**INFORMATION PAPER—SUPPLEMENT & DISCUSSION**

**March-in Rights Request by KEI to NIH and DoD Pertaining to Xtandi®**

This information paper is provided in support of the response to USAMRMC Tasker 1602042 which pertains to a request to the Secretary of Defense to exercise the Federal government’s march-in rights. The Request, dated January 14, 2016, was addressed to the Secretary of Health and Human Services (DHHS), the Director of the National Institutes of Health (NIH), and the Secretary of Defense (DoD). The requestors are Knowledge Ecology International (KEI) and The Union for Affordable Cancer Treatment (UACT), both non-profit organizations, hereinafter referred to as “KEI.” KEI has requested that DoD exercise its march-in rights under the Bayh-Dole Act[[1]](#footnote-1) with regard to the drug enzalutamide. Invention and development of enzalutamide was funded in part by NIH and DoD awards to the University of California at Los Angeles (UCLA). Enzalutamide is FDA approved and marketed under the brand name “Xtandi” by Astellas Pharma, hereinafter referred to as Astellas.[[2]](#footnote-2) Xtandi is used to treat prostate cancer.

NIH responded to KEI via letter on June 20, 2016 denying the request to exercise march-in rights with respect to Xtandi. Although we attempted to coordinate a joint response, NIH received requests for public hearings from members of Congress so they wished to respond directly.[[3]](#footnote-3) As this is a case of first impression for the DoD, we have needed to gather information and analyze how granting the request might affect the interests of the DoD.

We now recommend a similar response on behalf of the DoD. In summary, DoD’s exercise of the march-in authority could have a chilling effect on the willingness of contractors and others to partner with the DoD and jeopardize the ability of Federal technology transfer laws to drive innovation, product development and job creation in the U.S. In the biomedical realm, government partnering with private industry is necessary to take new drugs and vaccines through the FDA approval process. Uncertainty and concerns about government action could reduce the number of potential investors willing to support the development of needed medicines, equipment and treatments for the Warfighter. In addition, we believe that Requestor has misconstrued the purpose of the march-in authority and has attempted to apply it to a situation for which it was never intended, namely, price control of pharmaceuticals. Exercise of the march-in authority is not within DoD’s interest or realm of subject matter expertise at this time. The potential consequences of exercising rights on the U.S. economy may be far reaching and irrevocable. Industry, academia, and government must all weigh in on determining if, when and how march-in rights should be exercised for any given technology.

**What are “march-in rights”?**

Recipients[[4]](#footnote-4) of Federal funding agreements generally may retain title to any invention made or conceived while performing under a Federal government[[5]](#footnote-5) funding agreement such as a contract, grant, or cooperative agreement.[[6]](#footnote-6) These “subject inventions”[[7]](#footnote-7) may be commercialized and licensed by the Federal funding recipient. “March-in rights” refer to the United States government authority under 35 United States Code §203 to require the contractor, assignee or exclusive licensee of a Federally funded invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant under reasonable terms, if certain circumstances exist. If the contractor, assignee or exclusive licensee refuses to grant such a license, the government may grant the license itself.

March-in rights may be exercised by the government if any of the four following conditions exist: (1) the contractor or assignee has not taken or is not expected to take effective steps in a reasonable period of time to achieve practical application of the invention; (2) health or safety needs are not reasonably satisfied by the contractor, assignee or licensees; (3) public use requirements are not reasonably satisfied by the contractor, assignee or licensees; or (4) the preference for manufacture of the invention in the U.S. has not been satisfied and has not been waived by the government.

**Have march-in rights ever been exercised by the Federal government?**

The Federal government has never exercised the march-in rights available to it. There have, however, been several petitions directed to the NIH requesting such action. See Appendix C for further information on these petitions. The KEI request is the first ever directed to an agency of the DoD. As noted above, KEI’s request to exercise march-in rights is directed to both NIH and DoD.

**Who determines whether march-in rights should be exercised?**

35 U.S.C. 203(a) states that “the Federal agency under whose funding agreement the subject invention was made shall have the rights, in accordance with such procedures as are provided in regulations promulgated hereunder” to require the granting of the license. The regulations referenced were promulgated by the Department of Commerce and are contained in 37 C.F.R. 401.6 et seq. DoD does not have any supplementary procedures regarding the exercise of march-in rights.

