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Compulsory License: United States of America

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28 U.S.C § 1498 (a) (Governmental Use)

The United States (U.S.) does not have any provisions for a compulsory license. The closest provision that it does have to the licensing of medicines and vaccines is what is called March-in rights. March-in rights allow the U.S. government to grant licenses to patented inventions provided the development of invention was funded using federal funds and the patent owner has not taken steps to:

- achieve practical application of the invention;
- reasonably satisfy the health and safety needs of the country;
- reasonably meet requirements for public use specified by federal regulations; or
- grant an exclusive right to use the patented invention to a party without obtaining a required promise that the invention be substantially manufactured in the U.S., or where the licensee breaches this promise.

Theoretically, March-in rights are quite powerful, however from a practical perspective, to date, no federal agency has exercised its March-in rights.

In the case of Norvir®,

In January 2004,National Institute of Health (NIH) received petitions from Essential Inventions, Inc., the public and from members of the U.S. Congress, to exercise March-in rights for patents owned by Abbott laboratories, Inc. (Abbott) covering the drug Ritonavir, sold under the tradename Norvir®, a prescription drug used in treatment of AIDS. In 2003, Abbott raised the price of Norvir® to 400% for U.S. customers and refused to license Norvir® to another company for purposes of providing protease inhibitors formulated with Norvir®. The NIH denied the petition finding no grounds to exercise its March-in rights.

In the case of Xalatan®,

In January 2004, the Essential Inventions, Inc. petitioned N IH to adopt a policy of granting March-in rights to patents when the patent owner charged a significantly higher price in the U.S. than it did in other high income countries. Their request was based on Pfizer’s glaucoma drug being sold in the U.S. at prices two to five times the prices in other high income countries. The NIH held that the extraordinary remedy of

March-in rights was not an appropriate means for controlling prices.

In the case of Fabrazyme®,

On August 2, 2010, Dr. C. Allen Black, Jr. submitted a request on behalf of his patients with Fabry disease Department of Health and Human Services (HHS), asking the Government to exercise its March-in rights under the Bayh-Dole Act. The request concerned HHS to grant to open license to certain patents owned by Mount Sinai School of Health that were funded by NIH (and exclusively licensed by Mount Sinai to Genzyme Corporation) to permit manufacturing of Fabrazyme®.

On November 3, 2010, the NIH denied the petition of March-in rights stating that under the current FDA drug approval process, it would take years of clinical testing to bring a biosimilar of Fabrazyme® to the market and therefore granting March-in rights would not address the problem. The NIH also stated that it would continue to monitor the situation and if Genzyme could not meet its production deadlines, or if a third-party licensee requested a license, the March-in request would be revisited.

35 U.S.C. § 203 (Bayh- Dole Act of 1980)

35 U.S.C § 203 allows the U.S. government to exercise March-in rights for any invention conceived or first reduced to practice in the performance of work under a federal funding agreement. This statue is only invoked under special circumstances and requires reasonableness. To date, government agency has never exercised March-in rights.

In *University of Rochester v. G.D. Searle & Co., 358 F. 3d 916 (Fed. Cir. 2004)*, the Federal Circuit rejected a claim that Bayh- Dole altered the grounds for patentability. Quoting an *amicus curiae*, the Court stated that no connection existed between the Bayh-Dole Act and the legal standards employed to access patentability. Furthermore, none of the eight policy objectives of the Bayh-Dole Act encouraged or condoned less stringent application of the patent laws to universities than to other entities.

The recent "*Coronavirus Preparedness and Response Supplemental Appropriations Act*" enacted by the U.S. Congress allocated about $3 billion for the development of necessary countermeasures and vaccines in response to the coronavirus. March-in rights under Bayh-Dole Act would apply to products developed with these funds.

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