

ESSAY

PATENTS, PRODUCTS, AND PUBLIC HEALTH: AN ANALYSIS OF THE CELLPRO MARCH-IN PETITION

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ABSTRACT

Under an extraordinary provision of the Bayh-Dole Act, which governs the commercialization of government-funded technology, a federal agency may “march-in” and license a funding recipient’s inventions to a third party in certain circumstances. This march-in provision was invoked by a small start-up biotechnology company, CellPro, after it had been found liable for patent infringement. CellPro argued, inter alia, that government action was necessary to alleviate health or safety needs, since, infringement or not, it had an FDA-approved product on the market. Using the CellPro example as a case study, the authors critique the march-in authority and propose that its greatest value may well arise from the threat it poses and the resulting incentives for funding recipients to ensure appropriate commercialization of federally-funded inventions.

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Government-funded inventions are commercialized under the authorities granted to funding recipients by the Bayh-Dole Act. The Act allows

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funding recipients to obtain title to government-funded inventions, to patent and license them, and to seek and retain royalties from licensing. While providing broad discretion to funding recipients in managing inventions that arise from government funding, the Bayh-Dole Act also includes certain provisions protecting the public interest. One such provision, commonly known as "march-in," calls for mandatory licensing under certain conditions.

In August 1997, the Department of Health and Human Services ("HHS") became the first federal agency to respond to a formal petition to exercise this extraordinary provision of the Bayh-Dole Act. The march-in provision was invoked by CellPro, Incorporated ("CellPro"), a small Washington state biotechnology company, which sought to obtain from the government rights that it had been unable to obtain through more conventional channels. Specifically, CellPro had failed in its attempt to obtain a license to practice the invention from the patent holder or its licensee, and had been found liable for infringing the patent by the district court. CellPro, therefore, turned to the federal government, which funded the research that led to the discovery of the invention, for rescue.

This Essay provides an overview of the march-in authority and its implementing regulations using the CellPro Petition as a case study. In Part I, the Bayh-Dole Act is explained. Part II summarizes the NIH determination on the CellPro Petition. Part III discusses several legal and public policy issues illuminated by the CellPro Petition. Part IV discusses existing alternatives to government use of the march-in authority. We propose in light of existing government authorities that the greatest value of the march-in authority may be the threat it poses and the resulting incentives for federal funding recipients to ensure appropriate commercialization of their inventions.

I. FEDERAL TECHNOLOGY TRANSFER AND THE BAYH-DOLE ACT OF 1980

Technology transfer is the movement of technology and other resources between non-profit entities, government laboratories, and the private sector for further research, development and commercialization. Since the 1980s, with the passage of the Bayh-Dole Act¹ and the Stevenson-Wydler Technology Innovation Act of 1980,² federal laboratories and

1. 35 U.S.C. §§ 200-212 (1994).

2. Pub. L. No. 96-480 (1980) (current version at 15 U.S.C. §§ 3701-3717) (authorizing federal laboratories to, *inter alia*, enter into cooperative research and development agreements, and collect and retain royalties under patent license agreements).

federally-funded grantees and contractors³ engaged in research have pursued technology transfer, assuming as a public mission the business of licensing new technologies to the private sector for commercialization. Many technologies have now matured, and inventions that were patented and licensed in the early days of these laws are now in the marketplace.⁴

The Bayh-Dole Act, as the primary statutory authority promoting the transfer of technology developed under federal grants and contracts, is the foundation for the current technology transfer policy of the federal government. Prior to enactment of the Bayh-Dole Act, there was no uniform government policy regarding a funding recipient's right to elect title to a government-funded invention. Long-standing debate over whether the government should obtain title, or merely a license, to inventions made with federal funds caused different agencies to apply different rules.⁵ For example, the HHS regulations before implementation of the Bayh-Dole Act generally required research grants to provide that the ownership and disposition of all inventions be subject to determination by the Assistant Secretary of Health.⁶ Alternatively, ownership and disposition could be left to the funding recipient institution in accordance with its established policies and procedures provided that the funding recipient gave assurances that "the invention will be made available without unreasonable restrictions or excessive royalties" and other conditions.⁷ Obtaining rights to inventions made with funding from the government was burdensome and

3. Grantees and contractors are treated identically under the Bayh-Dole Act. *See* 35 U.S.C. § 201(c) (1994). Thus, for simplicity's sake, this Essay will use the term "funding recipient" for both types of award.