**What is the invention at issue, how did it arise and what is the price?**

Xtandi is an FDA approved prescription drug used to treat men with metastatic castration-resistant prostate cancer (CRPC). It has some advantages in route of administration and toxicity profile over other alternative treatments for CRPC. The drug was made with the support of a NIH SPORE grant and a grant from the Department of Defense Prostate Cancer Research Program (PCRP), managed by the Congressionally Directed Medical Research Program (CDMRP), an organization of the U.S. Army Medical Research and Materiel Command (USAMRMC),[[8]](#footnote-8) as well as support from private entities. Regents perfected its interest in the inventions under the Bayh-Dole Act by reporting the inventions to the government, electing to take title to the inventions, filing patent applications, executing confirmatory instruments and including government rights notices in the patent applications and resulting patents. The invention data in question have been registered in iEdison. The three U.S. patents listed below were licensed by Regents to Medivation, which in turn, sublicensed to Astellas.

U.S. Patent No. 7,709,517

Issued: May 4, 2010

U.S. Patent Application No. 11/433,829, Filed: May 15, 2006

Title: Diarylhydantoin Compounds

Inventors: Charles L. Sawyers, Michael E. Jung, Charlie D. Chen, Samedy Ouk, Derek Welsbie, Chris Tran, John Wongvipat, Dongwon Yoo

Assignee: The Regents Of The University Of California

U.S. Patent No. 8,183,274

Issued: May 22, 2012

U.S. Patent Application No. 12/708,523, Filed: February 18, 2010

Title: Treatment Of Hyperproliferative Disorders With Diarylhydantoin Compounds

Inventors: Charles L. Sawyers, Michael E. Jung, Charlie D. Chen, Samedy Ouk, Chris Tran, John Wongvipat

Assignee: The Regents Of The University Of California

U.S. Patent No. 9,126,941

Issued: September 8, 2015

U.S. Patent Application No. 13/448,964, Filed: April 17, 2012

Title: Treatment of Hyperproliferative Disorders With Diarylhydantoin Compounds

Inventors: Charles L. Sawyers, Michael E. Jung, Charlie D. Chen, Samedy Ouk, Chris Tran, John Wongvipat

Assignee: The Regents Of The University Of California

Since its inception in 1997, the Prostate Cancer Research Program (PCRP) has funded research targeted toward the program’s mission of eliminating death from prostate cancer and enhancing the well-being of men experiencing the impact of the disease. The PCRP has built a multidisciplinary portfolio of innovative basic, translational, and clinical research that complements initiatives sponsored by other federal agencies. Research awards are made using a two-tier review process composed of peer and programmatic reviews. An important element in the PCRP is its partnership with consumer advocates, who, along with scientists and clinicians, participate during both levels of review. Peer review evaluates the scientific merit of the research proposals, and programmatic review determines the relevance of proposals to the PCRP vision and goals. The Programmatic Panel, comprised of leading clinicians, scientists, and consumers, makes the final funding recommendations and provides guidance on the PCRP's investment strategies. The success of the PCRP has encouraged Congress to appropriate additional funds each year since FY97, totaling $1.53 billion through FY16. A total of 17,030 proposals have been received by the PCRP, and 3,051 awards have been funded.

USAMRMC Grant No. W81XWH-04-1-0129 was awarded to UCLA for a proposal submitted by Dr. Charlie Chen to the PCRP New Investigator Award funding opportunity. The grant provided Dr. Chen and UCLA $343,125 to investigate the role of nuclear receptor cofactors in hormone refractory prostate cancer. However, after Dr. Chen moved to another research institution, UCLA chose not to continue the award, and the funding was terminated in September 2005. After remaining funds were returned to the DoD, the amount that had been invested in this project was $170,193. The technical progress report did not detail any information that appeared directly relevant to the discovery or development of the agent that became enzalutamide, although UCLA did file an invention report citing the DoD award as a source of funding that supported the invention claimed in the patents. Thus, the DoD’s financial investment in the intellectual property that resulted in the creation of enzalutamide is relatively small.

