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July 27, 1984

Ms. Lynne M. Lester,
Manager, Divisions Office
The District of Columbia Bar
1426 H Street, N.W.
Eighth Floor
Washington, D.C. 20005-2184

Dear Lynne:

Comments by Division 14 (Patent, Trademark & Copyright Law) on H.R. 3605, The Drug Price Competition and Patent Term Restoration Act of 1984

Pursuant to section 13(a) of the Division Guidelines, I am enclosing the proposed statement unanimously adopted by the participating members of the steering committee of Division 14 on July 26, 1984. I was the only steering committee member that did not substantively participate, because of a possible conflict of interest. Also enclosed is a required one-page summary of the proposed statement and the mandatory disclaimer required by the guidelines.

Division 14 supports the overall objectives of the legislation but opposes specific provisions of the bill that distort desirable concepts of law. The division believes that full hearings should be held before the bill is reported out of Committee.

We are asking for your review on an emergency basis, because the Subcommittee on Courts, Civil Liberties and The Administration of Justice has already considered the bill

and it is being taken up by the full House Judiciary Committee on July 31, 1984. Consequently, we must submit our comments no later than July 31, 1984 if they are to have any effect. The steering committee only recently became aware of the activity on this bill, and because of its complexity and the traveling schedule of the steering committee members, the statement could not be completed earlier.

Respectfully submitted,

Allen M. Sokal

AMS:ar

Allen M. Sokal
Chairman, Division 14

Enc.

To the Board of Governors and
Division Chairpersons:

SUMMARY OF THE STATEMENT ON BEHALF OF
DIVISION 14, PATENT, TRADEMARK AND COPYRIGHT LAW,
ON H.R. 3605, THE DRUG PRICE COMPETITION AND
PATENT TERM RESTORATION ACT OF 1984

Attached hereto is the statement of Division 14 (Patent, Trademark and Copyright Law) opposing selected provisions of H.R. 3605, although supporting its overall objectives. Division 14 supports the general concept of patent term restoration, but opposes limitations on its application to many patents in section 156 of the bill. Division 14 also opposes section 202 of the bill, which would overrule Roche Products v. Bolar Pharmaceutical Co., decided by the United States Court of Appeals for the Federal Circuit on April 23, 1984, in which the court held that conducting experiments with a patented drug to obtain F.D.A. approval for the commercial sale of the drug constituted patent infringement. The division also opposes a provision in the bill that would make the mere submission of an abbreviated new drug application an act of patent infringement and that would force patent owners to sue within forty-five days after being notified of such infringement. Finally, Division 14 opposes provisions of the bill requiring new drug applicants to disclose trade secret information and recommends amendment to require disclosure of only a detailed summary of safety and effectiveness data, but not the complete raw data.

STATEMENT ON BEHALF OF DIVISION 14
PATENT, TRADEMARK AND COPYRIGHT LAW
DISTRICT OF COLUMBIA BAR* REGARDING
THE PATENT TERM RESTORATION BILL

To The Subcommittee on Courts,

Civil Liberties And the

Administration of Justice On HR 3605

Prepared By:

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Barry L. Grossman
Helen M. McCarthy
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Edward M. Prince
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*MANDATORY DISCLAIMER

The views exposed herein represent only those of Division 14 (Patent Trademark and Copyright Law) of the District of Columbia Bar and not those of the D. C. Bar or of its Board of Governors.

STATEMENT ON BEHALF OF DIVISION 14 PATENT, TRADEMARK AND COPYRIGHT LAW DISTRICT OF COLUMBIA BAR REGARDING THE PATENT TERM RESTORATION BILL

The District of Columbia Bar, Division of Patent, Trademark and Copyright Law (Division 14), is pleased to submit its comments on H.R. 3605, "The Drug Price Competition and Patent Term Restoration Act of 1984". In summary, we support the overall objectives of this legislation but have serious reservations over whether the bill, as written, will achieve those objectives. We appreciate the fact that this bill represents a compromise between allegedly conflicting interests within different segments of the pharmaceutical industry. With respect to the patent and data provisions of H.R. 3605, however, the compromise reached distorts traditional and, we believe, desirable concepts of law.

The District of Columbia Bar, Division of Patent, Trademark and Copyright Law, has a membership of over 900 persons who specialize in intellectual property law, including many who reside and practice in other states. We will limit our comments on H.R. 3605 to the areas within our expertise, intellectual property, including patents and proprietary information.

