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February 14, 1977

263-2831

The Honorable the Secretary of Commerce Washington, D. C. 20500

Madam:

It is distressing to find that the Secretary of the Department of Health, Education, and Welfare has urged the withdrawal of the "special" status which was very recently accorded patent applications involving recombinant DNA.

Upon careful consideration and analysis it would appear that accelerated processing of such applications in the Patent Office, under the conditions promulgated, comports with and implements the goal of early disclosure of the results of recombinant DNA research. In addition, such opportunity for handling has been extended to all DNA research, private- as well a Government-sponsored, and as a result of the conditions attendant upon its implementation, encourages compliance by private industry with the NIH guidelines for recombinant DNA research. At the same time, adequate safeguards are provided to preserve the proprietary interests of those who have sponsored and carried out such research. Consequently, the concern over the proposed "special" handling is difficult to understand unless it is couched in the emotionalism which has surrounded the whole recombinant DNA concept.

Unfortunately, where emotional issues are readily generated, as with this research, there are always those who are willing to capitalize upon those issues. There undoubtedly were, and for that matter, still are, those who have utilized the same approach, i.e., fear and emotionalism, in opposing atomic research and experimentation. In that situation, the exigencies of war time overrode many of the delays which otherwise would have been caused by such outcries thereby permitting the United States to achieve a position which has become essential to international coexistence. Nor does less urgency prevail in the fundamentally important field of DNA research.

There is no research without risk. In recombinant DNA research guidelines have been established for Government-sponsored research which are intended to minimize any of the hazards which might be involved and, most importantly and responsibly, the scientific community has responded to the expressed needs for such guidelines, having even acquiesced in a moratorium on DNA research until such guidelines had been generated in an effort to reduce the risk.

Inasmuch as the "special" handling accorded patent applications on recombinant DNA effectively extends the NIH guidelines to recombinant DNA research in the private sector and accelerates prosecution, leading to earlier disclosure, such handling would be totally consistent with the goal of reduced risk.

In view of the foregoing, one can only conclude that at best an incomplete staff analysis of the impact of the "special" status to be accorded patent applications on recombinant DNA occurred before withdrawal of such status was requested.

It is respectfully submitted that accelerated prosecution of patent applications relating to DNA should continue to be available under the conditions set forth in the notice of January 13, 1977 in the Federal Register.

Very truly yours,

Howard W. Bremer Patent Counsel

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cc--The Honorable the Secretary of Health, Education, and Welfare The Honorable Dale Bumpers The Honorable Edward Kennedy