NATIONAL INSTITUTES OF HEALTH
OFFICE OF THE DIRECTOR

In the Case of

NORVIR®

Manufactured by

ABBOTT LABORATORIES, INC.

Introduction

The NIH received letters from members of Congress and the public requesting that the Government exercise its march-in rights under the Bayh Dole Act (Act), 35 U.S.C. §§ 200-212, in connection with one or more patents owned by Abbott Laboratories, Inc. (Abbott). The letters expressed concern over the price of Norvir®, which is covered by the patents and marketed by Abbott for the treatment of patients with HIV/AIDS.

The march-in provision of the Act, 35 U.S.C. § 203, implemented by 37 C.F.R. § 401.6, authorizes the Government, in certain specified circumstances, to require the funding recipient or its exclusive licensee to license a Federally-funded invention to a responsible applicant or applicants on reasonable terms, or to grant such a license itself.

After careful analysis of the Bayh-Dole Act and considering all the facts in this case as well as comments received, the National Institutes of Health (NIH) has determined that it will not initiate a march-in proceeding as it does not believe that such a proceeding is warranted based on the available information and the statutory and regulatory framework.

Background on the Invention

From 1988 through 1993, ritonavir was developed at Abbott Laboratories partly through the use of Federal funds and falls within the claims of a number of patents owned by Abbott. [1] In 1996, ritonavir (sold under the tradename "Norvir®") was approved by the FDA for marketing.

Other U.S. and foreign patents may exist which cover certain aspects of the marketed compound including specific formulations or delivery techniques, and may not be subject inventions within the meaning of the term as defined in 35 U.S.C. § 201(e).[2] These inventions would not be

[1]These patents are: U.S. Patent Nos. 5,541,206,. 5,635,523, 5,648,497, 5,674,882, 5,846,987, and 5,886,036.

[2]The term "subject invention" means any invention of the funding recipient conceived or first actually reduced to practice in the performance of work under a funding agreement.

subject to the Government's march-in authority.

Statutory and Regulatory Background

The stated policy and objective of the Bayh-Dole Act is:

> to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

Act at § 200. Toward this goal, the Act addresses not only rules governing the licensing of Government-owned inventions, but also addresses the rights of Federal contractors[3] to elect title to inventions made with Federal funding.

In giving contractors the right to elect title to inventions made with Federal funding, the Act also includes various safeguards on the public investment in the research. For example, the Federal agency retains a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. See 35 U.S.C. § 202(c)(4). In addition, the Act includes march-in rights which provide a Federal agency with the authority, in certain very limited and specified circumstances, to make sure that a federally funded invention is made available to the public. The march-in provisions are set out in Section 203(a), which states that:

> With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a

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[3] Section 201(c) defines the term "contractor" as any person, small business firm, or nonprofit organization that is a party to a funding agreement. Executive Order 12591 expanded this definition to include large businesses.

nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such -

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

The Department of Commerce regulations implementing the Act and specifying the procedures that govern the exercise of march in proceedings are set forth at 37 C.F.R. § 401.6. The regulations provide that whenever an agency receives information that it believes might warrant the exercise of march-in rights, it may initiate a march-in proceeding after notification of the contractor and a request to the contractor for informal written or oral comments.

Public Comments

The NIH held a public meeting on May 25, 2004 at which comments were presented by advocates for and against the use of the Government's march-in authority in connection with Norvir®. The speakers presented differing perspectives regarding the interpretation and intention of the march-in provisions, the reasons for the increase in the price of ritonavir, and the anti-competitive effect of that price increase.

The NIH also has received written comments from a variety of groups and individuals representing universities, the AIDS community, pharmaceutical interests, drafters of the Bayh-Dole Act, and other interested parties. These comments along with those submitted at the public meeting are available on the NIH Office of Technology Transfer website at http://www.ott.nih.gov/policy/meeting/may25.htm.

The NIH is aware that members of Congress and the public have asked the Federal Trade Commission (FTC) to investigate the potential anti-competitive effects of the increase in the

price of Norvir®. The NIH agrees that the FTC is the appropriate agency to address this issue.

After carefully considering all the information provided and otherwise made available, the NIH does not believe the initiation of a march-in proceeding is warranted.

Discussion

The NIH is the steward of medical and behavioral research for the nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. Each year, a wealth of scientific discoveries emanates from the NIH intramural laboratories and from extramural activities under grants and contracts. Bringing these discoveries from "the bench to the bedside" requires drug and product development, scale-up, clinical testing, and finally marketing and distribution. Success in accomplishing this colossal task and fulfilling our primary mission of improving public health requires the participation of industry partners.

The NIH supports fundamental research that may lead to the development of pharmaceutical products. Occasionally, the NIH funds a technology that ultimately is incorporated into a commercial product or process for making a commercial product. It is important to the NIH that pharmaceutical companies commercialize new health care products and processes incorporating NIH-funded technology thereby making the technology available to the public. A central purpose of the Bayh-Dole Act involves the development and commercialization of such products out of federally-funded research.

Section 203(a) of the Act provides in part that march-in rights may be exercised by the funding Federal agency based on any of four conditions: (1) when "practical application" of the subject invention has not been achieved or is not expected to be achieved in a reasonable time, (2) when the action is necessary to alleviate health or safety needs, (3) when action is necessary to meet requirements for public use specified by Federal regulation that the contractor has failed to meet or (4) when the U.S. industry preference of Section 204 of the Act has not been met. The third and fourth conditions are not relevant to this discussion[4].

