the HIV/AIDS epidemic in sub-Saharan Africa, and announced its willingness to forgo any challenge to countries that needed to override patents to address HIV/AIDS. Unfortunately, this proposal was not accepted by certain Members.

- Further, the United States proposed an extension for all least-developed WTO Members until 2016 with regard to their obligations relating to all pharmaceutical patents, which was adopted by the WTO in 2002.

- The United States remains the largest bilateral donor of HIV/AIDS assistance, providing 45 percent of all international spending on AIDS. In fiscal year 2003, President George Bush has requested $1.3 billion to combat HIV/AIDS internationally. This is an 82 percent increase over the 2001 appropriations. The President has pledged $500 million to the Global Fund to combat the international scourge of HIV/AIDS, malaria and tuberculosis, and the President announced a new $500 million International Mother and Child HIV Prevention Initiative that seeks to prevent the transmission of HIV/AIDS from mothers to infants and improve health care delivery in Africa and the Caribbean.

Several U.S. pharmaceutical companies have formed partnerships with African countries and are working together to address many of the problems related to providing treatment to those in need. Their policies include the sale of critical medicines at very low prices, as well as the building of an improved infrastructure for getting these medicines to those in need. More than 50 percent of all new medicines are invented in the United States. Therefore, we recognize that the solution both to today's health problems - and tomorrow's - in terms of new medicines, will likely come from U.S. companies.

At the Doha Ministerial, Ministers acknowledged the serious public health crises afflicting Africa and other developing and least-developed countries, especially those resulting from HIV/AIDS, malaria, tuberculosis and other infectious epidemics. Ministers agreed on the need for a balance between the needs of poor countries without the resources to pay for cutting edge pharmaceuticals and the need to ensure that the patent rights system which provides the incentives for continued development and creation of new lifesaving drugs is promoted. One major part of the Doha Declaration was agreement to provide an additional ten-year transition period (until 2016) for least developed countries, as proposed by the United States and agreed upon by all WTO Members.

Paragraph 6 of the Doha Ministerial Declaration on the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement and Public Health recognizes that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement in order to address these health problems. WTO Ministers directed the TRIPS Council to find a solution to this problem and to report to the General Council before the end of 2002.

Under current WTO patent rules, a country is free to override a patent, under certain conditions, to allow production of the patented product in its domestic market. This is commonly referred to as "compulsory licensing." The Doha Declaration affirmed that Members may use compulsory licensing to address public health crises. However, under current WTO rules, products produced under compulsory license generally cannot be exported to other WTO Members. The U.S. solution is intended to eliminate this export restriction so medicine can be supplied to countries most in need that cannot manufacture their own pharmaceuticals.

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Statement PhRMA

December 20, 2002

Statement by Alan F. Holmer, President Regarding the
Postponement of the
WTO TRIPS Negotiations

We support the U.S. moratorium on non-enforcement of its WTO rights for AIDS, tuberculosis, malaria, and other infectious diseases of comparable gravity and scale for the poorest countries.

The essential, critical need is to help patients suffering from grave epidemics like HIV/AIDS, malaria, and TB in the poorest countries. The U.S. Government and the research-based pharmaceutical industry have never wavered in our commitment to do so.

The U.S. pharmaceutical industry, like the U.S. government, is committed to action rather than rhetoric in addressing this important issue. That's why our companies have donated more than $2 billion over the past five years to bring medicines, educational programs and improved health infrastructure to the developing world.

The industry urges that strong intellectual property protection remains the engine that drives high-risk, costly investment in drug R&D, which benefits patients and their families. As World Health Organization Director General Gro Harlem Brundtland has explained, patent protection for medicines is essential to public health, by encouraging such investment. Any widespread or significant dilution of patent protection for medicines is a setback for patients all over the globe who are eagerly awaiting new medicines and hopefully someday a cure for the disease from which they (and their families) suffer.

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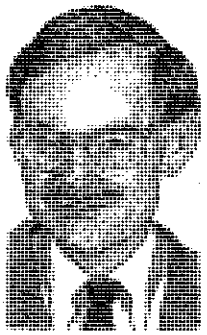
REVIEW & OUTLOOK

The Assault on Drug Patents

Among the greatest U.S. achievements during the last major round of world trade negotiations was the addition of intellectual property protections to the international system. This benefited premier U.S. industries such as entertainment, software and drugs and it also brought the rule of law and an incentive for innovation to countries around the world.

The U.S. ought to stand up for intellectual property rights.

But less than a decade later, much of the progress is at risk. A powerful alliance of countries and activist groups is trying to use the launch of the latest round of World Trade Organization negotiation to strip away protection for drug patents. Worse, there are worrying signs that U.S. Trade Representative Robert Zoellick, desperate for any appearance of progress, may acquiesce.



Robert Zoellick

WTO negotiators are meeting in Geneva to flesh out the meaning of last year's Doha declaration, which said the world's poorest countries should be allowed to ignore patents when faced with epidemics including HIV, malaria and TB. The U.S. went along with the measure because of its narrow scope, and even the drug industry didn't object.

But the list of alleged justifications for patent seizure seems to be growing longer by the day. The latest drafts we've seen would allow any country to import copycat drugs when faced with any self-declared epidemic—be it cancer or erectile dysfunction.

The prime movers here are countries like India and Argentina, which do not respect patents and have large knock-off pharmaceutical industries looking for new markets. These industries, in turn, fund activists who charge that the high price of patented drugs fuels epidemics like AIDS in Africa. And they've all found a willing ally in European Trade Commissioner Pascal Lamy, who sees the patent issue as a great way to divert Third World anger over the EU's protectionist agricultural policies. America, Britain and Switzerland—the only countries with innovative, research-based pharmaceutical industries—find themselves pretty much alone.

That doesn't mean the U.S., with consumers who fund the world's drug research, can't stand its ground. But clearly the folks producing these radical proposals don't believe Mr. Zoellick intends to go to the mat for an industry with little support on Capitol Hill. The Bush Administration has shown a worrying tendency to satisfy itself with Pyrrhic victories (the terror insurance and education bills) and has frittered away its credibility on international trade with steel tariffs and a European-style farm bill.

There is little evidence to support the complaints about drug patents. Many poor countries lack the health infrastructure to distribute medicines or even diagnose disease, which is why numerous attempts by pharmaceutical companies to provide them with cheap drugs have found few takers. If the anti-patent lobby gets its way, that won't change. Rather, a glimpse of the future can be seen in India, where 20,000-plus drug makers churn out cheap copies of Viagra and Rogaine for rich urbanites while treating less than 1% of the country's 4 million HIV cases. American pharmaceutical makers would lose the incentive to develop new drugs, while poorer countries would lose any incentive to develop research-based drug industries of their own.

American negotiators, moreover, would be naive to think that the attempted pillage will stop here. If the need for drugs justifies the seizure of intellectual property, why not the need for medical technology or software? Watch out, Bill Gates.

Today's crusade against drug patents is just the sharp end of a broader assault on intellectual property and global capitalism in general. The pressure is on to produce a text for a vote in December, and putting a stop to this challenge could well require courage on the part of the American team. The WTO's current intellectual property regime is the result of a decade of hard work—gains won in part because of the willingness of then-U.S. Trade Rep Carla Hills to walk away from a 1990 conference in Brussels. It would be foolish to throw that all away for the sake of a quick agreement now.

State's Saudi Surprise

Tucked away in the massive Homeland Security bill on its way to President Bush's [illegible] with few hard questions asked of her—and even fewer answered in any detail.

The visa provision is overdue to toughen re-

By Steven Malanga

When businessman Micha office as New York's mayor boldly declared that the city v ness." It was an essential me and the world from the new le less than four months earli devastating attack that blew a largest business district, kill people, and vaporized 90,000

Businessman Mayor

Today, less than a year l man mayor is declaring that for business. Facing a st brought on as much by the ci spending and Wall Street's b Sept. 11 attack, Mr. Bloombe lions of dollars in new taxes the most heavily taxed, bigg America. More incredibly, struggles to win back tens c that fled the city after the lapsed, the mayor is seeking of his new taxes on commut "Come back to New York," t runs—"even though you will rents because of our propert your employees will fork ov lars more in withholding ta

It's a toxic message fro looks increasingly like a va he morphs into a classic t liberal pol more concerned bloated budget and work fo economy. True, Mr. Bloom scribed liberal Democrat wh lican flag only because the p date. But his metamorphos able, spells disaster for the of global finance.

If there is one thing th years tell us, it is that Nev odic efforts to close its duced budget gaps with taxes are disastrous both f economy and for the city's and quality of life. It's a le Bloomberg should have from predecessors like David Dinkins, whom he i mayingly, resembles. Whe his aggressive social age faced a giant deficit—inst sonal income tax, pushed based corporate tax, and a tax on commuters, busin eight years the city lost ding 20% of its private w home to the headquarters 500 before Lindsay's time

This dramatically si couldn't support the huge Lindsay had constructed,

PhRMA

GLOBAL HUMANITARIAN PARTNERSHIPS

~ Industry Contributes $1.9 Billion To Global Health Initiatives over four years, $564 million in 2001 ~

- ***Abbott*** ~ through its Abbott Access program participates in efforts to expand treatment access, including the Accelerating Access Initiative, by offering its HIV protease inhibitors Norvir and Kaletra, and its rapid test Determine HIV at a loss to the company in all 68 African and Least Developed Countries; through its prevention of mother-to-child transmission (PMCTC) program will donate up to 20 million rapid HIV tests for the next five years to provide the testing element needed to conduct PMCTC in those 68 countries; launched Step Forward?for the world's children philanthropic program to help AIDS orphans and vulnerable children in Tanzania, Burkina Faso, India and Romania; supports relief efforts for victims of natural disasters around the world.

- ***Aventis***~ contracted with WHO on a 5-year program to combat sleeping sickness in sub-Saharan Africa. The program includes drug donations and financial support for disease management activities as well as for R&D in new treatments. The company has also established a partnership with the Nelson Mandela Foundation to expand the DOTS strategy to combat TB in South Africa.

- ***Bayer*** ~ is providing two drugs at no cost to treat sleeping sickness in Africa for five years; supports the development and use of mini-labs; donates $5.6 million in drug products to missionary aid projects in Bosnia, Romania, Mexico, and Central and South America; donates 3.8 million euros in supplies to earthquake victims in India; is developing new malaria medicine in partnership with the WHO for use in developing countries.

- ***Boehringer Ingelheim*** ~ donates Viramune to developing nations and $1 million to Elizabeth Glaser Pediatric AIDS Foundation to prevent mother-to-child transmission; establishes respiratory rehab center in Ecuador, pulmonary care centers in Argentina, Peru, Venezuela, Colombia, Indonesia, Vietnam and China, and pulmonary research facility in SA; participates in *Accelerating Access Initiative.*

- ***Bristol-Myers Squibb*** ~ sells ddI and Zerit below cost and makes Zerit patent available; expands *Secure the Future*; combats pediatric AIDS in Mexico; addresses infrastructure needs and cardiovascular disease in China; participates in *Accelerating Access Initiative.*

- ***Eli Lilly*** ~ donates medical relief to more than 50 countries each year; supports diabetes programs in developing countries; works with WHO and Doctors Without Borders to treat MDR-TB patients.

- ***GlaxoSmithKine*** ~ offers HIV and anti-infective medicines at cost to 63 developing nations; funds new HIV/AIDS clinic in SA; supplies 1.1 billion vaccine doses; develops treatments for diseases specific to developing countries; invests $32.5 million in *Action TB*; donates albendazole for Lymphatic filariasis; facilitates *Positive Action* program; provides on-going care to HIV/AIDS patients in Mpumalanga, SA; donates $1.5 million in grants to develop effective

malaria control in African communities; supports *Personal Hygiene and Sanitation Education*; participates in *LF Global Alliance* and *Accelerating Access Initiative.*

- ***Johnson & Johnson*** ~ supports *Humana People to People in the Total Control of the Epidemic* in Zimbabwe; supports the *Drop in Shelter*; hires a theater group to discuss HIV issues; supports *Healthy Children, Healthy Futures* to treat intestinal parasites and Operation Smile; supplies health kits through the *Global 2000 Guinea Worm Eradication Program*; supports treatment for burn patients in Soweto, infection control project in Vietnam and programs for orphaned HIV-infected children in Thailand.

- ***Merck*** ~ offers two ARVs to more than 60 developing countries at no profit; donates $50 million and ARVs to *Botswana Comprehensive HIV/AIDS Partnership;* donates medicine to eliminate river blindness; extended the *Merck Mectizan Donation Program* to treat lymphatic filariasis; provides one million doses of MMP II to Honduras; donates five million doses of hepatitis B vaccine; provides $5 million grant for the *Enhancing Care Initiative* for people living with HIV/AIDS; participates in *Accelerating Access Initiative.*

- ***Novartis*** ~ donates $30 million in treatment for leprosy patients from 2000 to 2005 and committed to eradicating leprosy; sells anti-malarial medicine at cost in Africa; supports programs in health, agriculture and social development in developing countries; donates medicines to disaster victims in China, Central America and Taiwan; core member of the *Global Alliance to Eliminate Leprosy.* As part of the Roll Back Malaria initiative, Novartis provides at cost its novel life-saving treatment, Coartem, for distribution through WHO

- ***Pfizer*** ~ donates anti-fungal to SA and least developed countries; establishes *Academic Alliance for AIDS Care and Prevention in Africa;* funds a study to identify the best community-based approaches for HIV/AIDS prevention; supports construction of first large-scale HIV/AIDS clinic in Africa; co-founded the *International Trachoma Initiative* and provides $45 million in donated medicine; supports initiative to recruit, train and equip medical volunteers to care for HIV-infected patients in SA.

- ***Pharmacia*** ~ provides $750,000 to develop the *Save the Mothers Initiative* for reduced maternal mortality in Central America, Ethiopia, Mozambique, Pakistan and Uganda; provides medicines and money to developing countries for disaster relief; donates 4,200 vials of Neosar in Tanzania to retreat children.

- ***Roche*** ~ provides HIV medicine at reduced price in Brazil; actively supports *SHARE* to teach health experts about HIV; supports HIV-NAT to conduct clinical studies in Thailand; supports research on infections including TB, malaria and viral hepatitis; set up *The Task Force Sight and Life* to combat vitamin A deficiency; donates drugs and equipment, provides free exams, and sets up health education programs in Indonesia village; supports Phelophepa Health Care Train, a project providing medical care in rural SA; participates in *Accelerating Access Initiative.*

- ***Schering-Plough*** ~ provides free medical products in Central and South America, India, Egypt and other countries; provides medical support including a prison conditions program in SA, hepatitis diagnostic support in India, rectal cancer screening in the Philippines and medical scholarship grants.

- ***Wyeth*** ~ donates anti-infectives, anti-fungals and analgesics including 10 million doses of its Hib conjugate vaccine to GAVI; contributes $2 million dollars to polio eradication program in Africa.

For a copy of "Global Partnerships: Humanitarian Programs of the Pharmaceutical Industry in Developing Nations", contact PhRMA at 202-835-3400 or visit our Web site at www.world.phrma.org

RECENT HIV/AIDS MEDICINES INITIATIVES

MAY 2000
Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., Inc., and Roche, together with five U.N. organizations (UNAIDS, WHO, UNICEF, UNFPA and the World Bank), establish the *Accelerating Access Initiative* to increase access to HIV/AIDS care and treatment in developing nations. Abbott Laboratories joined the Initiative subsequently.

JULY 2000
The Merck Company Foundation and the Bill & Melinda Gates Foundation agree to donate $50 million each over five years to the *African Comprehensive HIV/AIDS Partnerships* in Botswana, a joint initiative of the Government of Botswana, the Gates Foundation and Merck. Merck also makes a commitment to supply its ARVs free of charge for use in Botswana's treatment programs (according to government clinical practice guidelines) for the duration of the program.

