STATEMENT OF

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BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES

AND THE ADMINISTRATION OF JUSTICE

OF THE

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

ON

H.R. 3605

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

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My name is William E. Schuyler, Jr. For more than 40 years, I have been extensively involved in the patent profession in both the public and private sectors. During the period 1969-71, I served as the Commissioner of Patents and during that term represented the U.S. in negotiating the Patent Co-operation Treaty. I was appointed Ambassador and Head of the U.S. Delegation to the 1981 session of the Diplomatic Conference for Revision of the Paris Convention for the Protection of Industrial Property.

I am appearing today at the request of a coalition of many of our nation's leading research based pharmaceutical companies who asked me to review H.R. 3605 and provide the Committee with my views on the content and practical application of the bill in light of my experience in patent prosecution, litigation, international negotiation, and as a former Commissioner of Patents.

At the outset, let me make three key points:

o Provisions of this bill encourage premature litigation by patent owners in many situations where substantive commercial controversies will not later materialize.

o By denying extension to many patents on worthy inventions, the bill in its present form is a very real disincentive to research in those areas.

o By compelling the Executive Branch to disclose trade secrets of U.S. manufacturers to foreign competitors, that industry and our economy will be adversely affected by a loss of jobs

and by an unfavorable change in the balance of trade.

Patent Litigation

I would first like to focus on the provisions of Title I relating to patent infringement and validity issues. Provision is made for an Abbreviated New Drug applicant to notify a patent owner that an application has been submitted to obtain approval to engage in commercial manufacturing of a patented drug before the applicable patent expires. For forty-five days after such notice, the applicant is precluded from seeking a declaratory judgment that the patent is invalid or not infringed. If the patent owner sues the applicant for patent infringement within the forty-five day period, then approval of the ANDA will be delayed until the litigation is decided, but in no event more than 18 months. As the Committee is well aware, trial of complex civil suits, like patent suits, is almost never completed within 18 months. An average pendancy of four years would be a better estimate, due primarily to congestion in the courts.

Because the applicant may serve such notice at the time of first submitting an ANDA to the Food and Drug Administration, applicants will, at minimal expense, have the opportunity to serve the notice with respect to inumerable drug products. Patent owners will likely respond to virtually every notice by filing suits for patent infringement -- for a couple of reasons: First, failure of the patent owner to respond may support an estoppel or laches defense in subsequent litigation.

Second, the eighteen-month delay in approval of the infringing product will afford short term protection to the patent owner.

As a result, it is likely that the courts will be inundated with patent litigation of issues that will not necessarily result in commercial controversies. That will certainly complicate the current congestion in the Federal Courts, and cause even longer delays in civil litigation.

This bill is saving generic manufacturers a number of years and tens of millions of dollars now required to obtain approval of a new drug application by permitting them use of the data generated by the innovator. Even a two year delay of approval of an ANDA from the submission of a completed ANDA, as proposed in an earlier draft of the bill, leaves the scales balanced heavily in favor of the generic manufacturers.

To limit the litigation triggered by this bill to those situations involving bona fide commercial controversies, I suggest that the timing of the notices to the patent owner be made coincident with filing of a completed ANDA. At that point the infringer will have invested sufficiently in his application to show his true intent to reach the commercial market, and the numbers of law suits will be dramatically reduced by weeding out some of the notices of invalidity which border on the frivolous. Also, the abitrary and unrealistic eighteen month period for litigation should be eliminated, with the Court having discretion to make effective the ANDA before final adjudication only if the patent owner fails to reasonably cooperate in expediting the action.

Patents Ineligible for Extension

Title II excludes various types of patents from eligiblity for restoration and places substantial limitations on the length of restoration. Reportedly, the drafters of this legislation have chosen to do this because they believe certain types of patents are amenable to manipulation of patent issuance, and therefore expiration dates, and because they believe Congress has not received data on significant regulatory review delays on other than new chemical entity products. (See House Energy and Commerce Committee Report on H.R. 3605, page 30.) The first rationale has been addressed by provisions in the bill that limit the term of an extended patent to no more than 14 years after regulatory approval of the covered product. Moreover, there is a provision that limits restorable time to that occuring after the patent issues but before regulatory approval. In light of these two very substantial limitations, the patent exclusions set forth in Section 156(a) are excessive and unnecessary. If the second rationale is true, it is irrelevant because the bill does not grant restoration in the absence of regulatory delay. More importantly, any arbitrary exclusion of patents eligible for restoration may unwittingly skew research to less than optimal therapies.

