98TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 98-857
Part 2

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

AUGUST 1, 1984.—Committed to the Committee of the Whole House on the States of the Union and ordered to be printed

Mr. KASTENMEIER, from the Committee on the Judiciary, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany H.R. 3605]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments (stated in terms of the page and line numbers of the bill as reported by the Committee on Energy and Commerce) are as follows:

Page 14, line 22, strike out "(i)" and strike out line 9 on page 15 and all that follows through line 4 on page 16.

Page 27, line 3, strike out "(i)", insert close quotation marks at the end of line 19, and strike out line 20 on that page and all that follows through line 21 on page 28.

Page 37, line 24, strike out "or the Secretary of Agriculture".

Page 38, strike out lines 11 through 22, and insert in lieu thereof the following:

"(1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug

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product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additived are subject to the Federal Food, Drug, and Cosmetic Act.

Page 38, line 24, strike out "who is so notified".

Page 39, line 1, strike out "receiving the application".

Page 39, lines 8 and 13, strike out "making the determination".

Page 39, line 14 strike out "such" and insert in lieu thereof "the".

Page 39, beginning in line 18 strike out "of Health and Human Services".

Page 39, beginning in line 22 strike out "making a determination under clause (i)".

Page 40, line 3, strike out "making the determination".

Page 40, lines 5 and 13, strike out "such" and insert in lieu thereof "the".

Page 40, beginning in line 8 strike out "who is holding the hearing".

Page 41, line 21, strike out "drug product" and insert in lieu thereof "human drug product".

Page 42, line 1, strike out "drug product" and insert in lieu thereof "human drug product".

Page 42, beginning in line 2, strike out "new animal" and all that follows through line 6 and insert in lieu thereof the following:

or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)

Page 42, lines 20 and 21, strike out "512,".

Page 42, strike out lines 23 through 25.

Page 43, lines 8 and 12, insert "human" before "drug".

Page 43, strike out lines 14 through 25, and insert in lieu thereof the following:

"(i) the period beginning on the date an exemption under subsection (i) of section 505 or under subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

Page 44, strike out lines 3 through 7 and insert in lieu thereof the following:

human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

Page 46, strike out lines 15 through 17 and redesignate clauses (iii) and (iv) as clauses (i) and (iii), respectively.

Page 48, line 2, insert after "patented invention" the following: "(other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, Cosmetic Act and the Act of March 4, 1913))".

BACKGROUND OF PATENT TERM LEGISLATION

For the last 113 years patent terms have been set at seventeen years. Beginning in the late 1970's, however, patent owners began to complain that the period of Federal government regulatory review eroded the effective market life of their patents. This view was first formally voiced by President Carter's Advisory Committee on Industrial Innovation.

During the 96th Congress an attempt was made to legislate in this area. Congressman Kastenmeier, chairman of the Subcommittee on Courts, Civil Liberties and the Administration of Justice, requested that an amendment to an unrelated patent bill by Mr. Sawyer be withdrawn in return for an agreement that the bill would be given full consideration during the next Congress. This request was agreed to.

During the 97th Congress the Subcommittee held extensive hearings on H.R. 1937.[1] The Subcommittee also commissioned a study of the issue by the Office of Technology Assessment.

PATENT TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY (1981)

As a result of those hearings the Subcommittee marked up the bill and reported a clean bill, H.R. 6444. The Committee on the Judiciary approved H.R. 6444 on August 4, 1982.[2] The bill was brought up on the Suspension calendar in September 1982 but failed to achieve two-thirds by a narrow margin.

Also during the 97th Congress the Senate held hearings on patent term legislation.[3] The Senate passed S. 255 unanimously, but because of the failure of the House measure no public law ensued.

It should also be noted that during the 97th Congress opponents of patent term legislation, Congressmen Waxman and Gore, also held hearings on the subject.[4]

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Relatively early this Congress, Congressman Synar introduced H.R. 3502, a measure largely similar to the bill which had passed the Senate last Congress. In the Senate Senator Mathias introduced a companion bill, and has held hearings on the measure this Congress. The original Synar bill, H.R. 3502, had approximately one hundred co-sponsors, including leadership figures from both parties.

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[1] Patent Term Restoration Act of 1981: Hearings on H.R. 1937, H.R. 6444, and S. 255, Before the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary, 97th Congress, 1st Session (1981).

[2] H.R. Rep. No. 696, 97th Congress, 2nd Session (1982); see also S. Rep. No. 138, 97th Congress, 1st Session (1981).

[3] Patent Term Restoration Act of 1981: Hearings on S. 255 Before the Senate Comm. on the Judiciary, 97th Congress, 1st Session (1981).

[4] Health and the Environment Miscellaneous—Part 7: Hearings on Childhood Immunizations; Cost Effectiveness of the Influenza Vaccine; Proposed Family Planning Regulation; Orphan Drug Act—H.R. 5238, Before the Subcommittee on Health and the Environment of the House Comm. on Energy and Commerce, 97th Congress 2d Session (1982); Pharmaceutical Innovation—Promises and Problems: Hearings on Breakthrough Drugs Before the Subcomm. on Natural Resources, Agriculture Research and Environment and the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 97th Congress, 1st Session (1981).

Also early this Congress, Congressman Waxman introduced H.R. 3605, a bill relating to the approval process for generic drugs. The original Waxman bill was a page and a half in length. This bill was the subject of a day of hearings in the Committee on Energy and Commerce, Subcommittee on Health and Environment. The Subcommittee then reported the bill without amendment. After the markup was concluded, Congressman Waxman engaged in extensive negotiations with interested parties. The primary participants were the Generic Pharmaceutical Industry Association (GPIA) and the Pharmaceutical Manufacturers Association (PMA). As a result of these discussions, when the bill was marked up in the Committee on Energy and Commerce Mr. Waxman offered an amendment in the nature of a substitute. The substitute was adopted and forms the basic text of H.R. 3605. House Report 98–857, Part I.

Background on FDA Approval Process

Since the passage of the Drug Amendments of 1962, the FDA has permitted the marketing of generic drugs under two different sets of rules. With respect to drugs approved before 1962 (i.e. those approved under a standard of safety but not efficacy), FDA has permitted generic substitution without a requirement that the generic substitute duplicate previously approved tests. However, with respect to drugs approved after 1962, the FDA has adopted the view that generics must virtually duplicate the same health and safety tests conducted by the original applicant for marketing approval.

The FDA rules on generic drug approval for drugs approved after 1962 have had serious anti-competitive effects. The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. This is so because of the inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests.

The first serious attempts at rectifying the inequities of this drug approval process were undertaken in the 95th Congress. The Carter Administration, under the leadership of Secretary Califano of the Department of Health and Human Services, and Dr. Kennedy of the FDA, proposed sweeping changes in the drug approval process.[5] Secretary Califano urged Congress to act for three reasons: (1) the exclusion of generics was anti-competitive; (2) the requirements of duplicative tests on humans unnecessarily endangered human health; and (3) the approval process diluted the resources of the FDA.[6] During the 96th Congress additional hearings were held [7] and the Senate eventually adopted a bill which opened up the FDA

[5] The Administration bill was introduced, after extensive consultation as H.R. 11611, and S. 2755.

[6] "Drug Regulation Reform Act of 1978," Hearing before the Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce, United States House of Representatives, 95th Congress, 2d Session (1978); "Drug Regulation Reform Act of 1978," Hearings before the Subcommittee on Health and Scientific Research, Committee on Human Resources, United States Senate, 95th Congress, 2d Session (1978).

[7] "Drug Regulation Reform Act of 1979," Hearings before the Subcommittee on Health and Scientific Research, Committee on Labor and Human Resources, United States Senate, 96th Congress, 1st Session (1979).

drug approval process.[8] This comprehensive reform bill failed in the House for unrelated reasons.

SUMMARY OF H.R. 3605

H.R. 3605 contains two titles. The first title of the bill creates a new system for the approval of generic drugs by the Food and Drug Administration. This approval process for drugs approved by the FDA after 1962 has been severely criticized as too cumbersome and expensive. In essence the provisions of title I of H.R. 3605 extend the procedures for approval of generics for pre-1962 drugs to the later class of drugs.

Thus, under H.R. 3605 a general manufacturer may submit to FDA a request for approval of a generic substitute for any post-1962 drug. The generic manufacturer must establish that the proposed substitute is the same or therapeutically equivalent to the drug which has already been approved.

Under the approval process in H.R. 3605, a generic manufacturer may submit an application for approval to FDA before the so-called pioneer drug goes off patent. The generic may submit data establishing bioequivalency during this time period. In order to complete this application the generic manufacturer must conduct certain drug tests. In order to facilitate this type of testing, section 202 of the bill creates general exception to the rules of patent infringement. Thus, a generic manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval.

H.R. 3605 permits generic applications to be effective after a patent expires. In addition, H.R. 3605 provides that a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired. Under current law, this situation is not an issue because of the cumbersome approval process. If the generic manufacturer seeks such an approval it must allege that the existing patent is invalid or will not be infringed. In this instance notification must be given by the generic to the patent holder concerning the application for FDA approval. In these cases the FDA may not approve the generic application until either: (1) 18 months have expired or (2) a court has determined that no infringement will take place. After the expiration of 18 months, if there has been no intervening judicial determination, the FDA will approve the generic application, even if the drug is still on patent.

Finally, title I also provides for a four year grant of market exclusivity to be granted by the Commissioner of the FDA for unpatentable substances which have been approved for use as drugs by the FDA.

TITLE II

This title of the bill addresses the question of patent term extension. As noted above, proponents of this type of legislation have argued that the reduction of the effective market life of a patent

[8] S. Rept. 96-321, 96th Congress, 1st Session 42-44, 50-51 (1979); 125 Congressional Record 26244-26275 (Sept. 26, 1979).

because of Federal regulatory review should be restored through an extension of the patent term. Alternatively, or additionally, some proponents of this approach have argued that without some form of legislative relief in this area there would be a diminished stimulus to innovation and research. Thus, it is argued that patent term extensions will create incentives for increased research expenditures.

The patent term extension provisions of the bill are relatively complex, and differ in many respects from the bill approved by the Committee on the Judiciary last Congress. In general, the bill provides that a patent may be extended for a period of up to five years if the patented drug (or other item subject to regulatory review by the FDA) has undergone regulatory review. The bill provides several general rules for calculating the period of the extension. First, only one-half of the testing phase may be counted. Second, a year-for-year matching extension is available for any time in the drug approval process that the drug spends awaiting a decision by the FDA. The five year rule is available to all drugs which have not yet undergone testing by the FDA. With respect to drugs which have been patented and tested but not yet approved by the FDA, the maximum period of extension is two years.

In addition to the five year rule listed above, the bill places an additional cap on the possible extension. In no case may the period of patent extension, when added to the patent life left after approval of the product, exceed fourteen years. Finally, any part or all of the patent extension may be cancelled if the applicant for an extension failed to act with due diligence in conducting tests or in the submission of data to the FDA.

As noted above, the other feature of the drug patent part of the bill is to statutorily modify the rules with respect to patent infringement.

HISTORY OF THE BILL IN THE COMMITTEE ON THE JUDICIARY

On June 21, 1984, H.R. 3605 was sequentially referred to the Committee on the Judiciary for a period not to extend beyond the 1st of August, 1984. The bill was referred to the Subcommittee on Courts, Civil Liberties and the Administration of Justice which held one day of hearings on the bill on June 27, 1984. Formal presentations at that hearing were made by:

Honorable Gerald J. Mossinghoff, Assistant Secretary and Commissioner of Patents and Trademarks; a panel including Robert J. Lewis, representing the Pharmaceutical Manufacturing Association and William Haddad, representing the Generic Pharmaceutical Industry Association; a panel consisting of John Stafford, President, American Home Products; Norman Dorsen, Professor of Law, New York University School of Law and William E. Schuyler, Jr., Esq. and Dr. Ronald E. Cape, Chairman, Cetus Corporation, Emeryville, California.