Boehringer Ingelheim offers to supply VIRAMUNE free to developing nations for five years to prevent mother-to-child transmission of HIV.

DECEMBER 2000
Pfizer establishes the *Diflucan Partnership Program* with the South African Ministry of Health and donates free doses of the anti-fungal drug Diflucan® to treat cryptococcal meningitis and oesophageal candidiasis, life-threatening opportunistic infections associated with HIV/AIDS.

JANUARY 2001
Abbott begins work on *Tanzania Care*, a partnership with the government of Tanzania to build the country's AIDS response/management system, including a national AIDS program and national AIDS care guidelines, nationwide HIV testing system and training for medical professionals.

FEBRUARY 2001
GlaxoSmithKline extends its offer of a 90 percent discount on HIV/AIDS medicines to NGOs in developing countries and employers in Africa who offer care to their workers.

Roche and PharmAccess International, a not-for-profit Dutch-American organization, announce a new initiative to create access to anti-HIV drugs for patients in four African countries. The program is initiated in major urban treatment centers in Cote d'Ivoire, Kenya, Senegal and Uganda, with Roche providing funding, anti-retroviral agents, and diagnostic and monitoring tests as well as technical support for training of health care professionals and patient education.

MARCH 2001
Merck & Co., Inc. offers to sell its ARVs—Crixivan and Stocrin—at no-profit prices in the LDCs and those nations hardest hit by the epidemic, and at significant discounts in other countries in the medium category of the Human Development Index—more than 110 countries in all.

Bristol-Myers Squibb makes the patent for Zerit [d4T] available at no cost to treat AIDS in South Africa and offers to sell ddI and Zerit below cost.

Abbott, in establishing *Abbott Access*, offers to sell its ARVs Norvir and Kaletra and Determine HIV rapid test at no-profit prices in all of Africa and the 49 LDCs.

JUNE 2001
Pfizer expands eligibility for the *Diflucan Partnership Program* to include governments and NGOs in the 49 LDCs and sub-Saharan Africa.

GlaxoSmithKline extends its offer to sell AIDS and other infectious disease medicines, including Ziagen and Trizivir, at no-profit prices to 63 of the world's poorest countries, including all those in sub-Saharan Africa.

SEPTEMBER 2001
Roche provides the HIV medication Viracept® (nelfinavir) to the Brazilian Ministry of Health during 2002 at substantially reduced prices for those treated by the government.

DECEMBER 2001
By December 2001, the cost of ARV drugs offered individually by the companies participating in the *Accelerating Access Initiative* had decreased significantly, in some cases to as little as 10 percent of their prices in industrialized countries.

JANUARY 2002
Roche and PharmAccess International announce the start of patient enrollment in the CARE partnership pilot program to deliver comprehensive HIV health care in four African centers. A year later, with support and funding from Roche, the program is providing access to HIV care for patients throughout Africa. The program aims to sustain the wider access to HIV therapy by providing disease education and building up vital local medical infrastructure.

JUNE 2002
Abbott pledges to donate up to 20 million Determine HIV-1/2 rapid tests over five years to programs for the prevention of mother-to-child transmission in Africa and the 49 LDCs. Abbott also announces further reductions in the *Abbott Access* prices for its ARVs Norvir and Kaletra, offering to sell them at a loss to the company.

JULY 2002
At the International AIDS Conference in Barcelona, Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., Inc., and Roche sign statements of intent with two major regional groups of countries—Economic Community of Western African States (ECOWAS) and the Caribbean Community (CARICOM)—to expand access to HIV/AIDS care and treatment through the *Accelerating Access Initiative.*

Roche makes Invirase and Viracept pediatric powder available at no-profit prices to the LDCs and in sub-Saharan Africa.

SEPTEMBER 2002
GlaxoSmithKline further reduces the no-profit preferential prices of its HIV/AIDS medicines by up to 33 percent and its anti-malarial medicines by up to 38 percent. GSK will also supply these medicines at no-profit prices to all projects fully financed by the Global Fund to fight AIDS, TB and Malaria.

OCTOBER 2002
Merck & Co., Inc. offers to make new 600-mg. tablet formulation of STOCRIN available at less than one dollar per day in the LDCs and those hardest hit by the HIV/AIDS epidemic.

DECEMBER 2002
Pfizer and The Pfizer Foundation announce that the *Diflucan Partnership Program* will be extended indefinitely. By January 2003, the program was operating in 12 African nations and Haiti.

JANUARY 2003
Pharmacia Corporation announces the launch of a pilot program, in partnership with the International Dispensary Association Foundation that has the potential to benefit HIV/AIDS patients in 78 developing countries, including all of the countries in sub-Saharan Africa. Pharmacia will grant non-exclusive licenses for delavirdine, a medicine for HIV/AIDS, to generic pharmaceutical companies that agree to manufacture and supply the product to the world's poorest countries.

As of January 2003, 80 countries have indicated their interest in participating in the *Accelerating Access Initiative*. In 39 of these 80 countries, national plans to improve access have been or are being developed. A total of 19 countries, including a number of countries in sub-Saharan Africa, Chile, Honduras, Jamaica, Morocco and Ukraine, have reached agreement with manufacturers on significantly reduced drug prices.

Following discussions in Panama facilitated by the Pan-American Health Organization (in the framework of the *Accelerating Access Initiative*), the ministers of health of Panama, Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua reached individual agreements with representatives of Boehringer Ingelheim, Bristol-Myers Squibb, Roche, GlaxoSmithKline and Merck & Co., Inc. to implement or maintain pricing policies that will lead to significant discounts (up to 85 percent in some cases, and 55 percent on average) for antiretroviral treatments in Central America and to a substantial increase in the number of people in the region with access to HIV/AIDS care and treatment.

Congress of the United States

Washington, DC 20515

November 25, 2002

The Honorable Robert Zoellick
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Dear Ambassador Zoellick:

As you prepare for the latest round of negotiations on the Doha Declaration on the TRIPS Agreement and Public Health, we wanted to express our strong commitment to a solution that responds to the truly exceptional public health challenges faced by poor countries. Working with the international community, we must balance the public health needs of developing countries while maintaining our commitment to global trade standards that promote innovation and protect intellectual property.

The United States must devise a mechanism which will enable the poorest WTO Members afflicted with epidemics of HIV/AIDS, TB and malaria to obtain needed drugs by allowing them to procure low-cost medicines under certain circumstances. At the same time, TRIPS establishes disciplines that are beneficial to both economic development and innovation in the area of new drug therapies. As you know, the Trade Act of 2002 instructs USTR to seek agreements respecting the Declaration on the TRIPS Agreement and Public Health adopted at Doha in November 2001, which establishes such a balance.

The recent discussions in Sydney have resulted in a general agreement to help developing countries procure the drugs they need. Discussions, however, need to continue to define which diseases will be covered and which countries will benefit. An open-ended or unclear exception to the standards for patent protection would seriously undermine our interest and set back the long-term public health objectives Doha was designed to achieve. We urge you to negotiate a solution that is specifically limited to the diseases that were the focus of the Doha Declaration, namely HIV/AIDS, TB, Malaria and other epidemics of similar scale. In addition, it should be clear that only truly disadvantaged countries, such as those countries in sub-Saharan Africa, be the recipient of the changed rules.

We look forward to working with you to fashion a TRIPS Council outcome this year that will be consistent with the goal of maintaining the integrity of the TRIPS Agreement while respecting the important mandate set forth in the Doha Declaration.

Sincerely,

JENNIFER DUNN
Member of Congress

PHIL CRANE
Member of Congress

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ROY BLUNT
Member of Congress

DEBORAH PRYCE
Member of Congress

DAVID DREIER
Member of Congress

MICHAEL OXLEY
Member of Congress

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CLIFF STEARNS
Member of Congress

GARY MILLER
Member of Congress

DAVID PRICE
Member of Congress

CAL DOOLEY
Member of Congress

MIKE FERGUSON
Member of Congress

United States Senate

WASHINGTON, DC 20510

November 25, 2002

The Honorable Robert Zoellick
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Dear Ambassador Zoellick:

As you prepare for the latest round of negotiations on the Doha Declaration on TRIPS and Public Health, we wanted to express our strong commitment to a solution that responds to the exceptional public health challenges faced by poorer countries faced with the HIV/AIDS pandemic. While the United States works with the international community to address this issue, we must balance the public health needs of developing countries with maintaining global trade standards that promote innovation and protect intellectual property.

The United States must devise a mechanism which will enable the least developed WTO Members afflicted with epidemics of HIV/AIDS, tuberculosis and malaria to obtain needed drugs by allowing them to procure low-cost medicines under certain circumstances. At the same time, TRIPS establishes disciplines that are beneficial to both economic development and innovation in the area of new drug therapies. As you know, the Trade Act of 2002 instructs USTR to seek agreements that respect the exceptional circumstances outlined in the Doha Declaration in Doha in November 2001.

An open-ended or unclear exception to the standards for patent protection would seriously undermine our interest and set back the long-term public health objectives Doha was designed to achieve. We urge you to negotiate a solution that is specifically limited to the diseases that were the focus of the Doha Declaration, namely HIV/AIDS, tuberculosis, Malaria and other infectious epidemics of similar gravity and scale that may arise in the future. In addition, it should be clear that only truly disadvantaged countries, such as those countries in sub-Saharan Africa, be the recipient of the changed rules.

We look forward to working with you to fashion a TRIPS Council outcome this year that will be consistent with the goal of maintaining the integrity of the TRIPS Agreement while respecting the important mandate set forth in the Doha Declaration.

Sincerely,

Max Baucus John Breaux

Congress of the United States
Washington, DC 20515

December 6, 2002

The Honorable Robert B. Zoellick
United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Dear Ambassador Zoellick:

As you prepare for the latest round of negotiations on the Doha Declaration on TRIPS and public health, we want to join our Democratic and Republican colleagues in the House and Senate in expressing our strong commitment to a solution that responds to the exceptional public health challenges faced by poorer countries, particularly countries in sub-Saharan Africa, faced with the HIV/AIDS pandemic. As you know, we worked hard to enact the African Growth and Opportunity Act (AGOA), the goals of which are compromised by the devastating economic impact of HIV/AIDS on the populations in Sub-Saharan Africa.

The Doha Declaration sets a mandate for WTO members to devise a mechanism which will enable the least developed WTO Members afflicted with epidemics of HIV/AIDS, tuberculosis and malaria to obtain needed drugs by allowing them to procure low-cost medicines under appropriate circumstances.

We are aware that this negotiation has reached a critical stage. It is our sincere hope that the U.S. will advocate for a solution that will address the needs of the world's poorest patients, such as those in Sub-Saharan Africa, by ensuring that these countries remain the focus of the solution. The outcome of this negotiation should not allow the commercial interests of countries like India and China to undermine the effort to address the legitimate public heath emergencies identified in the Doha Declaration. Therefore, we urge you to negotiate a solution that is focused specifically on the diseases that were identified in the Doha Declaration, namely, HIV/AIDS, tuberculosis, malaria and other infectious epidemics of similar gravity and scale that may arise in the future. In addition, it should be clear that only truly disadvantaged countries, such as those in Sub-Saharan Africa, be the beneficiaries of the changed rules.

We look forward to working with you to achieve further progress in promoting economic growth and in working to stem the scourge of HIV/AIDS on the Continent.

Sincerely,

William J. Jefferson
Member of Congress

Adolphus Towns
Member of Congress

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Sheila Jackson-Lee
Member of Congress

Harold E. Ford, Jr.
Member of Congress

Donna M. Christian-Christensen
Member of Congress

Gregory W. Meeks
Member of Congress

BIO
BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

November 27, 2002

The Honorable Robert B. Zoellick
United States Trade Representative
600 17th St. N.W.
Washington DC 20508

Dear Ambassador Zoellick:

I am writing to express the serious concerns of the more than 1,100 members of the Biotechnology Industry Organization (BIO) over recent developments in Geneva concerning the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

BIO represents the interests of companies engaged in cutting-edge research that will provide innovative medicines, agricultural and environmental products to millions of people worldwide. The vast majority of our member companies are involved in research and development in the health care arena. In the developing world, biotechnology R&D can do its part by producing vaccines that do not require refrigeration and are nasally or orally delivered. Furthermore, biotechnology's innovative approaches can provide medicines for difficult to treat diseases such as malaria, tuberculosis and cholera. In a speech before a gathering of biotechnology leaders in June, I called on biotech health leaders to devise a comprehensive program for diseases of the developing world. The biotechnology industry is ready to do its share to combat the world's health problems.

But the reality is that the vast majority of our members are small start-up companies concentrating on research. In fact, more than 90 percent of biotechnology companies have yet to bring a product to market, and thus, they rely on patent portfolios as their only assets. What a biotech company owns and markets is essentially ideas: for example, the discovery of a potential point of intervention in a disease process or the identification of a gene or a regulatory compound that might affect that process. But earning a patent is only the beginning of the work. The ability of these companies to raise funding from the capital markets is linked directly to the availability, strength and

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security of their intellectual property rights. Without certainty in rights, our companies simply cannot raise funds to conduct their research and offer their products on the market. Without funding, products to treat unmet medical such as assistance to help patients suffering from HIV/AIDS and other intractable diseases will not be developed.

BIO supports the objectives of the Doha Declaration on the TRIPS Agreement and Public Health issued by the Doha Ministerial last November. We support the position because we appreciate that the intellectual property standards in the TRIPS Agreement permit countries to take action when faced with grave and immediate public health crises. We further support the Doha Ministerial's call for the WTO to devise a way for certain poor countries to gain access to alternative sources of pharmaceutical products if they cannot obtain them from the pioneer producer. The biotechnology industry is fully aware that there are special circumstances for which a legally secure mechanism should be developed to allow poor countries afflicted with epidemics of HIV/AIDS, tuberculosis and malaria to obtain drugs from alternative sources.

But we cannot support eliminating intellectual property protections throughout the developing world for all pharmaceutical products. This was never the intent of the Doha Ministerial. We are surprised and troubled therefore, that the draft legal text that recently emerged in Geneva after months of discussions deviates so dramatically from the mandate of Doha. The text that was widely circulated in the press last week would allow producers in large developing countries with significant manufacturing capabilities to manufacture any drug and to export it to any country to address any health-care situation. Such a "solution" would create a huge loophole in the protections guaranteed by the TRIPS Agreement and undermine the intellectual property protections that serve as incentives for investment in biotechnology research and development. If patent protection is uncertain, the biotechnology community cannot fulfill its promise of producing groundbreaking medicines for treating HIV/AIDS, malaria and tuberculosis, among others.

We are concerned that the tenor and direction of the current debate sends a very troubling and inaccurate message about the role of intellectual property protection and the steps our industry is taking to help these countries address their public health challenges. Next week BIO and the Bill and Melinda Gates Foundation will be hosting an unprecedented conference in Washington that will stimulate the formation of public-private partnerships to develop new drugs for diseases that are prevalent in the developing world. Preserving the essential market-based incentives for intellectual property is a critical component of these efforts.

We urge the administration to act now to ensure that any agreement reached by negotiators in Geneva reflects accurately the mandate of the Doha Declaration.