The KEI letter notes that the development of Xtandi benefited from federal research subsidies that include grants for clinical testing, and that several publications cite the DoD funded Prostate Cancer Clinical Trials Consortium (PCCTC). The PCCTC is a network of 13 academic institutions established in 2005 and as stated in all (FY05, FY06, FY08, and FY13) Program Announcements, the Clinical Consortium Award *does not provide funding for research*, but, rather, provides the support to develop and enhance collaborations and resource sharing between the member institutions to rapidly execute Phase I and II prostate cancer clinical trials. Examples of support include provisions for a Clinical Research Coordinator who interact with the Clinical Research Coordinators of other Clinical Research Sites, implementation of the consortium’s core data collection methodologies and strategies; and compliance with consortium-developed quality assurance and quality control procedures which can all be considered infrastructure. It is true that the PCCTC performed multiple (8 out of the 129 Xtandi clinical trials identified in the KEI letter i.e. 6%) successful early phase clinical trials of Xtandi, but PCCTC institutions have also performed over 140 other clinical trials on over 100 other drugs/drug combinations with potential for treating prostate cancer. The clinical trials are funded (sponsored) by industry, the National Cancer Institute or individual investigators, whereas DoD funding is directed toward consortium infrastructure needs thus facilitating the clinical trial process rather than directly supporting individual clinical trials of specific drugs. It is highly likely that Xtandi would have made it to FDA approval without PCCTC involvement, although it might have taken a longer time.

The KEI letter indicates that the average wholesale price (AWP) of Xtandi was $353.92 per day or $129,269.28 per year.[[9]](#footnote-9) However, it should be noted that the typical duration of treatment is 8 months and not 12 months, so the actual cost of treatment may really be closer to $84,940.80. When Xtandi was originally released in 2012 the wholesale price was set at $7,450 per month[[10]](#footnote-10) making the full treatment cost about $60,000. Currently, a one-month supply of Xtandi is available for $9097.15[[11]](#footnote-11) making the full treatment about $73,000. In addition to Xtandi, over the last decade a number of new treatment options for patients with advanced prostate cancer have been FDA approved. Table 1 lists these agents and the estimated cost of a full treatment regimen.

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| --- | --- | --- | --- |
| Chemical Name | Brand Name | Mechanism of Action | Estimated cost |
| Enzalutamide | Xtandi | Androgen receptor inhibitor | $73,000 |
| Abiraterone acetate | Zytiga | Androgen receptor inhibitor | $71,000 |
| Radium-223 dichloride | Xofigo | Radioactive tracer (radiopharmaceutical) | $69,000 |
| Cabazitaxel | Jevtana | Cell cycle arrest | $34,350 |
| Sipuleucel-T | Provenge | Immunotherapy | $93,000 |

As noted in Table 1, XTANDI isn't the only expensive new treatment for patients with advanced prostate cancer. And one of the other available agents, Abiraterone acetate (Zytiga) is a very similar agent that also works by targeting the Androgen Receptor (AR) pathway which is known to fuel prostate cancer cell growth, and is similar in cost to Xtandi.

Moreover, this pricing information may not reflect what payers or patients actually pay for Xtandi. The manufacturer (Astellas) provides multiple financial assistance plans that are available to patients through XTANDI Support Solutions. Patients with private health insurance who cannot afford the out-of-pocket costs may be eligible for the Patient Savings Program which provides co-pay assistance so that the patient pays no more than $20 per one-month prescription. Medicare covers XTANDI under the Medicare Part D prescription drug benefit but the patients’ direct costs varies between various plans. For Medicare patients in need of financial assistance, XTANDI Support Solutions provides assistance to identify those who may qualify for a low-income subsidy or assistance from independent copay foundations. For those patients who do not have health insurance or are underinsured who are qualified (annual adjusted household income of $100,000 or less) Astellas provides Xtandi for free under the Astellas Access Program; in 2015 Astellas claims this amounted to over 2000 patients. So, although Xtandi is expensive, the manufacturer has developed financial assistance programs to help patients access the treatment and mitigate how much patients actually pay for the drug.

We verified that some of the Army’s military medical center pharmacies stock Xtandi. In our conversations with military health care providers at the Walter Reed National Military Medical Center, they do not recall any instance where any of the 46 patients they have placed on this drug since 2011 have had any significant financial difficulties paying for XTANDI, and in fact most (if not all) patients do not pay out of pocket expenses for XTANDI. This is not surprising as military health centers and treatment facilities primarily serve military beneficiaries.

