STATEMENT OF GERALD J. MOSSINGHOFF
ASSISTANT SECRETARY AND
COMMISSIONER OF PATENTS AND TRADEMARKS
BEFORE THE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND
THE ADMINISTRATION OF JUSTICE
OF THE
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES

H.R. 3605 AS AMENDED
"DRUG PRICE COMPETITION AND
PATENT TERM RESTORATION ACT OF 1984"

JUNE 27, 1984

Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to testify on the subject of patent term extension which would improve our patent system by providing an equitable approach to the effective length of patent terms.

The inequity to certain industries, whose inventions are denied a full patent term due to Federal premarketing approval requirements, has been widely recognized. This Administration also recognizes the need for remedial action to increase innovation. Therefore, it strongly supports enactment of legislation to restore the effective patent term to inventions subject to Federal premarket review. Also, two high-level bipartisan panels which have studied this problem, the National Productivity Advisory Committee and the President's Commission on Industrial Competitiveness, have strongly

endorsed patent term restoration as a vehicle to promote renewed and increased innovation.

Mr. Chairman, I think it is fair to say that my previous testimony before this Subcommittee on H.R. 1937 during the last Congress and my prepared statement on H.R. 3502 submitted at hearings before your Subcommittee on March 28, 1984, fully explain the reasons for our support of legislation dealing with patent term restoration. Also, in his letter to you of June 20, 1984, the General Counsel of the Department of Commerce expressed the Administration's strong support for enactment of H.R. 5529, legislation which would provide for an extension of the patent term for patented products or patented methods for using or producing products which are subject to Federal regulatory review before commercial use. That legislation, however, is limited to products which are agricultural and industrial chemicals and animal drugs. H.R. 3605 as amended, does not apply to agricultural and industrial chemicals although it does extend its application to animal drugs.

Inventions in agricultural chemical technology and in the pharmaceutical field depend heavily on patent protection. Development of such inventions is extremely costly, and yet their imitation is often simple and inexpensive. Many other inventions need a far greater outlay of capital to duplicate, and they also may have a shorter commercial life before being overtaken by the advance of technology. Pharmaceutical and agricultural chemical inventions, on the other hand, often are commercially attractive even after the

expiration of the patent term. This is evidenced by the large interest that the production intensive or generic drug industry displays in exploiting those inventions. This interest is healthy, and open competition should be encouraged. However, to the extent that a shortened effective patent term lessens the incentive for industry to continue making large commitments toward research and development, we must move to insure that these incentives are restored. Effective patent protection is a necessary prerequisite to pharmaceutical and chemical research, given the enormous costs and risks involved. In this regard, H.R. 3605 as amended, is intended to strike a compromise between the research intensive and the production intensive sectors of the pharmaceutical industry.

Title I of H.R. 3605 as amended, amends Section 505 of the Federal Food, Drug, and Cosmetic Act to provide for the approval of Abbreviated New Drug Applications (ANDAs). It would also make amendments to the Act to require applicants who file Paper New Drug Applications (Paper NDAs) to make the same certifications mandated in the filing of ANDAs and require the Food and Drug Administration to make approvals for Paper NDAs effective under the same conditions that apply to ANDAs.

Title II of this bill would add a new section 156 to title 35 of the United States Code to provide for an extension of the patent term for patented products or patented methods for using or producing products, subject to regulatory review pursuant to Federal statutes, before they are permitted to be introduced for commercial use.

Under H.R. 3605 as amended, these Federal statutes would be limited to the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the virus, serum, toxin, and analogous products provisions of the Act of Congress of March 4, 1913. Title II would also amend section 271 of title 35, United States Code, dealing with patent intringement and would further amend section 282 of title 35 to provide for additional defenses in an action involving infringement of a patent during the period of the extension of its term.

It is our understanding that the broad concepts of Titles I and II of this bill were the subject of extensive negotiations between the two sectors of the pharmaceutical industry and represent a compromise acceptable both to the generic pharmaceutical industry as well as to a majority of the companies in the research intensive sector. The overall compromise to allow the generic companies to obtain ANDAs in exchange for patent term restoration to research intensive companies appears to be a reasonable solution, given that enactment of either concept by itself would have continued to receive strong opposition. Our expertise does not extend to the intricacies contained in Title I of this bill dealing with amendments to the Federal Food, Drug, and Cosmetic Act. Accordingly, I defer to the judgment of the Food and Drug Administration regarding the provisions of Title I. The provisions of Title II, however, strike us as being confusingly difficult and in some instances as unnecessary.

