

The Collaborative Research House That Bayh-Dole Built: Perfectly Constructed Or In Need Of Repairs?

By William H. Pratt¹

Introduction

In many ways, one might argue that we live in the golden age of collaborative research. As technological challenges continue to grow in complexity, we appear to depend more and more on the ability of governmental, non-profit, and for-profit entities to pool their intellectual resources to meet such challenges.

Without a doubt there are numerous reasons for this increase in collaborative research, including the transformation from a manufacturing-driven society to a technology-driven one. The complexity of the technological challenges facing industry, the increase in government research, and the influx of venture capital have all helped to fuel this development. Last, and perhaps most important, the increased status of patents and their recognition as a valuable income-producing asset have helped justify the increased investment in collaborative research.

As explored in this article, one of the “footers” upon which the modern collaborative research “house” is built is P.L. 96-517, Amendments to the Patent and Trademark Act of 1980 (commonly referred to as the Bayh-Dole Act (“BDA” or “the Act”). The BDA was passed with the intent of:

us[ing] the patent system to promote the utilization of inventions arising from federally supported research or development; ...to promote collaboration between commercial concerns and nonprofit organizations, including universities;... [and] to promote the commercialization and public availability of inventions made in the United States by United States industry and labor... .

(P.L. 96-517, §200). In doing so, Congress also built safeguards into the BDA “to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions...” (Id).

Given that the Act is now 30 years old, it is quite

natural for one to wonder whether the BDA has achieved its stated purpose. It is also an opportune time to examine any shortcomings, actual or perceived, and ask whether it is time to modify this historic piece of legislation. Any analysis of this sort must be careful to take into account the issues that this country faced in the late 1970s and the different issues and technological environment that we face today. Failure to consider such differences may lead to unjustified conclusions, positive or negative.

In this article, I examine the objective of the BDA and discuss whether it was successful in achieving such goals, either in whole or in part. I then examine criticisms of the BDA derived from publications, cases, and petitions filed with National Institutes of Health (NIH) as well as from my own practice. In doing so, I explore if such criticisms are justified or actually do arise from the legislation itself and, thus, can be addressed or repaired by amendments to the BDA or its implementing regulations.

BDA in a Nutshell

Because of the passage of time, it is important to revisit the environment in which the Act was created. To paraphrase Dickens, the late 70’s and early 80’s were clearly “the worst of times.” America stood in the throes of stagflation, high unemployment, and a general perception that we were losing our edge in technology innovation.

Part of the perceived problem was that despite the Government’s sizable investment in technology, inventions created with federal funding and owned by the U.S. Government were not being commercialized. Prior to the enactment of BDA, experts estimated that “only 5 percent of government owned patents were ever used in the private sector, although a portion of the intellectual property portfolio had potential for further development, application, and marketing.”²

Accordingly, Congress sought ways of promoting the commercialization of federally-funded inventions and fostering greater collaboration between govern-

1. This article was prepared by Mr. Pratt on behalf of the American Intellectual Property Law Association (AIPLA) specifically for contribution to this special issue of *les Nouvelles*. Ms. Jessica Cox, an associate attorney, assisted in the preparation of this article.

2. Wendy H. Schacht, “The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology,” *Congressional Research Service Report to Congress*, February 3, 2009, p. 2.

ment, universities, and the private sector. One of the initiatives adopted was the BDA with its stated intent of creating a “single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government financed inventions through the commitment of risk capital necessary to develop such inventions to the point of commercial applications.”³ By contrast at the time the BDA was passed, there were 26 different Federal Government agency policies in existence, each addressing the use of federally-funded inventions.⁴

The BDA’s approach was quite simple and, overall, quite balanced. In a nutshell, universities, non-profits, and small business (and eventually large for-profit companies)⁵ were permitted to retain title to any inventions that it conceived or first actually reduced to practice under federal funding (“Subject Inventions”). All such entities were permitted to obtain patents on its Subject Inventions and could commercialize the inventions themselves or assign/license (including exclusively) the inventions to others.

