

SHERROD BROWN
THIRTEENTH DISTRICT
OHIO

COMMITTEE ON
ENERGY AND COMMERCE

RANKING MEMBER,
SUBCOMMITTEE ON HEALTH

SUBCOMMITTEE ON
ENERGY AND AIR QUALITY

SUBCOMMITTEE ON COMMERCE, TRADE,
AND CONSUMER PROTECTION

COMMITTEE ON
INTERNATIONAL RELATIONS

SUBCOMMITTEE ON
ASIA AND THE PACIFIC

Congress of the United States
House of Representatives
Washington, DC 20515

March 27, 2004

DISTRICT OFFICES:
205 WEST 20TH STREET, SUITE M-230
LORAIN, OH 44052-3777
(440) 245-5350
FAX: (440) 245-5355
1-800-234-6413 (OH13)

1655 WEST MARKET STREET, SUITE E
AKRON, OH 44313-7021
(330) 865-8450
FAX: (330) 865-8470

WASHINGTON OFFICE:
2332 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-3401
FAX: (202) 225-2266

sherrod@mail.house.gov
<http://www.house.gov/sherrodbrown/>

Elias A. Zerhouni, M.D.
Director
National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Zerhouni:

Thank you for your March 25, 2004 testimony before the House Committee on Energy and Commerce, Subcommittee on Health.

At the hearing, I raised my concern that the Office of Technology Transfer has indicated it may make a recommendation on requests by over 200 groups and physicians that the Secretary of Health and Human Services open competition on the federally funded patents for the important AIDS drug, Norvir, without a public hearing.

This matter raises serious concerns. As I noted at the hearing, Norvir is a government funded invention that was being sold for multiple times the price in Canada and other Western European countries *before* a 400% price hike that was only applied in the U.S. and primarily when used with competitors' products. The march-in petitions ask the Department of Health and Human Services to determine whether this chain of events constitutes making a federally funded invention "available to the public on reasonable terms." 35 U.S.C. § 201(f); 37 C.F.R. 401.2(e); 37 C.F.R. 401.14.

At the hearing, you made a commitment that if the Bayh-Dole Act and implementing legislation give you any leeway, the National Institutes of Health (NIH) will grant the request of the petitioners for a public hearing so that all relevant issues can be fully aired before your decision. I want to thank you for that assurance.

My staff has reviewed the applicable legislative language and implementing regulations and confirms that there is no legal barrier to holding a hearing before you make a recommendation to the Secretary. Rather, the regulations grant NIH substantial discretion to tailor the procedures to meet interests of procedural fairness and public interest.

For example, 37 C.F.R. § 401.6(e) provides:

Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present.

37 C.F.R. § 401.6(l) further states: “Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.” These provisions give you ample authority to design an open and inclusive process for considering applications that have already been supported by over 200 organizations and individuals who care for people with AIDS in this country.

I recognize that, consistent with 35 U.S.C. § 202(c)(5),¹ NIH may close any portion of a hearing “that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees”. 37 C.F.R. § 401.6(e). This provision was not used in the CellPro proceedings to constrain access to information that does not touch on confidential business practices and plans. Indeed, much of the record of the CellPro case is publicly available from the NIH website. And, since the patent holder’s utilization plans are not an issue in this case, this should not present a problem.