Title II of H.R. 3605 as amended, deals with patent term restoration and contains several rather complex provisions. Section

156(a)(4)(A) permits a patent which claims the product or method of using that product to be extended if two requirements are met. The first is that the product must not have been claimed in another patent which was either extended or which has an earlier issue date. The second condition is that the product and the use for which it is approved are not identically disclosed or described in another patent which had been extended or which has an earlier issue date.

This provision clearly restricts the potential for patent term extension. Section 156(a)(4)(B) does provide for an exception to the rule laid down in paragraph (a)(4)(A) for certain product patents. It provides that a patent claiming a product which was also claimed in an earlier patent may be extended if the patents are not held by the same owner. Thus, an earlier issued patent which claims a broad genus of compounds would not block the possible extension of a later issued patent claiming a specific species of that genus where neither patent holder had a choice as to which patent to extend. The broad underlying policy reflected in these provisions appears to be that only the first patent which either claims the product or which fully discloses that product and its use is the one which should be rewarded with an extension. In cases where the patent owner only holds one patent this policy is not unreasonable. However, this policy does not necessarily encourage the owner of a product patent to invest the sums needed for research and development to find new uses for his already patented product, or to try to isolate certain species of a broad chemical genus. I

understand that the approval process for a new chemical entity is much longer than for subsequent new uses or species of that entity. Nevertheless, it would seem fair to allow patent term extension for subsequent patents which disclose new inventions.

Section 156(a)(5) specifies conditions for extension applicable to process patents. For patents claiming a process which does not primarily utilize recombinant DNA in the manufacture of the product, extension is possible only if no other patent had previously been issued claiming the product or method of using that product, and no other method of manufacturing the product is claimed in a patent having an earlier issue date. The underlying policy in this instance appears to be that the discovery of a new, non-recombinant DNA process for making an existing product does not warrant the reward of patent term extension. This appears somewhat unfair, especially if a newly discovered process for making a product, although not using recombinant DNA, otherwise represents a scientific and, therefore, possibly a commercial breakthrough.

Paragraph (B) of section 156(a)(5) makes an exception for manufacturing methods using recombinant DNA technology, but limits the possibility of patent term extension only to those cases in which the holder of a patent for that method does not also own a patent for the product or for a method of using that product. Again, in our opinion, this provision appears too strict.

If these complicated provisions have been included in this bill to prevent patent owners from benefitting from protracted patent protection through the obtaining of several patents relating to the same pharmaceutical product, then they are unnecessary. In my testimony on H.R. 1937, I addressed the subject of "evergreening" or "pyramiding" of patents. I stated then and repeat now that it is certainly possible to obtain process and use patents after a patent on the product itself. However, one should be clear exactly on what basis those patents are obtained and what kind of protection they afford. First, any patent issued must be patentably distinct from any other patent, which is to say, it must contain a different invention. If someone first obtains a product patent and later discovers another unexpected and patentable use for this product, that invention is entitled to protection. This is not an extension of the original patent or a merely obvious variation of the original invention; it is a separate and distinct invention, capable of being patented in its own right.

The same applies to a new discovery of a process for the manufacture of the originally patented product. If such a process is a separately patentable invention it is also entitled to protection. In such a case, the patentee of the original product has not extended the patent term of the product, he has made new inventive contributions to the technology. The patentee is therefore entitled to protection in turn for having publicly disclosed the invention.

However, what does a patent on a new use for a product or on a new process of making a product convey to the patentee? Regulatory review aside, if the original patent on the product has expired, the public is free to manufacture that product for all the uses for which the product was originally intended, as well as for any other use, except for the newly patented one. If a patent for a process or manufacture was also obtained, this particular new manufacture is protected, although the public is free to make the product in any other manner. As a consequence, the product itself does not enjoy continued and evergreening patent protection.

In two examples cited to us by the staff of the Committee on Energy and Commerce, to show how multiple patents may extend the protection of the original pharmaceutical, we found that the new use of the original products claimed in the later patents actually involved cancer treatments. The original use was only hormonal or bactericidal. We seriously question the wisdom of a policy which would not maintain the maximum incentives for investing in research to discover possible new cancer cures.

