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NIH INVITES PUBLIC COMMENT ON PETITION SEEKING DRUG PRICE CONTROLS

by

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The incentives for companies to make use of patented inventions emerging from federally-funded research may be shaped by the outcome of a petition filed with the U.S. Department of Health and Human Services (HHS) by a group called Essential Inventions. The petition contends that federal law gives federal agencies the authority to regulate the prices of products that are based on technology wholly or partly funded by federal grants and which have been licensed to the private sector. Although the petition is focused on the discretion of Abbott Laboratories to set prices for its drug Norvir, the legal theory underlying the petition — if upheld — would be applicable to all U.S. industries. HHS heard testimony on the petition at a May 25, 2004, hearing at the U.S. National Institutes of Health (NIH), and the agency has invited further comments from the public.

Licensing of federally-funded technology is governed by the Bayh-Dole Act of 1980, 35 U.S.C. § 200 *et seq.*, which Congress enacted to promote the commercialization of that technology. Licensees normally receive exclusive rights. To guard against "nonuse or unreasonable use" of the technology, the statute also provides that another applicant can "march in" and license it where the licensee "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application" of the technology, or if necessary "to alleviate health or safety needs which are not reasonably satisfied" by the licensee. 35 U.S.C. § 203. The Essential Inventions petition argues that this "march in" provision can be invoked based on a licensee's decision to set "unreasonable" prices for a product.

Notable at the NIH hearing was the testimony of former Sen. Birch Bayh, co-sponsor of the legislation, who argued that the petition misconstrues the Act, and that the "march-in" provisions were meant to avoid the scenario of firms licensing technologies simply "to suppress them because they could threaten existing products."

Parties interested in commenting should write to HHS Secretary Tommy Thompson, copying Dr. Mark Rohrbaugh, Director, Office of Technology Transfer, Office of Intramural Research, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852.

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