**Discussion of the key allegations and arguments of the KEI request**

KEI states that the price of Xtandi in the United States is far higher than the price of the drug in other countries, including high income countries. The average wholesale price of the drug in the United States is $129,269 per year.[[12]](#footnote-12) KEI asserts that Astellas “is exploiting the weak response of the United States to excessive pricing of drugs, and is charging U.S. consumers and third-party payers roughly two to four times as much as the prices in other high income countries.” KEI asks the DHHS, NIH and DoD to use its march-in authority to address the disparity in price of this drug and proposes an algorithm to determine whether U.S. prices are unreasonable in comparison with those of other countries.[[13]](#footnote-13) KEI also requests the government to use its march-in authority to address pharmaceutical pricing issues on a broader scale.

KEI proposes that the Federal government exercise its march-in rights by granting an open patent license to any generic drug manufacturer. KEI states that it does not anticipate difficulties obtaining FDA approval for generic versions of Xtandi once the open license is granted. It is unclear what role KEI would play in interacting with a generic drug manufacturer. In addition, there is no further description of what is meant by “open” license but one could conclude that the effect would be similar to a donation of the invention to the public domain.

KEI relies upon 35 U.S.C. §203(a)(1) and §201(f) as support for its request for exercise of march-in rights. Section 203(a)(1) requires the awardee to achieve practical application of the subject invention within a reasonable time. KEI argues that the definition of “practical application”[[14]](#footnote-14) includes a condition that the benefits of the invention be available to the public on reasonable terms and that Xtandi’s excessively high price does not constitute “reasonable terms.” That, in turn, leads to a failure to achieve practical application. KEI also argues that Xtandi is so expensive that the price effectively limits public access to the drug and that U.S. insurance companies and other third party payers have restricted access to the drug through limitations on plan coverage and increased administrative authorization procedures.[[15]](#footnote-15) KEI argues that the disparity in U.S. versus foreign pricing is discriminatory against the U.S. public, especially considering that the drug was made with Federal funding. KEI further argues that Astellas’ actions are not in accordance with the policy and objective of the Bayh-Dole Act which includes protecting the public against the unreasonable use of inventions.[[16]](#footnote-16)

**Discussion of the consequences of exercising march-in rights**

DoD’s exercise of the march-in authority could jeopardize the ability of the Bayh-Dole Act to drive innovation, economic activity and job creation in the United States. Injudicious use of this authority could have an adverse and possibly devastating effect on the government’s ability to transition technology from the Federal to private sector. A study produced by TechLink and the University of Colorado,[[17]](#footnote-17) covering years 2000-2014, illustrates that the Bayh-Dole Act is working well as a means of stimulating the nation’s economy. The study indicates that DoD invention licenses have resulted in $20.4 billion in total sales of new products and services, $3.4 billion in sales of new products to the United States military, $48.8 billion in total economic output nationwide, $1.6 billion in new tax revenues (federal, state and local), and 182,985 full-time jobs created or retained. One product, a respiratory syncytial virus (RSV) antibody, created at the Uniformed Services University of the Health Sciences accounted for about $14.1 billion in sales. The antibody is used in the drug Synagis to prevent serious lower respiratory tract disease in infants and young children.

A significant concern amongst Federal technology transfer professionals is that use of march-in rights could actually be counter-productive to achieving the Bayh-Dole Act’s goals of encouraging private investors to commit capital for commercial development of government made and government funded inventions. The pharmaceutical industry is particularly sensitive to risk and government regulation. Uncertainty and concerns about government action or “takings” could reduce the number of potential investors willing to support the development of needed medicines, equipment and treatments. This is especially true for high risk and smaller niche market biomedical products like orphan drugs used to treat rare diseases. And in the biomedical realm, government partnering with a private entity is absolutely necessary to take new drugs and vaccines through FDA licensure, especially since the Federal government is not in the business of manufacturing itself.

