H.R. 3605

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FEDERAL EXPRESS

July 16, 1984

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Dear Howie:

It was good to speak with you last Friday. In addition to my earlier letter, I thought the following comments concerning the principal areas where the Waxman bill (HR 3605, in the Senate S.2748) is badly in need of correction, might be helpful to you. Also, there are enclosed a few more documents which may be of interest which are mentioned in the following comments. The deficiencies in the legislation fall into three general areas, all of which need correction. They are

1. FDA issues;

2. Patent law issues;

3. Constitutional concerns.

The FDA Issues:

1.

Perhaps the most serious single problem in this area is that the bill, unlike current ANDA regulations for drugs approved before 1962 -- appears to curtail FDA's existing authority to

request safety and efficacy information from an ANDA applicant beyond the limited information specifically set forth in the bill. For many drugs, the bill does not permit the FDA to request data -- including safety and effectiveness data -- other than that which relates to the bioequivalence of the generic and the pioneer drugs. Nor does the bill authorize rejection of an ANDA for most drugs on the grounds of lack of safety or effectiveness.

We believe that failure to include simple clear authority in the bill will (1) raise questions about the scope of FDA's authority; (2) probably result in litigation; and (3) perhaps create a separate class of products subject to premarket approval requirements for which FDA will be unable to obtain adequate safety and efficacy data.

The FDA, which is charged by statute with protecting public health, should have the same authority for all products it approves to properly protect consumers. Simply stated: Congress should maintain FDA's explicit discretionary authority: (1) to require safety and effectiveness information from an ANDA applicant when needed to protect the public health; and (2) in such instances, to disapprove any ANDA if the applicant is unable to demonstrate that its drug product is safe and effective.

2.

Testimony given by Mark Novitch, Acting Commissioner of FDA, is consistent with our own concerns that the bill as now drafted would create serious administrative and managerial burdens on FDA. One of the chief areas of concern is that the bill fixes an 180 day term for FDA to act on the staggering number of ANDA applications that are expected to be filed. Commissioner Novitch testified, and we agree, that the FDA would simply be unable to act on each application in the time period allowed. An orderly phase-in of eligibility for ANDAs is the solution which he recommends and with which we agree.

3.

Commissioner Novitch testified against that part of the legislation which permits ANDAs for combination drugs. We agree with his judgment that, as a rule, ANDAs should be limited to drugs which have the same active ingredients as the pioneer drugs, and that it is not in the public interest to encourage the proliferation of new combinations without adequate clinical testing for safety and effectiveness.

4.

The proposed legislation would put an administrative burden on the FDA to monitor civil patent litigation -- a burden which the agency is not equipped to handle. FDA would be responsible for delaying the effective date of approvals pending a resolution of civil litigation or requests of reexamination of patentability to the Patent Office, and for delaying the effective date of the approval of subsequent generic applications until the first generic drug involved in the patent challenge had been marketed for 180 days.

5.

The bill would require an applicant for patent extension to submit to the Commissioner of Patents a brief description of the applicant's activities during the premarket regulatory review period and the dates of certain significant milestones that occurred during this period. The Commissioner of Patents would be required to send a copy of the application containing this information to the Secretary of HHS, who would be required, within 30 days, to determine the applicable regulatory review period. Having to determine and confirm the regulatory review period for each product would impose a significant burden on FDA, because the agency would have to store and retrieve information in a form which otherwise would be of little or no utility to it. We agree with Commissioner Novitch's statement that "We can perceive no public health reason to require FDA to determine the regulatory review period under a restrictive 30 day time schedule."

6.

The bill would require the Secretary to determine whether an applicant acted with "due diligence" during the regulatory period if the Secretary were petitioned to do so within 180 days after a patent extension determination is published. If the Secretary were to find that an applicant did not act with "due diligence" for some period of time, the amount of patent extension that the applicant would be entitled to could be reduced. The "due diligence" determination is likely to be both burdensome and nonproductive. Under the bill, FDA would be required to formulate regulations, review petitions, prepare due diligence determinations and conduct hearings. Commissioner Novitch has testified that this feature of the bill should be deleted because it appears that a complex system would be established that would require FDA resources to implement and maintain it at no net public benefit.