In addition, written statements suggesting amendments to the legislation have been received from Congressmen Mica and Coughlin. Written comments favoring the bill have also been received from the following labor organizations: the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO); International Union, United Automobile, Aerospace and Agricultural

Implement Workers of America (UAW); American Federation of State, County and Municipal Employees (AFSCME). Further statements in support of the bill have been received from the American Association of Retired Persons (AARP); Consumer Federation of America (CFA); National Council on Senior Citizens (NCSC). Additional comments have also been received by the American Society of Hospital Pharmacists in support of the bill.

Statements in opposition to parts of the bill have been received from the American Intellectual Property Law Association (AIPLA) and the Patent, Trademark and Copyright Section of the Bar Association of the District of Columbia.

SUMMARY OF HEARING

The proponents of the legislation urged its adoption as the best possible compromise between two competing economic interests. The Commissioner of Patents and Trademarks objected to the legislation on several grounds. Commissioner Mossinghoff urged the Committee to adopt the patent term procedures and rules contained in the Committee reported bill from last Congress and to reject the proposed changes in the law of patent infringement. Dr. Ronald Cape of CETUS Corporation urged expanded protection from the abbreviated new drug application process for biotechnology which uses recombinant DNA.

Finally, a group of drug companies opposed to the legislation in its current form articulated its reservations. They argue that the bill will hamper innovation and research, create unnecessary litigation and unconstitutionally take property from patent owners.

Committee on the Judiciary Deliberations

The Committee considered six amendments. Two amendments were adopted, and four amendments were rejected.

The first amendment adopted was first approved by the Subcommittee on Courts, Civil Liberties and the Administration of Justice and relates to animal drugs. This amendment deleted authority for patent term extension for animal drugs, because these substances were dealt with in another bill before the Committee, H.R. 6034.

The second amendment approved by the Committee was offered by Mr. Kastenmeier. This amendment deleted from the bill authority of the Commissioner of the Food and Drug Administration to grant exclusive marketing authority for unpatentable substances. The Committee concluded that such authority to issue second class "patents" should not be granted without a strong showing of need. There was no such showing. Further, the Committee concluded that authority to grant the equivalent of a monopoly is something which should be limited to appropriate Federal agencies such as the Patent and Trademark Office in the case of non-obvious, useful inventions.

The first amendment rejected by the Committee was offered by Mr. Hughes. The Hughes amendment would have permitted the granting of a patent term extension for the substances regulated by the bill for each regulatory review period. The net result of the amendment was to permit multiple patent term extensions on what was essentially the same drug product. This amendment was

supported by the Patent and Trademark Office (PTO). The PTO argued that the version of H.R. 3605 reported by the Committee on Energy and Commerce would create two different types of patents for drugs; those which are extendable and those which are not extendable. The latter category, they claim, includes subsequent use, method and composition patents.

The Committee considered these arguments and rejected them for two reasons. First, the Committee accepted the rationale put forward by the Committee on Energy and Commerce concerning the need to avoid multiple patent term extensions. Our sister Committee argued that the only patented product which experiences any substantial regulatory delay is the first product patent (or if there is no product patent, the first process patent). Therefore, they reason that subsequent patents on approved drug products are frequently not the same magnitude of innovation as occurs with respect to the initial patent. Thus, the Committee on Energy and Commerce concluded on public policy and health policy grounds that only the first patent on a drug-type product should be extended.

The second amendment rejected by the Committee was offered by Mr. Moorhead. This amendment would have permitted generic drug manufacturers to conduct FDA related tests during the life of a patent, but only during the last year of any period of patent term extension. The net effect of this amendment would have been to delay the opportunity of doing such testing for nearly two decades.[9] Mr. Moorhead argued that section 202 of the bill constituted an unconstitutional taking of property without just compensation in violation of the Fifth Amendment to the Constitution. The Committee rejected this argument for reasons set forth in greater detail in the section by section analysis. See page 26, infra. Mr. Moorhead also argued that it was unfair for persons holding existing patents to be forced to give up certain property rights during the life of that patent. He asserted that this amendment would permit such testing but only as a condition for obtaining a patent term extension.

The Committee rejected the Moorhead amendment for two reasons. First, 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. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial. Second, the Committee accepted the public policy rationale of our sister Committee on Energy and Commerce. They reasoned that without section 202 generic manufacturers would be required to engage in these bioequivalency tests after the expiration of the patent.[10] This would result in delays of about two years after the expiration of the patent before a generic could go on the market. Thus, the Committee on Energy and Commerce reasoned that sec-

[9] This is so became for the most part the bill is prospective as to patent extensions. So for a patent granted in 1985 with a 5-year extension the testing would not occur until 2006 (1985+17+5−1 year).

[10] Alternatively these tests could be conducted outside the United States in a country where the pioneer drug company does not have patent protection.

tion 202 of the bill was essential to implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent.

The third amendment rejected by the Committee was offered by Mr. Sawyer. This amendment would have changed the trigger which set in motion the commencement of patent validity litigation. Mr. Sawyer argued that the time period when the bill's litigation procedures come into play should occur later than is provided in the bill. The Committee rejected the amendment because the Committee reported bill provides that the initial submission by the generic manufacturer must be substantially complete (including the results of any required bioequivalency tests). See House Report 98–857, Part I, 24–25. Thus, the Committee concluded that requiring the patent litigation to await the formal acceptance of the data by the FDA would only serve to unnecessarily protract the resolution of that litigation.

The fourth amendment rejected by the Committee was also offered by Mr. Sawyer. This amendment would have required that the FDA may not approve a generic substitute for marketing during the life of a valid patent. Mr. Sawyer's amendment would have required that either the patent expire before approval, or that there be a final decision by a Federal District Court that the patent in question was not valid. The Committee rejected the amendment for several reasons. First, the Committee recognized that under current law the FDA has statutory and regulatory authority to approve of generic substitutes in three instances.[11] Under this existing authority the FDA does not examine or question the patent status of the previously approved drug.[12]

Also under current law, if the generic obtains approval and goes on the market before the patent expires, then the patent holder can sue for patent infringement. Thus, under current Federal law the FDA does not assist the patent holder in enforcing a patent.

The provisions of the bill reported by the Committee on Energy and Commerce modify this rule by providing that if a generic files for approval and requested marketing authority during the life of the patent that the FDA cannot act immediately. Under the bill the generic must notify the FDA that they are claiming that the patent is invalid.[13] The generic must also notify the patent holder. The patent holder must then commence litigation within 45 days to assert the validity of the patent. Once that litigation has commenced the FDA cannot grant approval until the earlier of two events occurs: (1) either the expiration of 18 months; or (2) a court decision finding the patent invalid. This provision was added by the Committee on Energy and Commerce to accommodate the competing concerns of the PMA and the generic manufacturers. The PMA

[11] FDA currently has authority to approve generic substitutes for pre-1962 drugs, antibiotics and a narrow class of post-1962 drugs where sufficient medical literature exists. See 21 U.S.C. 355(b); 43 Fed. Reg. 39127 (Sept. 1978) (relating to pre-1962 drugs); 21 U.S.C. 357 (a) and (b) (relating to antibiotics); 46 Fed. Reg. 27396 (May 19, 1981) (relating to post-1962 paper ANDA approvals); see *also* section 3(c)(1)(D)(i)–(iii) (relating to approval of generic pesticide substitutes by EPA whithout relation to patent status).

[12] "The patent laws do not have any hearing on the enforcement of the Federal Food, Drug and Cosmetic Act . . . FDA reviews application(s) without considering any patent issue." 45 Fed. Reg. 72598 (Oct. 31, 1980) (statement by FDA).

[13] Alternatively, the generic could claim that its application would not infringe an existing patent. This notification is likely to produce the same type of patent litigation.

was willing to compromise on the provisions of title I of the bill (relating to abbreviated new drug application procedures (ANDAs)) in exchange for some greater protection of existing human pharmaceutical patents. The generic manufacturers, on the other hand, were willing to live with an eighteen-month rule because of other provisions of the bill.

In light of the foregoing, the net effect of the Sawyer amendment would have been to substantially delay generics from getting onto the market when they seek to challenge the validity of a patent. According to the statistics of the Judicial Conference of the United States, the median time between filing and disposition of a patent suit is 36 months. Annual Report of the Director of the Administrative Office of the United States Courts—1982, at 253. Over ten percent of these cases take more than 77 months. Thus, a requirement that FDA defer generic approval until after a court decision of patent invalidity would substantially delay FDA approvals. Of course, in the event that the FDA approves a generic because of the expiration of 18 months without a court decision, and it is later determined that the patent is valid, the patent owner may still recover damages from the generic.[14] Therefore, in most cases the bill affords greater protection for patent holders than current law.

SECTIONAL ANALYSIS OF "DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984"

GENERAL

The Federal Food, Drug, and Cosmetic Act (hereinafter FDCA), 21 U.S.C. 355, establishes a system of premarketing clearance for drugs. Generally, the FDCA prohibits the introduction into commerce of any new drug unless a new drug application (NDA) filed with the Food and Drug Administration (FDA) is effective with respect to that drug. 21 U.S.C. 335(a). The FDA is part of the Department of Health and Human Services (HHS) and the Secretary of HHS has delegated her responsibilities under the Act to the Commissioner of Food and Drugs. 21 U.S.C. 21 CFR 5.10. A new drug is one not generally recognized by qualified experts as safe and effective for its intended use. 21 U.S.C. 321(p)(1). The Government can sue to enjoin violations, prosecute criminally, and seize and condemn articles. 21 U.S.C. 331(d), 332(a), 333 and 334.

The FDCA establishes an introduction procedure for new drugs, designed to elicit sufficient scientific information about a drug, including reports on investigations, composition, methods and precautions in manufacture, and samples of the drug, which will permit an intelligent assessment of its safety and efficacy. 21 U.S.C. 355(b).

The law provides standards under which, after notice and hearing, the FDA can refuse to allow a NDA to become effective, 21 U.S.C. 355 (c) and (d), or can withdraw a NDA in effect on the basis of new evidence that the drug was unsafe. 21 U.S.C. 355(e). Generally, the FDA must approve or disapprove an application within 180 days. The FDA is directed to refuse approval of NDA and to withdraw any prior approval of NDA if "substantial evidence" that

[14] See proposed section 271(e)(4) and 35 U.S.C. 271.

the drug is effective for its intended use is lacking. 21 U.S.C. 355 (d) and (e). Substantial evidence is defined to include "evidence consisting of adequate clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. 355(d).

FDA orders refusing or withdrawing a NDA are reviewable in the court of appeals. 21 U.S.C. 355(h). Other kinds of FDA orders may be reviewed in federal district courts under the Administrative Procedure Act (APA).

The Act provides an alternative procedure for drugs intended solely for investigational use. 21 U.S.C. 355(i). Compliance with a comprehensive set of FDA regulations is required. 21 CFR 312.1 et seq.

Finally, section 355(j) requires records and reports relating to clinical experience and other data or information regarding an approved drug to be made available to the FDA which shall handle them with due regard for the professional ethics of the medical profession and the interests of patients.

SUMMARY OF THE BILL

The "Drug Price Competition and Patent Term Restoration Act of 1984" (H.R. 3605) consists of two titles which affect introduction procedures and patent requirements for certain kinds of generic new drugs. Title I of the bill allows drug manufacturers to use an abbreviated new drug application (ANDA) when seeking approval to make generic copies of drugs that were approved by the FDA after 1962. Title II of the bill encourages drug manufacturers to assume the increased costs of research and development of certain products which are subject to premarketing clearance by restoring some of the time lost on patent life while the product is awaiting FDA approval.

Section 1 of the bill sets out the short title: "Drug Price Competition and Patent Term Restoration Act of 1984".

Title I—Abbreviated New Drug Applications

Section 101 amends section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355, to graft on the NDA procedure previously described, authority for an abbreviated new drug application (ANDA) procedure applicable to drug manufacturers seeking approval to make generic copies of drugs that were approved by the FDA after 1962. There are "[a]n estimated 150 drug products approved after 1962 [that] are currently off patent and would become available for generic copy using the ANDA procedure proposed in this bill." H. Rept. 98-857, Part I, at 19.

The new ANDA procedure is set forth in subsection (j) of the introductory procedure provisions of current law. 21 U.S.C. 355. As a consequence, existing subsection (j), relating to records and reports which have to be made available to the FDA by manufacturers of approved drugs, is redesignated subsection (k).