To protect the public against nonuse or unreasonable use of Subject Inventions, the BDA required that the Government be granted a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any Subject Invention throughout the world. The Act also imposed reporting, election of title, and other administrative requirements on the contractor to ensure that the government is aware of and can utilize its rights in these Subject Inventions. Lastly, the BDA expressly allowed the government to obtain title to a Subject Invention, if certain administrative requirements were not met.

In an effort to help in the creation of U.S. jobs, the Act also required an exclusive licensee to substantially manufacture in the United States any products embodied by a Subject Inventions or produced through the use of a Subject Invention. Lastly, the Act enabled the government to “march-in” and require the contractor or its assignee/exclusive licensee to grant subsequent licenses, if necessary: (a) to achieve practical application of the inventions; (b) to alleviate health or safety needs; (c) to meet public use requirements; or (d) if the “substantial manufacture” requirement has

not been met by the exclusive licensee.

Has the BDA met its goals?

Clearly, there are many reasons for the collaborative research success that we are experiencing in the United States. To be sure, criticisms (some more legitimate than others) of the Act and its implementation have been raised by scholars and practitioners alike. But, when all of the countervailing factors and criticisms are taken into consideration, the consensus appear to be that the BDA has been extremely successful in meeting its overall goal of promoting the commercialization of federally-funded inventions and fostering greater collaboration between government, universities, and the private sector.

The BDA has been described as “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century...More than anything, this single policy measure helped reverse America’s precipitous slide into industrial irrelevance.”⁶ There have also been numerous studies and reports, over the last twenty or so years, that document the substantial increase in collaborative research since the Act was enacted.

For example, a small 1987 study by the General Accounting Office found agreement among the universities interviewed that the BDA had been significant in stimulating business sponsorship of university research, which had grown 74 percent, in the first five years of the Act.⁷ A subsequent GAO report in 1998 found that both agency and university representatives believed that the BDA was meeting its articulated goals, that the BDA was a positive impact on all involved, and that universities were receiving greater benefits from its inventions and transferring technology better under BDA.⁸

According to the Association of University Technology Management (“AUTM”), the BDA has been pivotal to the development of university research. The AUTM notes that since enactment of the BDA, “more than 5,000 new companies have formed around university research results—the majority lo-

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3. House Committee on the Judiciary, “Report to accompany H.R. 6933,” 96th Cong., 2nd Sess., H. Rept. 96-1307, Part 1, 3.

4. Schacht, *supra* note 2, at p. 2.

5. The provisions of BDA were extended to large companies under the President Reagan’s 1983 Memorandum on Government Patent Policy.

6. *Economist Technology Quarterly*, Dec. 14, 2002.

7. Schacht, *supra* note 2, at p. 8.

8. *Id.* at p. 9.

cated in close proximity to the university.”⁹ University patenting has “exploded from 495 issued patents in 1980 to 3,278 in 2005.”¹⁰ Moreover, between 1998 and 2005, universities have helped introduce over 3,641 new products into the marketplace.¹¹ Lastly, number of AUTM members have grown from 113 in 1979 (the year before the BDA was enacted) to over 2,178 in 1999.¹²

Perhaps the most interesting statement of the success of the BDA is that an estimated 30 percent of the NASDAQ’s value is rooted in university-based, federally-funded research results, which might never have been commercialized had it not been for the BDA.¹³

To be fair, there are other factors, some of which were mentioned in the introduction, which can account for some of the tremendous growth in the collaborative research over the last 30 years. Moreover, it has been noted that much of the financial success in commercializing technology appears to concentrated among seven to nine universities.¹⁴ There are, of course, numerous reasons why collaborative research has grown since the BDA was passed. However, without the basic foundation of private ownership of federally-funded inventions, it is quite doubtful that the collaborative research house of today would be such a large structure. In my opinion, this dramatic change in government policy created a very strong foundation for a structure that many forces were involved in creating.

Is the Foundation Cracked?

A review of scholarly articles, congressional reports, case law, and petitions filed with the (NIH) reveal several criticisms that companies, special interest groups, and individual citizens have stated regarding the BDA or the manner in which it is implemented.