7.

The bill would reverse a longstanding FDA policy by allowing the disclosure of trade secret information in NDAs. The bill would permit FDA to release all safety and effectiveness data and information submitted in an NDA at the time the first ANDA is approved or could be approved. Those data and information may retain proprietary value in the United States and could be used by competitors to obtain product registration in foreign countries. Also, it is not clear in the bill that the term "information" is limited to safety and effectiveness information, as distinguished from other confidential data in NDAs such as manufacturing methods and processes.

We believe the bill should require FDA to make available a detailed summary of safety and effectiveness data, but ot he complete raw data. Also, it should be clarified that the term "information" relates only toinformation on safety and effectiveness.

The above list of FDA issues touches some but not all of the important concerns in this area. A more complete review is contained in the text of Commissioner Novitch's statement of June 28, 1984 and in the statement of Verne Willaman, a member of the Board of Directors and Executive Committee of Johnson & Johnson, dated June 28, 1984, both of which are enclosed.

The Patent Issues:

Several witnesses testified and provided statements with respect to the deficiencies of the proposed legislation from the viewpoint of patent law. They included Gerald Mossinghoff, Commissioner of Patents and Trademarks, former Commissioner William Schuyler, and John Stafford, President of American Home Products Corporation. Their statements are enclosed. Among the principal points they raised are the following:

1.

The bill contains limitations on the patent terms which can be restored. Under present law, a patent can be obtained containing a broad claim (genus) covering many compounds. It is possible subsequently to obtain a patent for specific claims (species) on a few specific compounds encompassed within the genus. Under the bill, should a patent holder obtain a patent with species claims covered by a previously issued genus patent, the patent holder could not obtain restoration of the term of the species patent. This is unfair to holders of

species patents whose owners may have invested substantial sums in research.

2.

Under present law, the Patent Office can require that the claims in a patent application be divided and prosecuted in separate patents. Under the bill, the first issued patent of the series would be the only patent term entitled to restoration, and subsequently issued patents of the series would be precluded from restoration. Accordingly, unless an FDA approved product is claimed within the first issued patent of the series, restoration of a patent term covering the product would not be available. During the patent application process, it is impossible to know which drug or drugs will ultimately be successfully tested and marketed. Therefore, a patent holder is being denied the benefit of patent term restoration due to circumstances beyond its control.

3.

Another exception to patent term restoration would occur where one patent covers two FDA approved drugs. Any claims in the patent covering the second FDA approved drug could not be restored. Accordingly, only one restoration is available per patent even though a company has expended considerable resources in developing each FDA approved product.

The Constitutional Issues:

Section 202 of the bill would allow persons to infringe existing pharmaceutical patents by making, selling or using the patented drug if done for purposes "reasonably related" to the submission or information to the Food and Drug Administration in order to engage in the commercial manufacture, use or sale of the drug after patent expiration.

As you are undoubtedly aware, existing patent law grants a patentee the exclusive right to make, sell or use the patented product. Recently, the Court of Appeals for the Federal Circuit reaffirmed this right where the infringer acted for purposes of obtaining data to be submitted to the government inorder to obtain pre-marketing clearance. Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., ____ F.2d ____, No. 84-560, Slip Op. (April 23, 1984). Section 202 would reverse that decision for all future patent and, retrospectively, for all existing drug patents.

Before the House Judiciary Committee, eminent authorities in the fields of patent and constitutional law opposed enactment of Section 202 of the bill in its present form.

On the patent law side, Commissioner Mossinghoff, speaking for the Administration, said that the Bolar decision clearly recited "hornbook patent law"; overruling it would "overturn 200 years of patent law." Reversing Bolar "would serve as an unfortunate precent in curtailing the exclusionary rights accorded a patentee during the patent term." Statement of Gerald J. Mossinghoff, Assistant Secretary and Commissioner of Patents and Trademarks, June 27, 1984 at 11. Commissioner Schuyler agreed with Commissioner Mossinghoff that Section 202 would reverse 200 years of patent law practice.