Paragraph (1) of proposed subsection (j) authorizes any person to file an ANDA.

Paragraph (2)(A) of proposed subsection (j) describes the information which has to be included in the ANDA. Specifically, the ANDA must include:

(i) sufficient information to show that the conditions of use prescribed, recommended or suggested in the proposed labeling for which the applicant is seeking approval are the same as those that have been previously approved for the listed drug;

(ii)(I) if that listed drug, referred to in clause (i), has only one active ingredient, sufficient information to show that the active ingredient of the generic is the same as that of the listed drug, or

(ii)(II) if the listed drug, referred to in clause (i), has more than one active ingredient, sufficient information to show that all of the active ingredients in the generic drug are the same as those of the listed drug, or

(ii)(III) if that listed drug, referred to in clause (i), has more than one active ingredient, and if one of the active ingredients in the generic drug is different and the applicant is seeking approval under paragraph (2)(C), relating to ANDAs for drugs which are different, sufficient information to show that the other active ingredients of the generic are the same as the active ingredients of the listed drug as well as sufficient information to show that the different active ingredient is an active ingredient or a listed drug or of a drug that is not a new drug as defined by section 201(p) of the Act, 21 U.S.C. 321(p), and such other information about the different active ingredient that the ANDA may require.

(iii) sufficient information to show that the route of administration, the dosage form and the strength of the generic drug are the same as those of the listed drug, or if the generic departs from the listed drug in any one of these particulars, such information regarding that difference as the FDA may require;

(iv) sufficient information to show that the generic drug is bioequivalent [15] to the listed drug, except that if the applicant is seeking approval under paragraph (2)(C), relating to ANDAs for drugs which are different, sufficient information to show that the active ingredients of the generic are of the same pharmacological or therapeutic class as those of the listed drug and can be expected to have the same therapeutic effect when administered to patients for an approved condition for use;

(v) sufficient information to show that the proposed labeling for the generic drug is the same as that of the listed drug except for approved changes when approval has been obtained under paragraph (2)(C), relating to ANDAs for drugs which are different, or because the generic and the listed drug are produced or distributed by different manufacturers;

(vi) the scientific information about a generic that is required for a NDA under existing law, 21 U.S.C. 355(b)(2)–(5), as redesignated by section 103(a) of this bill (§ 355(b)(1)(B)–(F)), namely a full list of its component articles and composition, a

[15] The term bioequivalent is defined in section 101 of the bill.

full description of methods and precautions in manufacture, drug and component article samples, and a specimen of the proposed label;

(vii) a certification by the applicant (in the opinion of the applicant and to the best of such applicant's knowledge) of patent information applicable to the listed drug if that information has been submitted under subsections (b) and (c) of existing law as proposed to be amended by section 102(a)(1) and (a)(2) of the bill, infra. With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval, i.e., a controlling use patent, the applicant must certify, in the opinion of the applicant and to the best of the applicant's knowledge—

(I) that the patent information as required under subsections (b) and (c) of existing law as proposed to be amended by section 102; (a)(1) and (a)(2) of the bill, infra, has not been filed;

(II) that one or more of the product or controlling use patents as hereafter required to be provided for NDAs have expired;

(III) that one or more of the product or controlling use patents as hereafter required to be provided for NDAs will expire on a specified future data, and

(IV) that one or more of the product or controlling use patents as hereafter required to be provided for NDAs either are invalid or will not be infringed.

(viii) a statement when appropriate that an applicant is seeking approval for an indication not previously claimed by any use patent.

The FDA cannot require that an ANDA contain information above and beyond that required by clauses (i) through (viii), supra.

Paragraph (2)(B) of proposed subsection (j) requires additional patent information to be included in the ANDAs of applicants who certify pursuant to subparagraph (A)(vii)(IV), supra, that one or more of the product or controlling use patents either are invalid or will not be infringed. Proposed subparagraph (B)(i) provides that the ANDA in these circumstances shall state that the notice required by clause (ii) of this subparagraph has been given to the affected owner(s) of a patent which is subject to the certification requirement or their representatives and to the affected holder of an approved NDA which contains the patent information required by introduction procedures of existing law as amended by section 102(a)(1) and (a)(2) of the bill.

Clause (ii) provides that the required notice shall state that an ANDA which contains data from bioavailablity or bioequivalence studies has been submitted along with a certification seeking approval for marketing a drug covered by an unexpired patent. Additionally, the notice shall explain in detail the legal and factual basis of the applicant's opinion that the relevant patent is invalid or will not be infringed.

Subparagraph (iii) requires that in the case of an ANDA which is subsequently amended so as to bring it within this notice require-

ment, notice shall be given when the amended application is submitted.

Paragraph (2)(C) of proposed subsection (j) relates to ANDAs for drugs which are different from the listed drugs. Generally, a person would be prohibited from submitting an ANDA in these circumstances unless the variance is one permitted by the law as amended by this bill and the FDA has granted a petition requesting the change. If an applicant wishes to vary one active ingredient or the route of administration, dosage form or strength of the generic drug from the listed drug, it must petition the FDA for permission to file an ANDA for the differing generic drug. The FDA has 90 days to approve or disapprove the petition from the date of its submission. The FDA shall approve a petition to submit an ANDA for a differing generic drug unless clincial studies are needed to show the safety and effectiveness of the change.

Paragraph (3) of proposed subsection (j) requires the FDA to approve an ANDA unless it finds one of the following:

(A) that the methods used in, or the facilities and controls used for, the manufacture, processing and packing of the generic drug are inadequate to assure and preserve its identity, strength, quality and purity;

(B) that the ANDA does not contain sufficient information to show that each of the conditions for use for the generic drug have been previously approved for the listed drug;

(C)(i) that the active ingredient of the generic drug is not the same as that of the listed drug and the listed drug has only one active ingredient,

(C)(ii) that the active ingredients of the generic drug are not the same as those of the listed drug and the listed drug has more than one active ingredient, or

(C)(iii) that the active ingredients of the generic drug differ from those of the listed drug and a petition permitting a change in one active ingredient has been granted but the other active ingredients of the generic drug are not the same as those of the listed drug or the different active ingredient in the generic is not a listed drug or if the different active ingredient is a new drug as defined by section 201(p) of the Act, 21 U.S.C. 321(p);

(D)(i) that an ANDA does not show that the route of administration, dosage form, or strength of the generic drug are all the same as those of the listed drug, or

(D)(ii) that an ANDA for a generic drug which has a different route of administration, dosage form, or strength from the listed drug but the petition regarding the change has not been approved under paragraph (2)(C);

(E) that an ANDA does not contain all of the information that the FDA required in previously granting a petition allowing for a difference in the generic drug from the listed drug;

(F) that an ANDA for a generic drug whose active ingredients are the same as those of the listed drug does not show that the generic drug is bioequivalent to the listed drug or, if a petition regarding a change in one of the active ingredients in a combination generic has been granted, that the ANDA does not show that the active ingredients of the generic drug are of

the same pharmacological or therapeutic class as those of the listed drug or does not show that the differing generic combination drug can be expected to have the same therapeutic effect as the listed combination product when administered to patients for an approved condition of use;

(G) that the ANDA does not show that the proposed labeling for the generic drug is the same as that of the listed drug (except for changes in the proposed labeling of the generic drug because a petition regarding a change has been granted and changes from a switch in producer or distributor);

(H) that on the basis of intrinsic or extrinsic information the inactive ingredients of the generic drug are unsafe for use under the conditions prescribed, recommended, or suggested in the proposed labeling for the generic drug or because the composition of the generic drug is unsafe under approved conditions of use;

(I) that approval of the listed drug has been withdrawn or suspended for reasons of safety or effectiveness;

(J) that an ANDA does not meet any of the requirements set forth in paragraph (2)(A), relating to ANDA's for drugs which are the same;

(K) that an ANDA contains any untrue statement of material fact.

Paragraph (4)(A) of proposed subsection (j) requires the FDA to approve or disapprove an ANDA within 180 days of the initial receipt of the application. By mutual agreement of the FDA and the applicant, that period may be extended.

Paragraph (4)(B) of proposed subsection (j) allows an ANDA approval to become effective according to relevant patent-related circumstances. Thus, under clause (i) if an applicant certifies in an ANDA that patent information has not been supplied with respect to a NDA as hereafter is required or that the relevant patents have expired, approval of the ANDA would become immediately effective. Under clause (ii), if the applicant on the basis of supplied information certifies that the patent or patents will expire on a specified future date, approval of the ANDA becomes effective on that date.

Clause (iii) would authorize a flexible schedule of ANDA approval-effectiveness dates when the applicant certifies that one or more of the product or controlling use patents are invalid or not infringed. Generally, approval of the ANDA in these circumstances could become effective after a 45-day hiatus. An approval of an ANDA would not become effective in these circumstances, however, if within 45 days of the receipt of notice of the certification an action is brought for patent infringement regarding one or more of the patents subject to that certification. In that event, approval of the ANDA could not be effective until 18 months after the notice of the certification was provided or until a court decision issues, if before the expiration of the 18 month time period a court decides such patent is invalid or not infringed the approval shall be made effective on the date of the courts order. If the court decides such patent has been infringed under 35 U.S.C. 271(e) the approval shall be made effective on the date the court orders.

Each party to a patent infringement suit is charged to reasonably cooperate in expediting the action. Failure by either party to cooperate in a reasonable manner may be used by the court to reduce or lengthen the time, as appropriate, before an ANDA approval becomes effective. No action for a declaratory judgment regarding patent infringement can be brought within the 45 days allowed for notice of certification of patent invalidity or non-infringement. An action for a declaratory judgment regarding infringement of a patent shall be brought in the judicial district where the defendant has its principal place of business or a regular or established place of business.

If an ANDA certifying patent invalidity or non-infringement is filed subsequent to an ANDA for the same listed drug that has made a similar certification, clause (iv) provides that the approval of the subsequent ANDA can be made effective sooner than 180 days after the previous applicant has begun commercial marketing, or the date on which the court rules the patent invalid or not infringed, whichever occurs first.

Paragraph (4)(C) of proposed subsection (j) provides that in the event of FDA disapproval of an ANDA, the agency shall give the applicant notice of the opportunity for a hearing on the issue of the approvability of the ANDA. In order to obtain a hearing, the applicant shall request it in writing within 30 days of the notice. The hearing may begin not later than 120 days after the notice. However, a later date may be set by mutual agreement. The hearing shall be conducted as expeditiously as possible. The FDA's decisional order shall be issued within 90 days after the date for filing final briefs.

Paragraph (4)(D) of proposed subsection (j) provides for an interim rule regarding ANDA approval effectiveness in the case of certain generic drugs whose listed drugs were originally approved between January 1, 1982 and the date of enactment of this bill. The clause provides that during this transitional period the FDA may not make effective the approval of an ANDA for a drug which includes an active ingredient (including any ester or salt of the active ingredient) until 10 years after the date of approval of the NDA.

Paragraph (5) of proposed subsection (j) relates to the consequences on an approved ANDA worked by withdrawal or suspension of approval of the listed drug. The approval of an ANDA shall be withdrawn or suspended for safety or effectiveness reasons as provided in section 505(e)(1)–(4) of the Act, 21 U.S.C. 355(e)(1)–(4). Similarly, the approval of an ANDA will also be withdrawn or suspended if it refers to a drug whose approval is withdrawn or suspended under this paragraph. Finally, the approval of an ANDA shall be withdrawn or suspended if the FDA determines that the listed drug has been voluntarily withdrawn from sale due to reasons of safety or effectiveness.

The ANDA must be withdrawn or suspended from sale for the same period as the approval of the drug to which it refers has been withdrawn or suspended. When the listed drug has been voluntarily withdrawn from the market and the FDA has determined that the listed drug was withdrawn due to safety or effectiveness reasons, the approval of the ANDA likewise must be withdrawn until

such time as the FDA determines that the listed drug was not withdrawn from sale for safety or effectiveness reasons.