Exclusion 4 produces the greatest deleterious effect by providing that a patent claiming a product (or a method of using the product) may be extended only if the product is not claimed

and the product and approved use are not identically disclosed or described in another patent having an earlier issuance date or which was previously extended.

To appreciate the mischief generated by this provision, one must have some understanding of pharmaceutical research and patent practice.

Pharmaceutical research is normally conducted on families of compounds sharing similar structural features and (it is hoped) similar biological characteristics. The object is to study a sufficient number of compounds in the family so that enough commercial candidates will appear to provide a likelihood of generating at least one commercial compound. I should note in passing that the research and development expenses to bring one commercial compound from discovery to commercialization have been estimated to be on the order of $70-85 million dollars.

The practice of pharmaceutical research to concentrate on families of compounds leads inevitably to the filing of patent applications on these families of compounds which were discovered. Since a patent application must be filed at an early stage of research to avoid potential loss of patent rights, only preliminary screens of the compounds will have been conducted. There is generally no suggestion at the time the patent application is filed as to which members of the family (if any) will be commercially successful.

Divisional Applications

In the normal course of examining a pharmaceutical patent application, the Patent Office frequently requires that the claims in the application be divided into several applications for "subfamilies", depending on the classification system employed by the Patent Office and on the Examiner's decision as to the appropriate scope of protection for a single application. The patent owner must then select one of the subfamilies for examination in the originally-filed ("parent") application and file additional applications (called "divisional applications") claiming each of the other promising subfamilies of compounds. These divisional applications would contain the same disclosure as the parent application but each would contain claims directed to a different subfamily. The decision to divide the application into a number of subfamilies is made solely by the Patent and Trademark Office.

With this as background, it will be apparent to the Committee that the later-issued divisional applications would be precluded from extension by exclusion number 4 because of the earlier-issued parent application disclosing the entire family of compounds and their intended use. Since the patent owner generally has no idea at the time of filing the "divisional application" which member of the family of compounds (if any) will be commercially successful, he is unable to insure that the commercial compound is claimed in the parent application. Exclusion 4 would therefore arbitrarily deny extension to patents covering approved products merely because an earlier issued patent discloses the product. It is unnecessary and should be

eliminated.

First filed, later issued applications

The committee should also appreciate that patents do not always issue in the order in which they are filed. Some applications encounter difficulties and problems in the Patent Office, while others are allowed quickly. By making the issue date the operative criterion, this provision of the bill could injure a party whose earlier-filed patent issues later. For example, a research-based pharmaceutical company might discover a family of compounds which appear, in preliminary screens, to have utility for treatment of certain forms of cancer. If this company files an application directed to these compounds, it is certain to face a rigorous examination by the Patent Office because of the general skepticism with regard to cancer treatment. Continuing along with the example, suppose that other researchers at this company develop a new and patentable process for preparing these compounds and that a second patent application is filed claiming the process. Because of the requirements of patent law that a patent application claim a useful invention, the second patent application would necessarily have to disclose the compounds which are made by the new process and their therapeutic utility. If the second-filed application issues first (as well it might), the first-filed application directed to the compounds would be ineligible for extension under exclusion 4.

Interferences

The United States Patent System awards a patent to the first inventor, not necessarily to the first person to file an application. If two applications are filed claiming the same invention, a contest occurs (called an "interference") to determine priority of invention and thus ownership of the resulting patent. This contest can occur not only between two or more applications, but also between one or more applications and an issued patent. If in such a situation the owner of the patent application were determined to have priority over an issued patent, his resulting patent would nevertheless be barred from extension because his invention had been claimed in an earlier-issued patent. As a result of winning the interference he loses his right to an extension. This is but another example of the injustice created by exclusion 4. It should be eliminated for it serves no useful purpose.

Genus/Species

Moreover, a certain type of patent, known as a "species patent" would be ineligible for extension under exclusion 4 if the owner also owns a "genus" patent.

Because pharmaceutical research requires a continual exploratory and refining process along parallel pathways, new candidates for commercialization are, not uncommonly, chemical

"species" falling within a broad class ("genus") of chemical compounds claimed in a patent.