The constitutional issues arise because patents are a form of property. Retroactive legislation like Section 202, which would deprive patentees of their existing rights to exclusive use, raises the most serious issues under the Fifth Amendment of the Constitution. That Amendment prohibits the taking of private property for a public use without just compensation.

Two constitutional law scholars, Professor Norman Dorsen of New York University School of Law, and Professor Henry Monaghan of Columbia University Law School, have provided statements to the House Subcommittee on Courts, Civil Liberties and the Administration of Justice which describe the basis for their concerns under the Fifth Amendment's taking clause. Their statements are enclosed. Professor Dorsen testified that, "I am forced to conclude that Section 202 very likely violates the Fifth Amendment's prohibition against the taking of property for a public use without just compensation." Statement of Norman Dorsen, June 27, 1984 at 2-3.

On July 3, 1984, Professor Dorsen wrote to the House Subcommittee in order to respond to questions raised at the hearing. He also described the relevance of a decision by the Supreme Court in Ruckelshaus v. Monsanto Co., which came down the day before the hearing. As Professor Dorsen indicates, the Court held that disclosure of trade secrets by the Environmental Protection Agency contrary to the reasonable investment-backed expectations of the owner constituted a taking of property within the meaning of the Fifth Amendment. That decision is directly applicable to the proposed legislation where exclusive patent rights would be taken -- not just trade secrets. (Professor Dorsen's letter is also enclosed.)

Separately, we had asked Professor Laurence Tribe of the Harvard Law School to examine the constitutional issues in

Section 202. He wrote the Senate Subcommittee on Patents on July 2, 1984 stating that he is convinced that the constitutional problems are "of a very serious character and raise difficulties of real substance both in their philosophical dimensions and in their fiscal implications. . . ." He expressed the hope that the subcommittee would hold hearings to explore the complex constitutional questions that Section 202 unavoidably represents. (Professor Tribe's letter is also enclosed.)

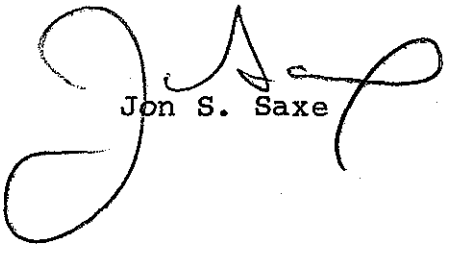
* * *

You can see from the foregoing description that the problems connected with this legislation are extremely serious for those interested in promoting pharmaceutical research and maintaining the benefits of the patent system.

I encourage you to develop interest among your colleagues at the University of Wisconsin and elsewhere to have the Senate Judiciary Committee chaired by Senator Thurmond and the Patent Subcommittee, chaired by Senator Mathias, seriously consider amending the bill to cure the shortcomings described in this letter. Also, I understand the bill is scheduled for markup in Congressman Kastenmeier's Subcommittee on or about July 25. Interaction with Congressman Kastenmeier and his staff is of obvious importance.

I would be pleased to discuss this matter further with you at your convenience. It is of considerable importance to me, both as a member of the pharmaceutical industry and as a patent professional.

Sincerely yours,



Jon S. Saxe

JSS:SMD
Enclosures

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P.S. Since I dictated this letter, a letter written to Congressman Kastenmeier by Bill Pravel, current President of the AIPLA came to my attention. A copy is enclosed. His recommendation on the last page of the letter seems like a supportable compromise position. Since it wouldn't impact the normal scope and term of a patent, it would avoid the problem focused upon by Commissioner Mossinghoff who testified that reversal of the Bolar case, "would serve as an unfortunate precedent in curtailing the exclusionary rights accorded a patentee during the patent term." and that the U.S. Patent Office has "spent a lot of time working to convince other countries that they should strengthen their protection of intellectual property and patents, and this [i.e. legislative reversal of Bolar] would be a clear case of Congress deciding to weaken the rights normally given to patentees."