Paragraph (6)(A), of proposed subsection (j) authorizes a program whereby information about listed drugs which could be copied would become available. Within 60 days after enactment of this bill, the FDA is required to publish and make available a list of drugs eligible for consideration in an ANDA. The list must include in alphabetical order the official and proprietary name of each drug which has been approved for safety and effectiveness prior to the date of enactment of this bill. If the drug was approved after 1981, the list must include the date of its approval and its NDA number. The list must specify whether in vitro or in vivo bioequivalence studies, or both, are required for ANDAs. Clause (i).

At 30-day intervals thereafter, the FDA must update the list to include drugs that have been approved for safety and effectiveness after enactment of this bill and drugs approved in ANDAs under this subsection. Clause (ii).

The FDA must include in the list patent information on listed new drugs required under section 102(a)(1) and (2) of this bill as that information becomes available. Clause (iii).

Paragraph 6(B) of proposed subsection (j) provides that a drug approved for safety and effectiveness under section 505(c) of the Act, 21 U.S.C. § 355(c) or under subsection (j) if this bill is enacted, shall be considered as published and thus eligible for approval in an ANDA on the date of its approval or the date of enactment, whichever is later.

Paragraph (6)(C) of proposed subsection (j) provides that a drug may not be listed as eligible for consideration in an ANDA if the approval of the former or pioneer drug is withdrawn or suspended for safety or effectiveness reasons under section 505(e)(1)–(4) of the Act, 21 U.S.C. § 355(e)(1)–(4), or if approval of the generic drug was withdrawn or suspended under paragraph (j)(5), supra, as authorized by this bill. Also, a drug may not be listed if the FDA determines that it has been voluntarily withdrawn for reasons of safety or effectiveness. In the event such a drug has already been listed, it must be immediately removed from the list.

A drug may not be listed so long as its approval is withdrawn or suspended. If the drug has been voluntarily withdrawn from market, it may not be listed until the FDA determines that the drug was not withdrawn from sale for safety or effectiveness reasons. A notice removing any drug from the FDA list regarding availability for copy shall be published in the Federal Register.

Paragraph (7) of proposed subsection (j) spells out the term "bioavailability" and the significance of bioequivalence for purposes of subsection (j) as authorized by the bill. The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

A drug is to be considered bioequivalent to a listed drug if the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single or multiple doses. Clause (1). A generic drug may also be

considered to be bioequivalent to a listed drug if the extent of absorption of the generic drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the generic drug is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentration on chronic use, and is considered medically insignificant for the drug.

Section 102(a)(1) of the bill amends section 505(b) of the Act, 21 U.S.C. 355(b), to require certain patent related information to be filed with all new drug applications (NDAs) and with all NDAs previously filed but not yet approved. The FDA is required to publish the patent information upon approval of the NDA.

Section 102(a)(2) of the bill amends section 505(c) of the Act, 21 U.S.C. 355(c), to require that any previously approved NDA be amended within 30 days of enactment of this bill to include certain patent related information. The FDA is required to publish the patent information upon its submission. In order to accommodate these provisions, the current text of section 505(c) of the Act, 21 U.S.C. 355(c), is designated paragraph (1) and the new patent related provisions authorized by this bill would be designated paragraph (2)(A) and (B).

The patent information required includes the patent number and the expiration date of any patent which claims the drug in the NDA or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engages in the manufacture, sale or use of the drug. When a patent is issued after the filing of a NDA, but before its approval by the FDA, the application would have to be amended to include the patent number and expiration date.

Section 102(a)(3)(A) of the bill amends section 505(d) of the Act, 21 U.S.C. 355(d), to provide that pending and future NDAs may not be approved unless they contain the described patent information. Appropriate redesignations of clauses of subsection (d) are authorized to accommodate this change.

Section 102(a)(3)(B) of the bill amends section 505(e) of the Act, 21 U.S.C. 355(e), to provide that a NDA may be revoked if the patent information is not filed within 30 days after receipt of a written notice from the FDA specifying the failure to provide that information.

Section 102(b)(1)–(6) of the bill amends provisions of existing law, as appropriate, in order to reconcile internal references to substantive and sectional changes that are proposed by the bill.

Section 103(a) of the bill amends section 505(b) of the Act, 21 U.S.C. 355(b), relating to the filing of a NDA, to redesignate subsection (b) as subsection (b)(1), and clauses therein presently numbered (1) through (6), as clause (A) through (F). Substantively, the changes proposed by section 103 of the bill require an applicant filing a Paper NDA for a listed drug under subsection (j)(6) of the bill, relating to drugs that may be considered for generic treatment, to make the same certifications regarding patents as apply

to the filing of an ANDA under subsection (j) of this bill. The FDA is required to make approval of Paper NDAs under the same conditions that apply to ANDAs submitted under proposed subsection (j). Finally, section 103 would apply the 10 year transition rule and the 4 year unpatentable substances rule to Paper NDAs.

Paper NDAs are defined as any application submitted under section 505(b) of the Act, 21 U.S.C. 355(b), in which the investigations relied upon by the applicant to show safety and effectiveness were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person who conducted the investigations or for whom the investigations were conducted. Proposed paragraph (2).

Under subparagraph (2)(A), a Paper NDA which is submitted for a listed drug under subsection (j)(6) would have to include a certification by the applicant regarding the status of certain patents applicable to the listed drug if such information has been provided to the FDA. With respect to all product patents which claim the listed drug and all use patents which claim an indication for the drug for which the applicant is seeking approval (i.e., controlling use patent), the applicant must certify, as to one of four circumstances.

First, the applicant may certify that the patent information required under section 505 (b) and (c) of the Act, 21 U.S.C. 355 (b) and (c), as amended by this bill, has not been submitted if that is the case. Second, if appropriate, the applicant may certify that one or more of the product or controlling use patents provided have expired. Third, the applicant may certify when appropriate that one or more of the product or controlling use patents will expire at some specified future date. Finally, an applicant may certify on the basis of non FDA—supplied information that one or more of the product or controlling use patents are invalid or will not be infringed. Proposed subparagraph (2)(A)(i)–(iv).

When applicable, a Paper NDA for a listed drug must also state that the applicant is not seeking approval for an indication which is claimed by any use patent for which it has not made a certification. Proposed subparagraph (2)(B).

If an applicant certifies that any product or controlling use patent is invalid or will not be infringed, paragraph (3)(A) requires that it must give notice of such certification to either the owner of the patent or the representative of the patent owner who was designated under section 505 (b) or (c) of the Act, 21 U.S.C. 355 (b) or (c), as amended by this bill.

Paragraph (3)(B) requires that such notice state that a Paper NDA has been submitted to obtain approval of the drug to engage in the commercial manufacture, use or sale of the generic drug before the expiration of the patent which has been certified as invalid or not infringed.

Paragraph (3)(C) provides that if a Paper NDA is amended after submission to include a certification that a product patent or controlling use patent is invalid, notice of such certification must be given to the appropriate parties at the time the amended application is submitted.

Section 103(b) of the bill deals with the effectiveness of approval of a Paper NDA for a listed drug. Accordingly, section 505(c) of the Act, 21 U.S.C. 355(c), as amended by section 102(a)(2) of the bill, is

further amended to require the FDA to make approval effective as appropriate in light of relevant, patent-related circumstances.

If the applicant certified in the Paper NDA that no patent information was supplied or that the relevant patents have expired, approval of the Paper NDA may be made immediately effective. If the applicant certified on the basis of supplied information that the patent would expire on a specified future data, the Paper NDA may be approved and the approval becomes effective on that date.

Generally, if the applicant certifies that one or more of the product or controlling use patents were invalid or not infringed, approval of the Paper NDA becomes immediately effective. However, if within 45 days after receipt of notice of the certification of invalidity or non-infringement, an action for patent infringement regarding one or more of the patents subject to the certification is brought, approval of the Paper NDA may not be made effective until 18 months after the notice of certification was provided or a court decision issued. If the court finds the patent is valid or not infringed, then approval shall be effective on the date of the court's order. If the court decides the patent has been infringed an order under 35 U.S.C. 271(e) shall issue. Each party to the action has an affirmative duty to reasonably cooperate in expediting the action and the court may shorten or extend the 18-month period, as appropriate, when either party breaches that duty.

No action for a declaratory judgment with respect to the patent may be brought before the expiration of the 45 day period which begins with the giving of notice of the certification of patent invalidity or non-infringement. At the end of the 45 days, a suit for declaratory judgment regarding the patent in question may be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

Subparagraph (D) denies the FDA the authority to make effective the approval of a Paper NDA for a drug which contains an active ingredient (including any ester or salt of the active ingredient) that was approved for the first time in an NDA between January 1, 1982 and the date of enactment of this bill until 10 years after the date of approval of the NDA.

Section 104 of the bill adds a new subsection (1) to section 505 of the Act, 21 U.S.C. 355, which makes hitherto undisclosed safety and effectiveness information that has been submitted in an NDA available to the public upon request. Absent extraordinary circumstances, safety and effectiveness information and data shall be disclosed in the following circumstances: (1) if the NDA is abandoned; (2) if the FDA has determined that the NDA is not approvable and all legal appeals have been exhausted, (3) if approval of the NDA under section 505(c) of the Act, 21 U.S.C.A. § 355(c), has been withdrawn and all legal appeals have been exhausted, (4) if the FDA has determined that the drug is not a new drug, or (5) upon the effective date of approval of the first ANDA which refers to the drug or upon the date which an ANDA could have been approved if an application had been submitted.

Section 104 of the bill adds a new subsection (m) to section 505 of the Act, 21 U.S.C. § 355, to define the term "patent" to mean a patent issued by the Patent and Trademark Office of the Department of Commerce.

Section 105(a) of the bill requires the FDA to promulgate rules to implement new subsection (j). These rules, which shall be issued within one year of enactment of this bill, shall be promulgated in accordance with the informal rulemaking requirements of the APA, 5 U.S.C. 553.

Section 105(b) of the bill establishes an interim procedure for approving ANDAs for post-1962 drugs until the final regulations become effective. During the year following enactment of this bill, ANDAs for listed post-1962 drugs may be submitted in accordance with the current regulations applicable to pre-1962 pioneer drugs: 21 C.F.R. 314.2. In the event of inconsistencies between current regulations and the Act as amended by this bill, FDA shall follow the latter. However, the FDA may not approve an ANDA or Paper NDA under this interim procedure for a drug which is described in section 505(c)(3)(D) or section 505(j)(4)(D) of the Federal Food, Drug and Cosmetic Act.

Section 106 of the bill amends 28 U.S.C. 2201 to insert a cross reference indicating that certain declaratory judgment actions involving patents controversies cannot be brought except as authorized by this bill.

Title II—Patent Extension

Section 201 of the bill adds a new section 156 to title 35, to extend the normal 17 year term of a product, use, or process patent in the case of a patented product which is subject to pre-marketing clearance (as defined in this Act).

Under proposed section 156(a) the term of a patent which claims a product, a method of using a product, or a method of manufacturing a product is extended from its original expiration date if certain, specified conditions are met. The conditions that permit an extension of patent life are set forth in eight numbered paragraphs.

Paragraph (1) requires the patent to be in force at the time an application for extension is submitted to the Commissioner of Patents and Trademarks.

Paragraph (2) allows extension only if the term of the patent has never been extended. Thus, the extension authorized by the bill is a one time extension.

Paragraph (3) requires the application for extension to be submitted by the owner of record of the patent, or its agent, in accordance with the requirements of subsection (d), infra.

Paragraph (4), which consists of two subparagraphs, applies to product and use patents, not process patents. Subparagraph (A) permits a product or use patent to be extended if two requirements are met. First, the approved product has to be one that has not been claimed in another product patent which was issued earlier or which was previously extended. Second, the approved product and the use approved for the product may not have been identically disclosed or described in another product patent which was issued earlier or which was previously extended.

Subparagraph (B) permits a product patent to be extended notwithstanding that it would not qualify under subparagraph (A) under certain circumstances. In order to be extended in these cir-

cumstances, the holder of either of the two product patents must never have been and must never become the holder (i.e., patent owner or an exclusive licensee of the owner) of the other patent.

Paragraph (5) describes conditions applicable only to manufacturing method or process patents. Subparagraph (A) permits a process patent which does not primarily use recombinant DNA in the manufacture of the approved product to be extended if two conditions are met. First, no other patent has been issued which claims the product or a method of using the product and claims a method of using the approved product for any known therapeutic purpose. Second, no other method of manufacturing the product which does not use recombinant DNA technology in the manufacture of the product may be claimed in an earlier process patent.

