

JUN 11 '97 03:04PM

P.2/5

Medtronic, Inc.
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William W. George
Chairman and Chief Executive Officer

June 11, 1997

Harold Varmus, M.D.
Director
National Institutes of Health
Building One, Room 126
9000 Wisconsin Avenue
Bethesda, MD 20892

Dear Dr. Varmus:

Granting a license to CellPro for Johns Hopkins patents through "march-in-rights" would be a wrong precedent that will greatly impede the transfer of technology from federally funded research to beneficial products for everyone. On behalf of our over 12,000 employees and the tens of thousands of patients that have benefited from our products, Medtronic, Inc. strongly urges you not exercise "march-in-rights" under the Bayh-Dole Act in the licensing and patent dispute between Johns Hopkins University and CellPro, Inc. The conditions foreseen in the act for "march in-rights" are not present in the CellPro case. Hopkins invented processes that have a practical application in stem cell transplantation and properly received patents for the inventions. Hopkins has properly licensed the invention under dispute and has developed a plan with its licensees to ensure that clinicians and patients will have continuous access to this important treatment.

The exercise of "march-in rights" in this case would have a powerful negative impact on the productive relationship that has developed between universities and private industry in the years since the Bayh-Dole Act went into effect. An unanimous federal jury determined, in March 1997, that CellPro, Inc. knowingly and willfully infringed two patents owned by Johns Hopkins University through the manufacture and sales of its Cerepra® SC system. CellPro, Inc. has now petitioned to exercise "march-in-rights" in order to circumvent the court decision. The Bayh-Dole Act was enacted to promote the transfer the innovations of public sponsored research to the public through the expertise of private industry, has been undeniably successful in doing so.

Prior to the Bayh-Dole Act, fewer than 250 patents were issued to universities each year, and many of those patents did not reach the public. Today an average of 1,500 patents are issued annually to universities with many licensed to private industry. The Bayh-Dole Act allowed this to happen by ensuring the certainty of title in the universities to inventions made with

JUN 11 '97 03:05PM

P.3/5

Harold Varnus, M.D.

June 11, 1997

Page Two

government funds and allowing for the exclusive licensing of these inventions. University inventions usually require an industrial partner to secure the capital investment for the development necessary to bring the product to the public.

Medtronic is proud to have brought many important, new treatments to patients through partnerships with universities and non-profit research institutes, but our company can only incur the financial risk to invest in these innovative medical technologies under the protection of patent law. If a license was granted to CellPro under a march-in proceeding, there will be a dangerous precedent set. As a result, any patent for an invention that may affect public health would be bound-up in uncertainty. This sort of uncertainty would destroy a system that has brought significant health benefits to the public. It would be a tragedy to allow the knowing and willful infringement of a patent to inhibit the progress of medical technology.

Please consider the impact this decision will have in impeding the transfer of important new technology to beneficial products for everyone and do not grant a license to CellPro.

Sincerely,

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