Sincerely,

Carl B. Feldbaum
President
Biotechnology Industry Organization

CBF:lf
cc: Peter Allgeier Deputy United States Trade Representative
Joe Papovich Assistant United States Trade Representative
Linnett Deily U.S. Ambassador to World Trade Organization
James E. Rogan Undersecretary of Commerce
Gary Edson, Deputy Assistant to the President

IOWA
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Univ. of Iowa

Jack Sualock
Cargill Corn Milling

December 2, 2002

The Honorable Robert B. Zoellick
U.S. Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: Doha Declaration – Agreement on Trade-Related Aspects of Intellectual Property

Dear Ambassador Zoellick:

The Iowa Biotechnology Association has recently learned of a very serious international issue, which if left unaddressed would do significant damage to the growth of biotechnology and life sciences. The heart of the emerging life science industry is the ability to protect and preserve intellectual property. Recent reports that several developing countries and socialist non-governmental organizations are seeking to expand the Doha Declaration to cover all diseases would serve a fatal blow to business, as we know it in the United States.

Of the more than 70 members of the Iowa Biotechnology Association and those awaiting their birth through scientific research and development, diluting the Doha Declaration would place patent and intellectual property protection as valueless. Maintaining the focus on HIV/AIDS, tuberculosis and malaria will speak to many of the grave public health crises found in some developing countries without jeopardizing new innovations or existing markets.

Ernst & Young have recently reported the United States is home for 72% of the worldwide investments in biotechnology and 75% of the jobs. This remarkable record is due to having a free-market economy and the ability to preserve and protect valuable intellectual property.

On behalf of the members and non-members of Iowa's life science industry, we implore you to stand fast for the Doha Declaration.

Sincerely,

Doug Getter
Executive Director

CC: Senator Charles Grassley
Senator Tom Harkin

The Iowa Biotechnology Association is a young organization of over 75 life science companies, academic institutions and others interested in the growth and development of life sciences in Iowa.

PENNSYLVANIA HEALTHCARE TECHNOLOGY NETWORK
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December 3, 2002

The Honorable Robert B. Zoellick
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick:

As executive director of the Pennsylvania Healthcare Technology Network, representing more than 27 pharmaceutical and biotechnology companies and trade associations, I am writing to voice grave concerns regarding recent trade discussions that would strip away patent protections and could ultimately hamper the vital research conducted by these companies.

We recognize the need to address health crises in poor countries and support efforts to find a solution to this ongoing challenge. However, we believe the solution must stay true to the intent of the Doha Declaration – specifically that poor countries facing HIV/AIDS, TB, malaria and other infectious epidemics of similar gravity and scale are allowed to use the mechanism if necessary because they truly lack productive capacity in the pharmaceutical sector.

Without this narrowly defined scope, patent protections will be eroded, stifling private-sector innovation and hurting patients worldwide who are counting on America's pharmaceutical companies to deliver new cures.

We urge you to protect American innovation and the millions of patients around the world who benefit from it by staying true to the intent of the Doha Declaration and rejecting all efforts to expand its scope.

Sincerely,

Kathi Cullari
Executive Director
Pennsylvania Healthcare Technology Network



WISCONSIN BIOTECHNOLOGY ASSOCIATION

AMERICA'S THIRD COAST BIOTECH COMMUNITY

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John Neis
Venture Investors Management LLC

J. Eric Stahre
GE Medical Systems

Professor Michael Sussman
University of Wisconsin Biotechnology
Center

December 3, 2002

VIA FAX 202-395-4549

The Honorable Robert B. Zoellick
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick:

The members of our state association of biotechnology companies, doing business in the Midwest of the United States, is very concerned about recent developments in Geneva concerning the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

Our organization supports the goals of the Doha Declaration on the TRIPS Agreement and Public Health issued by the Doha Ministerial last November. We appreciate that the intellectual property standards provided in the TRIPS Agreement which permit countries to take action when faced with grave public health crises. We further support the Doha Ministerial's call for the WTO to devise a way for certain poor countries to secure alternative sources of pharmaceutical products if conventional sources prove to be unavailable. Our biotechnology community is aware that there are special circumstances for which a legally secure mechanism should be developed to allow poor countries afflicted with epidemics of HIV/AIDS, tuberculosis and malaria to obtain drugs from alternative sources.

Nonetheless, we oppose the elimination of intellectual property protections throughout the developing world for all pharmaceutical products.

We do not believe that this proposed elimination of intellectual property protections was ever the intent of the Doha Ministerial. We are disappointed that the draft legal text apparently has emerged in Geneva after months of discussions deviates so dramatically from the mandate of Doha. The text that was widely

circulated in the press last week would allow producers in India, Brazil and China to manufacture any drug and to export it. This proposal would create a gap in the protections guaranteed by the TRIPS Agreement.

The proposal would eliminate the intellectual property protections that serve as incentives for investment in biotechnology research and development. If patent protection is uncertain, biotechnology cannot fulfill its promise of producing ground-breaking medicines for treating HIV/AIDS, malaria and tuberculosis, among others.

Please consider our concerns in this very important matter. The 140 member companies need your assistance in protecting their intellectual property rights.

Sincerely,

Ron Kuehn
Executive Vice President

RWK:mb
cc: Senator Herbert H. Kohl (Via Fax 202-224-9787)
Senator Russell D. Feingold (Via Fax 202-224-2725)

MISSOURI BIOTECHNOLOGY ASSOCIATION

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Phone: 573.636.5252 • Fax: 573.636.5363
Website: www.mobio.org

MISSOURI: STATE-OF-THE-ART IN THE LIFE SCIENCES

December 3, 2002

DIAMOND MEMBER:
Monsanto
GOLD MEMBERS:
Quintiles
Bryan Cave, LLP
Thompson Coburn, LLP
CRB Consulting Engineers
McCarthy Building Companies, Inc.
University of Missouri Systems
Washington University
Advantage Capital Partners
Wyeth BioPharma
RCCI
SILVER MEMBERS:
HOK Architects
Sigma-Aldrich
Tripos

The Honorable Robert B. Zoellick
U.S. Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: Doha Declaration – Agreement on Trade-Related Aspects of Intellectual Property

Dear Ambassador Zoellick:

As our U.S. Trade Representative, you serve the United States business interests, as well as the healthcare associations. Soon you will be helping to decide important changes to the Doha Declaration, and the Agreement on Trade-Related Aspects of Intellectual Property. Because we appreciate your efforts in these negotiations, we are asking you to take the time to read this letter.

MOBIO's membership includes emerging biotechnology companies, as well as academic institutions whose innovative research will spawn new disease-fighting products. Their intellectual properties are their greatest assets. They rely on these assets as equity to attract timely investment that will further their research, as well as bring products to market.

The current intent of the Doha Declaration protects the intellectual property assets of our members. Changing the text to allow the manufacture of any drug and to export it to any country to address any health-care situation would circumvent any intellectual property protection.

If patent protection is uncertain, biotechnology cannot fulfill its promise of producing ground-breaking medicines for treating HIV/AIDS, malaria and tuberculosis, among others. Encouraging patent infringement in the name of public health in America and Europe will render the entire process useless. The result might mean lower prescription drug prices for consumers in the short term, but inevitably it will stifle private-sector innovation as profits dry up.

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ADVISORS: Julie M. Edge, PhD, Fleishman-Hillard, Inc.; Daniel P. Mahon, Missouri Chamber of Commerce
Bill Ramjue, Executive Director, MOBIO

Ambassador Zoellick, we ask that you deny the opponents of democratic capitalism the opportunistic seizure of our U.S. consumer-financed, long-term medical research harvest. On behalf of the members and non-members of Missouri's life science industry, we implore you to stand fast for the Doha Declaration.

Sincerely,

Bill Romjue
Executive Director

CC: Senator Kit Bond
Senator Jim Talent

The Missouri Biotechnology Association is a nonprofit trade association dedicated to development and growth of the Missouri biotechnology and biomedical industry. By supporting basic research in the life sciences, development of a highly educated work force and providing a friendly environment for attracting and founding new business, the Missouri Biotechnology Association intends to make a significant impact on Missouri economic development.

MNBIO

Dedicated to growing and promoting Minnesota's biotechnology industry.

Dec. 4, 2002

The Honorable Robert B. Zoellick
U.S. Trade Representative
600 17th Street NW
Washington DC 20508

Re: Doha Declaration - Agreement on Trade-Related Aspects of Intellectual Property

Dear Ambassador Zoellick:

Biotechnology is a young but very important emerging industry in Minnesota. One of the strongest assets we have is the ability to protect and preserve the intellectual property developed here. Recent reports that some developing countries and socialist non-governmental organizations are seeking to expand the Doha Declaration to cover all diseases would be very detrimental to our biotech industry and its future growth.

Our association represents 85 organizations encompassing thousands of jobs. Diluting the Doha Declaration would make patent and intellectual property protection worthless. Maintaining the focus on HIV/AIDS, tuberculosis and malaria will speak to many of the grave public health crises found in some developing countries without jeopardizing new innovations or existing markets.

The free market economy and the ability to preserve and protect valuable intellectual property has been the foundation that has allowed the United States to be the world leader in biotech with 75% of the biotech jobs and 72% of worldwide investment in biotech.

On behalf of all of Minnesota's biotechnology community we ask you not to expand the Doha Declaration to cover all diseases. Thank you.

Sincerely,

Raymond Frost

Raymond Frost
Executive Director

CC: Senator Mark Dayton
Senator Dean Barkley

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From the Office of the

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December 3, 2002

The Honorable Robert B. Zoellick
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick:

On behalf of the Colorado Biotechnology Association, I am writing to express serious reservations and concerns about recent developments related to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

Our goal is to provide innovative, cutting edge medicines. As a result of the biotech industry's contributions in this arena, great progress has been made in providing improved approaches to meet the needs of catastrophic epidemics such as malaria, HIV/AIDS, and cholera. The developing world benefits each day from these innovations.

A vast number of biotech firms concentrate on the research they hope will provide some positive impact on a disease process. This investment – their patent portfolio – is their only asset. This portfolio is essential in raising the capital to bring these life-saving and life-altering therapies to market.

We support the goals of the Doha Declaration on the TRIPS Agreement. We know the declaration enables countries to act when faced with grave and catastrophic health crises. We applaud efforts enabling poor countries to develop alternate sources of essential pharmaceutical products. The catastrophic epidemics create special circumstances for those countries.

This being said, we cannot support the elimination of intellectual property protections throughout the developing world for all pharmaceutical products. The Doha Ministerial never intended this to be the result.

America's pharmaceutical researchers are the leading companies in the world engaged in the discovery of life-saving cures. Diminishing the longstanding international protections provided these researchers will do great harm to the health of the global community. We urge you not to distort the intention of the Doha Declaration and maintain essential patent portfolios.

Sincerely,

Denise Brown
Executive Director

WBBA
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WBBA

December 3, 2002

The Honorable Robert B. Zoellick
United States Trade Representative
600 17th St NW
Washington, DC 20508

Dear Ambassador Zoellick:

I am writing to express the serious concerns of the more than 360 members of the Washington Biotechnology & Biomedical Association (WBBA) over recent developments in Geneva concerning the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

WBBA represents the interests of companies engaged in cutting-edge research that will provide innovative medicines, agricultural and environmental products to millions of people worldwide. The majority of our member companies, organizations, and institutions are involved in research and development in the health care arena. In the developing world, biotechnology R&D can do its part by producing vaccines that don't require refrigeration and are nasally or orally delivered. Furthermore, biotechnology's innovative approaches can provide medicines for diseases such as malaria, tuberculosis and cholera for which there is not current adequate treatment. A growing number of WBBA's member companies and research institutions are focusing on infectious diseases and other maladies plaguing public health in underdeveloped regions around the world.

As you know, the Biotechnology Industry Organization (BIO), with which WBBA works closely, has made a visionary commitment to bring biotechnology solutions to problems plaguing the developing world. As further demonstrated by increasing partnerships with organizations like the Bill and Melinda Gates Foundation, the biotechnology industry is ready to do its share to combat the world's health problems.

However, one must consider that, as is typical throughout the biosciences community, the bulk of WBBA's biotechnology & medical device company members, are small start-up companies concentrating on research. In fact, more than 90 percent of all biotechnology companies have yet to bring a product to market, and thus, they rely on patent portfolios as their only assets. What a biotech company owns and markets is essentially ideas: for example, the discovery of a potential point of intervention in a disease process or the identification of a gene or an inhibiting compound that might affect that process. But earning a patent is only

the beginning of the work. The ability of these companies to raise funding from the capital markets is linked directly to the availability, strength and certainty of their intellectual property rights. Without certainty in rights, our companies simply cannot raise funds to conduct their research and offer their products on the market. Without funding, products to treat unmet medical needs and to help patients suffering from HIV/AIDS and other intractable diseases will not be developed.

In addition to the critical role patents play in the scientific and fiscal health of growing biotechnology companies, WBBA's membership is particularly sensitive to changes in international trade regimes, particularly intellectual property, given the tremendous impact of international trade on Washington state's economy. From biotechnology to Microsoft there is a widespread dependence of fair and equitable systems of protection for intellectual property that are essential not only to Washington state's economy, but the ever evolving economy of this nation.

Consequently, WBBA strongly supports the goals of the Doha Declaration on the TRIPS Agreement and Public Health issued by the Doha Ministerial last November. We support the declaration because we appreciate that the intellectual property standards in the TRIPS Agreement permit countries to take action when faced with grave public health crises. We further support the Doha Ministerial's call for the WTO to devise a way for certain poor countries to reach out to alternative sources of pharmaceutical products if they cannot obtain them from the pioneer producer. As an industry we are fully aware that there are special circumstances for which a legally secure mechanism should be developed to allow poor countries afflicted with epidemics of HIV/AIDS, tuberculosis and malaria to obtain drugs from alternative sources.

At the same time, WBBA cannot support eliminating intellectual property protections throughout the developing world for all pharmaceutical products. This was never the intent of the Doha Ministerial. We are surprised and troubled, therefore, that the draft legal text that apparently has emerged in Geneva after months of discussions deviates so dramatically from the mandate of Doha. The text that was widely circulated in the press last week would allow producers in India, Brazil and China to manufacture any drug and to export it to any country to address any health-care situation. Such a "solution" would create a huge loophole in the protections guaranteed by the TRIPS Agreement and undermine the intellectual property protections that serve as incentives for investment in biotechnology research and development. If patent protection is uncertain, biotechnology cannot fulfill its promise of producing ground-breaking medicines for treating HIV/AIDS, malaria and tuberculosis, among others.

The biosciences community is also concerned that the tenor and direction of the current debate sends a very troubling and inaccurate message about the role of intellectual property protection and the steps our industry is taking to help these countries address their public health challenges. This week BIO and the Gates Foundation will be hosting an unprecedented conference next week in Washington that will stimulate the formation of public-private partnerships to develop new drugs for diseases that are prevalent in the developing world. Preserving the essential market-based incentives for intellectual property is a critical component of these efforts.

WBBA joins BIO in urging the administration to act now to ensure that the deal reached by negotiators in Geneva reflects accurately the mandate in Doha—or to ensure that no deal is reached at all.

Sincerely,

Ruth M. Scott

Ruth M. Scott
President

Cc:
Senator Patty Murray
Senator Maria Cantwell
Congresswoman Jennifer Dunn

T★H★B★I

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Executive Vice President and General Counsel
Lexicon Genetics Incorporated

★

President
Thomas R. Kowalski
THBI

December 3, 2002

The Honorable Robert B. Zoellick
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick:

On behalf of the Texas Healthcare and Bioscience Institute, one of the country's premier biotech organizations, I am writing to express serious reservations and concerns about recent developments related to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

Our goal is to provide innovative, cutting edge medicines. As a result of the biotech industry's contributions in this arena, great progress has been made in providing improved approaches to meet the needs of catastrophic epidemics such as malaria, HIV/AIDS, and cholera. The developing world benefits each day from these innovations.

A vast number of biotech firms concentrate on the research they hope will provide some positive impact on a disease process. This investment – their patent portfolio – is their only asset. This portfolio is essential in raising the capital to bring these life-saving and life-altering therapies to market.