Subparagraph (B) permits a process patent which primarily utilizes recombinant DNA in the manufacture of the approved product to be extended if several conditions are met. First, the holder of the process patent (I) is not the holder of the product or use patent; (II) is not owned or controlled by a holder of a product or use patent or by a person who owns or controls such a holder, and (III) does not own or control the holder of such a patent or a person who owns or controls a holder of such a patent. Second, no other method of manufacturing the product primarily using recombinant DNA technology is claimed in an earlier process patent.

Paragraph (6) authorizes an extension if the product which is claimed in the product patent has been subject to a regulatory review period before its commercial marketing or use.

Paragraph (7)(A) generally permits an extension if the approval after regulatory review is the first approval for commercial marketing or use of that product under an applicable Federal law.

Paragraph (7)(B) authorizes an exception to the first time requirement of paragraph (7)(A) in the case of an approved product made under a patented process which primarily uses recombinant DNA technology. An approved product of this kind can receive its second approval for commercial marketing or use provided that it is the first time a product made by the claimed process has been approved.

Paragraph (8) provides that in the case where two different approved products are the subject of the same patent, an extension will be granted only for the first approved product which has been the subject of a regulatory review period.

The balance of proposed section 156(a) defines as "approved product" when used elsewhere in the bill the product referred to in paragraphs (4), (5), (6) and (7), supra. Also, it defines the holder of a patent for purposes of paragraphs (4)(B) and (5)(B) as being any person who is the owner of record of the patent or who is the exclusive licensee of the owner of record of the patent.

Proposed section 156(b) extends all the rights of patent law to the patent during the period of extension subject to the following limitations:

> (1) When a product patent claiming the approved product is extended, the holder's rights are limited to any use of the approved product which was approved before the expiration of the extended term of the patent under the provision of law under which the applicable regulatory review period occurred.

(2) When a use patent claiming a method of using the approved product is extended, the holder's rights are limited to any use of the product which is claimed in the use patent and which was approved before the expiration of the extended term of the patent under the provision of law which the applicable regulatory review period occurred.

(3) When a process patent claiming a method of manufacturing the approved product is extended, the holder's rights are limited to the method of manufacturing which is claimed in the process patent and which is used to make the approved product.

Proposed section 156(c) prescribes the manner by which the length of the period of extension is determined. Generally, the length of the extension will coincide with the length of the regulatory review period in which the approved product was approved. The latter, however, shall be reduced for several reasons. First, each phase of the regulatory review period is reduced by any time that the applicant for extension did not act with due diligence during that phase. See (d)(2)(B), infra. Second, after any such reduction, only one-half of the time remaining in the testing phase shall be added to the time remaining in the approval phase to comprise the total period eligible for extension, except that total patent term may not exceed 14 years.[16]

Proposed section 156(d) sets forth procedures for applying for an extension. To obtain an extension, subsection (d)(1) requires the patent owner or its agent submit an application to the Commissioner of Patents and Trademarks within 60 days of approval of the approved product. The application shall contain the following information:

(A) the identity of the approved product;

(B) the identity of the patent to be extended and identification of each claim of that patent which claims the approved product or a use or process of the approved product;

(C) the identity of every patent known to the owner that claims or identically discloses the approved product or a use or process of the approved product;

(D) the identity of all other products approved under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and which are associated with claims disclosed in subparagraph (C), supra;

(E) information that would enable the Commissioner to determine the eligibility of a patent for extension and the rights that will derive from the extension as well as information to the FDA to determine the period of extension;

(F) a brief description of the activities undertaken by the applicant during the regulatory review period with respect to the approved product and when; and

(G) any other information the Commissioner may require.

Subsection (d)(2)(A) provides that within 60 days of the submission of an application, the Commissioner notify the Secretary of

[16] Section 156(g)(4), infra, adds further limitations on the period of extension depending on whether the approved product was developed before or after the date of enactment of this bill.

HHS (relating to drug products, devices and food additives which are subject to the Federal Food, Drug, and Cosmetic Act) to review the dates contained in the application for the regulatory review period. Within 30 days, the Secretary shall make a determination as to those dates, notify the Commissioner, and publish them in the Federal Register.

Subsection (d)(2)(B) authorizes any interested person to petition the Secretary for a determination regarding whether the applicant for an extension acted with due diligence during the regulatory review period of the appproved drug. The petition must be submitted within 180 days of the publication by the Secretary of a determination of the regulatory review period and must state that the applicant did not act with due diligence (defined in subsection (d)(3)), infra, during some part of the regulatory review period. The Secretary has 90 days to make a decision on the matter raised by the petition. The Secretary of HHS cannot delegate the authority to decide the merits of the petition to any office below that of the Commissioner of the FDA.

After making the determination, the Secretary shall notify the Commissioner of Patents and Trademarks and publish the decision in the Federal Register. Any interested person may request an informal hearing within 60 days of publication of the determination. If a timely request is made, the Secretary must hold a hearing within 30 days, give notice of the hearing to the patent owner and any interested person, and provide them with an opportunity to participate. Within 30 days of the hearing, the Secretary must affirm or revise the determination, notify the Commissioner of Patents and Trademarks, and publish it in the Federal Register.

"Due diligence" is defined to mean "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."

The applicant for an extension is subject to any disclosure requirements prescribed by the Commissioner of Patents and Trademarks.

Proposed section 156(e) provides that the Commissioner's determination that a patent is eligible for extension is to be made *solely* on the basis of information contained in the application. If it is determined that the patent is eligible for an extension, the Commissioner shall issue a certificate of extension, under seal, for the period determined, in accordance with procedures authorized by subsection (c). The certificate shall be recorded in official patent files and becomes a part of the original patent.

In the event that the original term of the patent for which extension is sought will expire before a final decision by the Commissioner on that extension, the Commissioner may issue an interim extension certificate for a period of up to one year.

Proposed section 156(f) contains the definitions of various terms for purposes of that section.

The term "product" is defined in subsection (f)(1) to include a drug product and any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

The term "human drug product" is defined in subsection (f)(2) to mean the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

The term "major health or environmental effects tests" is defined in subsection (f)(3) to mean a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of tests results are not to be included in determining if the conduct of a test required at least six months.

Subsection (f)(4)(A) states that any reference to section 351 means section 351 of the Public Health Service Act, 42 U.S.C.A. 262, relating to the regulation of biological products.

Subsection (f)(4)(B) states that any reference to section 503, 505, 507, or 515 is a reference to section 503, 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. sections 353 (relating to exemptions of drugs and devices from labeling requirements when processed, labeled, or repacked by other than the original processor), 355 (introductory or premarketing clearance procedure), 357 (relating to the certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenical, bacitracin or any other antibiotic drug), 360b (relating to new animal drugs, and 360e (relating to premarketing approval of a class III device).

The term "informal hearing" is defined in subsection (f)(5) to have the same meaning as prescribed for such term by section 201(g) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 (cf. APA, 5 U.S.C. 554, 556, 557).

The term "patent" is defined in subsection (f)(5) to mean a patent issued by the United States Patent and Trademark Office.

Proposed section 156(g) provides various definitions of the term "regulatory review period". Although it differs for each product that can be the subject of patent extension, the regulatory review period consists of a testing phase and an agency approval phase. As respects drug products, food and color additives, and medical devices, the term "initially submitted" is used to describe the date when the testing phase is completed and the agency approval phase begins.

Under section 156(g)(1) the regulatory review period for drug products is the sum of the periods: (1) beginning when an exemption under 505(i) or 507(d) was granted and ending when the initial submission of an application for approval under section 351 of the Public Health Service Act, 505, 507, of the Federal Food, Drug, and Cosmetic Act; and (2) beginning when an application for approval was initially submitted under the mentioned laws and ending when the application was approved.

Under section 156(g)(2) the regulatory review period for food and color additives is the sum of the periods: (1) beginning when a major health or environmental effects tests for a food or color additive was initiated and ending when a petition requesting the issuance of a regulation for use of the additive was initially submitted;

and (2) beginning when a petition for the issuance of a regulation was initially submitted and ending when the regulation became effective.

However, if permission for commercial marketing was delayed because objections were filed to the regulation, or if such permission was initially granted and later revoked before actual marketing began because objections were filed to the regulation, the period described above would end when the objections were resolved and commercial marketing was permitted.

Under section 156(g)(3) the regulatory review period for medical devices is the sum of the periods: (1) beginning when human clinical investigations were commenced and ending when an application for approval was initially submitted; and (2) beginning when an application for approval was initially submitted and ending when the application was approved, or beginning when a notice of completion of a product development protocol was initially submitted and ending when the protocol was declared completed.

Section 156(g)(4), provides different maximum periods depending on whether the approved product was developed before or after the date of enactment of this bill.

Under (g)(4),[17] the total period of regulatory review which can be counted towards extension shall not exceed five years when: (1) the patent to be extended was issued after the date of enactment of this bill; or (2) the patent was issued before the date of enactment of this bill, but the approved product's regulatory review period had not begun on the date of enactment of this bill. The total period of eligible regulatory review would not exceed two years when: (1) the patent to be extended was issued before the date of enactment; and (2) the approved product's regulatory review period had begun before the date of enactment but the product had not been approved by that date.

Proposed section 156(h) authorizes the Commissioner of Patents and Trademarks to establish such fees as he or she determines appropriate to cover the costs to his or her office of receiving and acting upon application for patent extensions.

Section 201(b) of the bill amends the analysis of chapter 14 of 35 U.S.C. to add a reference to section 156 "Extension of patent time" authorized by section 201(a) of the bill.

Section 202 of the bill amends 35 U.S.C. 271 relating to patent infringement, to add a new subsection (e).

Proposed subsection (e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs.

Proposed subsection (e)(2) provides that it shall be an act of patent infringement to submit an ANDA for a drug (1) which is claimed in a valid product patent, or (2) a use of which is claimed in a valid use patent, if the purpose of submitting the ANDA is to get its approval with an effective date prior to the expiration of such patent.

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[17] Additional restrictions are found in proposed section 156(c)(2).

In an infringement action pursuant to section 271, of the law, no injunctive or other relief may be granted to prohibit the activity which is authorized by subsection (e)(1).

Proposed subsection (e)(4) makes certain remedies available and exclusive in the event a patent is valid and has been infringed pursuant to subsection (e)(2). The court must order the effective date of any ANDA relating to a drug involved in the infringement to be a date not earlier than the expiration date of the infringed patent. Injunctive relief may be granted to prevent commercial marketing under an approved ANDA and monetary damages or monetary relief are authorized when commercial marketing has begun.

CONSTITUTIONALITY OF SECTION 202

The provisions of section 202 of the bill have the net effect of reversing the holding of the court in *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*, — F.2d, — No. 84-560, slip op. (Fed. Cir. April 23, 1984). Opponents of the bill have suggested that section 202 raises serious constitutional issues. The Committee has examined those issues and concluded that the provisions in the bill are sound and constitutional.[18]

[18] This view is consistent with the opinion of the Library of Congress, American Law Division:

CONGRESSIONAL RESEARCH SERVICE, THE LIBRARY OF CONGRESS, WASHINGTON, DC, JULY 24, 1984

To: House Judiciary Committee, Subcommittee on Committee on Courts, Civil Liberties, and the Administration of Justice (Attn: David Beier).

From: American Law Division.

Subject: Constitutional Objections to Section of Patent Term Restoration Bill to Define Use.

This memorandum responds to your request to review and assess the constitutional objections raised to § 202, of H.R. 3605, the patent term restoration bill. Because of time constraints, this memorandum is necessarily brief.

