News Release

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NIH REJECTS ACTIVISTS' CHALLENGE TO PATENT EXCLUSIVITY

(*In re Xalatan*)

The National Institutes of Health (NIH) recently announced that it will not grant a "march-in" petition seeking to abrogate the exclusivity of patent rights held by a pharmaceutical company. The petition, filed by a group called Essential Inventions, argued 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. NIH's decision was a victory for WLF, which had filed comments on August 9, 2004, urging NIH to deny the petition.

Licensing of federally-funded technology is governed by the Bayh-Dole Act of 1980, 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.

The Essential Inventions petition claimed that Pfizer had set excessive prices for its drug glaucoma Xalatan (latanoprost) by charging more for the drug in the U.S. than overseas. The petition argued that the march-in provision of the Bayh-Dole Act could be invoked based on a licensee's decision to set "unreasonable" prices for a product. WLF's response analyzed the Act and its legislative history to show that the Act was never intended to serve as a price-control law. Rather, it was intended to stimulate investment in inventions arising from federally-supported research – a purpose that would be undermined by adding price controls that Congress did not authorize and for which neither the companies nor the government ever bargained.

In denying the petition, NIH stated, "The issue of whether drugs should be sold in the United States for the same price as they are sold in Canada and Europe has global implications, and thus, is appropriately left for Congress to address legislatively."

WLF is a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. Since its founding in 1977, WLF has engaged in litigation and advocacy to defend and promote individual rights and a limited and accountable government. In the area of health care, WLF successfully challenged the constitutionality of Food and Drug Administration restrictions on the ability of doctors and patients to receive truthful information about off-label uses of FDA-approved medicines. WLF has also sought to promote the accessibility of medicines by submitting comments to the Centers for Medicare and Medicaid Services (CMS) urging the agency to commit to continued coverage of off-label anti-cancer therapies based on FDA-approved medicines in its "Part B" program, its forthcoming "Part D" program, and its Section 641 demonstration project for self-administered cancer medicines.

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