Even though march-in rights have never been exercised, potential licensees of Federally funded inventions often raise concerns about the possibility of the government exercising march-in rights. If march-in rights are ever exercised, it will be much more difficult for funding recipients to develop products as well as for agencies to license their in-house created inventions. Federal licensing professionals must strike a delicate balance of providing notice that exercise of march-in rights is possible but an unlikely possibility. Pharmaceutical companies are typically conservative and some will be unlikely to assume such future business risk if march-in rights are ever exercised with respect to a pharmaceutical product. The impact of this is that fewer medical treatments and drugs would be developed and this could have a cascade effect--if there are fewer new drugs, there will be fewer alternative treatments, and fewer generic drugs.

Exercising march-in rights may also make private investors reluctant to contribute to university research and development projects as those projects are frequently funded by a combination of awards from the Federal government, non-profits and private companies. As of 2009, Federal support accounted for over half of the research conducted at colleges and universities in the U.S.[[18]](#footnote-18) Under this scenario, government funding could put the entire project at risk because government exercise of march-in rights could affect the rights, and therefore viability, of the private funders. Universities may begin to believe they must decline federal assistance to preserve their relationships with private funders and maximize opportunities for commercialization. Or vice versa, universities will continue to accept Federal funding but the number of their commercialization relationships will decrease.

The exercise of march-in authority could also have an effect in the DoD contracting realm, making potential contractors reluctant to work with the government to develop medically beneficial inventions for the DoD and for the public. Any uncertainty whether the DoD might attempt to control the market for a successful product will decrease the appeal of licensing, patenting and entering into collaborative agreements with the DoD. Reduction in the pool of contractors could actually drive the price of procurement up as contractors may believe they have lost any real ability to benefit from exploitation of subject inventions. Exercise of march-in rights may also adversely affect DoD’s Cooperative Research and Development Agreement (CRADA) program. As discussed above, there may be a resulting in a decrease in the number of contractors who become potential collaborators--especially considering that the DoD does not provide funding through these agreements. Instead, DoD often receives funding, personnel, equipment, and intellectual property from the CRADA collaborator. These resources would be at risk by loss of potential collaborators and reduction in discretionary research funds that could be used to engage in the collaboration.

In some cases, pharmaceutical products are covered by multiple patents, some of which may not have resulted from Federal funding. Exercise of march-in rights may negatively affect the value of those other privately funded and patented inventions and that might jeopardize the entire patent portfolio. In addition, the government may only have the ability to march-in with respect to one patent, or a specific field of use, and, in order for the directed licensee to make the product, additional licenses would have to be acquired from the owners of the privately funded patents. Coordinating licenses from multiple owners could increase the cost of the product time and the time to market. Finally, current licensees may have specialized knowledge (“know-how”) that makes them better positioned to commercialize a particular product than another company and the government cannot compel the sharing of that know-how if not a deliverable under contract or included in a patent. The march-in authority applies only to subject inventions and not to tangible materials of unpatented technical know-how.[[19]](#footnote-19) For example, the current licensee may have trade secrets, other patented technologies related to product development, experience with the FDA approval process, or marketing and distribution channels that make it more likely to achieve practical application of the invention.

Exercising march-in rights may not achieve the quick result most requestors are seeking. A decision to exercise march-in rights and the subsequent implementation can take a long time to effect. Although there were demonstrated shortages of Fabrazyme discussed in the NIH Determination In The Case of Fabrazyme Manufactured By Genzyme Corporation, NIH declined to exercise march-in rights because the lengthy clinical trial period required of a directed licensee would not address the immediate short term problem in the supply chain. Furthermore, the regulations governing the march-in process require due process be afforded the awardee. The agency must notify the awardee, in writing, that it has information it believes might warrant the exercise of its march-in authority and provide the awardee an opportunity to oppose the decision. A final decision adverse to the awardee will be held in abeyance until the exhaustion of awardee’s judicial remedies, which could take years.[[20]](#footnote-20)

Even if a license were granted to another manufacturer to produce Xtandi, that company would still need to acquire the necessary regulatory approvals and to ramp up manufacturing processes. Note also, that neither the government nor the Federal funding recipient is required to grant a royalty-free license under the march-in authority. Given all of the potential consequences of exercising march-in rights there is ultimately no guarantee that the price of the pharmaceutical would be less expensive than the price set by the current licensee.