Practical Application of the Subject Inventions

A composition or product, such as Norvir®, that has achieved practical application is defined in Section 201(f) to mean that it is manufactured "under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."

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[4]The last two conditions are clearly not relevant. Subparagraph (3) narrowly applies to "public use" specified by Federal regulations, but there are no regulations that apply in this case. Subparagraph (4) is not relevant because Abbott manufactures Norvir® in the United States.

In 1997, the NIH reviewed a march-in request from CellPro, Inc. that asserted Baxter Healthcare Corporation (Baxter) had failed to take effective steps to achieve practical application of the subject inventions. NIH determined that Baxter "met the statutory and regulatory standard for practical application" as evidenced by its "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public…." Accordingly, the NIH determined not to initiate march-in proceedings.[5]

Similarly, the record in this instance demonstrates that Abbott has met the standard for achieving practical application of the applicable patents by its manufacture, practice, and operation of ritonavir and the drug's availability and use by the public.

Ritonavir has been on the market and available to patients with HIV/ADDS since 1996, when it was introduced and sold under the tradename Norvir® as both a standalone protease inhibitor and a booster to increase the effectiveness of protease inhibitors marketed by other companies. Thus, the invention has reached practical application because it is being utilized and has been made widely available for use by patients with HIV/AIDS for at least eight years.

Health or Safety Needs

Norvir® has been approved by the Food and Drug Administration as safe and effective and is being widely prescribed by physicians for its approved indications. No evidence has been presented that march-in could alleviate any health or safety needs that are not reasonably satisfied by Abbott. Rather, the argument advanced is that the product should be available at a lower price, which is addressed below. Thus, the NIH concludes that Abbott has met the statutory and regulatory standard for health or safety needs.

Drug Pricing

Finally, the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand.[6] In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling

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[5]The determination also evaluated the health or safety need prong and found that Baxter had "taken appropriate steps to reasonably satisfy this need." The other two prongs were held to be "clearly not relevant."

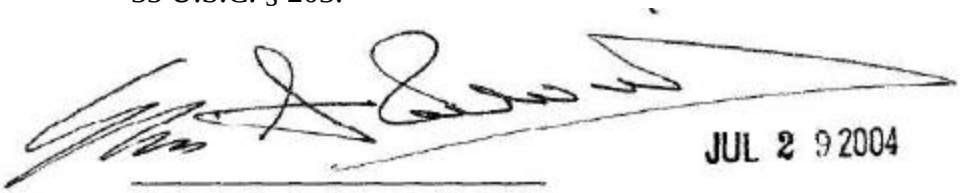
[6]In addition, NIH addressed "The NIH 'Reasonable Pricing' Clause Experience" in its report to Congress, "A Plan to Ensure Taxpayers' Interests are Protected," July 2001, available at http://www.nih.gov/news/070101wyden.htm.

prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.

Conclusion

Norvir® has been available for use by patients with HIV/AIDS since 1996 and is being actively marketed by Abbott and prescribed by physicians primarily as a booster drug. Accordingly, this drug has reached practical application and met health or safety needs as required by the Bayh-Dole Act. The NIH believes that the issue of drug pricing is one that would be more appropriately addressed by Congress, as it considers these matters in a larger context. The NIH also maintains that the FTC is the appropriate agency to address the question of whether Abbott has engaged in anti-competitive behavior.

The NIH is cognizant of the care with which Congress crafted the march-in language and understands that it has the responsibility to exercise its march-in authority deliberately and with great care. As such, the NIH has determined that it does not have information that leads it to believe that the exercise of march-in rights might be warranted in this case within the meaning of 35 U.S.C. § 203.



Elias A. Zerhouni, M.D.
Director, NIH

Introductory Remarks by Dr. Mark Rohrbaugh

List-of-Speakers

Written Comments Received:

Senator Birch Bayh

Robert Huff, Editor GMHC Treatment Issues

Norman J. Latker, former Patent Counsel, HEW

John Erickson, President & CSO Sequoia Pharmaceuticals

Dan Ravicher, Executive Director, Public Patent Foundation

C. Peter Magrath et al, NASULGC, AAU and ACE

Carl E. Gulbrandsen, Managing Director WARF

Katharina Phillips, Council on Governmental Relations

Patricia Harsche Weeks, Immediate Past President AUTM

Joseph P. Allen, President NTTC

Heather L. Mason, V.P. Pharmaceutical Specialty Optns., Abbott Labs

Benjamin Young, OHHP

Lynda Dee, Co-Chair AIDS Treatment Activists Coalition

Julie Britton Haden, West Virginia Coalition for People with HIV/AIDS

Rhonda Connard & Amanda Lowther, Covenant House

Michael Weinstein, President AIDS Healthcare Foundation

Stephan E. Lawton, V.P. & General Counsel, BIO

David D. Ho, The Aaron Diamond AIDS Research Center

David Gollaher, California Health Care Institute

David Miller President iBioTM

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James Love Pres. Essential Inventions Inc.

Jerome Reichman Duke Univ.