We support the goals of the Doha Declaration on the TRIPS Agreement. We know the declaration enables countries to act when faced with grave and catastrophic health crises. We applaud efforts enabling poor countries to develop alternate sources of essential pharmaceutical products. The catastrophic epidemics create special circumstances for those countries.

This being said, we cannot support the elimination of intellectual property protections throughout the developing world for all pharmaceutical products. The Doha Ministerial never intended this to be the result.

America's pharmaceutical researchers are the leading companies in the world engaged in the discovery of life-saving cures. Diminishing the longstanding international protections provided these researchers will do great harm to the health of the global community. We urge you not to distort the intention of the Doha Declaration and maintain essential patent portfolios.

Sincerely,

Thomas R. Kowalski
President

TEXAS HEALTHCARE & BIOSCIENCE INSTITUTE
815 Brazos Street, Suite 310 ★ Austin, Texas 78701 ★ (512) 708-8424 ★ Fax: (512) 708-1607 ★ Email: info@thbi.com



December 10, 2002

The Honorable Robert B. Zoellick
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick:

We are writing to express the serious concerns of the more than 120 biotechnology companies in New Jersey over recent developments in Geneva concerning the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

The Biotechnology Council of New Jersey represents companies engaged in biopharmaceutical, biomedical and bioagricultural businesses. Most of the companies in New Jersey are small start-up companies concentrating on research. In fact, more than 90 percent of biotechnology companies in the country have yet to bring a product to market, and thus, they rely on patent portfolios as their only assets. What a biotech company owns and markets is essentially ideas: for example, the discovery of a potential point of intervention in a disease process or the identification of a gene or an inhibiting compound that might affect that process. But earning a patent is only the beginning of the work. The ability of these companies to raise funding from the capital markets is linked directly to the availability, strength and certainty of their intellectual property rights. Without certainty in rights, our companies simply cannot raise funds to conduct their research and offer their products on the market. Without funding, products to treat unmet medical needs and to help patients suffering from HIV/AIDS and other intractable diseases will not be developed.

BCNJ supports the goals of the Doha Declaration on the TRIPS Agreement and Public Health issued by the Doha Ministerial last November. We support the declaration because we appreciate that the intellectual property standards in the TRIPS Agreement permit countries to take action when faced with grave public health crises. We further support the Doha Ministerial's call for the WTO to devise a way for certain poor countries to reach out to alternative sources of pharmaceutical products if they cannot obtain them from the pioneer producer. As an industry we are fully aware that there are special circumstances for which a legally secure mechanism should be developed to allow poor countries afflicted with epidemics of HIV/AIDS, tuberculosis and malaria to obtain drugs from alternative sources.

We cannot support eliminating intellectual property protections throughout the developing world for all pharmaceutical products. This was never the intent of the Doha Ministerial. We are

1 AAA Drive, Suite 102, Trenton, New Jersey 08691 ▪ 609-890-3185 Fax 609-581-8244
E-mail: bcnj@hq4u.com ▪ www.newjerseybiotech.org

surprised and troubled, therefore, that the draft legal text that apparently has emerged in Geneva after months of discussions deviates so dramatically from the mandate of Doha. The text that was widely circulated in the press and would allow producers in India, Brazil and China to manufacture any drug and to export it to any country to address any health-care situation. Such a "solution" would create a huge loophole in the protections guaranteed by the TRIPS Agreement and undermine the intellectual property protections that serve as incentives for investment in biotechnology research and development. If patent protection is uncertain, biotechnology cannot fulfill its promise of producing ground-breaking medicines for treating HIV/AIDS, malaria and tuberculosis, among others.

We also are concerned that the tenor and direction of the current debate sends a very troubling and inaccurate message about the role of intellectual property protection and the steps our industry is taking to help these countries address their public health challenges.

We urge the Administration to act now to ensure that the deal reached by negotiators in Geneva reflects accurately the mandate in Doha—or to ensure that no deal is reached at all.

Regards,

H. Joseph Reiser, Ph.D.
Chairman

Debbie Hart
Executive Director

Remington, Michael J.

Subject: Letter to zoellick from deans of schools of public health

-----Original Message-----
From: James Love [mailto:james.love@cptech.org]
Sent: Friday, December 20, 2002 7:52 AM
To: ip-health@lists.essential.org
Subject: [Ip-health] Rachel Cohen: Letter to zoellick from deans of schools of public health

Rachel Cohen from MSF forwards this letter from Deans of medical and public health programs at Yale, Columbia, Berkeley and Southern Florida Universities.
Jamie

-------- Original Message --------
Subject: letter to zoellick from deans of schools of public health
From: "Rachel COHEN" <Rachel.COHEN@newyork.msf.org>
Date: Fri, December 20, 2002 7:33 am
To: ip-health@venice.essential.org

[list still in formation]

Ambassador Robert B. Zoellick
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Sent Via Facsimile Transmission

December 19, 2002

Dear Ambassador Zoellick,

We are writing as deans of the leading schools of public health in the United States to share our views with you on the status of negotiations at the World Trade Organization (WTO) on public health, access to medicines, and intellectual property rights. At the 4th Ministerial Conference of the WTO in Doha last year, the imperative of public health was affirmed by all WTO member states through the adoption of the Ministerial Declaration on the TRIPS Agreement and Public Health. Just one year after this historic agreement was reached, this advance is at risk of being compromised, to the detriment of millions of people suffering from diseases throughout the world.

The WTO was charged with producing a solution to the problem expressed in paragraph 6 of the Doha Declaration, which states that:

"6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

Negotiations on the solution to this problem should be guided by the needs and interests of poor people who are suffering without access to medicines, and by the Doha Declaration itself, which states that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

We urge you to consider the following:

1. The solution must not be restricted to medicines and medical technologies for the treatment of HIV/AIDS, tuberculosis and malaria. While there is no doubt that these epidemics are

ravaging developing countries, they cannot be considered the sole public health threats in poor regions--either now or in the future. Furthermore, the WTO is not the appropriate forum for determining sovereign countries' national public health priorities and needs.

2. The solution must not be limited to medicines only. Vaccines, diagnostics, and monitoring tests, for example, are important medical technologies for developing countries. They should not be excluded from any solution.

3. The solution must not include overly burdensome "safeguards." Low-cost medicines intended for consumption in poor countries should not be diverted to wealthy country markets. However, any system of safeguarding against such diversion should not put too heavy a burden on developing countries, and should not be so burdensome as to counter to the goal of the system itself to broaden access to affordable medicines.

4. The solution must be workable and must not include overly burdensome procedural requirements. Complex, restrictive conditions for making use of the solution will only serve to undermine the overall objective of protecting public health.

Increasing the pace of innovation in pharmaceuticals is necessary if the medical and public health community is to have any hope of success in battling major public health problems. But rewarding innovation must not come at the expense of equitable and sustainable access to these essential inventions.

As health professionals and concerned citizens, we urge you in the strongest possible terms to reject any solution that includes any of these restrictions.

Sincerely,

Allan Rosenfield, MD
DeLamar Professor and Dean
Mailman School of Public Health
Columbia University*

Michael H. Merson, MD
Anna M.R. Lauder Professor and Dean of Public Health
Chairman, Department of Epidemiology & Public Health
Yale University*

Laurence G. Branch, Ph.D
College of Public Health
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Stephen M. Shortell, Ph.D.
Dean, School of Public Health
University of California, Berkeley*

* Institutional affiliation for identification purposes only.

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H

Experimental Use and Research Issues

A Federal Circuit decision, *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), has created controversy. In *Madey*, the Federal Circuit denied the experimental use exception in the patent law to all academic scientific research, even when that research is manifestly noncommercial. The court held that the exemption is not available to nonprofit universities because scientific research at those universities serves legitimate educational purposes. For additional information about the *Madey* case, *see* attached Brief for American Medical Colleges, et al., as Amicus Curiae in Support of Petition for Certiorari.

A major landmark in this regard was *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), wherein the Federal Circuit held that the experimental use exemption did not cover one pharmaceutical company's use of another's patented drug for the purpose of performing tests necessary to obtain regulatory approval of its own competing version of td drug. Congress determined that *Roche* had inappropriately narrowed the exemption and overruled it in the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) (the "Act"). The Hatch-Waxman Act itself represented a congressional compromise (between innovator and generic pharmaceutical companies) to create a level playing field on which the companies operate. The Act added subsection 271(e)(1) to Title 35, of the United States Code:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States ... a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.

Effectively, a "safe harbor" was created that serves to insulate activities "reasonably related to the development and submission of information" (subsection 271(e)(1)) to certain governmental agencies necessary to obtain regulatory approval.

Under conventional rules of statutory construction, exceptions or exemptions should be read narrowly. A narrow reading would indicate that section 271(e)(1), although worded broadly, was designed to immunize the bioequivalency testing needed to secure FDA approval of generic drugs (which was the issue raised in *Roche v. Bolar*). Some courts have so held. The Act's legislative history reveals that the "only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. H. Rep. No. 98-857 (Part II), 90th Cong., 2d Sess. (1984).

Courts have departed from a narrow reading, finding that section 271(e)(1) should be read broadly. *See, e.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998). A recent case (*Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2001 U.S. Dist. LEXIS 19361 (S.D. N.Y. 2001)) held, in essence, that the plain meaning of section 271(e)(1) covers all information required to obtain approval of a drug (in essence, basic research, animal testing, human clinical trials, synthesis of new drug candidates, their initial testing, and a determination of whether drug candidates should be pursued). A party which develops such information but decides not to submit an application for approval is also protected as long as the development was done to determine whether or not an application for approval would be sought. In effect, new product screenings are covered, and exempt from allegations of patent infringement.

Potentially, patents claiming research tools (such as cell-based assays) and biologics/genomics are implicated, and potentially jeopardized. Given the success of major

research institutions for engaging in basic research and also in developing research tools and applications, universities and non-profits should closely monitor judicial developments relating to subsection 271(e)(1).

The ability of university/non-profit patent holders to protect their patents may be severely compromised by both a broad research exception (*Bristol-Myers*) and a non-existent one (*Madey*). On one hand, a dilution in the strength of patents, especially those related to basic research tools and applications could be harmful to the public interest because investments will not be made in the commercial exploitation of these tools and applications. On the other, the inability to conduct noncommercial research for teaching purposes could chill academic innovations. Ultimately, serious public policy issues may have arisen that warrant the attention of the United States Congress.

No. 02-1007

IN THE

Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M.J. MADEY,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether universities are precluded from asserting the federal common law experimental use exemption from liability for patent infringement merely because their scientific research programs serve legitimate educational purposes.*

* The thiry-one *amici curiae* are listed in the Appendix, *infra.*

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Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343 (Fed. Cir. 2000)	7
Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc., 122 S.Ct. 1889 (2002)	17
Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002)	9, 17
Pitcairn v. United States, 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978)	10
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FEDERAL REGISTER	
64 Fed. Reg. 72090 (1999)	13, 14

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MISCELLANEOUS Page

E. Barash, "Experimental Uses, Patents, and Scientific Progress," 91 Nw. U. L. Rev. 667 (1997) 11, 13
L. Bruzzone, "The Research Exemption: A Proposal," 21 AIPLA Q. J. 52 (1993) 9, 13
R. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 U. Chi. L. Rev. 1017 (1989) 5, 13
R. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," 97 Yale L.J. 177 (1987) 9, 13
I. Feit, "Biotechnology Research and the Experimental Use Exception to Patent Infringement," 71 J. Pat. & Trademark Off. Soc'y 819 (1989) 6, 12, 14
R. Hantman, "Experimental Use as an Exception to Patent Infringement," 67 J. Pat. & Trademark Off. Soc'y 617 (1985). 7
M. Heller & R. Eisenberg, "Can Patents Deter Invention? The Anticommons in Biomedical Research," 280 Science 698 (1998) 11, 12, 14, 15
S. Michel, "The Experimental Use Exception to Infringement Applied to Federally Funded Inventions," 7 High Tech. L. J. 369 (1992) 12, 13
J. Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools," 76 Wash. L. Rev. 1 (2001) 5-6, 7, 14, 15-16
National Science Foundation, *Science and Engineering Indicators 2002* (2002) 2

TABLE OF AUTHORITIES—Continued

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Note, "Universities Ask Supreme Court to Reverse Patent Ruling," 299 Science 26 (January 3, 2003). 3

M. O'Rourke, "Toward a Doctrine of Fair Use in Patent Law," 100 Colum. L. Rev. 1177 (2000) 6, 9

M. Thayer & R. De Liberty, "The Research Exemption to Patent Infringement: The Time Has Come for Legislation," 4 J. Biolaw & Bus. 1 (2000) 11

J. Walsh, A. Arora, and W. Cohen, "The Patenting and Licensing of Research Tools and Biomedical Innovation," in National Academy of Sciences, *Patents in the Knowledge-Based Economy* (2003) 8

IN THE

Supreme Court of the United States

No. 02-1007

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M.J. MADEY

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICI CURIAE* [1]

Amici curiae represent universities whose faculties engage in scientific research. They consist of the **Association of American Medical Colleges,** whose membership includes 125 medical schools, nearly 400 teaching hospitals and health systems, and 92 academic societies with an aggregate indi-

[1] The following representations are made pursuant to Sup. Ct. R. 37: The parties have consented to the filing of this brief; no counsel for either party authored any portion of this brief; no persons other than *amici curiae* made any monetary contribution to the preparation or submission of this brief.

vidual membership of approximately 100,000; the **American Council on Education,** representing approximately 1800 colleges and universities and serving as a forum for consideration of higher education issues of national importance; the **Association of American Universities**, whose 62 members include most of the nation's leading public and private research universities; the **National Association of State Universities and Land Grant Colleges**, representing public universities from all 50 states; the **Council on Governmental Relations**, an association of 150 research-intensive universities devoted to maximizing the scientific benefit from federal investment in academic research; the **Association of University Technology Managers**, a non-profit organization of approximately 3300 professionals dedicated to issues related to technology transfer; **Public Citizen, Inc.**, a public interest advocacy group; the **Howard Hughes Medical Institute**, which supports research conducted by faculty with joint appointments at universities and the Institute; and the following individual colleges, universities, and medical schools: **Baylor College of Medicine; The Regents of the University of California; Carnegie Mellon University; Emory University; University of Florida; Georgetown University; The George Washington University; Iowa State University of Science and Technology; Johns Hopkins University; University of Kentucky; University of Maryland; Massachusetts Institute of Technology; Mount Sinai School of Medicine; New York University; The University of North Carolina at Chapel Hill; University of Pittsburgh; Rutgers, the State University of New Jersey; University of Texas at Austin; Texas A&M University; Vanderbilt University; University of Washington; Washington State University; and Yale University.**

Universities spent more than $30 billion on scientific research and development in calendar year 2000. National Science Foundation, *Science and Engineering Indicators*

2002, App. Table 5-2 (2002). The *amici curiae* all directly engage in or actively support such university-based scientific research. The decision by the Federal Circuit in this case, however, poses a serious threat not only to the viability of many individual academic research projects but also to the vitality of academic scientific research generally. The *amici curiae* have an obvious and very strong interest in this case and in the reversal of the decision below.

INTRODUCTION

The Federal Circuit's decision limiting the scope of the common law experimental use exemption from liability for patent infringement is of immense importance to all universities whose faculties engage in scientific research. By effectively eliminating the exemption for even noncommercial academic scientific research, the decision erects a significant roadblock to the advancement of science. The *amici curiae* are deeply disturbed by this ruling. *See* Note, "Universities Ask Supreme Court to Reverse Patent Ruling," 299 Science 26 (January 3, 2003). In the past, university-based research has been crucial to scientific progress on almost every front. The decision below threatens to stifle that research and thereby endanger this nation's continued leadership in science and technology. The question presented by this case is vital to the nation's scientific wellbeing.