If the policy of these provisions is to allow extension only for patents claiming new chemical entities, then it changes nearly 200 years of patent law by instituting a system in which one patent is preferred over another. In our opinion, all patents should be treated equally. If a patent has lost a certain portion of its effective patent life to Federal premarket regulatory review, it should be made whole again. Only in this manner will the patent system continue to be a strong encouragement to innovation.

Lastly, these provisions place an unaccustomed burden on the Patent and Trademark Office. The determination which would be required by sections 156(a)(4) and (5) is not one which is now made by patent examiners who evaluate whether a particular claim in an application is patentable. These provisions would require determinations of infringement, involving concepts such as the doctrine of equivalents and file wrapper estoppel -- determinations usually made by courts. To be sure, examiners can be trained to make these determinations. But to the extent that these provisions attempt to cure a problem which we do not think exists, we do not favor having to expend our otherwise scarce resources. Should the Congress, however, decide that this is the appropriate policy, the provision in section 156(e)(1), to the effect that the determination may be made solely on the basis of information contained in the application for extension, is the only practical way to carry out this task.

Section 156(c) specifies the rules by which the length of the period of extension is determined. The calculation made under these rules is further limited by the requirements of section 156(g)(4). Under section 156(c), the length of the extension is based on the length of the regulatory review period in which the product was approved. All regulatory review periods are divided into a testing phase and an agency approval phase. Each phase of the regulatory review period is first reduced by any time during which the applicant for extension did not act with due diligence. The determination of any lack of due diligence is made under section 156(d). After any reduction in the period for lack of due diligence, one-half of the

time remaining in the testing phase would be added to the time remaining in the approval phase to comprise the total period eligible for extension. This period by itself cannot exceed five years in accordance with section 156(g)(4). However, even if entitled to an extension of five years, this period would be further reduced in accordance with section 156(c)(3) if it exceeded the total remaining patent term by more than 14 years. This formula strikes us as being somewhat arbitrary. For example, we are at a loss to explain the reason why a patent, which is eligible for five years of extension and had ten years of the original patent term left at the end of its regulatory review period, should only be entitled to an extension of four of those five years to reach a total of 14 years.

With respect to the five-year cap, we supported the seven-year cap in earlier bills, because this period was based on data tending to support the claim that, on the average, a pharmaceutical patent lost that much time to the Federal regulatory review process. We do not know why this cap has been reduced by two years. To the extent, however, that such a reduction is the result of a compromise between the different interest groups involved, the Administration will not object to such a compromise.

Section 202 of Title II of the bill would add a new paragraph (e) to section 271 of title 35, dealing with patent infringement. Specifically, this section would provide that the making, using or selling of a patented invention solely for uses reasonably related

to the development and submission of information needed for Federal regulatory review would not be an act of infringement. In this respect, the proposed legislation would overrule the recent decision of the Court of Appeals for the Federal Circuit in Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., ___F.2d___, 221 USPQ 937 (Fed. Cir., April 23, 1984). In that case, the Court held that the experimental use of a drug product prior to the expiration date of a patent claiming that product constituted patent infringement, even though the only purpose of the experiment was to seek FDA approval for the commercial sale of the drug after the patent expires.

Overruling this decision would serve as an unfortunate precedent in curtailing the exclusionary rights accorded a patentee during the patent term. It has been alleged that one should be entitled to experiment with the patented product during the term of a patent to allow immediate competition the day after the patent term expires. It appears to us somewhat unfair to have the effective term of a patent begin somewhere in the middle of the 17-year term because of Federal premarket regulatory review and to let others use the patented product, or make or sell it during the patent term, solely to escape any delay caused by that same Federal review. In other words, if there is to be a policy to encourage competition immediately after the end of the patent term, it should also ensure that the patentee is accorded the full effective patent term to which patents on nonregulated inventions are entitled.

There are other specific provisions in H.R. 3605 as amended, which are either ambiguous, or could lead to different interpretations, especially in those parts of the bill which require the Commissioner of Patents and Trademarks to make a determination of whether a patentee is entitled to an extension of the patent term. I have not specifically addressed those issues because I believe that they could be resolved. A better solution to this bill, for instance, could be to maintain the overall compromise of combining the concept of obtaining ANDAs and patent term restoration, but to substitute in place of Title II of H.R. 3605 as amended, the simpler mechanism of patent term restoration along the lines of the bills on this subject in the last Congress, or as now contained in H.R. 3502.

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