**What is the NIH position on exercising march-in rights with respect to Xtandi?**

NIH responded to KEI in a letter dated June 20, 2016, denying the request to exercise march-in rights with respect to the drug Xtandi. NIH’s position is that practical application has occurred and that the product is broadly available to and in use by the public. There is no evidence to suggest that the drug is currently or will be in short supply. This position is consistent with the analysis conducted in the prior march-in requests NIH has adjudicated. NIH has consistently declined to exercise march-in authority because market dynamics could be affected for all products subject to the provisions of the Bayh-Dole Act.

**Discussion regarding use of the march-in authority to control pharmaceutical prices**

NIH has stated many times that it does not believe that the march-in authority in the Bayh-Dole act was ever intended to address drug pricing; it was designed to address unavailability of drugs due to lack of commercialization or lack of supply.[[21]](#footnote-21) Certain members of Congress disagree with this interpretation and assert that excessive price can become an issue of access. NIH believes that the drug pricing is an issue more appropriately left to the legislature.

We also assert that price setting is not a DoD function. The mission of the USAMRMC is to responsively and responsibly create, develop, deliver, and sustain medical capabilities for the Warfighter. This mission includes development of medical products that can be commercialized so that DoD can purchase these products for the Warfighter on a commercial off-the-shelf basis. A side benefit of USAMRMC efforts is that our medical products can often benefit the public at large. The DoD’s ability to make an informed and far reaching decision on pricing of pharmaceuticals is limited. DoD is unlikely to have the expertise to analyze the economics of private sector pharmaceutical pricing. An evaluation of disparate pricing between products sold in the U.S. and in foreign countries and a determination on the equities of pricing is also outside the realm of responsibility and interest for DoD.

The Honorable Birch Bayh, one of the drafters of the Bayh-Dole Act, has stated that price control was never the intent of the march-in authority. March-in rights were provided as a tool for the government in the event that a licensee might want to suppress Federally funded technology that threatened or competed with existing products. The drafter’s intent was to ensure that licensees were making reasonable efforts to bring products to market; if efforts to commercialize were insufficient or ineffective, the government could step in and require other companies be licensed. Likewise, if the licensee could not satisfy health and safety requirements, another company could be licensed to produce the products.[[22]](#footnote-22)

The march-in authority is available to all federal agencies and applies to all technologies. But because of the dual-use nature of DoD’s biological inventions, such inventions may be more likely to be the subject of continuing requests for government intervention regarding pricing. Congress could choose to amend the Bayh-Dole Act to include a reasonable pricing requirement but there would be difficulty in defining a “reasonable” price. Such an amendment might achieve a short term goal but would not alleviate the possible consequences of price setting on Federal technology transfer goals and the U.S. economy. In fact, NIH attempted to include a “reasonable pricing” requirement in collaboration agreements but later abandoned its use. The clause did not provide more protection for consumers, instead, it deterred industry from collaborating with NIH scientists.[[23]](#footnote-23)

**Conclusion**

Xtandi is FDA approved and available for use for the treatment of prostate cancer. It is actively marketed by Astellas and prescribed by physicians. This drug has achieved practical application as required by the Bayh-Dole Act. KEI argues that march-in authority should be utilized by the government in an attempt to lower the price of the drug but they have not presented evidence that the price of products was intended to be a component of “reasonable terms” under the march-in authority. Instead, Senator Bayh’s testimony regarding the legislative history of the Bayh-Dole Act contradicts the idea that march-in rights were intended to be used to effect price controls. Although expensive, the cost for a course of treatment with Xtandi is similar to the cost of alternative treatments. USAMRMC has not received or discovered information that would lead us to recommend initiating a march-in proceeding with respect to Xtandi. For that reason, KEI’s request to DoD to exercise march-in rights should be denied.

LIST OF APPENDICES

APPENDIX A. NIH Response And Copies of Letter Submitted by Congressional Members

APPENDIX B. A discussion of the Bayh-Dole Act.

APPENDIX C. Information on Petitions to and Determinations by NIH Regarding Exercise March-in Rights.

APPENDIX D. Request of Knowledge Ecology International (KEI) and The Union for Affordable Cancer Treatment (UACT) with OTSG and USAMRMC Taskers.

APPENDIX E. Applicable law.

APPENDIX F. National Economic Impacts from DoD License Agreements With U.S. Industry 2000-2014, Submited by TechLink, Montana State University, and Business Research Division of Leeds School of Business, University of Colorado.