9. “The Bayh-Dole Act: Important to our Past, Vital to Our Future,” Association of University Technology Management, available at [http://www.autm.net/Content/NavigationMenu/TechTransfer/BayhDoleAct/BDTalkPts_031407.pdf]

10. *Id.*

11. *Id.*

12. “The Bayh-Dole Act—A guide to the Law and Implementing Regulations,” University of California, Office of Technology Transfer, available at [<http://www.ucop.edu/ott/faculty/bayh.html>].

13. “The Bayh-Dole Act: Important to our Past, Vital to Our Future,” *supra* note 9, citing statements made by the former President of the NASDAQ.

14. See Schacht, *supra* note 2, at p. 8-9; Michael J. Remington, “Technology Transfer: Payoffs or Pitfalls,” Remarks at Licensing Executive Society Workshop #7, Salt Lake City, Utah, February 2003, p. 2.

Indeed, I have also run across issues in my own practice stemming from the ambiguity of the Act and its implementation that create concerns which can affect a company’s decision to acquire or license a Subject Invention. While some of these criticisms can be effectively addressed by either amending the Act or improving the way it is implemented, others should be addressed, to the extent required, through other means. The following summarizes criticisms:

Failure to Report and Elect to Retain Title.

The BDA imposes numerous requirements on the contractor in return for its ability to retain title to a Subject Invention. Such requirements include:

1. Reporting the invention to the sponsoring agency and electing to retain title within specified timeframes;
2. Filing patent applications in the United States and abroad within specified timeframes;
3. Providing the U.S. Government with a written document confirming its royalty free license;
4. Submitting periodic reports upon request;
5. Including a statement in the issued patent indicating that the invention was created with Government support; and
6. Notifying the government of any decision to discontinue prosecution of patent applications, payment of maintenance fees, or not to defend a reexam or opposition proceeding.

These conditions are designed to protect the government’s residual interest in the Subject Invention. However, other than the first requirement (reporting and election of title), the Act does not impose any specific consequences for failure to comply.

Moreover, there appears to be very little, to no, oversight for determining if a contractor has complied with any of these requirements. In a 1999 report, the GAO found that the databases for recording the government’s royalty-free licenses were inaccurate, incomplete, and inconsistent, and that some inventions were not being recorded at all. The GAO concluded that government agencies, contractors, and grantees were not complying with the Act’s reporting requirements.¹⁵ Despite efforts by the government to improve its databases, those involved with the BDA are left with the sense that these reporting requirements are not monitored or enforced.

15. “Technology Transfer Reporting Requirements for Federally Sponsored Inventions Need Revision,” U.S. General Accounting Office Report to the Chairman, Committee on the Judiciary, U.S. Senate, August 1999, GAO/RCED-99-242.

One has the impression that, absent egregious circumstances, federal agencies do not actively seek to obtain title to a Subject Invention if a contractor fails to comply with the reporting and election requirements. See *Campbell Plastics Eng'g. & Mfg. Inc. v. Brownlee*, 73 U.S.P.Q.2d 1357 (Fed. Cir. 2004). However, given the government's right to obtain title to a Subject Invention within sixty days of learning of an infraction, failure to comply with the reporting/election requirements leaves a cloud over that title. This issue often arises during a due diligence investigation, or when an infringement action is brought and needs to be addressed prior to filing suit or acquiring a patent for a federally-funded inventions. This uncertainty may hinder one's ability to commercialize the patent, which, in turn, defeats the entire purpose of the BDA.

Failure to Comply with Other BDA Requirements.

The Act does not impose any specific consequences for failure to comply with Requirements 2-6, previously listed. Moreover, there is very little useful guidance, in the form of case law or administrative actions, as to the consequences of failing to comply with these provisions. This is particularly disturbing given that the failure to comply with some of the aforementioned requirements may result in the loss of government rights in the federally-funded invention.

In a 2004 decision, the CAFC opined, *in dicta*, that failure to provide NIH with a written document may enable NIH to void the contractor's title to a patent for a federally-funded invention, but declined to address the issue noting that NIH had shown no interest in pursuing this issue. *Central Admixture Pharmacy Services, Inc v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347 (Fed. Cir. 2004).

