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ATTENTION: KENNETH BERKOWITZ
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The Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts
Civil Liberties and the
Administration of Justice
U.S. House of Representative
2232 Rayburn House Office Building
Washington, D.C. 20515

RE: Patent Term Restoration
(H.R. 3605)

Dear Mr. Chairman:

The American Intellectual Property Law Association (AIPLA) is a national bar association of more than 4800 attorneys engaged in the practice of patent, trademark, copyright, licensing, and related fields of law affecting intellectual property.

AIPLA supports the enactment of patent term restoration legislation because we believe it will serve the public interest. Our belief is not based on an analysis of the impact of the Federal regulatory process on those industries or American Industry in general. Rather, we believe history teaches that an effective patent system, premised on a commercially viable 17-year patent grant, has been of immense direct benefit to our country since the patent laws were enacted by the First Congress in 1790.

However, we are opposed to the enactment of H.R. 3605 with the inclusion of Section 202 which makes exceptions to fundamental, long standing, and important principles of patent law. In our opinion Section 202 (1) presents a constitutional issue which raises significant financial and public policy questions and (2) represents a significant negative precedent to the development of both United States and international patent laws. These points are discussed below. We also offer for your consideration an approach to eliminate the problem so the H.R. 3605 can go forward towards enactment.

(1) Section 202 raises a serious constitutional issue. When the Food and Drug Administration prevents a patent owner from selling a drug to the public until the drug is approved it does not interfere with rights conferred by the patent.

A patent bestows no right to sell but only to exclude others from practicing the invention. In Bloomer vs. McQuewan, 14 Howard 539 (1852) Chief Justice Taney said:

> "The franchise which the patent grants consists altogether in the right to exclude everyone from making, using, or vending the thing patented without the permission of the patentee. This is all that he obtains by the patent".

It is equally well stated that "patents are property and entitled to the same rights and sanctions as other property". Continental Paper Bag Company vs. Eastern Paper Bag Company, 210 U.S. 405 (1908).

However, new Sections 271 (e) (1) and 271 (e) (3) proposed in Section 202 deprive owners of existing patents of the right to exclude others from making, using, or selling their patented drug under certain circumstances. The Supreme Court in James v. Campbell, 104 U.S. 356 (1881) said:

> That the government of the United States when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt.

The Court elaborated in Hollister v. Benedict Manufacturing, 113 U.S. 59 (1885):

> It was authoritatively declared in James v. Campbell, 104 U.S. 356, that the right of the patentee, under letters patent for an invention granted by the United States, was exclusive of the government of the United States as well as of all others, and stood on the footing of all other property, the right to which was secured, as against the government, by the constitutional guaranty which prohibits the taking of private property for public use without compensation.

The patent owner's rights are not wholly extinguished by Section 202. However, "property is taken in the constitutional sense when inroads are made upon an owners use of it..." United States v. Dickinson, 331 U.S. 745 (1947). Also, Acts of Congress, like actions of the Executive Branch, cannot by retroactive effect deprive persons of existing property rights without compensation. Lynch v. United States, 292 U.S. 571 (1934).

While Congress may be willing to pay enormous sums to hasten the availability of lower cost drugs to the public, we seriously question the wisdom of the public policy which directly and substantially subsidizes generic drug manufacturers. The valuable rights obtained by this industry will be paid for by the Government with public funds.

(2) Section 202 amends Section 271 of title 35 which defines patent infringement. Proposed Section 271 (e) (1) and 271 (e) (3) create an unprecedented "commerical use" exception to basic patent rights for the purpose of solving special problems involving a certain industry. The specific problem addressed is caused by other federal laws and regulations.

Proposed Section 271 (e) (2) is also an unprecedented departure from United States and foreign patent laws. That Section provides that it shall be an act of infringement "to submit an application under 505 (j) of the Federal Food, Drug and Cosmetic Act for a drug claimed in a patent or the use of which is claimed in a patent." In the United States, and as defined specifically in 35 USC 271 (a), the manufacture or use or sale of a patented product constitutes an act of patent infringement. In most foreign countries, the act of manufacture or use or sale or importation constitutes patent infringement.

Property rights in patents granted by the United States or other countries have no extraterritorial reach. An American inventor who wishes to prevent the making, using, or selling of his invention outside the United States must obtain a patent in each and every country where he desires protection. Under proposed 35 USC 271 (e) (2), the United States would add as a fourth act of patent infringement the mere filing of a paper with a government agency which may be based upon acts of use engaged in outside of the United States. If a person tests the patented drug of another in a foreign country without authorization, the U.S. patent owner may or may not have a cause of action in that country depending on his patent rights there. To project U.S. patent rights beyond American borders amounts to the creation of a legal fiction resting only on a jurisdictional ground.

These two departures from conventional principles of patent law represent very unfortunate precedents for the future development of patent law in the United States. But these negative proposals have broader ramifications. During the past four years the United States has assumed a prominent role in the diplomatic conferences on the revision of the Paris Convention in urging the developing countries to adopt and use strong and effective patent laws. We point with pride to our patent system. We believe, and have tried to convince these countries to believe, that the clear protection of patent rights is in their best interest. We have urged them not to adopt local

weakening exceptions to that protection. Of course, strong local protection of U.S. owned technology we would like to export to developing countries is also in our interest.

Should the Congress enact Section 202, the world patent community would learn that the United States accepts expedient special exceptions which erode fundamental principles of our own patent system.

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We fully understand that H.R. 3605 requires that a number of legitimate interests be reconciled. Therefore, to that end, we recommend that you consider that the bill be redrafted so that clinical trials in anticipation of an ANDA filing after a drug goes off patent be allowed only during the patent term restored by H.R. 3605. This bill envisions that, in the future, patented drugs approved by the FDA will be entitled to some period of restored term after the original patent has expired. The bill should provide that when a patent owner petitions to gain that extension he thereby consents to allow testing in anticipation of ANDA filings by others. Having the owners consent will overcome the problems generated by the Constitution. This approach also greatly ameliorates the negative precedent of creating a commercial use exception to patent rights because the granted patent will have expired before the exception can apply. This approach would also allow the abandonment of the proposal of infringement by filing a paper as is found in 271 (e) (2).

H.R. 3605 does not extend the patent term of drugs already approved and on the market. The owners of those patents will never recover any patent time lost to them by regulatory delay. The approach we recommend makes this bill prospective for all parties. The copyists will not receive the time benefits which accrue with the reversal of Roche v. Bolar, as they do under H.R. 3605 as to drugs already patented and on the market. However, such result is equitable since the time the copyist would gain by having the bill retroactive in its effect would be considerably less than the time lost by the inventor of the drug due to regulatory delay.

Thank you for considering our views.

Sincerely,

B. R. Pravel
President

cc: Honorable Carlos J. Moorhead
Honorable Jack Brooks
Honorable Romano L. Mazzoli
Honorable Mike Synar
Honorable Patricia Schroeder
Honorable Dan Glickman
Honorable Bruce A. Morrison
Honorable Barney Frank
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