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COGR Testimony at NIH Hearings on March-in Rights

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Andrew Neighbour, a member of the COGR Board of Directors, delivered testimony at the NIH on march-in rights

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**NIH Hearing on Essential Inventions' Request for Implementation of the
Agency's March-in Rights Under 35 U.S.C. §203**

Good morning and thank you Dr. Zerhouni and Director Rohrbaugh for providing this opportunity to speak before this public meeting today. My name is Andrew Neighbour. I am Associate Vice Chancellor for Research at the University of California, Los Angeles. I stand here today, however, to represent the Council of Governmental Relations (COGR) of which I am a Board Member and Chair of its Contracts and Intellectual Property Committee.

COGR is an association of 150 leading research universities in the United States and several affiliated hospitals and research centers. The work of our association is focused on seeking a clear understanding of and complying with federal regulations that govern sponsored research at universities. An important aspect of these regulations and policies is their impact on the transfer of federally funded research to the private sector in accordance with the Bayh-Dole Act of 1980.

It is not my purpose here today to comment specifically on the merits of the proposal in question from Essential Inventions. Clearly the plight of the AIDS population throughout the world and the need for access to effective and affordable treatment options is of critical concern to all research universities. Indeed, discovering, preserving, and transferring the ongoing flow of important, life-saving new discoveries for the benefit of the public is a major element of every research university's mission. The University of California, for example, has more than 1,200 inventions licensed to the private sector that were supported in whole or in part with federal extramural research funds.

We are speaking here today, because of our serious concern that the process that fosters and encourages this transfer of federally funded inventions to the private sector may be in serious jeopardy if NIH upholds Essential Inventions' request by using the Bayh-Dole Act as the means to achieve their ends..

As you have heard, the Bayh-Dole Act is a practical and inspired piece of legislation. Furthermore, government funded research is crucial to US economic growth and competitiveness. The achievements of this Act derive from its consistency with America's commitment to free enterprise, and from the notion that market need and value govern the adoption and commercialization of innovation. In COGR's view, the Act and its future implementation are in serious jeopardy from this proposal of Essential Inventions.

We recognize that this situation is both unusual and unprecedented. The development and testing of Abbott's drug Norvir[©] was supported directly with federal grants, there being no license of a university invented technology to Abbott. However, our concern stems from the reality that utilizing the march-in provision to take a proprietary drug from its creator or to apply pressure to control its pricing will severely damage the balance between the government, academia and industry that is serving the public so well.

We acknowledge that the language of the Act allows the funding agency to march-in and identify a new licensee if the original licensee or owner fails to [quote] "take effective steps to achieve practical application of the subject invention" [end quote] (35 USC §1.a). Further, the term "practical application" is defined in the legislation as [quote] "the invention[']s...benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms" [end quote].

Herein lies the crux of this issue. Under the law, the government can march-in when “effective steps to achieve practical application of a subject invention in such field of use” have not been taken. In this case, however, “practical application” of the government-funded invention was undertaken by the owner, and the public now has access to Norvir. In COGR’s opinion, Bayh-Dole only regulates *licensing* and, in that context, requires that the licensing terms must be reasonable to encourage diligent commercialization of a product for the public good. “Reasonable terms” does not in our view apply to pricing of the resulting product in this or any other situation. Further, the government funding agency does not play a role in defining the reasonableness of the licensing terms. This is a market-driven process arising from negotiations between the licensor and the licensee.

While the legislation states that the owner of the federally funded technology should make it available to the public, NIH has itself confirmed in its July 2001 document entitled “NIH Plan to Ensure Taxpayers' Interests are Protected” that Bayh-Dole does not empower the government in any way to influence or dictate licensing or commercialization terms. This includes defining the consideration that is provided the patent owner in return for the license as well as the pricing of the eventual product.

Why then is COGR seriously concerned about this proposal? Universities license their early stage innovations to industry because, as non-profit centers of academic teaching and research, it is not their role to produce commercial products. They need an industrial partner to complete the product design, manufacturing, testing and distribution of products that incorporate the inventions made on our campuses. When the invention is supported in whole or in part with federal funds, we are required to notify the licensee of the government’s retention of a non-

exclusive right to use and the potential of the march-in provision. Companies accept these terms in the license because they believe that they will be diligent in developing and commercializing the invention and, thus, do not expect the march-in to be invoked. They view it as a protection for the university and the public against the possibility that the invention would be warehoused. If potential licensees believed that the march-in provision would allow the government to use its option to wrestle away the technology if any applicant felt that the market price was too high, they would be extremely unlikely to execute the license. This would have profound effects on the ability of universities to find licensees for its technology in all industry segments. The biopharmaceutical industry would be especially sensitive because of the enormous investment they must make in the development and testing of a new drug prior to placing it on the market. Embarking on that path, only to find after millions of dollars investment that the rights were to be taken away, would be a major deterrent to licensing the invention, thereby destroying the relationship that exists between the government, universities and the private sector that is so necessary for effective technology commercialization.

We firmly believe that Bayh-Dole was not intended to provide the funding agency with the power to control the market. Other mechanisms exist by which this can be achieved.

In the twenty-four years since the enactment of Bayh-Dole, there has been no implementation of the march-in provision. This clearly indicates that the market is providing the required checks and balances for assuring that public interests are served. Multiple federal audits on university technology transfer programs over the years have also not identified any situation to which practical application was not made by a licensee. To use the march-in right in this situation as a means to pressure Abbott to adjust the price of Norvir would be a dangerous precedent that would severely undermine the value of this essential legislation.

Furthermore, while this unfortunate circumstance should be examined further, it is not appropriate in our opinion to use it as the test case by which the Bayh-Dole legislation be reinterpreted or changed. Such a process should only occur after intensive dialog and analysis by all stakeholders involved in the transfer of federally-funded technologies.

For these reasons, COGR urges the NIH to make a strong statement in support of the proper exercise of march-in rights and seek alternate remedies to address this situation as appropriate. We see no reason to tamper with this proven platform for promoting government investment in discovery and its application for public use and benefit as this will significantly undermine the public/private partnership that serves our nation so well.

Thank you, Dr. Zerhouni, Dr. Rohrbaugh, and everyone here for your attention.

Andrew Neighbour

May 25th, 2004