DRAFT

Reasonable Pricing - A New Twist for March-In Rights under the Bayh-Dole Act

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(1)

In 1980, the Bayh-Dole Act gave universities and small businesses the right to own their inventions made with federal funding. Prior to this time, the only existing statutes required certain agencies to own inventions arising from funded research.

Although there was spirited opposition to Bayh-Dole when it was brought before Congress ~~in 1980~~, a broad political consensus was ultimately built around the notion that market forces would do a ~~far~~ better job of disseminating government-sponsored inventions than bureaucracies ~~ever~~ could.

~~This~~ law ~~was developed with bipartisan support and the principal sponsors were Senators~~ Robert Dole, ~~a Republican from Kansas and Birch Bayh, a Democrat from Indiana~~. In a memorandum[3] in 1983 and Executive Order 12591[4] in 1987, President Reagan ~~applied~~ extended this law to large business contractors.

IN practice, Bayh-Dole

~~It~~ has fostered a potent four-way partnership between researchers, their institutions, government and industry. That partnership has evolved into the most powerful engine of practical innovation in the world, producing innumerable advances that have extended life, improved its quality and reduced suffering for hundreds of millions of people.

The Act in particular

Universities have been very successful in commercializing their inventions. ~~Bayh-Dole~~ is generally credited for contributing to the dramatic increase over the last 20 years in the number of university inventions, patents, ~~licenses and royalties~~.

reported granted, royalty bearing licenses negotiated collaborative agreements and New startups. F.N. 1.c Economist Autm

Under Bayh-Dole, the Government has certain rights including a paid-up license[5] and march-in rights.[6] Although the Government has never[7] exercised march-in rights under this law, there have been several petitions to the Department of Health and Human Services (HHS).

On March 3, 1997, HHS was asked by CellPro, Inc. to march-in against Johns Hopkins University and its licensees of three stem cell patents. The matter was referred to NIH, which funded the research. NIH concluded that march-in proceedings were not warranted and denied the petition on August 8, 1997.[8]

(2)

move the language of the B-D

An article by Peter S. Arno and Michael H. Davis[9] asserts that march-in rights should be used to combat the high price of drugs invented by universities with federal funding.[10] On January 29, 2004, James Love and Sean Flynn filed two petitions to HHS on behalf of Essential Inventions, Inc. relying on this theory. These petitions are still pending.[11] But before examining this theory, we should first consider the history of march-in rights.

move

History

was a condition of ownership a government funded inventing

March-in Rights were first suggested ~~as part~~ in the 1947 Attorney General's Report and Recommendations to the President on an appropriate government patent policy considered ~~Negotiated~~ ~~Necessitated~~ necessary by the expanding government research and development program after WWII.

... That Report recommended that "[t]he contractor (or his assignee) shall be required to offer nonexclusive licenses at a reasonable royalty to all applicants" if the contractor or assignee does not place the invention in adequate commercial use within a designated period.[16]

Thereafter, similar provisions were used

March-in rights ~~existed prior to Bayh-Dole and were described~~ in the Presidential Memoranda and Statements of Government Patent Policy by Kennedy (1963)[12] and Nixon (1971)[13]. These were implemented in the Federal Procurement Regulations[14] and various agency procurement regulations. ~~In addition, they were mentioned in the Attorney General's Report in 1947.~~[15]

as part of

(3)

According to section 1(f) of the Kennedy Memorandum, the Government shall have the right to require the granting of a nonexclusive royalty-free license to an applicant if (1) the contractor or grantee who has been permitted to own[17] the invention, its licensee or assignee has not taken effective steps within three years after the patent issues to bring the invention to the point of practical application[18] or (2) has made the invention available for licensing royalty free or on terms that are reasonable in the circumstances or (3) can show why it should be able to retain ownership for a further period of time. There was also a march-in right in section 1(g) if the invention is required for public use by Government regulations or as may be necessary to fulfill health needs or other public purposes stipulated in the contract or grant. However, the required licensing could be royalty-free or on terms that are reasonable in the circumstances. As stated in the fourth paragraph of the Kennedy Memorandum, the reason for march-in rights was to "guard against failure to practice the invention."

as in the 1947 Attorney General's Recommendation limited

The march-in rights in section 1(f) of the Nixon Memorandum are very similar[19] to those in the Kennedy Memorandum except that the working requirement was expanded to assignees and licensees and the Government could also require the granting of an exclusive license to a responsible applicant on terms that are reasonable under the circumstances. The health march-in right in section 1(g) was expanded to refer to safety. It is interesting that the concept of "reasonable terms" is used in the Presidential Memoranda with respect to the required licensing and not to the availability or price of a patented invention arising from federally funded research.

if the patent owner was not pursuing practice of the invention

eliminating the arduous task of justifying such ownership after identification of such inventions

Prior to Bayh-Dole, there was little[20] activity in march-in rights. At most, the focus was on whether a particular invention funded by the Government was being used.

use by all federal

a contractual agreement to elect ownership

Institutional Patent Agreements

The Bayh-Dole Act relies heavily on Institutional Patent Agreements (IPA) which were used by NIH beginning in 1986 and NSF in 1973 to handle inventions for universities with an approved patent policy. Under the IPA, the university had ~~the automatic rights~~ to any invention made with NIH or NSF funds ~~and did not have to request rights under a deferred determination policy~~. Bayh-Dole can be considered a codification[21] of the IPA, which was authorized for all agencies in 1978. The model IPA was developed by the University Patent Policy Ad Hoc Subcommittee[22] of the Committee on Government Patent Policy of the Federal Council of Science and Technology after receiving comments from many agencies and universities. However, implementation of the IPA was postponed for 120 days at the request of Senator Gaylord Nelson on March 17, 1978, who held hearings.[23] The IPA regulation became effective on July 18, 1978.[24]

and had march-in provision similar to —.

During the Nelson hearings, march-in rights were discussed. In particular, Donald R. Dunner, 1st Vice President of the American Patent Law Association, indicated that:

> "Much has been said about march-in rights. . . . The point has been raised that march-in rights have been available for 10 years, and they have never been used; ergo, they are a failure. We submit that is not the case. There is no evidence to indicate that march-in rights should have been used in a specific situation and were not used. In fact, we submit the high probability is quite the contrary. Where an invention is significant, we submit that the marketplace will take care of the situation. Competitors who want to use a given piece of technology follow a standard routine procedure. They first determine whether there is any patent cover on the development, and then they evaluate the patent cover. If they feel they want to get into the field, they will try to get a license. If they cannot get a license in a Government-owned situation, they will go to the Government agency involved, and they will say, 'I cannot get a license.' They will point to the conditions which the IPA specify as to when march-in rights should be applied; they will provide the information necessary for that evaluation to be made, and we submit in any given situation where march-in should be applied, they will be applied."[25]

(more Cell-Pro and Essential Inventions here as example of how Right Burden was)

Soon after WWII the decision by the gov't to finance early scientific research and development prompted the White House to ask the U.S. Attorney General to report on how inventions, resulting from such support, should be disposed. I suggest a policy on ownership of inventions made in performance of this contract. The attorney general recommended government ownership so as to assure the availability of such inventions to public on an equal basis. The recommendations were primarily based on the dangers of his brief of anti-trust background and widely held belief by anti-trust attorneys that patents result in monopoly. Adoption of this recommendation resulted in the growth of a large bureaucracy equal to its implementation.