Again, the failure to provide express clear guidance with respect to the consequences of failing to comply with these administrative requirements creates uncertainty around the patent title. Such uncertainty may, in turn, hinder one's ability to commercialize the patent, which defeats the purpose of the BDA.

What does "Substantially Manufacture" mean?

The BDA states that if an exclusive license is granted, any products embodied by the Subject Invention or produced through the use of such an invention must be manufactured substantially in the United States. If the exclusive licensee is in breach of this provision, the federal agency has the right to force the parties to grant additional licenses.

Despite this potential draconian measure, the BDA does not define "Substantially" or "Manufacture" or for that matter provide any guidance on how to in-

terpret such terms. For example, does this provision require that the entire article, including all materials and components be manufactured in the U.S? We note that NASA's regulations covering cooperative agreements state that "manufactured substantially in the United States means the product must have over 50 percent of its components manufactured in the United States. This requirement is met if the cost to the recipient of the components mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all components required to make the product." 14 C.F.R. §1274.9111(9). Can an exclusive licensee rely on this interpretation if the Subject Invention was funded by another agency?

The Public is not Receiving the Benefits of the BDA.

Perhaps the issue that has gotten the most notoriety over the last few years is the argument that the public is not receiving benefits commensurate with the taxpayers' contributions to federally-funded inventions. The argument centers around the cost or, in some cases, the availability of pharmaceuticals and medical devices derived from federally-funded research. Such concerns have reached the public's attention as a result of petitions requesting the NIH to exercise its march-in rights under the BDA and force the subsequent license of the Subject Inventions.

In the case of Norvir[®], the petitioner, Essential Inventions, alleged that the prices being charged for this protease inhibitor was unreasonable, anticompetitive and threatened the health and safety of people with AIDS.¹⁶ As a result of such pricing, Essential Inventions claimed that Abbott Labs had failed to achieve practical application of the invention, which the BDA defines, *inter alia*, as making the benefits of the inventions available to the public on reasonable terms.¹⁷ Essential Inventions requested that an open license be granted to interested parties on reasonable terms with a royalty to Abbott as well as a contribution to be made to a research and development fund to support AIDS research.¹⁸

In rejecting the petition, the NIH correctly noted that because Norvir[®] has been made available to patients for eight years and is being actively marketed by Abbott, the drug has reached practical application and has met the health and safety requirements of

16. Petition To Use Authority Under Bayh-Dole Act To Promote Access to Ritonavir, Supported by National Institute of Allergy and Infectious Diseases Contract No. AI27220, filed by Essential Inventions, Inc. January 29, 2004, p. 2.

17. *Id.* at 8-9.

18. *Id.* at 13.

the BDA.¹⁹ The NIH went on to say, quite properly, that the drug pricing issue is one that would be more appropriately addresses by Congress, as it considers these matters in a larger context and that the FTC is the appropriate agency to address allegations of anti-competitive behavior by Abbott.²⁰

In a second march-in rights petition filed with the NIH, Baxter Healthcare was the exclusive licensee of a Johns Hopkins patent for stem-cell isolation technology developed under federal funding. After being enjoined at the U.S. District Court from selling a product found to infringe the Hopkins patents, the Petitioner, CellPro, alleged in its petition that Baxter was using its exclusive license to suppress CellPro's product while failing to successfully commercialize its own product based on the Hopkins patent. CellPro requested NIH to assert its march in rights and grant CellPro a license in order to alleviate health and safety needs that have arisen because of the injunction.