Universities will be forced to bear substantial administrative and financial costs to cover patent searches, infringement opinions, licensing agreements, and the inevitable litigation that will be engendered by the Federal Circuit's new rule of patent law. The money diverted into such uses will no longer be available for actual research. As a result of these additional costs and also the associated delays occasioned by patent searches and the negotiation of licenses, university-based research programs will be curtailed and research projects abandoned. In many situations patent holders are likely to use the court's ruling as a basis for imposing onerous

financial or nonfinancial licensing terms or even as a means of barring entire lines of what they may view as potentially competing scientific research. These developments place in jeopardy the research plans and activities of thousands of science graduate students and faculty researchers.

There is a serious risk that the Federal Circuit's decision will significantly impede this nation's scientific progress. In the end, the burden will be borne by the general public in its capacity as consumer and beneficiary of the scientific advances the patent system is intended to foster. The *amici curiae* ask this Court to grant review and reverse in order to avert the drastic consequences that otherwise can be expected to flow from the decision below.

SUMMARY OF ARGUMENT

The experimental use exemption historically has protected noncommercial research from claims of patent infringement; although prior to this case there had been virtually no litigation with respect to academic scientific research *per se*, the scientific community had every reason to believe that the exemption would protect noncommercial academic research just as it protected other noncommercial research.

The decision below radically departs from prior law. Without inquiring into the commercial or noncommercial nature of the research at issue, the Federal Circuit announced that universities are ineligible to claim the experimental use exemption for the paradoxical reason that the scientific research in which they are engaged serves legitimate educational purposes. The obvious result of this ruling is to deny the experimental use exemption with respect to all scientific research conducted at universities and other nonprofit research institutions, even when that research is manifestly noncommercial.

The Federal Circuit's holding in this case will have a significant chilling effect on all academic scientific research,

and especially that in biotechnology and biomedicine. Depriving university scientists of the experimental use exemption will directly and significantly increase the cost of basic research, the great majority of which is supported by competitively awarded federal funds. In many situations, the unanticipated need to negotiate licenses before initiating or while in the midst of research projects may forestall or seriously disrupt ongoing research. In some circumstances, patent holders may refuse licenses and thus bar research from going forward at all. The *amici curiae* are gravely concerned that, if the experimental use exemption is no longer available, the proliferation of patents on upstream tools for biotechnological, biomedical, and advanced electronic research will have a very adverse effect on basic and applied downstream research activity at universities and other nonprofit research institutions.

This Court should grant review to restore the federal common law experimental use exemption to its traditional role as a safe haven for noncommercial scientific inquiry.

ARGUMENT

A. The Experimental Use Exemption Historically Has Protected Noncommercial Research From Claims Of Patent Infringement

"[T]he courts have long recognized . . . that a purely 'experimental use' of a patented invention, with no commercial purpose, should be exempt from infringement liability." R. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 U. Chi. L. Rev. 1017, 1018-19 (1989). This experimental use exemption, which was first articulated by Justice Story in *Whittemore v. Cutter,* 29 F. Cas. 1120 (C.C.D. Mass. 1813), serves a purpose somewhat analogous to that of the fair use doctrine of copyright law. J. Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement

for Biomedical Research Tools," 76 Wash. L. Rev. 1, 42-43 (2001); M. O'Rourke, "Toward a Doctrine of Fair Use in Patent Law," 100 Colum. L. Rev. 1177, 1192-94 (2000). The exemption ultimately is grounded in the same constitutional rationale as the patent system itself: scholarly freedom to use and build upon patented advances in the course of noncommercial scientific inquiry is of critical importance to "the Progress of Science and useful Arts." U.S. Const., Art 1, Sec. 8. *See* I. Feit, "Biotechnology Research and the Experimental Use Exception to Patent Infringement," 71 J. Pat. & Trademark Off. Soc'y 819, 839 (1989).

In determining the type of "experimental use" entitled to exemption, courts historically drew the line between commercial and noncommercial research. Noncommercial research was protected. For example, the exemption covered the federal government's use of a patented alloy "for experimental purposes." *Chesterfield v. United States,* 159 F. Supp. 371, 375 (Ct. Cl. 1958). In the only reported case involving an academic institution (the Colorado School of Mines) the court explained that the "making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement." *Ruth v. Stearns-Roger Mfg. Co.,* 13 F. Supp. 697, 713 (D. Colo. 1935), *rev'd on other grounds,* 87 F.2d 35 (10th Cir. 1936).

In contrast, commercial research was not protected. A major landmark in this regard was *Roche Products, Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed. Cir. 1984), where the Federal Circuit held that the experimental use exemption does not cover one pharmaceutical company's use of another's patented drug for the purpose of performing tests necessary to obtain regulatory approval of its own competing version of the drug. The court explained, "[w]e cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,'

when that inquiry has definite, cognizable, and not insubstantial commercial purposes." *Id.* at 863. *See also Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (holding, in a patent dispute between two commercial competitors, that the experimental use exemption does not protect research performed "expressly for commercial purposes").

"[A]fter *Roche,* scientists engaged in research and development having more than negligible commercial purpose could no longer rely on the experimental use doctrine." J. Mueller, *supra*, 76 Wash. L. Rev. at 24. Yet with its emphasis on the distinction between commercial and noncommercial purposes, *Roche* appeared to confirm that genuinely noncommercial scientific research undertaken by university scientists or government researchers remained protected by the experimental use exemption. As one writer put it shortly after *Roche*, "[f]ew would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function." R. Hantman, "Experimental Use as an Exception to Patent Infringement," 67 J. Pat. & Trademark Off. Soc'y 617, 633 (1985).

Subsequent developments provided further support for the view that traditional noncommercial scientific research falls well within the protective scope of the experimental use exemption. Congress, believing that *Roche* had improperly narrowed the exemption, enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 271(e), reversing the result in that case and thereby extending protection even to certain specified commercial research activities. The Federal Circuit seemingly took this to heart, giving the new statute a broad reading in *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 405-06 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

This history afforded university communities and patent holders alike strong reason to believe that Justice Story's experimental use exemption continued to protect noncommercial academic research from claims of patent infringement. A recent study, based upon "70 interviews with personnel at biotechnology and pharmaceutical firms and universities," confirms that "university researchers, to the extent that they are doing noncommercial work, are largely left alone" and that in those rare instances when universities received letters alleging infringement "the typical response was effectively to ignore such letters and inform the [patent] holder that the university was engaged in research, did not intend to threaten the firm's commercial interests, and would not cease its research." J. Walsh, A. Arora, and W. Cohen, "The Patenting and Licensing of Research Tools and Biomedical Innovation," 2, 35, in National Academy of Sciences, *Patents in the Knowledge-Based Economy* (2003).

B. The Decision Of The Federal Circuit In This Case Radically Departs From Prior Law By Denying The Experimental Use Exemption To All Academic Scientific Research, Even When That Research Is Manifestly Noncommercial

The Federal Circuit in this case eschewed any inquiry into whether the research at issue was genuinely noncommercial. Instead, the court issued a broad ruling effectively denying the experimental use exemption to all university-based research in all circumstances.

In an opinion frankly hostile to the experimental use exemption, the Federal Circuit essentially disavowed prior law with its clearly drawn distinction between commercial and noncommercial research. The court held, instead, that the exemption is not available to nonprofit universities *because scientific research at those universities serves legitimate educational purposes*:

> [M]ajor research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. . . .
>
> In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.

Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

This decision is both bad law and bad policy. The distinction between commercial and noncommercial research always has been the touchstone of the experimental use exemption. Indeed, when he first articulated the doctrine in *Whittemore* Justice Story was specifically contrasting "philosophical experiments" with "use [of the patented invention] for profit." 29 F. Cas. at 1121. Scientific research directed toward "educating and enlightening students and faculty," *Madey*, 307 F.3d at 1362, is exactly the sort of activity embraced by the early nineteenth-century expression "philosophical experiments." L. Bruzzone, "The Research Exemption: A Proposal," 21 AIPLA Q. J. 52, 60 (1993).

Noncommercial academic scientific research logically lies at the very core of the experimental use exemption. R. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," 97 Yale L.J. 177, 223 (1987). Yet the Federal Circuit appears now to have made the exemption inapplicable to virtually all truly serious scientific research. This creates a substantial likelihood that "the patent system

[will] function to thwart the very innovation that it is intended to foster." M. O'Rourke, *supra*, 100 Colum. L. Rev. at 1180.

The Federal Circuit was led astray by language in *Pitcairn v. United States,* 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied,* 434 U.S. 1051 (1978), holding that the experimental use exemption did not apply when the government was merely engaged in testing newly purchased helicopters to make sure that they worked properly. There can be no quarrel with the result in *Pitcairn*: routine testing of equipment is not truly scientific research and need not be protected as "experimental use." In justifying that unexceptionable result, however, the *Pitcairn* court explained, somewhat infelicitously, only that the government's use of the helicopters had been "in keeping with the legitimate business of the using agency." *Id.* at 1125-26.

The expression "legitimate business" was seized upon by the Federal Circuit in this case without paying due attention to context. The *Pitcairn* court had employed that expression offhandedly, as a way of indicating that the government was not actually engaged in scientific research but rather was simply ascertaining, before placing its helicopters in regular use, that they were capable of being operated in the manner intended. The Federal Circuit here misread *Pitcairn,* making the inquiry focus on the relationship of the patented invention's use to the defendant's "business" rather than on whether that use genuinely constitutes noncommercial scientific research. The court lost sight of the values furthered by the experimental use exemption and, in doing so, constructed an apparently absolute barrier to a claim of exemption by any modern research university (or by any government agency or other nonprofit organization, for that matter) engaged in the "business" of noncommercial scientific research.

C. The Decision Below Will Have A Significant Chilling Effect On Academic Scientific Research, Especially In Biotechnology And Biomedicine

"[A] significant portion of scientific innovation occurs in university, government, and private non-profit environments . . . ." E. Barash, "Experimental Uses, Patents, and Scientific Progress," 91 Nw. U. L. Rev. 667, 696 (1997). Much of this scientific innovation results from basic research that is directed toward the general acquisition and dissemination of scientific knowledge and has no explicit commercial objective.

Universities and university scientists—to the extent they consider the issue at all—assume that their noncommercial research is exempt. *See* M. Thayer & R. De Liberty, "The Research Exemption to Patent Infringement: The Time Has Come for Legislation," 4 J. Biolaw & Bus. 1, 2 (2000). They "rarely check the patent literature to determine whether their proposed research will infringe on any patents." E. Barash, *supra*, 91 Nw. U. L. Rev. at 698. Nor are they in a position to do so. "While corporations have legal departments geared towards answering potential legal quagmires, universities do not have the infrastructure to render routine opinion work to researchers." *Id.* Universities are "ill equipped to handle multiple transactions for acquiring licenses to use research tools." M. Heller & R. Eisenberg, "Can Patents Deter Invention? The Anticommons in Biomedical Research," 280 Science 698, 700 (1998).

The decision below works a drastic change in the legal environment. Depriving university scientists of the experimental use exemption will directly and significantly increase the cost of basic research even when patent holders are willing to make licenses available:

> [L]icensing patented inventions used in basic research poses special problems. The need to obtain licenses would add significant administrative and financial bur-

> dens to researchers in fields where patent protection is widespread. Most research builds on prior discoveries. If a significant number of these are patented, obtaining licenses on each would generate mounting royalty and transaction costs.

S. Michel, "The Experimental Use Exception to Infringement Applied to Federally Funded Inventions," 7 High Tech. L. J. 369, 398 (1992). The need to allocate scarce university resources to the processing of scientifically unproductive administrative and legal paperwork will involve a significant diversion of funds away from educationally more important activities, including actual scientific research.

There will be not only greater costs but longer delays in getting research started if, indeed, patent holders permit it to be undertaken at all. The need to obtain licenses will constitute an initial and major hurdle in the path of many projects. "Delays in negotiating multiple agreements to use patented processes, reagents, and gene fragments could stifle the creative give-and-take of academic research." M. Heller & R. Eisenberg, *supra*, 280 Science at 700.

The added cost of conducting patent searches and paying for licenses, and the concomitant delays in launching research projects, are not the only, and may not be the worst, problems facing universities and their researchers in the wake of the decision below. The unanticipated need to acquire licenses in the midst of a project can seriously disrupt if not entirely derail ongoing research. It simply "is not practical for researchers to wait for a patent infringement evaluation each time they perform a basic laboratory technique." I. Feit, *supra*, 71 J. Pat. & Trademark Off. Soc'y at 822. Research does not follow in a straight line. One line of inquiry will often open up an entirely new line of inquiry not contemplated at the outset. To halt research in mid-stream for months or years in the face of an unanticipated need to obtain a license—or even worse, to be required to abandon the

research altogether upon the denial of a license—will have a very serious deleterious effect on the competitive advantage American universities' research programs currently have in the world. *See* R. Eisenberg, *supra*, 56 U. Chi. L. Rev. at 1056.

In some circumstances, the absence of an experimental use exemption may make it altogether impossible to undertake a planned research project. As the National Institutes of Health has observed, "[p]rogess in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories throughout the government, academia, and industry." 64 Fed. Reg. 72090, 72093 (1999). It follows that "intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research . . . ." *Id.* at 72092. The problem is that "some patent holders will undoubtedly object to the use of their inventions in subsequent research and, in the absence of an experimental use exemption, might use their exclusive rights to stop valuable research from proceeding." R. Eisenberg, *supra*, 56 U. Chi. L. Rev. at 1072. This "could undermine a critical mechanism of the scientific community for facilitating the progress of science." R. Eisenberg, *supra*, 97 Yale L.J. at 225.

Even before the decision below, many commentators were concerned that the Federal Circuit's emphasis in *Roche* on the narrowness of the experimental use exemption "could have significant chilling effects on research efforts." L. Bruzzone, *supra*, 21 AIPLA Q. J. at 65; *see also, e.g.*, S. Michel, *supra*, 7 High Tech. L.J. at 389-90; E. Barash, *supra*, 91 Nw. U. L. Rev. at 698. By effectively abolishing the experimental use exemption for all academic scientific research, the decision below magnifies the problem enormously. The Federal Circuit's opinion in this case will have a very damaging chilling effect on all university-based scientific research.

This chilling effect will be felt in all scientific areas where patent protection has been granted to intellectual advances that may form part of the foundation for further research, including chemistry, physics, and advanced electronics. The problem may be at its most severe, however, in biotechnology and biomedicine:

> The explosion of biotechnological and biomedical research and development in the United States in the past twenty years, with a corresponding increase in patenting activity, particularly in the area of genomics, has concomitantly heightened difficulties of access to and dissemination of patented research tools. Burgeoning research and development will require ever-greater numbers of proprietary tools, giving rise to transaction costs associated with acquiring the right to use each tool. In some cases, the patentee may refuse to license the research tool altogether.

J. Mueller, *supra*, 76 Wash. L. Rev. at 5-7. The *amici curiae* are gravely concerned that the decision below will encourage patent holders to assert claims in a manner that will impede or altogether frustrate university scientists' ability to make further basic advances in critical areas of biotechnology and biomedicine.

The past two decades have seen "a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research." M. Heller & R. Eisenberg, *supra*, 280 Science at 698. "Patented research tools" now include such things as "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools." 64 Fed. Reg., *supra*, at 72092 n.1. For example, "[m]any of the pioneering developments in basic laboratory methods necessary for recombinant DNA experiments have been patented." I. Feit, *supra*, 71 J. Pat. & Trademark Off. Soc'y at 820.