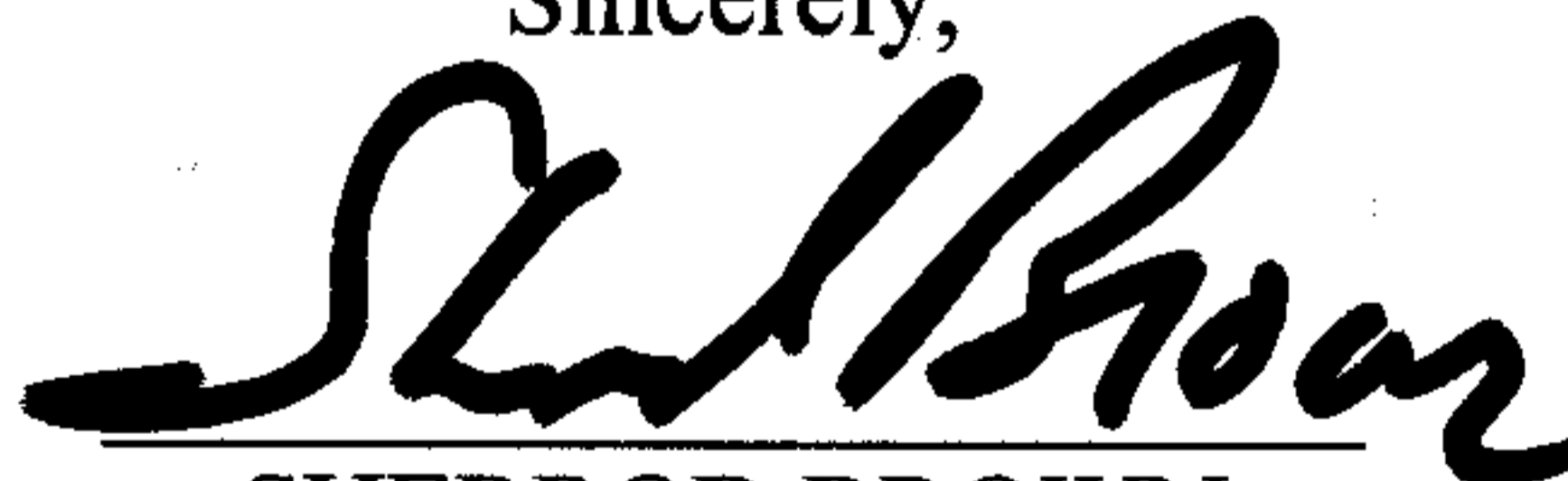
The petitioners and their supporters have requested a hearing to address factual disputes, such as the effects of prices and practices on public health and welfare, the reasonableness of the terms under which the patents are available to the public, the degree to which the government march-in rights are sufficient for generic competition (the “patent landscape” on ritonavir) and other matters of general public concern and knowledge.

You suggested in your testimony that NIH might consider the issue of pricing of a federally funded pharmaceutical invention an issue that “goes beyond NIH.” I trust this statement was intended to support your desire to “tend toward openness” in the process of reviewing march-in petitions. If, however, it was meant to express a legal conclusion that the Bayh-Dole Act’s “reasonable terms” grounds for a march-in do not include pricing considerations I would appreciate a further explanation of how that view comports with the language of the Bayh-Dole Act, its legislative history and the clear intent of the Congress.²

Finally, I suggest NIH consult with the Federal Trade Commission to obtain their expertise on the possible anti-competitive aspects of the discriminatory price increase, and what will be the likely impact on competition in the protease inhibitor market.

Given your commitment on March 25, and the context of a permissive legal and regulatory framework, I expect that you will ensure that a public hearing is held on the march-in petitions before NIH makes a recommendation to the Secretary. I would appreciate it if you keep my office informed about when the hearing will be held, how it will be publicized to increase participation by affected communities and what procedures will be followed. If my conclusion that your office will hold a hearing is mistaken, please identify any legal or other obstacle to holding a hearing NIH has identified.

Sincerely,



SHERROD BROWN
Member of Congress

¹ 35 U.S.C. § 202(c)(5) provides that “any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter [authorizing march-in proceedings] shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.”

² See Peter S. Arno and Mickey Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part From Federally Funded Research*, 75 Tul. L. Rev. 631 (2001) (reviewing the legislative history of the march-in provisions and Congress’s focus on price and competition concerns); S. Rep. No. 96-480, at 30 (noting an objective to avoid “windfall profits” on federally funded inventions).