In § 202, Congress would provide that it is not an infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information for the purpose of obtaining FDA premarketing approval of a drug. The purpose of the provision is to overturn the ruling in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F. 2d 858 (C.A.F.C. 1984). That case held that Bolar infringed a patent owned by Roche when, during the patent term, Bolar used the patented substance to prepare a submission to FDA for the purpose of enabling Bolar to market the drug after the patent expired. Crucial to the decision was the court's interpretation of the word "uses" in 35 U.S.C. § 271(a), which makes it an infringement for anyone who without authority "makes, uses or sells any patented invention". Congress has never defined "uses", the court in *Roche* acknowledged; it has gained meaning through judicial elucidation, but the courts have never applied the word to bar every use. *Id.*, 861. And, insofar as it appears from the opinion, the court's ruling is the first case to determine whether Roche's use was a proscribed use within the meaning of § 271(a). In fact, the district court decision overturned by the appeals court was that no infringement had occurred.

It has been objected before the Subcommittee that, in its application to existing patents, § 202 would constitute a "taking" under the Fifth Amendment which would mandate "just compensation" to the patent holder. Of course, it is clear that a patent is property and thus if it were taken for a public use compensation would have to be paid. See, e.g., *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 & n. 11 (1945). But the threshold question is whether there is a "taking" or whether there is a permissible regulation. Indeed, the Court has never clearly established the standards for applying a "taking" analysis or a due process analysis to regulation that necessarily diminishes the value of property held by someone. Thus, the first question that must be asked is whether § 202 should be analyzed in the context whether it constitutes a "taking" or whether it should be evaluated as a regulation of property, and it is not at all clear that the "taking" analysis chosen by the Subcommittee witnesses is the correct one.

Difficulty in distinction has arisen because the Court has not drawn the line where it could easily be applied. That is, a taking might be deemed to occur only when the government has physically appropriated one's property and transferred it elsewhere. See, e.g., *Hawaii Housing Auth. v. Midkiff*, 104 S. Ct. 2321 (1984). Due process analysis could then be applied to any police power regulation that diminished the value of property. See, e.g., *PBGC v. R. A. Gray & Co.*, 83-245 (June 18, 1984). However, at least since *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922), it has been a maxim "that while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking." Having permitted the blurring thus of the line, the Court has not enunciated clear standards by which we may discern when one or the other analysis applies. See, e.g., *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 120-122 (1978); *Pruneyard Shopping Center v. Robins*, 447 U.S. 74, 82-84 (1980).

Our reason for suggesting that, perhaps, a due process analysis is the more appropriate one springs from a look at what it is § 202 does. The basis of the section apears to be a conclusion that *Roche* was wrongly decided, that Congress did not intend the word "uses" in § 271(a) to extend so broadly. Congress has previously legislated to change what it perceived to be incorrect judicial decisions and in so doing has adversely affected property rights of the prevailing side in those cases. For example, in the "portal to portal" cases, the Supreme Court held that "work week," which Congress had not defined, in the FLSA included a vast amount of preliminary and incidental activities of employees in connection with their work, exposing employers to considerable unexpected expense. *Tennessee Coal Co. v. Muscoda Local,* 321 U.S. 590 (1944); *Jewell Ridge Corp. V. Local No. 6167,* 325 U.S. 161 (1945); *Anderson v. Mt. Clemens Pottery Co.,* 328 U.S. 680 (1946). Congress thereupon passed a law changing the rulings and wiping out the substantive liabilities owed by employers under the decisions. The lower courts uniformly ruled against challenges that the act's retroactive operation destroyed vested rights in violation of the due process clause. E.g., *Battaglia v. General Motors Corp.,* 169 F. 2d 254 (C.A. 2), *cert. den.,* 335 U.S. 887 (1948); *Thomas v. Carnegie-Illinois Steel Corp.,* 174 f. 2d 711 (C.A. 3, 1949). While the Supreme Court itself never reviewed the act on the merits, it did, on timely motion, after it had denied *certiorari* to a case applying its earlier rulings, revoked its denial of *certiorari* and remanded to permit consideration by the district court of the new act, which had the effect of nullifying the prior judgment.

149 Madison Avenue Corp. v. Asselta, 331 U.S. 795 (1947). On subsequent reconsideration, see 79 F. Supp. 413, 90 F. Supp. 442 (S.D.N.Y., 1948, 1950).

Just recently, the Supreme Court has affirmed, not in the context of legislative revision of a judicial ruling, that, if "the retroactive application of a statute is supported by a legitimate legislative purpose furthered by rational means," it passes the due process test. *PBGC v. R. A. Gray & Co., supra.* In that case, the Court sustained an ERISA provision imposing liabilities for employer withdrawals from a multiemployer pension plan which was made retroactive to April 29, 1980, although the law was not enacted until September 26, 1980. The employer withdrawal from the plan on June 1, 1980, permissible when it was accomplished, thus became impermissible because of the retroactivity of the provision. See also *Usery v. Turner-Elkhorn Mining Co.,* 428 U.S. 1 (1976) (sustaining imposition upon employers of cost of industrial illnesses contracted while in employer's workforce prior to enactment of act as a permissible means of allocating costs); *United States v. Darusmont,* 449 U.S. 292 (1981) (upholding retroactive tax).

Thus, whether Congress views § 202 as a correction of a judicial misreading of a prior law or as a rational means of pursuing the public good through regulation of existing property rights, there is considerable judicial precedent to sustain the provision under the due process clause as an exercise of the police power.

On the other hand, similarly there is precedent to sustain the validity of an enacted § 202 under a " taking" challenge. The section in reality would modify an advantage that derives not from the patent law in and of itself but from the operation of law respecting FDA approval of drugs before they can be marketed. If one must wait until expiration of the patent to use the patented item to develop the necessary tests results for submission to FDA for its approval, the lapse of time between testing through submission to approval to marketing is likely to be a period of years, all of which time the original patent holder enjoys the benefit of his patent past its expiration date.

Much reliance was placed during the hearing on *Ruckelshaus v. Monsanto Co.,* 83–196 (June 26, 1984), as establishing the validity of the taking challenge. The reverse appears to be the case. *Monsanto* involves, in its relevant aspect here, disclosure provisions of FIFRA under which companies were required to submit data, including trade secrets, to obtain regulatory approval for marketing and under which data, including trade secrets, could be disclosed. During the period for which the Court held a taking could occur through disclosure, federal law specifically prohibited disclosure. Trade secrets, the Court held, were property under state law. That being so, the Court was concerned with whether a taking had occurred through disclosure. It admitted that regulation resulting in economic injuries could be deemed a taking only through an "ad hoc, factual" inquiry, under which the Court was to consider such factors as "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations." The latter factor was determinative to the Court. For the period when legislation guaranteed against disclosure, the firm had a justifiable expectation that its submissions would not be disclosed; its investment-backed expectations were, in other words, objectively sound. For the other periods, when legislation was either silent or ambiguous or when it specificially permitted disclosure, the firm could not have relied on any expectation of secrecy and when it submitted the data it gave up its expectancy.

With respect to § 202, we have much the same situation that existed in FIFRA prior to 1972. There, the law itself was silent but it was arguable that the Trade Secrets Act, 18 U.S.C. § 1905, afforded the firm protection. Only in *Monsanto* itself, 12 years after the last year in which the Trade Secrets Act could have been the basis of reliance, did the Court hold that Act inapplicable. If Monsanto did rely on it, the firm was mistaken; its expectancy was unjustified. Here, we have a judicial interpretation of a word in the patent laws which was unsettled previously and which because of the possibility of Supreme Court review or congressional alteration remains unsettled.

The difference in the degree to which investment-backed expectations were justifiable in *Monsanto* and appear to be less justifiable as respects § 202 seems to be significant and lessens the reliance of witnesses on *Monsanto.*

With regard to the other two factors mentioned in *Monsanto,* they too seem to suggest in their applicability the defensibility of § 202. The second factor was "economic impact" of the governmental action. Without reviewing extensively the cases in which a taking challenge was denied despite a substantial economic loss to the regulated entity, it can be said that generally the Court holds that if the regulated entity still has a profitable use for his property, even if not the

best use, the most profitable use, no taking will be found. Thus, in *Andrus v. Allard*, 444 U.S. 51 (1979), the Court observed that while the owners could not sell the articles they could display them and make some profit. Loss of future profits was not viewed as a serious threat of harm. Similarly, in the *Penn Central case, supra*, while the owners were deprived of the most profitable use, the property was still economically viable.

Here, § 202 does not in the least touch upon the economic worth of the patents during the terms of the patents. They retain all the value the holders had in them. What the provision does is remove or reduce the economic value inhering in the period after expiration when other companies are starting up and processing their goods.

The third factor is the character of the governmental action. That character in this instance appears to be a pure police power kind of regulation which the government pursues in numerous instances to improve and protect the public health and safety, i.e., the promotion of increased numbers of medicines and drugs on the market to the benefit of health and price competition. The character, thus, is like the regulation approved in *Penn Central, supra*, and unlike the action disapproved in *Kaiser Aetna v. United States*, 444 U.S. 164 (1979).

In conclusion, while the constitutionality of § 202 is far from a settled question, it does appear that respectable precedent exists by which to sustain it under the Fifth Amendment challenge, whether as a taking or a denial of due process.

JOHNNY H. KILLIAN, *Senior Specialist, American Constitutional Law.*

It is alleged by some witnesses that the provisions of the bill which permit the limited testing of drugs while they are on patent in order to assist in the preparation of an abbreviated new drug application is a "taking" without just compensation in violation of the requirements of the Fifth Amendment. As the Supreme Court itself has said regarding determinations of whether legislation or other acts of government constitute a taking:

> this Court, quite simply, has been unable to develop any "set formula" for determining when "justice and fairness" require that economic injuries caused by public action be compensated by the government. *Penn. Central Transp. Corp.* v. *New York City*, 438 U.S. 104, 124 (1978) (hereinafter *Grand Central*).

The Court has identified several factors for consideration in such cases: the economic impact of the action and the character of the government action. *Grand Central, supra*, at 124. Particularly important in this assessment is whether the interference with the property right arises from a "public program adjusting the benefits and burdens of economic life to promote the public good". *Grand Central, supra.*

In this case the benefits to the government and the general citizenry will be substantial. As a result of section 202 generic drugs will be able to be placed on the market between 18 months and 2 years earlier than without this provision. The availability of such generic substitutes will assist in the reduction of health care costs. In view of the high percentage of individual income devoted to medical costs, these reductions will be especially important to the poor, the under-insured, and the elderly. The government itself, as purchaser of prescription drugs, will also save money as a result of this amendment.

On the other hand, the competing claim of the pioneer drug companies holding the patents on these drugs seems much less tangible. As the Court of Appeals for the Federal Circuit itself said in *Roche*, the Congress has never had occasion to define the term "use". Thus, the Congress has never had occasion to evaluate the competing policy considerations presented by this bill. In addition, until the *Roche* case itself there never was an appellate case dealing with this question. Therefore, it is not altogether clear that the

"distinct investment backed expectations" of pioneer drug company patent holders are all that settled.

Assuming for the sake of argument that such "expectations" are settled, the Supreme Court has also suggested that Congress examine the nature of the governmental interference.[19] Just this term the Court said "legislation readjusting rights and burdens is not unlawful solely because it upsets otherwise settled "expectations". *Pension Benefit Guaranty Corp.* v. *R. A. Gray & Co.*, 52 U.S.L.W. 4810 (June 18, 1984).

In this case the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is *de minimus.* To hold otherwise would be to protect the pioneer drug company from competition for a period of up to 2 years after the patent has expired.

The nature of the interference with patent rights created by this bill is necessitated by the very nature of the industry involved. For example, in the automobile industry there would be no need to permit testing of a patented auto engine before a patent expires because—unlike the FDA in the drug area—there is no government regulatory agency in place which would delay marketing of that new product and prevent competition once the patent has expired.

In this case the Committee has merely done what the Congress has traditionally done in the area of intellectual property law; balance the need to stimulate innovation against the goal of furthering the public interest.[20] Just as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. That is all this bill does.

Section 203 of the bill amends 35 U.S.C. 282, relating to the presumption of validity and available defenses in a patent infringement suit, to add a new defense. An improper grant of patent extension, or any portion thereof, because of a material failure by the applicant or by the Commissioner of Patents and Trademarks to comply with the requirements of proposed section 156, is a defense in any action involving the infringement of the patent during the period of patent extension. However, a due diligence determination made under proposed section 156(d)(2) is not subject to review in a patent infringement action.