Appendix G. GAO Report 09-742, Federal Research: Information on the Government’s Right to Assert Ownership Control over Federally Funded Inventions

Appendix H. Written Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004 and “Our Law Helps Patients Get New Drugs Sooner, The Washington Post, April 11, 2002.

1. See 35 U.S.C. 200 et seq. The Bayh-Dole Act (Act) provides the statutory basis for federal technology transfer activities, including the patenting and licensing of inventions made under federal funding agreements by recipients of those funds. Recipients of federal funding agreements generally may retain title to any invention made or conceived while performing under a government funding agreement such as a contract, grant, or cooperative agreement. [↑](#footnote-ref-1)
2. Astellas Pharma US, Inc. is the U.S. affiliate of Tokyo-based Astellas Pharma, Inc. Astellas Pharma, Inc. was formed in April 2005 through the historical merger of Japan's third and fifth largest pharmaceutical companies - Yamanouchi, founded in 1923, and Fujisawa, founded in 1894. [↑](#footnote-ref-2)
3. See Appendix A for NIH’s response and copies of the letters submitted by Congressional members. [↑](#footnote-ref-3)
4. “Recipients” of federal funding agreements and “awardees” are used interchangeably. [↑](#footnote-ref-4)
5. “Federal government” and “government” are used interchangeably. [↑](#footnote-ref-5)
6. The right of the recipient to take title is conditioned upon fulfilling its obligations under the Bayh-Dole Act: reporting the making of the invention, electing to take title to the invention; and filing patent applications. There are time limits for each of these actions, see Appendix B. [↑](#footnote-ref-6)
7. See Appendix E, 35 U.S.C. 201(e). The term “subject invention” means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement. [↑](#footnote-ref-7)
8. NIH SPORE grant number 5P50 CA092131 and Army grant W81XWH-04-1-0129. [↑](#footnote-ref-8)
9. See RED BOOKTM, 2015 (http://micromedex.com/products/product-suites/clinical-knowledge/redbook). [↑](#footnote-ref-9)
10. See “Xtandi: Prostate Cancer Drug Approved By FDA”, www.huffingtonpost.com, August 31, 2012. [↑](#footnote-ref-10)
11. See m.goodrx.com, Walgreens listed price with coupon. [↑](#footnote-ref-11)
12. See Appendix D, Request, page 2, footnote 1. [↑](#footnote-ref-12)
13. See Appendix D, Request, page 23. [↑](#footnote-ref-13)
14. See Appendix E, 35 U.S.C. 201(f). The term “practical application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms. [↑](#footnote-ref-14)
15. See Appendix D, Request, page 6. [↑](#footnote-ref-15)
16. See Appendix E, 35 U.S.C. § 200. [↑](#footnote-ref-16)
17. See Appendix F, National Economic Impacts from DoD License Agreements With U.S. Industry 2000-2014, Submitted by TechLink, Montana State University, and Business Research Division of Leeds School of Business, University of Colorado. [↑](#footnote-ref-17)
18. See Appendix G, GAO Report 09-742, Federal Research: Information on the Government’s Right to Assert Ownership Control over Federally Funded Inventions, page 1. [↑](#footnote-ref-18)
19. See Appendix C, NIH Determination In The Case of Fabrazyme Manufactured By Genzyme Corporation, page 2, <http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf>. [↑](#footnote-ref-19)
20. See Appendix E, 37 C.F.R. 401.6 for regulations governing the process. [↑](#footnote-ref-20)
21. Testimony and conversation between Dr. Francis Collins, Director of NIH, and Senator Richard “Dick” Durbin at the Congressional hearing of 7 April 2016. [↑](#footnote-ref-21)
22. See Appendix H, Written Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004, pages 2-3 and “Our Law Helps Patients Get New Drugs Sooner, The Washington Post, April 11, 2002. [↑](#footnote-ref-22)
23. See NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers’ Interests are Protection, July 2001, page 10, <http://www.ott.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf> and <http://www.apnewsarchive.com/1995/NIH-Drops-Reasonable-Price-Clause-for-Drug-Company-Collaboration/id-0fda3df8eb88951d7ec747e5db381f7f> and <http://articles.latimes.com/1995-04-12/business/fi-53899_1_research-agreements>. [↑](#footnote-ref-23)