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October 21, 1998

Dr. Patricia A. O'Looney
Director
Research and Training Programs
National Multiple Sclerosis Society
733 Third Avenue
New York, NY 10017-3288

Re: Request for Standing Exception to the Patent Policy of the National Multiple Sclerosis Society
for the University of California

Dear Dr. O'Looney:

It was a pleasure speaking with you regarding the University of California (University) request for a standing exception to certain provisions of the National Multiple Sclerosis Society (NMSS) Policies and Procedures (Policy) as will be discussed below. As you know, the NMSS and the University have had a long and beneficial research relationship. The University appreciates the NMSS's research support and shares its commitment to promptly make the results of that research available for the public benefit. The University has successfully transferred research results for over 40 years. The University Office of Technology Transfer is comprised of approximately 70 individuals dedicated to the prompt transfer of all potentially beneficial discoveries. Among our successfully licensed products and processes are the Cohen-Boyer Process for Splicing Genes that launched the biotechnology industry, the Hepatitis-B Vaccine, the Human Growth Hormone, and the Nicotine Patch. A copy of our FY97 Technology Transfer Program Annual Report is enclosed for your information.

Pursuant to Policy, the University has an obligation to notify NMSS of "all inventions made with the support, in whole or in part, of NMSS research or training grant funds..." To ensure effective licensing of these technologies, the University requests that NMSS consider granting a standing exception to Policy, as discussed below. This standing exception would apply to all active and future NMSS-funded invention cases and awards to the University.

Section 5 of Policy

The following provision of the Policy seriously compromises our ability to transfer the results of NMSS-funded research:

"The grantee institution shall agree that if it or its licensee has not taken effective steps, within three years after a U.S. patent issues on an invention supported by Society funds and administered by the institution, to bring that invention to the point of practical

application, or has not made such invention available for licensing, the Society shall have the right, unless prohibited by federal law, to assume assignment of the patent, to cancel any existing licenses, and to grant new licenses."

The University makes every effort to license its technologies promptly, in accordance with its federally-mandated obligations. However, this NMSS provision is problematic because during negotiations for an exclusive license agreement, we must inform the potential licensee of the conditions imposed by this NMSS provision. Licensees predictably find this requirement highly objectionable, making licensing the invention difficult if not impossible. Obtaining a patent on an invention is a costly and time consuming process. Our experience in licensing technologies is that companies must invest significant resources to develop a commercial product. Once a license agreement is executed, it may take a licensee in excess of ten years to fully develop the technology. In addition, the commercialization process includes the development and implementation of production and marketing programs. One example of this process may include constructing a model, entering and completing preclinical and clinical trials and obtaining all necessary approvals from the United States Food and Drug Administration (FDA). FDA approval, alone, may cost hundreds of millions of dollars to bring a product to market. After such a major financial commitment, a commercial entity wants a guarantee that its license will not be inappropriately cancelled or reduced to a nonexclusive license. Potential licensees are reluctant to accept a licensing agreement whereby, in addition to the University, the sponsor of the research leading to the invention can second-guess both the licensee's and the University's judgment on diligent commercial development and terminate the license. The University is required under the provisions of 35 USC 200 et. seq. to monitor its licensees' diligence. We always include diligence provisions in our licenses, monitor compliance with these provisions and enforce them vigorously. We have terminated licenses in the past based on lack of performance in this regard.

The University proposes a standing exception that would waive the above stated NMSS provision from Policy for NMSS awards made to the University.

Section 7 of Policy

NMSS and the University have previously agreed, as outlined in the October 5, 1983 letter from Dr. Stephen C. Reingold (attached), to an alteration of the income sharing provisions in Policy for the University. I would like to reaffirm the University's income sharing obligations to NMSS as follows:

"NMSS shall participate in income derived from any invention resulting from its support when net royalty income for such invention exceeds \$500,000. NMSS's share shall be proportional to the amount contributed by NMSS for the research project from which the invention arose. "Net royalty income" shall mean gross royalties received less fifteen percent (15%) for the overhead plus deduction of out-of-pocket costs for obtaining and maintaining patents."

Mr. Reingold's letter also states that NMSS is agreeable to such an understanding for the University, however NMSS would prefer to consider each proposal individually as it is submitted. And, upon approval and funding of the award, NMSS will include the following in the award letter:

"In making this award to the University of California (hereafter University) the National Multiple Sclerosis Society (hereafter Society) recognizes that the University takes exception to

paragraph (7) of the Society's Patent Policy, as revised on June 23, 1983. Accordingly, for the purposes and duration of this award, the following paragraph is substituted for the Society's paragraph (7)."

Currently, the parties specifically address this issue each and every time a proposal is submitted and an NMSS award is issued. However, it appears the language stated above has not been inserted into many of the NMSS awards to the University. When this specific language is inadvertently excluded from the award letter, the campus must contact NMSS to confirm this understanding for that particular award. In an effort to streamline administrative processes for both parties, I propose that NMSS consider a standing exception that allows the previously agreed upon income sharing arrangement, as stated above, to apply to all active and future NMSS-funded invention cases and awards made to the University.

If NMSS agrees to grant a standing exception to Policy for the University, as outlined above, please sign below and return one copy of the letter to my attention at the address above. Approval of this request would eliminate the need for the University to repeatedly request waivers for each invention and for NMSS to re-visit these issues for each University invention.

If you would like to discuss this further, I can be reached at (510) 587-6061. If I have not heard from you by November 11, 1998, I will give you a call. We believe that approval of this request will support our mutual interest in making research results available for the public benefit in a timely manner while adding administrative efficiencies to the process. I look forward to your reply.

Sincerely,



M. Jeremy Trybulski
Campus/Sponsor Liaison Analyst

Enclosure

Approved:

National Multiple Sclerosis Society

Name

Title

Date

cc: Associate Director Acanfora