The bill reported by the Committee on Energy and Commerce amends the purpose line of this bill to include a reference to title II, i.e., patents, as well as title I, drugs, to wit: "A bill to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications and to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes."

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[19] The situation presented in H.R. 3605 does not result in the total extinguishment of the patent owner rights, because the patent owner still maintains a right to exclude others from the commercial marketplace. Thus, the bill creates a situation similar to the statute upheld in *Andrus* v. *Allard*, 444 U.S. 51, 65–66 (1979), and unlike that questioned in *Ruckelshaus* v. *Monsanto Corp.*, 83–196 (U.S. Sup. Ct. June 26, 1984).

[20] It is important to note that most patent holders affected by section 202 will also receive a benefit from the bill in the form of patent term extension. This type of exchange of property interests was upheld by the court in the *Grand Central* case, albeit in a different context.

OVERSIGHT FINDINGS

The Committee makes no oversight findings with respect to this legislation.

In regard to clause 2(l)(3) (D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

NEW BUDGET AUTHORITY

In regard to clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, H.R. 3605 creates no new budget authority or increased tax expenditures for the Federal Government.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the bill will have no foreseeable inflationary impact on prices or costs in the operation of the national economy.

FEDERAL ADVISORY COMMITTEE ACT OF 1972

The Committee finds that this legislation does not create any new advisory committees within the meaning of the Federal Advisory Committee Act of 1972.

COST ESTIMATE

In regard to clause 7 of rule XIII of the Rules of the House of Representatives, the Committee agrees with the cost estimate of the Congressional Budget Office and estimates that the additional cost to the government which will be incurred as a result of enactment of this bill is set forth in the CBO cost estimate.

STATEMENT OF THE CONGRESSIONAL BUDGET OFFICE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, and section 403 of the Congressional Budget Act of 1974, the following is the cost estimate on H.R. 3605 prepared by the Congressional Budget Office.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC.

Hon. PETER W. RODINO, Jr.,
Chairman, Committee on the Judiciary, U.S. House of Representatives, Rayburn House Office Building, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984, as ordered reported by the House Committee on the Judiciary on July 31, 1984.

We estimate that enactment of this bill could result in increased personnel costs to the federal government of approximately $2.2 million annually. The bill, however, does not specifically authorize additional appropriations for the Food and Drug Administration (FDA) or the United States Patent and Trademark Office (PTO).

This bill may also result in savings if cheaper, generic drugs are made available for purchase by the federal government. These savings would occur in various programs throughout the budget such as Medicare, Medicaid, and the Veterans Administration. However, the magnitude of these savings is unknown.

TITLE I

Title I of this bill would allow drug manufacturers to use an abbreviated new drug application (ANDA) when seeking approval to make generic copies of drugs that were approved by the FDA after 1962. An estimated 150 drug products approved after 1962 are currently off patent and would become available for generic copy using the ANDA procedure proposed in this bill.

The FDA estimates that the enactment of H.R. 3605 would at least triple the workload of the division responsible for approving ANDAs. Currently, this division reviews ANDAs for generic copies of pre-1962 approved drug products. The workload would increase as several manufacturers file an ANDA for each drug product that becomes available for generic copy. Because they would be reviewing information on new drugs, the FDA believes it would take them a year to process each of the new applications. This is about three months longer on average than it currently takes to process a pre-1962 ANDA. FDA expects an increased workload in other areas as well from carrying out the activities described in the bill. We estimate that implementing Title I could cost the FDA about $1.5 million. The actual cost to the federal government would depend on the extent to which FDA would expand to accommodate the increased workload.

Enactment of this legislation could also result in savings to the federal government. In fiscal year 1983, the federal government spent approximately $2.4 billion for drugs in the Medicaid program, and in veteran and military hospitals. Data on drug costs in the Medicare program are unavailable. If the federal government is currently purchasing these 150 copiable drug products at higher, brand name prices, savings may result if lower priced, generic copies of these drugs are substituted.

It is difficult to know in advance which if the available 150 drug products manufacturers would choose to copy. It is also difficult to estimate the price at which these generic copies would be sold. Generic versions of ten popular drug products show their price to be on average 50 percent less than their brand name equivalent. The dollar amount the federal government currently spends on these 150 brand name drug products is unknown.

TITLE II

Title II of this bill would extend the amount of time for which certain patents are issued to include some or all of the time required for a manufacturer to test a product for safety and efficacy and to receive marketing approval. Products affected by this legislation would be drugs, medical devices, and food and color additives.

The activities described in Title II of this bill would be performed by both the FDA and the PTO. FDA would be responsible for deter-

mining the applicable regulatory review period for a product used in setting the length of the patent extension. FDA would also monitor diligence in product testing which must be shown in order for a manufacturer to receive the maximum possible patent extension. FDA estimates it would cost them $0.7 million to implement these provisions. PTO would be responsible for handling patent extension applications and for determining extension eligibility. The bill states that the PTO Commissioner may charge manufacturers a fee to cover the cost of receiving and acting upon applications. Additional costs to PTO would be less than $500 thousand.

STATE AND LOCAL GOVERNMET IMPACT

Enactment of this bill would not directly affect the budgets of state or local governments. To the extent that these governments purchase drugs, they may realize savings if cheaper, generic drugs are made available by this bill. The magnitude of these potential savings is unknown.

PREVIOUS CBO ESTIMATE

On June 19, 1984, CBO prepared a cost estimate for H.R. 3605 as ordered reported by the House Committee on Energy and Commerce. In terms of the cost to the federal government, the two versions of the bill are the same except that Title II of the Energy and Commerce bill also applied to animal drugs and veterinary biological products. In the previous estimate, however, we showed potential increased personnel costs to the federal government of $1.1 million. FDA has since more carefully studied the possible affects of this bill on their agency. Given this new information, we believe that personnel costs could increase by $2.2 million as a result of enactment of this legislation.

Please call if I can be of additional assistance or members of your staff may wish to contact Carmela Pena (226–2820) of our Budget Analysis Division for further details on this estimate.

Sincerely,

RUDOLPH G. PENNER, *Director.*

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted by the Committee on Energy and Commerce is enclosed in black brackets, new matter proposed to be inserted by the Committee on Energy and Commerce is printed in italic, matter proposed to be omitted by the Committee on the Judiciary is printed in linetype, new matter proposed to be inserted by the Committee on the Judiciary is printed in boldface roman, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) *or (j)* is effective with respect to such drug.

(b)*(1)* Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application [(1)]*(A)* full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; [(2)]*(B)* a full list of the articles used as components of such drug; [(3)]*(C)* a full statement of the composition of such drug; [(4)]*(D)* a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; [(5)]*(E)* such samples of such drug and of the articles used as components thereof as the Secretary may require; and [(6)]*(F)* specimens of the labeling proposed to be used for such drug. *The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.*

(2) An application submitted under paragraph (1) for a drug listed under subsection (j)(6) for which investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant or for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant has given the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application, which includes data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.

(c)(*1*) Within one hundred and eighty days after the filing of an application under [this] subsection (*b*), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

[(1)](*A*) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

[(2)](*B*) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of

using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when the application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the eighteen-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision, or

(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five day period beginning on the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(D)~~(i)~~ If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

~~*(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using for any known therapeutic purposes such drug, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of four years from the date of the approval of the application previously approved under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.*~~

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect

to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or *(6) the application failed to contain the patent information prescribed by subsection (b); or* [6] *(7)* based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or *(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or* [(4)] *(5)* that the application contains any untrue statement of a material fact: *Provided,* That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application *submitted under subsection (b) or (j)* with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has re-

peatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection [(j)]*(k)* or to comply with the notice requirements of section 510[(j)]*(k)*(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug,

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or

strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant has given the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commerical manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice

shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients of the drug or of the route of administration, the dosage form, or strength which differ from the listed drug.

(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the eighteen month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision, or

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of the forty-five-day period beginning on the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection containing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application

is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(D)~~(i)~~ If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

~~*(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection and if the holder of the approved application certifies to the Secretary that no patent has ever been issued to any person for such drug or for a method of using such drug and that the holder cannot receive a patent for such drug or for a method of using such drug because in the opinion of the holder a patent may not be issued for such drug or for a method of using such drug for any known therapeutic purposes the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of four years from the date of the approval of the application under subsection (b) unless the Secretary determines that an adequate supply of such drug will not be available or the holder of the application approved under subsection (b) consents to an earlier effective date for an application under this subsection.*~~

(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and ef-

fectiveness under subsection (c) before the date of the enactment of this subsection;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(7) For purposes of this subsection:

(A) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the

difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

[(j)(1)] *(k)(1)* In the case of any drug for which an approval of an application filed [pursuant to this section] *under subsection (b) or (j)* is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section: *Provided, however,* That regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, or similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(l) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(m) For purposes of this section, the term "patent" means a patent issued by the Patent and Trademark Office of the Department of Commerce.

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SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

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PROTECTION FOR UNPATENTED DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 527. (a) Except as provided in subsection (b), if the Secretary—

(1) approves an application filed pursuant to section 505(b), or

(2) issues a license under section 351 of the Public Health Service Act

for a drug designated under section 526 for a rare disease or condition and for which a United States Letter of Patent may not be issued, the Secretary may not approve another application under section [505(b)] *505* or issue another license under section 351 of the Public Health Service Act for such drug for such disease or condition for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

(b) If an application filed pursuant to section [505(b)] *505* is approved for a drug designated under section 526 for a rare disease or condition or a license is issued under section 351 of the Public Health Service Act for such a drug and if a United States Letter of Patent may not be issued for the drug, the Secretary may, during the seven-year period beginning on the date of the application approval or of the issuance of the license, approve another application under section [505(b),] *505,* or, if the drug is a biological product, issue a license under section 351 of the Public Health Service Act, for such drug for such disease or condition for a person who is not the holder of such approved application or of such license if—

(1) The Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or

(2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such seven-year period.

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SECTION 2201 OF TITLE 28, UNITED STATES CODE

§ 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1954 or a proceeding under section 505 or 1146 of title 11, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

"(b) For limitations on actions brought with respect to drug patents see section 505 of the Federal Food, Drug, and Cosmetic Act.

TITLE 35, UNITED STATES CODE

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PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

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CHAPTER 14—ISSUE OF PATENT

Sec.
151. Issue of patent.

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156. Extension of patent term.

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§ 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

(1) the term of the patent has not expired before an application is submitted under subsection (d) for its extension;

(2) the term of the patent has never been extended;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);

(4)(A) in the case of a patent which claims the product or a method of using the product—

(i) the product is not claimed in another patent having an earlier issuance date or which was previously extended, and

(ii) the product and the use approved for the product in the applicable regulatory review period are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended; or

(B) in the case of a patent which claims the product, the product is also claimed in a patent which has an earlier issuance date or which was previously extended and which does not identically disclose or describe the product and—

(i) the holder of the patent to be extended has never been and will not become the holder of the patent which has an earlier issuance date or which was previously extended, and

(ii) the holder of the patent which has an earlier issuance date or which was previously extended has never been and will not become the holder of the patent to be extended;

(5)(A) in the case of a patent which claims a method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product—

(i) no other patent has been issued which claims the product or a method of using the product and no other patent which claims a method of using the product may be issued for any known therapeutic purposes; and

(ii) no other method of manufacturing the product which does not primarily use recombinant DNA technology in the manufacture of the product is claimed in a patent having an earlier issuance date;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product—

(i) the holder of the patent for the method of manufacturing the product (I) is not the holder of a patent claiming the product or a method of using the product, (II) is not owned or controlled by a holder of a patent claiming the product or a method of using the product or by a person who owns or controls a holder of such a patent, and (III) does not own or control the holder of such a patent or a person who owns or controls a holder of such a patent; and

(ii) no other method of manufacturing the product primarily using recombinant DNA technology is claimed in a patent having an earlier issuance.

(6) the product has been subject to a regulatory review period before its commercial marketing or use;

(7)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; and

(8) the patent does not claim another product or a method of using or manufacturing another product which product received permission for commercial marketing or use under such provision of law before the filing of an application for extension.

The product referred to in paragraphs (4), (5), (6), and (7) is hereinafter in this section referred to as the 'approved product'. For purposes of paragraphs (4)(B), (5)(B), the holder of a patent is any person who is the owner of record of the patent or is the exclusive licensee of the owner of record of the patent.