The NIH ultimately determined, with apparent good reason, that "Hopkins and Baxter have taken, or are expected to take within a reasonable time, effective steps to achieve practical application of the applicable patents, as demonstrated by Hopkins' licensing activities and Baxter's manufacture, practice, and operation of the Isolex 300, and the device's availability to and use by the public to the extent permitted at this time under applicable law (i.e., foreign sales as well as widespread clinical research use in the U.S.)."²¹ The NIH also noted that the public health needs were currently being met, during the FDA approval process, given that Hopkins and Baxter had modified the injunction to allow CellPro to continue to sell its infringing product until three months after Baxter product is approved by the FDA.²²

A third march-in rights petition was recently filed with the NIH by three individuals suffering from Fabry's disease. The Petition requests that NIH exercise its march-in rights and grant an open license to use patents related to the manufacture of Fabrazyme® (agalsidase beta) on the grounds that the patent owner and its exclusive licensee have harmed the public health by severely rationing the supply of this

drug, which is the only approved therapeutic treatment for Fabry's disease.²³

The genesis of this petition appears to be the substantial manufacturing problems that the exclusive licensee, Genzyme Inc., is alleged to be encountering in manufacturing Fabrazyme®. This petition poses an interesting dilemma and challenge for NIH, given that the exclusive licensee allegedly cannot produce adequate supply.²⁴ Over the last 30 years, this author is unaware of any instances where march-in rights have been exercised by the executive branch.

However, even if NIH were to decide to exercise its march-in rights, such action presupposes that a license under this one federally-funded invention, which covers the gene-sequence, would be sufficient for manufacturing the drug. In other words, to the extent that there are other proprietary or patented technologies required for the production of this drug, such technologies would not be encompassed by the march-in procedure.

Alleged Corruption at Universities.

Over the years, there have been those who claim that the BDA has corrupted the Universities by creating conflict of interests, redirecting efforts from basic research to applied, and creating an environment where researchers are less willing to share their results or publish.²⁵

The conflict of interest concern is based on the assumption that private sector funding has created an environment where researchers' direct financial interest (e.g., consulting fees, royalties, or equity positions in spin offs) in their research project may affect or undermine their judgment. Critics also argue that as universities become "engines of growth" they focus more on applied research and less on basic research, which is the traditional role of universities.²⁶ There have been university studies that both support and contradict this position.²⁷

The third criticism is that the economic incentive to patent and commercialize delays publication and

19. In the Case of Norvir® Manufactured by Abbott Laboratories, Inc., issued by NIH Office of the Director, July 29, 2004, p. 6.

20. Id.

21. In the Case of Petition Of CellPro, Inc., issued by NIH Office of the Director, August 1, 1997.

22. Id.

23. Petition To Use Authority Under The Bayh-Dole Act To Promote Access To Fabrazyme® (Agalsidase Beta), An Invention Supported By And Licensed By The National Institutes Of Health Under Grant No. DK-34045, filed by Carik, et al., August 2, 2010.

24. See <http://www.pharmalot.com/2010/08/patients-ask-hhs-to-break-patent-on-genzyme-drug/>.

25. See Schacht, *supra* note 2, at p. 16-20 for an in-depth discussion of these concerns.

26. Id. at 19.

27. Id.

inhibits the sharing of results. Studies have confirmed that delays in publications and deletion of information from publication do occur as a result of industry-university collaboration.²⁸ Other noted experts, however, maintain that the importance of academic freedom and the role that publication plays in career development in a university setting keep concerns such as conflict of interest and publication delays at bay.²⁹

Whether such criticisms are well-founded or not is beyond the scope of this article. The issue, however, for our purposes is whether this is criticism of the BDA or some inevitable consequence of its success. Moreover, is this a sole consequence of the BDA or do the many other factors associated with the increased financial success of collaborative research share in this unintended consequence?

Even if one were to assume that such criticisms are

well founded and are due in whole or in part to the success of the BDA, it would appear that these are issues that individual universities are best equipped to address through their own internal policies and regulations.

Summary

Despite the criticisms addressed in this article, one is left with little doubt that the BDA has been a resounding success and forms part of the foundation upon which the modern collaborative research house is built. While there are certain questions or possible inadequacies with the Act and its implementing regulations, all of these can be addressed through amendments or regulatory guidance. Moreover, even though the success of the BDA has, in some cases, generated concerns or criticisms, these particular issues are best served through unrelated legislative actions or self-regulation by the Universities. ■

28. *Id.* at 17-18.

29. *Id.* at 18.