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Honorable Peter W. Rodino, JR
Chairman
Committe on the Judiciary
2137 Rayburn House Office Building
Washington, D.C. 20515

June 21, 1984

Dear Congressman Rodino,

I am writing with respect to a proposed bill which would amend the Federal Food, Drug and Cosmetic Act to revise procedures for abbreviated new drug applications and would amend title 35 of the United States Code to authorize the extension of patents for certain regulated products. This proposed House bill was published as a Committee Print on June 5. It is my understanding that it was to be formally introduced sometime in June (and perhaps already has been) and that there has been some effort to have it receive committee and Congressional approval without first holding hearings.

This bill would make it easier to obtain FDA approval, by means of an abbreviated new drug application, for the commercialization of drugs which are the same as those previously approved by the FDA for others. It also would provide limited extensions of terms of patents on new drugs to compensate for the part of the normal patent term used up by regulatory review prior to receiving FDA or other required approval.

This proposed bill is complicated, contains many controversial provisions and raises substantial questions concerning the possibly unconstitutional taking of property without compensation. It seems to me extremely unwise to enact such legislation without opportunity for all viewpoints and concerns to be expressed and thoroughly considered. I would urge that this bill not be enacted without first holding hearings.

Honorable Peter W. Rodino, JR
Chairman
Committee on the Judiciary
2137 Rayburn House Office Building
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As a former U.S. Commissioner of Patents and Trademarks, I am particularly concerned that there be no hasty passage of legislation that may affect the incentives provided by the patent laws in ways not contemplated or inadequately considered.

Without trying to go into the merits or to be exhaustive, several provisions may be mentioned which should receive full consideration before adoption.

- Under the recent decision by the Court of Appeals for the Federal Circuit in Roche v. Bolar, use of a patented product during the patent term, to carry out tests aimed at obtaining FDA approval is an infringement of the patent. Section 202 of the bill would reverse this result and is applicable not only to patents issued hereafter, but also to patents now in existence.

- Under section 103 a prospective infringer of a drug patent may give the patent owner notice of his opinion that the patent is invalid o not infringed and the patent owner then has 45 days in which he may file suit. FDA approval could then be given the infringer no later than two years after the notice (I believe this period has now been changed to 18 months), even though the litigation would not ordinarily be completed in that time.

- Some of the limitations on patent term extensions appearing in section 201 seem illogical or inconsistent. Thus the term of a patent on a method of manufacturing a new drug may not be extended if there exists an earlier patent on a <u>different</u> method of manufacture. Similarly a patent on a new method of using the drug may not be extended if the <u>product</u> had previously been patented or if there had been a previous patent on a different, even a non-pharmaceutical use of the product.

This legislation will have important impact on the public availability of new drugs, both as it affects incentives for discovering and developing such drugs and as it encourages their competitive supply. It calls for a fine-tuned compromise of sometimes opposing objectives. In my judgment this is not fully achieved by the bill in its present form.

Honorable Peter W. Rodino
Chairman
Committee on the Judiciary
2137 Rayburn House Office Building
Washington

It is respectfully urged that this bill not be enacted until there have been full hearings before the appropriate committees.

With kindest regards,

Sincerely,

C. Marshall Dann

C. Marshall Dann

cc. Hon. Hamilton Fish, Jr.
Hon. Robert W. Kastenmeier
Hon. Carlos J. Moorehead