(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and ap-

proved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.

(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection (g); and

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years.

(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

(A) the identity of the approved product;

(B) the identity of the patent for which an extension is being sought and the identification of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) the identity of every other patent known to the patent owner which claims or identically discloses or describes the approved product or a method of using or manufacturing the approved product;

(D) the identity of all other products which have received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and which are claimed in any of the patents identified in subparagraph (C);

(E) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services~~or the Secretary of Agriculture~~ to determine the period of the extension under subsection (g);

(F) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(G) such patent or other information as the Commissioner may require.

(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph ~~(1), the Commissioner shall notify—~~

~~(i) THE SECRETARY OF AGRICULTURE IF THE PATENT CLAIMS A DRUG PRODUCT OR A METHOD OF USING OR MANUFACTURING A DRUG PRODUCT AND THE DRUG PRODUCT IS SUBJECT TO THE VIRUS-SERUM-TOXIN ACT, AND~~

~~(ii) THE SECRETARY OF HEALTH AND HUMAN SERVICES IF THE PATENT CLAIMS ANY OTHER DRUG PRODUCT, A MEDICAL DEVICE, OR A FOOD ADDITIVE OR COLOR ADDITIVE OR A METHOD OF USING OR MANUFACTURING SUCH A PRODUCT, DEVICE, OR ADDITIVE AND IF THE PRODUCT, DEVICE, AND ADDITIVE ARE SUBJECT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.~~ **(1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act**

of the extension application and shall submit to the Secretary ~~who is so notified~~ a copy of the application. Not later than 30 days after the receipt of an application from the Commissioner, the Secretary ~~receiving the application~~ shall review the dates contained in the application pursuant to paragraph (1)(E) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

(B)(i) If a petition is submitted to the Secretary ~~making the determination~~ under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary ~~making the determination~~ shall, in accordance with regulations promulgated by ~~such~~ **the** *Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than 90 days after the receipt of such a petition. The Secretary ~~of Health and Human Services~~ may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.*

(ii) The Secretary ~~making a determination under clause (i)~~ shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty day period beginning on the publication of a determination, the Secretary ~~making the determination~~

to hold an informal hearing on the determination. If such a request is made within such period, ~~such~~ **the** *Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary ~~who is holding the hearing~~ shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, ~~such~~* **the** *Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.*

(3) For purposes of paragraph (2)(B), the term "due diligence" means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the information contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) If the term of a patent for which an application has been submitted under subsection (d) would expire before a determination is made under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f) For purposes of this section:

(1) The term "product" means:

(A) A **human** *drug product.*

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

*(2) The term "***human** *drug product" means the active ingredient of a new drug, antibiotic drug, ~~new animal drug, or human or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Virus-Serum-Toxin Act)~~* **or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)** *including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.*

"(3) The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use.

Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 507, 512, or 515 is a reference to section 503, 505, 507, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

~~*(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (31 U.S.C. 151–158).*~~

(5) The term "informal hearing" has the meaning prescribed for such term by section 201(y) of the Federal Food, Drug, and Cosmetic Act.

(6) The term "patent" means a patent issued by the United States Patent and Trademark Office.

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1)(A) In the case of a product which is a **human** *drug product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.*

(B) The regulatory review period for a **human** *drug product is the sum of—*

~~*(i) the period beginning on the date—*~~

~~*(I) an exemption under subsection (i) of section 505, subsection (d) of section 507, or subsection (j) of section 512, or*~~

~~*(II) the authority to prepare an experimental drug product under the Virus-Serum-Toxin Act,*~~

~~*became effective for the approved drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, 507, or 512 or the Virus-Serum-Toxin Act, and*~~

(i) the period beginning on the date an exemption under subsection (i) of section 505 or under subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved ~~*drug product under section 351, subsection (b) of such section 505, section 507, section 512, or the Virus-Serum-Toxin Act and ending on the date such application was approved under such section or Act.*~~ **human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.**

(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

(B) The regulatory review period for a food or color additive is the sum of—

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and

Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

(B) The regulatory review period for a medical device is the sum of—

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and—

(i) no request for an exemption described in paragraph (1)(B) was submitted,

~~*(ii) no request was submitted for the preparation of an experimental drug product described in paragraph (1)(B),*~~

~~*(iii)*~~ **(ii)** *no major health or environmental effects test described in paragraph (2) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or*

~~*(iv)*~~ **(iii)** *no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted,*

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.

(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.

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PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

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CHAPTER 28—INFRINGEMENT OF PATENTS

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§ 271. Infringement of patent

(a) * * *

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(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention **(other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913))** *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.*

(2) It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(g)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

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CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

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§ 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of section 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Claims Court, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires.

Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—

(1) by the applicant for the extension, or

(2) by the Commissioner,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due dili-

gence determination under section 156(d)(2) is not subject to review in such an action.

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ADDITIONAL VIEWS

We are supportive of many of the ideas contained in H.R. 3605 which the Judiciary Committee worked on and developed last Congress. However, changes made by the Committee on Energy and Commerce will have a substantial effect on the Patent and Trademark Office and a substantial effect on a patent owners' ability to protect his invention.

H.R. 3605 reflects a compromise worked out by Congressman Waxman between the Pharmaceutical Manufacturers Association, representing the pharmaceutical industry and the generic drug industry. Eleven major drug companies did not go along with that compromise.

H.R. 3605 as drafted would place a heavy administrative burden on the Patent and Trademark Office. Congressman Hughes with the support of Chairman Rodino, Mr. Fish, Mr. Moorhead and others tried to correct this with an amendment that lost with bipartisan support on a record vote of 16 opposed and 13 in favor.

This amendment would not seriously alter the basic compromise reached by Mr. Waxman but it's particularly important to the Patent Office. In an overabundance of caution the Commerce meeting overreacted to a non-problem. The private patent bar told the Judiciary Committee Subcommittee that so-called "evergreening" is not a problem. The Patent Office looked into it and reported back that it's not a problem. No creditable information was submitted to the Subcommittee showing that drug firms obtain a chain of patents relating to the same product for the purpose of prolonging their patent.

But in spite of all of this H.R. 3605 provides three pages of procedures requiring the Commissioner to make a determination as to whether a particular patent could be eligible for an extension which is equivalent to an evaluation for which his examiners are not now trained. Regardless of what some have said the role of the Commissioner is not ministerial and would require a specially trained staff to handle these determinations.

In addition, the amendment would modify the present policy reflected in H.R. 3605 that generally only the first patent claiming the product or fully disclosing that product and its approved use be rewarded with an extension. Our solution achieves substantially the same result, but is much simpler to administer and much fairer to patent holders. Present practice provides that when you file for a patent it's usually for one of three different types of patent: a patent on the product which is the most valuable, a patent for a particular type of use and/or a patent for the process by which something is made. You may obtain one or all three of these patents depending on what type of patent is involved and whether they meet the tough standards required in order to obtain a patent. What usually happens is that a person receives a patent

on the product and a patent on a particular use of that product. Later a new use is discovered and a new patent obtained. Under H.R. 3605 you cannot receive an extension on the new use discovered but only on the earliest issued patent. This will discourage research and innovation. Under our amendment should another later patent, such as one for a new use of an old product, undergo a subsequent regulatory review, it would be eligible for an extension.

This amendment is supported by the Department of Commerce, by the Patent and Trademark Office, American Intellectual Property Law Association, and bar groups from around the country.

These concerns warrant further consideration in the event that amendments are offered on the Floor of the House.

WILLIAM J. HUGHES.
PETER W. RODINO, JR.
JACK BROOKS.
SAM B. HALL, JR.
HENRY J. HYDE.
HAL SAWYER.
THOMAS N. KINDNESS.
CARLOS J. MOORHEAD.
HAMILTON FISH, JR.
DAN LUNGREN.
F. JAMES SENSENBRENNER, JR.
GEORGE W. GEKAS.
MICHAEL DEWINE.

ADDITIONAL VIEWS

In addition to the amendment that may be offered on the Floor by Congressman Hughes (explained elsewhere in this report) which we very much support, we also intend to offer three other amendments that are critical if we are to maintain our present patent system as the central motivating force to invent which it has been for almost two hundred years. Mr. Moorhead will offer one amendment relating to the reversal of *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.* and Mr. Sawyer will offer two amendments relating to the filing of an Abbreviated New Drug Application and the eighteen month marketing delay period.

Mr. Moorhead's amendment will be to Sec. 202 of the bill.

The present provision of section 202 of H.R. 3605 would add paragraphs (e)(1) and (3) to section 271 of title 35, United States Code, thereby overruling the recent decision of the Court of Appeals for the Federal Circuit in *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.* (Fed. Cir., April 23, 1984). In that case, the court held that use of a drug patented by another, in preparation for marketing the drug after the patent expired, constituted patent infringement. The present language of H.R. 3605 would establish a "commercial use exception" to the fundamental rights of patent owners and would make that exception apply retroactively. Because of the many problems which may result from such sweeping language, our amendment takes a different and more limited approach.

First, instead of providing an outright commercial use exception during the life of all drug patents, this amendment would require that a patentee, applying for an extension of a drug patent, waive certain rights of exclusivity in the application for extension. Thus, any limitation on exclusivity would only apply to patents whose term had been extended and not apply retroactively. As testimony of Professor Dorsen and others pointed out at the hearings, retroactive modification of the exclusive rights awarded a patent holder without payment of just compensation may constitute an unconstitutional taking of property.

Second, the waiver of exclusivity would be effective only during the last year of the extended term of the patent.

Third, the waiver of all remedies against infringement of the patent during the final year of the extended term would apply only for uses directly related to the development and submission of information under a federal law regulating the manufacture, use or sales of drugs.

This amendment is a compromise. It reverses the *Bolar* decision but in such a way so as to avoid the problems created in H.R. 3605.

Mr. Sawyer's first amendment will simplify the notice provisions and guarantee added certainty by making a single event—filing of a complete application—the mandatory notice date. It replaces language which would have permitted an applicant to give notice on

the date of submission of an Abbreviated New Drug Application (ANDA).

H.R. 3605 permits the ANDA applicant, in effect, to compel the patent owner to commence litigation on the validity of a patent within 45 days of receiving notice of the submission of an ANDA application, whether complete or not. This amendment safeguards patent owners from premature defenses of their patent rights that could create needless litigation and divert and drain resources. Patent litigation would not be permitted until after the generic manufacturer has at least demonstrated a legitimate interest in a drug by investment in preparing a complete ANDA. This complete filing requirement parallels the requirement applicable to full New Drug Applications (NDA) that a filing must be complete before being given full consideration. The effect of the amendment is that the trigger mechanism can occur only upon the acceptance of an ANDA or paper NDA as complete. As used in the context of the Federal Food, Drug, and Cosmetic Act, this means acceptance for "filing" by FDA of a complete application.

Mr. Sawyer's second amendment will make clear that FDA cannot approve an Abbreviated New Drug Application (ANDA) or a paper New Drug Application (NDA) where the validity of a patent covering that drug is being challenged in patent litigation until after the trial court enters its final judgment or such other period as the trial court may determine because one of the parties is being dilatory. It eliminates the requirement in the current bill directing FDA to permit the marketing of a generic copy eighteen months after the initiation of the patent infringement litigation.

This amendment also provides that, where a district court's determination that a patent is invalid is reversed on appeal, the case must be remanded to the district court with instructions to enjoin further sale of the infringing product during the remaining life of the product.

Under our system of law, patents are presumed valid. By contrast, H.R. 3605 would direct FDA to approve an ANDA or a paper NDA for a generic copy while litigation testing the validity of the patent is still ongoing. Except in those cases where the pioneer manufacturer is unduly delaying the litigation in order to keep a generic drug off the market, no ANDA or paper NDA should be made effective until the patent has expired or has been held to be invalid.

We urge you to support these amendments.

CARLOS J. MOORHEAD.
HAL SAWYER.
DANIEL E. LUGREN.
HAMILTON FISH, JR.
THOMAS N. KINDNESS.
F. JAMES SENSENBRENNER, JR.
MICHAEL DEWINE.

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