Many patents in the field of biotechnology do not cover products or even methods but are essentially informational in nature, covering such matters as anonymous gene fragments and protein crystalline coordinates. *See, e.g.,* M. Heller & R. Eisenberg, *supra*, 280 Science at 699. For example, patents have been granted on the identification of "small segments of complimentary DNA [that] have no presently known utility [but] are believed to be useful as probes in searching for corresponding full-length genes." J. Mueller, *supra*, 76 Wash. L. Rev. at 13-14. The inability to work with such information could blunt the promise of the remarkable achievement of the Human Genome Project by crippling follow-on basic research in fields such as genomics and proteomics (the study of proteins and their functions within the cell) and significantly impair academic researchers' ability to achieve important new breakthroughs in biomedical science.

The magnitude of the problem is suggested by recent action taken by Hoffman-La Roche Corporation ("Roche") with respect to its patents over the thermostable enzyme Thermus aquaticus YTl DNA polymerase ("Taq") and polymerase chain reaction ("PCR"). Taq is a basic biotechnology tool "widely used in DNA sequencing." J. Mueller, *supra*, 76 Wash. L. Rev. at 2. PCR is "the revolutionary DNA amplification process that utilizes Taq." *Id.* at 3. In 1995,

> Roche accused more than forty U.S. universities and research institutes (including Harvard, Stanford, Massachusetts Institute of Technology, the Salk Institute, the Scripps Research Institute, and the National Cancer Institute) and more than 200 individual scientists of infringing these patents. . . . Roche officials professed no concern about the use of Taq for 'pure research' purposes, but stated that they felt compelled to take

> action against those scientists engaged in what Roche termed 'highly practical' research with potential profit-making potential.

Id. Roche and other similarly situated patentees may be emboldened by the decision below to extend their aggressive patent enforcement to noncommercial "pure research" as well. *See id.* ("a Roche spokesperson . . . warned that she 'wouldn't want to predict what action Roche would take relative to any patent . . . in the future'"). This poses a major threat to the continued vitality of noncommercial academic biotechnological and biomedical research programs.

This nation has benefited enormously in the past from noncommercial academic scientific research, as more discoveries and greater understanding of the unknown have pointed toward and facilitated commercial research leading to new and socially beneficial products and applications. The Federal Circuit's decision threatens to retard this process significantly. Even before the decision below, there was grave concern in the scientific and public policy communities that "the proliferation of patents on 'upstream' basic tools of biotechnological and biomedical research will stymie the development of . . . downstream application[s]." J. Mueller, *supra*, 76 Wash. L. Rev. at 7. The denial of experimental use protection for noncommercial academic scientific research will make a difficult situation much worse.

D. This Court Should Grant Review To Restore The Federal Common Law Experimental Use Exemption To Its Traditional Role As A Safe Haven For Noncommercial Scientific Inquiry

This Court should grant the petition for certiorari and hold that universities are not precluded from asserting the experimental use exemption merely because their research programs serve legitimate educational purposes.

The issue clearly is important. Respondent may argue, however, that certiorari should be denied because there is no conflict among the circuits and the matter is interlocutory. In the circumstances of this case, those factors do not genuinely militate against review.

The Federal Circuit has exclusive appellate jurisdiction over cases arising under federal patent law. 28 U.S.C. § 1295(a)(1). Thus there is and will be no conflict among the circuits on the reach of the experimental use exemption. But this does not mean that this Court should defer to the Federal Circuit's presumed expertise and leave standing the harmful and misguided ruling below. As Justice Stevens recently noted, "decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias." *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 122 S.Ct. 1889, 1898 (2002) (concurring). This case presents an issue of federal common law that is too important to be left to a specialized patent court; this Court, with its broader perspective, should intervene to resolve the issue.

Although the case nominally is interlocutory, there is nothing further to be done on remand with respect to the experimental use exemption. The Federal Circuit has noted that Duke University's scientific research projects "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty" and has held that any act "in furtherance of the alleged infringer's legitimate business . . . does not qualify for the very narrow and strictly limited experimental use defense." *Madey*, 307 F.3d at 1362. As a practical matter, that forecloses Duke from asserting the experimental use defense on remand. Moreover, even if on remand Duke were to prevail on other grounds, the Federal Circuit's ruling with respect to experimental use still would stand as the radically new and disruptive law of the land.

As long as it does remain standing, the Federal Circuit's ruling will raise serious concerns and cause serious harm to American universities, to the academic scientific research community, and to "the Progress of Science and useful Arts." U.S. Const., Art 1, Sec. 8. The case warrants immediate plenary review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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January 2003

APPENDIX

LIST OF *AMICI CURIAE*

The foregoing brief is filed on behalf of the following organizations as *amici curiae*:

American Council on Education
Association of American Medical Colleges
Association of American Universities
Association of University Technology Managers
Baylor College of Medicine
Carnegie Mellon University
Council on Governmental Relations
Emory University
Georgetown University
Howard Hughes Medical Institute
Iowa State University of Science and Technology
Johns Hopkins University
Massachusetts Institute of Technology
Mount Sinai School of Medicine
National Association of State Universities and Land Grant Colleges
New York University
Public Citizen, Inc.
Rutgers, the State University of New Jersey
Texas A&M University
The George Washington University
The Regents of the University of California
The University of North Carolina at Chapel Hill
University of Florida
University of Kentucky
University of Maryland
University of Pittsburgh
University of Texas at Austin
University of Washington
Vanderbilt University
Washington State University
Yale University

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THE ASSOCIATION OF GOVERNING BOARDS OF UNIVERSITIES AND COLLEGES

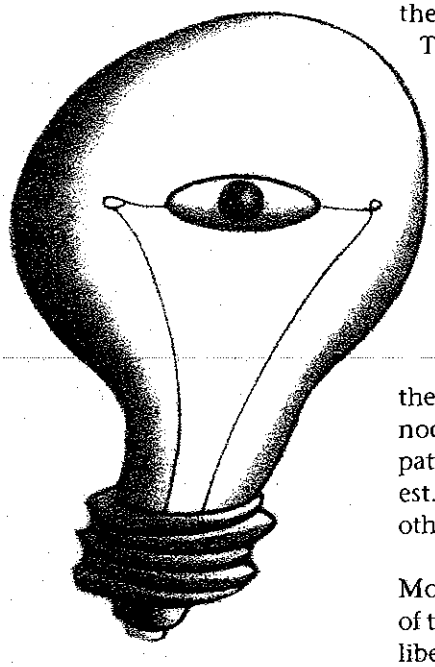
NOVEMBER/DECEMBER 2004

TRUSTEESHIP



Boards need more than a passing acquaintance with ways to balance the academic mission with valuable opportunities for taking campus research to the marketplace.

A Board's Primer ON Technology Transfer



A PHILOSOPHICAL CHASM PERSISTS in higher education between those who think universities should own and commercially exploit patents and those who think technology transfer has the potential to conflict with an institution's academic mission.

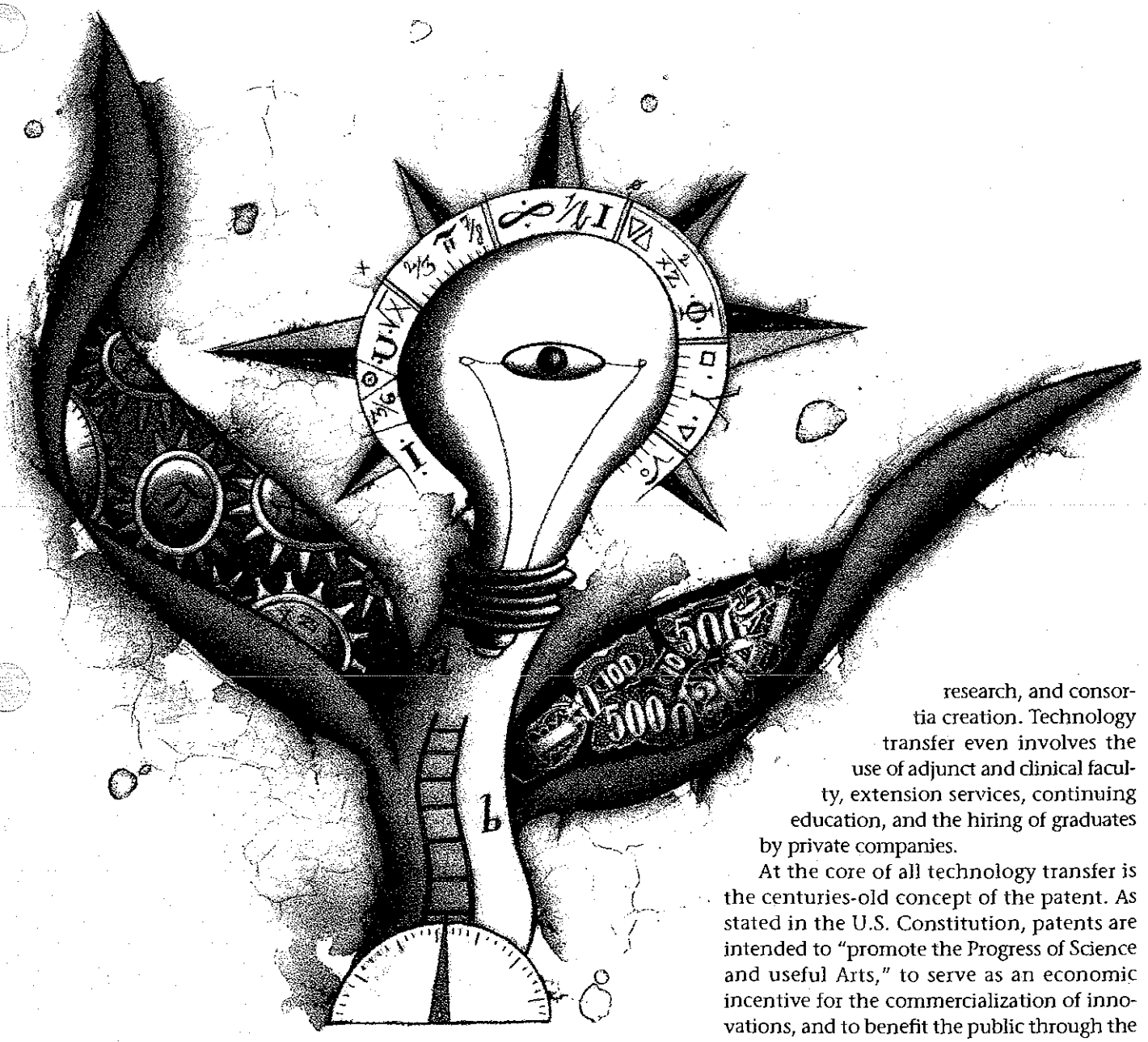
Arranged marriages between universities and corporations, under the stern eye of the federal government, do not unfold smoothly. The fundamental goals of a university are to teach students, develop new knowledge, and disseminate that knowledge. Corporations exist to maximize profits and build value for shareholders. The responsibility of the federal government is to promote the general welfare of the citizenry.

How, then, can a conscientious academic president or trustee reconcile these seemingly conflicting goals with those inherent in the process of technology transfer—the flow of expertise, new products, and start-up companies from the campus to the marketplace?

To fulfill their responsibilities for balancing these interests on their own campuses, trustees and chief executives need more than a nodding acquaintance with scientific research, technology transfer, patent law, private-sector commercialization, and conflicts of interest. Obviously, the challenges affect some institutions more than others (see the sidebar on page 17).

Modern Patent Law. Technology transfer today is an integral part of the missions of most major universities (less so or not at all at small liberal arts and religious colleges). Traditionally, the process simply meant the movement of technological innovations from the laboratory to the marketplace, chiefly through patents, copyrights,

• BY MICHAEL J. REMINGTON •



and trademarks that researchers or their universities license to, say, start-up companies.

During the past two decades, however, revolutionary advances in communications and biotechnology have globalized information flows, peer-to-peer networks of ideas, advances in diverse and interactive fields of scientific inquiry, and partnerships in increasingly complicated research. Consequently, today's definition of technology transfer also includes collaborative research, sponsored research, and consortia creation. Technology transfer even involves the use of adjunct and clinical faculty, extension services, continuing education, and the hiring of graduates by private companies.

At the core of all technology transfer is the centuries-old concept of the patent. As stated in the U.S. Constitution, patents are intended to "promote the Progress of Science and useful Arts," to serve as an economic incentive for the commercialization of innovations, and to benefit the public through the disclosure of ideas.

A patent grant provides an inventor (or patent owner) with means to collect returns on a protected invention through the exercise of exclusive rights for the life of the patent, which today is 20 years from the date of filing. Essentially, a patent confers the right to exclude others from practicing the invention claimed in the underlying patent document itself. Patent protection is intended to encourage investments necessary to generate a commercial technology.

The rationale for limiting a patent's boundaries is understood by the U.S. Supreme Court,

Illustration by Pol Turgeon

Technology transfer entails partnerships and entrepreneurial risk-taking. The edge between rightful action and wrongdoing often is razor sharp.

which opined last May that "the monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not." (*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*)

For this reason, the patent laws require inventors to disclose their work in full and exact terms. (The law does not, however, require immediate disclosure, and prior to moving through the system, many owners protect unpublished research results by nondisclosure agreements.) Public disclosure is valuable not only to the inventor, who relies on it to bring forth the invention, but to the public, because it stimulates other individuals, firms, or universities to learn from the patent and to invent "around" it. Moreover, after the patent term has expired, the public reaps further benefits when the pool of publicly available knowledge is expanded and individuals adapt the invention freely.

Patents are largely compatible with the missions of the modern-day university. They serve to protect the individual inventor and ensure proper use of inventions, but like any property (such as the student union or university heating plant) patents must be managed responsibly.

The Bayh-Dole Act. The national patent law, like most laws, reflects societal changes. The seminal Patent and Trademark Laws Amendments of 1980 (with its 1984 amendments) is known by the names of its chief sponsors, Senators Birch Bayh (D-Ind.) and Robert Dole (R-Kan.). The act's purpose is to promote patents in the utilization and commercial exploitation of inventions arising under federally funded research by nonprofits. By creating a uniform patent policy among federal agencies that fund research, Congress linked the federal government, universities, small businesses, and the corporate world. More than any other factor, the Bayh-Dole Act influences universities' technology transfer.

The act is balanced in its approach. On one hand, universities may retain title to and market the inventions they create using federal research funds, and they may collect royalties on the inventions. On the other hand, federal agencies are permitted to grant exclusive licenses for federally owned inventions to provide increased incentives to businesses.

In the university context, rights to an invention created in whole or in part with federal funds cannot be assigned without the permission of the government (except that an assignment may be made to an entity, such as a university foundation, that has as its primary function the management of inventions). The act requires the sharing of royalties generated by the invention with the inventor and the use of the balance of the royalties, after expenses, for support of educational or research activities.

In all cases, the federal government retains a royalty-free, nonexclusive license to work with the invention for governmental purposes and reserves so-called "march in" rights if a contractor (a university or small business) has not taken "effective steps to achieve practical application of the invention" or if the invention is "necessary to alleviate health or safety needs which are not reasonably satisfied" by the contractor or licensee. (To date, the federal government has never exercised "march in" rights.) The act also provides protections against disclosure by federal agencies of confidential information pertaining to an invention while a university (or other contractor) is pursuing a patent.

The benefits of Bayh-Dole are far reaching. Universities annually receive billions of dollars in federal funds. Federal agencies also

provide research and development funding to nonprofits other than universities (research hospitals, independent laboratories, and other research-specific institutes) that are managed by universities. Before Bayh-Dole, universities were filing fewer than 250 patents a year; in 2000, the figure was more than 6,300.