Frequently, the compound approved by FDA is not even specifically mentioned in the original patent, but is identified only after years of additional expensive research. An early promising compound may later be found to exhibit a problem such as an undesirable side effect, requiring the inventor to abandon it in favor of other "species" compounds falling under the same genus patent. Species patents can be obtained on later developments that are not specifically disclosed in the original genus patent if they meet the statutory requirements of novelty, usefulness, and unobviousness. Such patents are more important today than ever, because, with the advent of new drug delivery systems and the new biotechnologies, substantial new health care advances frequently occur many years following the original grant of the genus patent. But, the existence of a generic claim in the earlier patent will preclude extension of the later patent to a commercially viable "species."

Denial of extension of the term of species patents acts as a research disincentive and serves to curb and impair scientific research in this fruitful area, denies the public the benefit of important medical advances, and reduces jobs in the research-based pharmaceutical industry.

Because of its inherent faults, I recommend the removal of exclusion 4 from the bill.

Other Restraints on Extension

The effects of exclusions 2 and 8 are well considered together. Exclusion 2 would deny extension to a patent which has been previously extended, while exclusion 8 would deny extension to a patent claiming another product (other than the one with respect to which extension is now sought) or method of using or manufacturing another product, which product has been previously approved by the FDA.

Bearing in mind that the extension of a patent is limited by the bill to the particular compound and the use approved, the fact that a patent covers one compound which has already been approved (and with regard to which the patent may have been extended) should not prevent an extension with respect to an additional compound claimed by that same patent. Please let me emphasize that I am not recommending serial extensions, but simply the applicable extension of the original term with regard to a second compound claimed by the patent. If the two products under consideration were claimed by separate patents, each patent would be eligible for extension with respect to the applicable product and the approved use. No different outcome should result because the two products happen to be claimed in the same patent. Exclusion 2 should be deleted to rectify this inequity.

Exclusion 8 is much the same, except that it would deny extension to a patent with respect to a particular product merely because it also claims a previously-approved product (even though the patent was not extended with respect to this previously-approved product). As an example of the reach of this exclusion,

it is easy to conceive of a patent covering a family of compounds, one of which is rapidly approved as (e.g.) a topical antifungal. Because of the timely approval of this antifungal compound, the patent is not eligible for extension with regard to that compound. Included in the same family of compounds, however, is a compound which is useful for treatment of a more life-threatening disease, such as cancer. The approval process for this compound, both in the clinical testing and in the registration process, could be lengthy indeed and it might be many years after the issuance of the patent that this cancer-treatment compound is approved for commercial sale. To deny extension to the patent with respect to the cancer-treatment compound because of the previous approval of the antifungal compound would appear unjust. For this reason, exclusion 8 should be deleted.

It appears that the criteria for extension are designed to prevent supposed abuses in the patent system by which patent owners might to extend their period of exclusivity. I respectfully submit, however, that any such abuses of the patent prosecution process are adequately addressed by the provisions of the bill limiting the maximum extension of five years, and limiting any extended patent life to 14 years from the date of regulatory approval. Alleged abuses of the patent prosecution process cannot result in prolonging a patent beyond the term of 14 years after the date of regulatory approval.

Disclosure of Proprietary Data

Allow me to focus a moment on section 104, which would hurt American companies trying to compete overseas by forcing disclosure of confidential data, including trade secrets. It gives unfair advantage to foreign companies seeking health registrations in their own countries. Most foreign countries give preference to their own nationals, making it easier for them to obtain approval to market drug products. At present, a number of countries do not even recognize drug product patents. Of these, more than half require submission of a substantial amount of technical information to obtain drug marketing approvals; and the number is increasing. These countries account for some $ 585 million dollars of total pharmaceutical exports from the U.S. The point is that if confidential data are disclosed to the public, we make it much easier for foreign companies to use those data to obtain approval and a head start in their countries.

The bill strikes two blows against American companies. First, it deprives American companies of trade secrets obtained at great cost (often measured in tens of millions of dollars). Second, it deprives American companies of the ability to make first use of these costly data to obtain approval overseas, thereby hurting their ability to compete effectively in those foreign markets, with adverse side effects on the balance of trade and domestic employment. To avoid this disaster, I believe it is essential that this valuable proprietary data be protected.

Conclusion

For reasons stated, I recommend removal of exclusions 2, 4 and 8 from the bill. While the revisions I have suggested will resolve some basic problems, there are many additional technical points requiring careful attention. Also, I should point out that there are serious constitutional questions raised in the bill, one being the legislative overruling of the Roche v. Bolar decision as to patents issued prior to the effective date of the legislation. These questions also deserve careful attention in order to avoid future successful legal attack on the legislation.