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WISCONSIN ALUMNI RESEARCH FOUNDATION

July 16, 1984

The Honorable Robert W. Kastenmeier
House of Representatives
2232 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Kastenmeier:

We have had an opportunity to review H.R. 3605 relating to proposed amendments to the Drug Price Competition and Patent Term Restoration Act of 1984 and we are writing to you to indicate our concern that this bill, as well as the companion bill in the Senate, S. 2748, may be passed without a full hearing and sequential referral. From review of testimony given and a reading of the bill it is evident to us that the bill is complicated, contains many provisions which will be difficult to administer and raises substantial questions of unconstitutionality in the taking of property without compensation. In addition the bill, as a compromise measure, appears to trade off valuable patent protection for accommodations under the Food, Drug and Cosmetic Act and it does little to spur innovation in this country at a time when technology and its transfer has become a currency of high value in the conduct of foreign affairs.

The various aspects of the bill reflect in our mind the short term philosophy which has come to so dominate the business outlook in this country as to put it at a disadvantage with foreign nations and companies, particularly Japan, where long term planning and profitability is a greater consideration. It would seem that the premise of the bill arises from dissatisfaction with the length of time that is required for a generic drug manufacturer to be able to market drugs because of FDA regulatory requirements. The generic companies have, of course, coupled with this the emotionally appealing emphasis of being able to make the drug available at a lower price in the marketplace, with a projected, but not established, equivalent degree of safety and effectiveness as a patent-protected drug. This, of course, completely disregards the effort needed to transfer a new chemical identity into a publicly accepted pharmaceutical product and the necessity to offer some inducement for the private sector to commit the high risk money necessary to accomplish that transition.

In this circumstance, it would appear that we are again facing a situation where science is being made subservient to politics and that, upon analysis, some of the provisions of this bill would in fact weaken our patent system as we now know it. In today's technology transfer atmosphere the protection afforded by the intellectual property right for the heavy investment required in development is more necessary than ever since the lead time given by exclusive knowledge or patents is shorter than ever

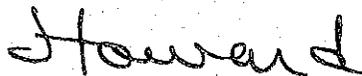
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before. If that lead time disappears through the weakening of the ability to extend exclusive rights to intellectual property or through further weakening of the patent system it may become economically sound to be second in the field. It is such a result that we see being stimulated by some of the terms and provisions of this piece of legislation.

To our eyes the content of this bill evinces that that second-place philosophy already exists in the medical field and we see it philosophically leading to a second place attitude in U.S. industry broadly and as the almost predictable next step, of a willingness to become a second place nation.

The university community through its basic research generates new chemical entities which prospectively can become curative drugs. Other investigations of the application of these various new chemical entities to different disease states is also an ongoing activity at many universities, as is the design of new processes for producing such entities. We are, therefore, concerned with any piece of legislation which adversely affects technology transfer capability and innovation but are particularly concerned with any effort to hastily pass legislation as an accommodation that would affect the patent laws which represent the basis and incentive for effective technology transfer and the strength of this country.

Very truly yours,



Howard W. Bremer
Patent Counsel

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