The increasing number of patents granted to universities generally fall into key technology areas and involve life-saving advances. "These patents," says Carl Gulbrandsen, managing director of the Wisconsin Alumni Research Foundation, "since they arise primarily from the results of basic research, can often afford the basis for whole new products or even industries, as in, for example, the biotechnology industry."

The certainty of intellectual property title in universities has promoted a closer relationship with the private sector under Bayh-Dole. At the same time, the act protects academic freedom to conduct research and reinforces the mission of the academic community to discover and transmit knowledge to the betterment of the public. A university is free not to patent new knowledge that is patentable, and a patent can operate to put an invention in the hands of the public that paid for its development.

The act, nonetheless, has detractors. "The taxpayers pay to invent a promising drug, then give a monopoly to one company," says prescription drug-price activist James Love, director of the Ralph Nader-affiliated Consumer Project on Technology. "And the company's role? To agree to sell it back to us."

Over the past two decades, proposals have been floated in Congress to require that the prices charged for technical advances developed with federal funds be reasonable. Columnist Ellen Goodman has written that encouraging faculty members to combine "science and business, nonprofit and profit," is mixing "altruism and chumphood." She speculates that Dr. Jonas Salk might have been considered a chump for giving away his work on the polio vaccine.

Congressional oversight of patent law effectiveness is necessary. Just this year, Congress debated whether state universities should be allowed to bring lawsuits for monetary damages in federal court to enforce their patent rights and whether patent administrative formalities for prescription drugs should be tightened to the detriment of the universities and pharmaceutical companies with which they collaborate.

Current Challenges. Presidents, faculty, and the news media frequently inquire about the benefits and downsides of the increasingly close ties between academe and private industry. Not everyone understands the issue. For example, a strategic alliance between the University of California at Berkeley and a Swiss pharmaceutical company was pilloried in the press as the "corporatization of the university" without concrete evidence that academic research had been compromised. When perception becomes reality, universities must react.

To replicate success and fulfill their responsibilities for protecting the public trust regarding technology transfer, boards and chief executives must take affirmative steps to understand scientific research, economic incentives for faculty members, the private-sector mindset, and ethical constraints. That means addressing ten challenges:

1. Intellectual-property law is complex; it is a specialty within the practice of law with subspecialties: patents, copyrights, trademarks, privacy and publicity, and elements of state law (including trade secrets and misappropriation). The obtaining of a patent, and inventing around someone else's patent, require a patent lawyer and technical experts knowledgeable in the pertinent scientific field. Universities must determine the size of in-house legal staffs, decide whether to retain outside counsel, and coordinate legal activities.

2. If intellectual property is created as a result of federal funding, regulations make the university (rather than the department or school) or its affiliated foundation the responsible entity for administering the property. Because the utility of patents varies among industrial sectors—they are more important in the pharmaceutical and chemical industries than in semiconductors and aerospace,

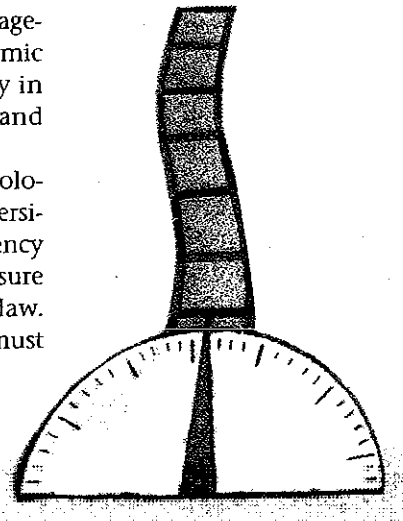
for example—different university departments (even within the sciences) may have differing views. Universities must apply standardized compliance rules across all federally funded activities.

3. Adding technology transfer and intellectual property issues to the modern university's menu does not necessarily mean they become the main course. Internal governance structures, such as departmental committees and academic standards boards, should not be upstaged. Universities must adhere to the commitments they make to the public and its representatives.

4. Faculty participation in private-sector affairs, through the creation of start-up companies for which a professor may serve as chief executive officer, can compromise the academic mission or create conflicts of interest. Potential and actual conflicts must be confronted through the application of clear standards, which must be applied with great sensitivity so that star faculty members do not take their inventions out the back door to be commercialized without benefit to the university. Even in ideal circumstances, the best faculty members increasingly are being recruited to the private sector, and universities are struggling to retain them.

5. Many universities have pursued technology transfer by establishing affiliated foundations, licensing offices, and trustee committees on research. Money and management often are key factors. To reap economic returns, universities must invest money in infrastructure and qualified personnel, and this money must be properly managed.

6. The administration of federal technology-transfer law is decentralized, and university personnel must recognize that each agency that awards R&D funds is required to ensure that grant recipients comply with the law. The self-regulatory aspects of Bayh-Dole must be understood and respected.



THE ECONOMIC AND PRACTICAL BENEFITS OF TECHNOLOGY TRANSFER

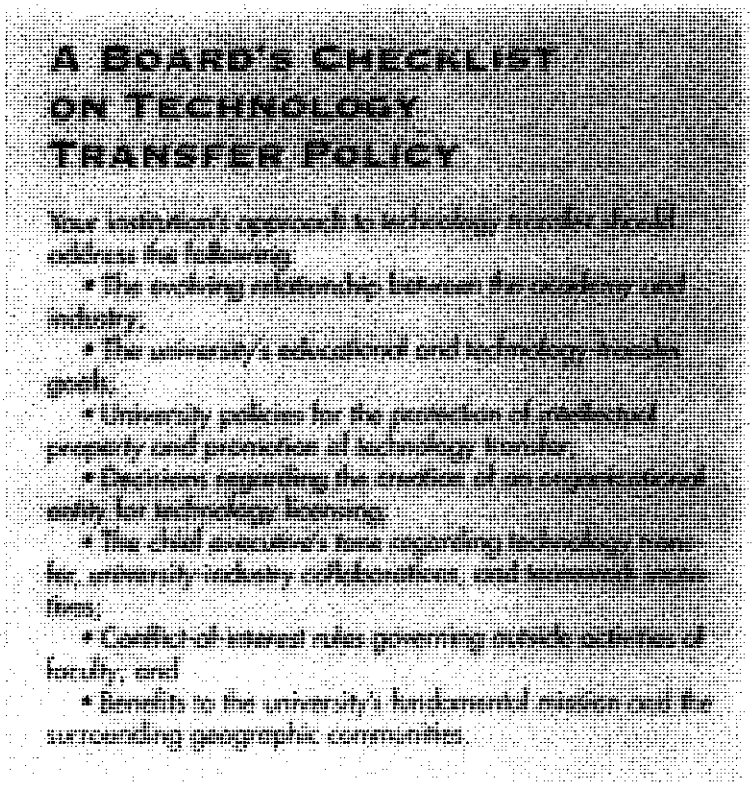
Innovations on campuses resulted in 6,375 new U.S. patent applications in 2000 alone, a 15 percent increase from the preceding year. Also in 2000, universities and nonprofits spent a record $29.5 billion on research and development. Sales of goods developed from products transferred from university research centers produced a whopping $42 billion in revenues, and U.S. universities, research institutes, and hospitals recouped almost $1.2 billion in gross income.

The practical benefits of such innovations are increasingly known to the public. In 2000, 347 products based on university research and technology transfer to the private sector were made available. Among them were a device to increase the comfort and accuracy of mammograms, an environmentally safer alternative to treated plywood, and a dictating technology for safer air and land transportation.

The federal government contributed $18.1 billion, or almost 60 percent of university research support in 2000. That was an increase of 8 percent over 1999, a growth rate that is replicated in industry-sponsored collaborative research as well.

Aggregate statistics, however, mask the fact that most major universities are not getting rich off of "blockbuster" patents and other intellectual property. Of almost 21,000 licenses active in 2000, less than 1 percent generated income in excess of $1 million.

The institutions most successful in commercializing their professors' work, according to the Association of University Technology Managers, were Stanford University, the University of California System, the University of Wisconsin-Madison (through the Wisconsin Alumni Research Foundation), the University of Washington (Washington Research Foundation), Massachusetts Institute of Technology, the State University of New York Research Foundation, the University of Pennsylvania, the Texas A&M University System, Johns Hopkins University, and the University of Michigan. —M.T.R.



A BOARD'S CHECKLIST ON TECHNOLOGY TRANSFER POLICY

Your institution's approach to technology transfer should address the following:

- The evolving relationship between the academy and industry.
- The university's educational and technology-transfer goals.
- University policies for the protection of intellectual property and promotion of technology transfer.
- Decisions regarding the creation of an organizational entity for technology licensing.
- The chief executive's line reporting responsibility for university-industry collaborations, and economic interests.
- Conflict-of-interest rules governing outside activities of faculty, and
- Benefits to the university's fundamental mission and the surrounding geographic community.

7. Technology transfer entails partnerships with the private sector and entrepreneurial risk-taking in a very competitive environment. The edge between rightful action and wrongdoing often is razor sharp. Universities must be prepared to take the offensive to enforce rights through litigation and to mount a staunch defense if they are sued.

8. The desire to maximize financial returns and customer satisfaction, a high priority for corporations and their shareholders, may interfere with academic freedom and the core university mission of educating. The board should monitor developments that potentially could conflict with the institution's academic mission (or assign a monitoring role to a responsible party) to avoid interference that harms the public trust.

9. The responsibility for amending federal laws rests with Congress. State-funded universities must undergo the scrutiny of state legislatures. Boards—through their institution's state and federal government-relations staffs—should monitor legislative changes and stimulate cooperation with policymakers. Technology-transfer managers may need to enter the policy fray in serious situations.

10. Trustees and chief executives must pay attention to long-term scientific, legal, and economic trends; exercise institutional oversight of the division of financial spoils; act to retain key faculty; satisfy local, state, and federal officials; and promote the institution's general interests.

The Ideal Habitat. Science matters, but it does not just happen. Any scientific endeavor must be incubated, nourished, and mentored. Though the university environment is an ideal habitat, the reality is that scientific research requires infusions of substantial cash, and the academic community coexists in the same environment as federal, state, and local officials and the private sector.

Cultural disparities between these players are significant but need not be adversarial. It should be possible to reconcile the twin goals of developing the intellectual commons as a public good and protecting property rights. A constructive tension contributes to the success of many technology-transfer programs.

Academic laurels—grades, grants, degrees, or scholarships—are temporal. So too are inventions, licenses, and investments. In a constantly changing society, trustees and chief executives must ask questions and insist upon answers with an eye on harnessing changes that occur both outside and within the academic community. Like judges, they must weigh conflicting, educational, societal, political, economic, and technological interests.

An informed approach to technology transfer strengthens the university's research and educational mission and enhances its prestige—something all trustees desire. Ultimately, the fire of their diligence will ignite the fuse of the academic genius. If the pitfalls are avoided, the payoffs can be impressive.

Michael J. Remington is an attorney with Drinker Biddle & Reath, LLP, in Washington, D.C. He is the former long-time counsel to the House subcommittee on courts and intellectual property. Among his clients are the Wisconsin Alumni Research Foundation and the American Council on Education.

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BNA's

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News

Legislation/PTO Budget Funding Proposal and Fee Bill Are Announced to Advance Strategic Plan

The Bush administration Feb. 3 disclosed its 2004 budget for the Patent and Trademark Office and the following day did the same for a proposed fee bill designed to implement and fund features of the PTO's 21st Century Strategic Plan.

Budget Proposal

The PTO's 2004 budget proposal includes increased funding of the agency to the tune of $1.404 billion and less diversion of PTO fee revenue to other government programs.

According to the PTO, the proposal represents a five percent increase over the FY 2003 budget request, and would be supported by revenues generated by proposed fee increases. In addition, the agency reports that the proposal would divert approximately 50 percent less in fee revenues to other government programs than would the 2003 budget.

The 2004 budget and fee package is designed to finance the second year of the PTO's 21st Century Strategic Plan, which includes the following initiatives:

- End-to-end electronic processing of patents;
- New hiring of 750 "highly qualified" patent examiners;
- Initiating competitive sourcing of patent searches;
- Certifying knowledge, skills and abilities of examiners and managers;
- Improving training and in-process reviews, starting pre-employment testing;
- Offering additional competitive compensation packages for patent examiners; and
- Beginning the move to consolidated space in Alexandria, Va.

Fee Bill

The PTO Feb. 4 unveiled its long-awaited fee bill, which imposes heavy increases on patent applications with many pages and many claims. Offered as a necessary

ingredient of the Bush administration's 2004 funding proposal, the fee bill is designed to align the expense of prosecuting a patent application with the costs to the agency and to fund the improvements of the agency's 21st Century Strategic Plan.

The new fee structure reflects the intention to distinguish filing, searching, and examining, applying a separate fee to each activity. Thus, the current $750 basic application fee would be replaced with a $300 filing fee, a $500 search fee, and a $200 examination fee.

For any application with a specification and drawings that exceeds 100 sheets of paper, a fee of $250 is imposed for each additional 50 sheets of paper. For any application with more than three independent claims, a fee of $200 is imposed for each claim after the third. For any application with more than 20 claims of any type, a fee of $50 is imposed for each claim after the twentieth. The proposal also states the following: "The Director may, by regulation, provide for a refund of any part of the fee specified in this paragraph for any claim that is canceled before an examination on the merits ... has been made of the application under section 131 of this title."

Revised Strategic Plan

Together with these funding announcements, the PTO also posted on its Web site a revised version of its 21st Century Strategic Plan.

The plan was initially unveiled last June (64 PTCJ 125, 6/7/02), and was subjected to criticism by the IP bar associations the following month at a hearing before the House Subcommittee on Courts, the Internet, and Intellectual Property (64 PTCJ 296, 7/26/02). The bar groups again detailed their complaints to the PTO last October (65 PTCJ 7, 11/1/02) and entered into negotiations with the agency to resolve their concerns.

In the end, those concerns were addressed and the bar groups registered their approval in a letter addressed to Office of Management and Budget Director Mitchell E. Daniels (65 PTCJ 97, 11/29/02). The following revisions of the plan are included on the PTO's Web site:

- An administrative alternative to deferred examination.

- The PTO will contract with private sector commercial search organizations rather than require applicants to commission search reports.

- The requirement for mandatory Information Disclosure Statements is withdrawn, and the PTO will continue to rely on voluntary submissions.

- The plan's concepts will be tested and evaluated, especially the proposed outsourcing, quality enhancements, and "e-government."

- Pendency of 18 months until first Office action and pendency of 27 months until issue will be achieved by 2008; the goal of 18-month pendency until issue will require a decade.

The PTO fee proposal has also been modified. The proposal to increase fees for applications with excessive claims and pages now provides for a "linear increase" rather than an increase that multiplies with each increase of claims or pages. Among the items eliminated from the original plan are: (1) surcharges on filing continuations

and on patentably indistinct claims; (2) a separate fee to trigger examination; and (3) authority to reduce examination fees for "micro-entities."

Lingering Qualms

Despite the IP bar's general endorsement of the PTO's budget and operations plan, it still has some reservations about the fee increase and the prospect that those revenues could be diverted to other government programs. The administration would like the bar associations to endorse the fee increases as a necessary step to making improvements in PTO operations, but they recognize that the trump card on diversion is still in the hands of Congress.

The complaints about diversion made to the oversight committees on Capitol Hill have been like singing to the choir, but there is still no sympathetic refrain from the appropriators.

The proposed fee legislation appears in the text section of this issue.

The revised 21st Century Strategic Plan is available at http://www.uspto.gov/web/offices/com/strat21/index.htm

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PhRMA

1100 Fifteenth Street, NW • Washington, DC 20005 • www.phrma.org

July 2002

PhRMA

PRINCIPLES ON **CONDUCT** OF CLINICAL TRIALS AND **COMMUNICATION** OF CLINICAL TRIAL RESULTS

Preamble

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members discover, develop, manufacture and market new medicines and vaccines to enable patients to live longer and healthier lives.