The District of Columbia Bar supports the general concept of patent term restoration. If the seventeen-year term of a patent is effectively diminished as a result of required premarket federal regulatory reviews, it is both equitable and consistent with overall public policies supporting the patent system that the term of that patent should be extended so that the patent holder has the opportunity to enjoy the full seventeen-year term which Congress intended. While the problem of diminution of effective patent terms due to federal regulations is

certainly not limited to drug patents, it is most acute in that field. Patent term restoration is a concept which, we believe, will encourage research and development of new drugs.

H.R. 3605 embraces the general concept of patent term restoration, but Section 156 of the bill unduly limits its application by imposing artificial constraints on the patents and patentees eligible for patent term restoration. These limitations are unnecessary and will, in many instances, defeat the desirable objectives of this bill. In our view, each patent for which patent term is sought should be treated independently.

Under Section 121 of Title 35, each patent defines a separate and distinct invention. Any technological development may have within it several patentable aspects, each one of which would support a patent. For example, a product is patentable separately from the method of making the product. They are separately patentable because the patent law treats each as a separate invention. Additionally, in many cases various aspects of the technological development are submitted to the Patent and Trademark Office in a single patent application. The Patent and Trademark Office may require the applicant to divide the initial applications into separate applications for each distinct invention. The bill, however, draws distinctions based, in part, upon separate inventions disclosed in earlier issued patents. The law governing this aspect of patent law is complex and the subtle distinctions which this bill attempts to draw to deny extension to certain patents will be difficult at best to implement. We believe that the desirable objectives of the bill can be better effectuated by treating all patents and patentees independently.

The bill would obligate the Patent and Trademark Office to become involved in determining issues analogous to infringement. The Patent and Trademark Office has neither the expertise nor the resources to become involved in such considerations. In addition, the time periods for extension in the bill seem somewhat arbitrary.

We oppose Section 202 of the bill, which would overrule the Roche Products v. Bolar Pharmaceutical Co., Inc. case decided by the Court of Appeals for the Federal Circuit on April 23, 1984. In this case, the Court held that the use of a patented drug product prior to the expiration date of the patent for the purpose of conducting experiments required to obtain FDA approval for the commercial sale of the drug after the patent expired constituted patent infringement. The patent grant bestows upon the patent holder the right to exclude others from making, using, or selling the patented invention. While there is a well-recognized "experimental use" exception to the right to exclude bestowed by a patent, as the CAFC recognized in Roche, that exception has always been more narrowly construed than it would be under Section 202. We believe that it would be undesirable to expand the "experimental use" exception in the manner proposed in Section 202.

H.R. 3605 would impose undesirable and artificial constraints on patent enforcement. It would force patent holders to sue abbreviated new drug application (ANDA) applicants within an arbitrary 45 days after being notified that an ANDA has been submitted for a drug which infringes the patent. If the patent holder sues the ANDA applicant, ANDA approval is delayed until the litigation is resolved, but no more than 18 months. In effect, this provision makes the mere

submission of an ANDA an act of infringement for which the patentee can sue. In our view, mere submission of an ANDA should not itself be an act of infringement. If an ANDA applicant would infringe a patent in order to develop the data or information required in an ANDA, the patentee may bring an infringement action under current law, as exemplified by Roche. We see no reason to spur premature litigation and thus recommend against changing the current law.

Since our Division is concerned with the legal rights affecting all intellectual property, including trade secrets, we feel obligated to voice our objection to the provisions of H.R. 3605 which require disclosure of confidential trade secret data. This data is among the most valuable property rights owned by a company. To confiscate this property right by forcing new drug applicants to disclose their trade secret data is a certain way to diminish the incentives to undertake expensive research and development of new drugs. It will also reveal to foreign competitors valuable and practical research information of our most innovative companies. Consequently, we urge that these provisions of H.R. 3605 be amended to require the FDA to make a detailed summary of safety and effectiveness data, but not the complete raw data.

We appreciate the opportunity to present our views on the patent aspect of H.R. 3605. It is important legislation. The concerns noted above are merely representative of other numerous questions raised by the bill. We believe full hearings should be held before the bill is reported out of Committee. With further consideration and hearings, we are certain the bill will achieve its purpose and help to ensure the continued leadership of the United States in the development and production of new pharmaceutical products.