The development of new therapies to treat disease and improve quality of life is a long and complex process. A critical part of that process is clinical research, the study of a pharmaceutical product in humans (research participants). Clinical research involves both potential benefits and risks to the participants and to society at large. Investigational clinical research is conducted to answer specific questions, and some aspects of the therapeutic profile (benefits and risks) of the product(s) tested may not be fully known without study in humans. In sponsoring and conducting clinical research, PhRMA members place great importance on respecting and protecting the safety of research participants.

Principles for the conduct of clinical research are set forth in internationally recognized documents, such as the Declaration of Helsinki and the Guideline for Good Clinical Practice of the International Conference on Harmonization. The principles of these and similar reference standards are translated into legal

requirements through laws and regulations enforced by national authorities such as the U.S. Food and Drug Administration. PhRMA members have always been committed, and remain committed, to sponsoring clinical research that fully complies with all legal and regulatory requirements.

Many different entities and individuals contribute to the safe and appropriate conduct of clinical research, including not only sponsoring companies but also regulatory agencies; investigative site staff and medical professionals who serve as clinical investigators; hospitals and other institutions where research is conducted; and institutional review boards and ethics committees (IRBs/ECs).

PhRMA adopts these voluntary principles to clarify our members' relationships with other individuals and entities involved in the clinical research process and to set forth the principles we follow.

The key issues addressed here are:

- Protecting Research Participants
- Conduct of Clinical Trials
- Ensuring Objectivity in Research
- Disclosure of Clinical Trial Results

These principles reinforce our commitment to the safety of research participants, and they provide guidance to address issues that bear on this commitment in the context of clinical trials that enroll research participants and are designed, conducted and sponsored by member companies.

Commitment to Protecting Research Participants

We conduct clinical research in a manner that recognizes the importance of protecting the safety of and respecting research participants. Our interactions with research participants, as well as with clinical investigators and the other persons and entities involved in clinical research, recognize this fundamental principle and reinforce the precautions established to protect research participants.

Conduct of Clinical Trials

We conduct clinical trials in accordance with applicable laws and regulations, as well as locally recognized good clinical practice, wherever in the world clinical trials are undertaken. When conducting multinational, multi-site trials, in both the industrialized and developing world, we follow standards based on the Guideline for Good Clinical Practice of the International Conference on Harmonization.

a. Clinical Trial Design. Sponsors conduct clinical trials based on scientifically designed protocols, which balance potential risk to the research participant with the possible benefit to the participant and to society. Scientific, ethical and clinical judgments must guide and support the design of the clinical trial, particularly those aspects directly affecting the research participants such as inclusion/exclusion criteria, endpoints, and choice of control, including active and/or placebo comparator.

b. Selection of Investigators. Investigators are selected based on qualifications, training, research or clinical expertise in relevant fields, the potential to recruit research participants and ability to conduct clinical trials in accordance with good clinical practices and applicable legal requirements.

c. Training of Investigators. Investigators and their staff are trained on the clinical trial protocol, pharmaceutical product, and procedural issues associated with the conduct of the particular clinical trial.

d. IRB/EC Review. Prior to commencement, each clinical trial is reviewed by an IRB/EC that has independent decision-making authority, and has the responsibility and authority to protect research participants.

- The IRB/EC has the right to disapprove, require changes, or approve the clinical trial before any participants are enrolled at the institution or investigative site for which it has responsibility.
- The IRB/EC is provided relevant information from prior studies, the clinical trial protocol, and any materials developed to inform potential participants about the proposed research.

e. Informed Consent. We require that clinical investigators obtain and document informed consent, freely given without coercion, from all potential research participants.

- Potential research participants are to be adequately informed about potential benefits and risks, alternative procedures or treatments, nature and duration of the clinical trial, and provided the opportunity to ask questions about the study and receive answers from a qualified health care professional.
- Clinical investigators are encouraged to disclose to potential research participants during the informed consent process that the investigator and/or the institution is receiving payment for the conduct of the clinical trial.
- In those cases where research participants—for reasons such as age, illness, or injury—are incapable of giving their consent, the informed consent of a legally acceptable representative is required.
- Because participation in a clinical trial is voluntary, all research participants have the right to withdraw from continued participation in the clinical trial, at any time, without penalty or loss of benefits to which they are otherwise entitled.

f. Clinical Trial Monitoring. Trials are monitored using appropriately trained and qualified individuals. The sponsor will have procedures for these individuals to report on the progress of the trial including possible scientific misconduct.

- These individuals verify compliance with good clinical practices, including (but not limited to) adherence to the clinical trial protocol, enrollment of appropriate research participants, and the accuracy and complete reporting of clinical trial data.

- If a sponsor learns that a clinical investigator is significantly deficient in any area, it will either work with the investigator to obtain compliance or discontinue the investigator's participation in the study, and notify the relevant authorities as required.

g. Ongoing Safety Monitoring. All safety issues are tracked and monitored in order to understand the safety profile of the product under study. Significant new safety information will be shared promptly with the clinical investigators and any Data and Safety Monitoring Board or Committee (DSMB), and reported to regulatory authorities in accordance with applicable law.

h. Privacy and Confidentiality of Medical Information. Sponsors respect the privacy rights of research participants and safeguard the confidentiality of their medical information in accordance with all applicable laws and regulations.

i. Quality Assurance. Procedures are followed to ensure that trials are conducted in accordance with good clinical practices and that data are generated, documented and reported accurately and in compliance with all applicable requirements.

j. Clinical Trials Conducted in the Developing World. When conducting clinical trials in the developing world, sponsors collaborate with investigators and seek to collaborate with other relevant parties such as local health authorities and host governments to address issues associated with the conduct of the proposed study and its follow-up.

Ensuring Objectivity in Research

We respect the independence of the individuals and entities involved in the clinical research process, so that they can exercise their judgment for the purpose of protecting research participants and to ensure an objective and balanced interpretation of trial results. Our contracts and interactions with them will not interfere with this independence.

a. Independent Review and Safety Monitoring. In certain studies, generally large, randomized, multi-site studies that evaluate interventions intended to prolong life or reduce risk of a major adverse health outcome, the patients, investigators and the sponsor may each be blinded to the treatment each participant receives to avoid the introduction of bias into the study. In such cases, monitoring of interim study results and of new information from external sources by a DSMB may be appropriate to protect the welfare of the research participants. If a DSMB is established, its members should have varied expertise, including relevant fields of medicine, statistics, and bioethics. Sponsors help establish, and also respect, the independence of DSMBs.

- Clinical investigators participating in a clinical trial of a pharmaceutical product should not serve on a DSMB

that is monitoring that trial. It is also not appropriate for such an investigator to serve on DSMBs monitoring other trials with the same product if knowledge accessed through the DSMB membership may influence his or her objectivity.

- A voting member of a DSMB should not have significant financial interests or other conflicts of interest that would preclude objective determinations. Employees of the sponsor may not serve as members of the DSMB, but may otherwise assist the DSMB in its evaluation of clinical trial data.

b. Payment to Research Participants. Research participants provide a valuable service to society. They take time out of their daily lives and sometimes incur expenses associated with their participation in clinical trials. When payments are made to research participants:

- Any proposed payment should be reviewed and approved by an independent IRB/EC.
- Payments should be based on research participants' time and/or reimbursement for reasonable expenses incurred

during their participation in a clinical trial, such as parking, travel, and lodging expenses.

- The nature and amount of compensation or any other benefit should be consistent with the principle of voluntary informed consent.

c. Payment to Clinical Investigators. Payment to clinical investigators or their institutions should be reasonable and based on work performed by the investigator and the investigator's staff, not on any other considerations.

- A written contract or budgetary agreement should be in place, specifying the nature of the research services to be provided and the basis for payment for those services.
- Payments or compensation of any sort should not be tied to the outcome of clinical trials.
- Clinical investigators or their immediate family should not have a direct ownership interest in the specific pharmaceutical product being studied.

- Clinical investigators and institutions should not be compensated in company stock or stock options for work performed on individual clinical trials.

- When enrollment is particularly challenging, reasonable additional payments may be made to compensate the clinical investigator or institution for time and effort spent on extra recruiting efforts to enroll appropriate research participants.

- When clinical investigators and their staff are required to travel to meetings in conjunction with a clinical trial, they may be compensated for their time and offered reimbursement for reasonable travel, lodging, and meal expenses. The venue and circumstances should be appropriate for the purpose of the meeting.

Public Disclosure of Clinical Trial Results

Availability of clinical trial results in a timely manner is often critical to communicate important new information to the medical profession, patients and the public. We design and conduct clinical trials in an ethical and scientifically rigorous manner to determine the benefits, risks, and value of pharmaceutical products. As sponsors, we are responsible for receipt and verification of data from all research sites for the studies we conduct; we ensure the accuracy and integrity of the entire study database, which is owned by the sponsor.

a. Communication of Study Results. Clinical trials may involve already marketed products and/or investigational products. We commit to timely communication of meaningful results of controlled clinical trials of marketed products or investigational products that are approved for marketing, regardless of outcome. Communication includes publication of a paper in a peer-reviewed medical journal, abstract submission with a poster or oral presentation at a scientific meeting, or making results public by some other means.

- Some studies that sponsors conduct are of an exploratory nature (early-phase or post-marketing). These are often highly proprietary to the sponsoring company,

and due to their limited statistical power, serve primarily to generate hypotheses for possible future trials. Sponsors do not commit to publish the results of every exploratory study performed, or to make the designs of clinical trial protocols available publicly at inception, as in a clinical trials registry. If the information from an exploratory study is felt to be of significant medical importance, sponsors should work with the investigators to submit the data for publication.

- In all cases, the study results should be reported in an objective, accurate, balanced and complete manner, with a discussion of the strengths and limitations of the study.

b. Authorship. Consistent with the International Committee of Medical Journal Editors and major journal guidelines for authorship, anyone who provides substantial contributions into the conception or design of a study, or data acquisition, or data analysis and interpretation; and writing or revising of the manuscript; and has final approval of the version to be published should receive appropriate recognition as an author or contributor when the manuscript is published. Conversely, individuals who do not contribute in this manner do not warrant authorship.

- Companies sometimes employ staff to help analyze and interpret data, and to produce manuscripts and presentations. Such personnel must act in conjunction with the investigator-author. Their contributions should be recognized appropriately in resulting publications—either as a named author, a contributor, or in acknowledgments depending on their level of contribution.

- All authors whether from within a sponsoring company or external, will be given the relevant statistical tables, figures, and reports needed to support the planned publication.

c. Related Publications. For a multi-site clinical trial, analyses based on single-site data usually have significant statistical limitations, and frequently do not provide meaningful information for health care professionals or patients and therefore may not be supported by sponsors. Such reports should not precede and should always reference the primary presentation or paper of the entire study.

d. Investigator Access to Data and Review of Results. As owners of the study database, sponsors have discretion to determine who will have access to the database. Generally, study databases are only made available to regulato-

ry authorities. Individual investigators in multi-site clinical trials will have their own research participants' data, and will be provided the randomization code after conclusion of the trial. Sponsors will make a summary of the study results available to the investigators. In addition any investigator who participated in the conduct of a multi-site clinical trial will be able to review relevant statistical tables, figures, and reports for the entire study at the sponsor's facilities, or other mutually agreeable location.

e. Research Participant Communication. Investigators are encouraged to communicate a summary of the trial results, as appropriate, to their research participants after conclusion of the trial.

f. Sponsor Review. Sponsors have the right to review any manuscripts, presentations, or abstracts that originate from our studies or that utilize our data before they are submitted for publication or other means of communication. Sponsors commit to respond in a timely manner, and not suppress or veto publications or other appropriate means of communication (in rare cases it may be necessary to delay publication and/or communication for a short time to protect intellectual property). Where

differences of opinion or interpretation of data exist, the parties should try to resolve them through appropriate scientific debate.

g. Provision of Clinical Trial Protocol for Journal Review. If requested by a medical journal when reviewing a submitted manuscript for publication, the clinical trial sponsor will provide a synopsis of the clinical trial protocol and/or pre-specified plan for data analysis with the understanding that such documents are confidential and should be returned to the sponsor.

This document is effective from October 1, 2002.

Under these principles, may a clinical investigator who owns stock in Company A be employed to conduct a clinical trial sponsored by Company A?

Yes. Ownership of stock in the sponsoring company does not disqualify the investigator from participating in clinical research for the company. However, sponsors may not compensate investigators with stock or stock options for work performed on individual clinical trials. Under the laws and regulations of some countries, stock ownership by investigators may need to be disclosed to regulatory authorities.

A physician has discovered a potential product. The physician licenses the compound to Company B for a royalty payment for any future sales. Can the physician be a clinical investigator of that compound for Company B?

No. Direct ownership interests in a product (such as patent rights or rights to royalty payments) present an inherent conflict of interest, which could introduce bias into the conduct of the clinical trial.

Companies that acquire rights to products which have arrangements that are in conflict with the above should take reasonable steps to modify the relationship.

Company C has just completed a controlled clinical trial evaluating the efficacy and safety of an investigational product versus placebo. The trial provides no information other than the relative merits of the investigational product versus placebo. Does Company C have a commitment to communicate the results of this trial?

Perhaps. If the product is ultimately approved for marketing, the results are likely meaningful because they provide information about the safety and efficacy of the marketed product, and should be communicated. The proprietary nature of the trial may be considered when assessing the timing of communication.

If the product never reaches the market and the results are only informative with regard to the specific product being studied, the results are likely not of significant medical importance and need not be communicated.

However, if the results are thought to be of significant medical importance, the sponsor should work with the investigators to communicate the results of the trial.

Company D has completed an exploratory, controlled trial of a product involving a novel and highly proprietary study design. Should Company D communicate the results of this trial?

Perhaps. Exploratory trials rarely provide information of significant medical importance. However, if they do, the sponsor should work with the investigators to communicate the results of the trial.

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INFORMATION CONTACTS

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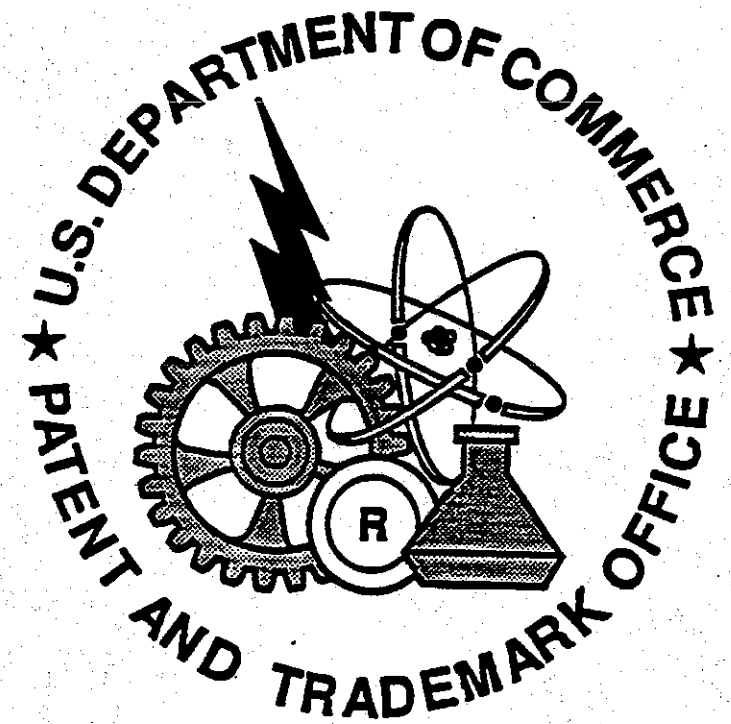

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