4. For example, at the National Institutes of Health, 990 licensed technologies generated approximately \$40 million in fiscal year 1998. *See* NIH Office of Technology Transfer, GAO Report RCED-99-173—Technology Transfer: Number and Characteristics of Inventions Licensed by Six Federal Agencies 33-34 (June 1999), available at <<http://www.nih.gov/od/ott/rc99173.pdf>>. Many products, including new research tools, diagnostics, vaccines, and therapeutics, are on the market and benefitting the public as a result of NIH's technology transfer program. *See id.*

5. For a discussion of the history of government patent policy with respect to technology transfer, see, for example, Rebecca S. Eisenberg, *Symposium on Regulating Innovation: Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996). For a review of the historical patent policies of various federal agencies, see Ralph C. Nash and Leonard Rawicz, George Washington University, Government Contracts, Monograph No. 10, Patents and Technical Data 74-78 (1983).

6. *See* 45 C.F.R. § 8.1(a) (1996) ("Inventions and Patents (General)"), made obsolete and superseded by the Bayh-Dole Act and implementing regulations. *See* 61 Fed. Reg. 54743, 54743-44 (Oct. 22, 1996).

7. 45 C.F.R. § 8.1(a) (1996). Contracts for research were similarly handled. *See* 45 C.F.R. § 8.6 (1996).

inefficient. Technology often languished while the bureaucracy processed requests for patent rights.⁸ With the Bayh-Dole Act, Congress modified this scheme and created a uniform patent policy with regard to small businesses and non-profit institutions.⁹

Under the Bayh-Dole Act, funding recipients generally have the right to elect title to inventions made with federal funding.¹⁰ By giving funding recipients the benefit of their inventions, Congress sought to promote the utilization, commercialization, and public availability of federally-funded inventions.¹¹ Congress also retained certain rights for the government to ensure that the public benefits from its investment.¹² For example, the funding recipient is required to disclose each subject invention¹³ to the funding agency within a reasonable time after it becomes known to the funding recipient¹⁴ and to elect within two years of disclosure whether it will retain title to the invention.¹⁵ The funding recipient must file patent applications for any invention in which it wishes to retain title within the appropriate statutory period.¹⁶ If the funding recipient fails to take any of these required steps, the federal government may receive title to the in-

8. Of the more than 28,000 patents in the government's patent portfolio obtained from its funding recipients, only 4% were successfully licensed. *See* S. REP. NO. 96-480, at 2 (1979).

9. In 1983, President Reagan issued a memorandum instructing all federal agencies, to the extent not prohibited by law, to grant all recipients the same right to their inventions as the Bayh-Dole Act provided small businesses and non-profit institutions. Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, Pub. Papers 252 (Feb. 18, 1983). This was subsequently acknowledged in law. *See* 35 U.S.C. § 210(c) (1994).

10. Funding recipients do not obtain title to inventions, however, when the government makes a determination of "exceptional circumstances" and under other circumstances set forth at 35 U.S.C. § 202(a) (1994).

11. *See* 35 U.S.C. § 200 (stating that the policy objectives of the Bayh-Dole Act include ensuring that "inventions ... are used in a manner to promote free competition and enterprise" and promoting "the commercialization and public availability of inventions made in the United States by United States industry and labor").

12. *See id.* (stating that the Act seeks "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"); *see also* 35 U.S.C. § 202 (1994).

13. A "subject invention" means any invention of the funding recipient conceived or first actually reduced to practice in performance of work under the funding agreement. *See* 35 U.S.C. § 201(e) (1994).

14. *See* 35 U.S.C. § 202(c)(1) (1994). Regulations implementing this portion of the Act are set forth at 37 C.F.R. Part 401.

15. *See* 35 U.S.C. § 202(c)(2) (1994).

16. *See* 35 U.S.C. § 202(c)(3) (1994).

vention.¹⁷ In addition, the Bayh-Dole Act provides that the federal funding agency retains a nonexclusive, paid-up license to practice an invention or have it practiced for or on behalf of the United States throughout the world.¹⁸

Another significant public interest safeguard in the statute is its march-in provision. This provision at 35 U.S.C. § 203(1) authorizes a federal agency, in limited circumstances, to ensure that a federally-funded invention is available to the public. Section 203(1) states that for any invention for which title has been retained by a small business firm or non-profit organization, the federal funding agency may require the title owner or its licensee to license the invention on terms “reasonable under the circumstances,” if certain criteria are met.¹⁹ To exercise this march-in right, the government must determine that such action is necessary:

- (a) ... because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- (b) ... to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- (c) ... to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- (d) ... because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.²⁰

Although march-in, as a safeguard of the public interest, is a purely governmental authority, the legislative history of the Act indicates that Congress anticipated that third parties, such as CellPro, would inform the federal government of the possible need for march-in.²¹ This is what hap-

17. See 35 U.S.C. § 202(c)(1)-(3) (1994).

18. See 35 U.S.C. § 202(c)(4) (1994). Specifically, “[w]ith respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, non-transferable, irrevocable, paid up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world....” *Id.*

19. 35 U.S.C. § 203(1) (1994).

20. 35 U.S.C. § 203(1)(a)-(d) (1994).

21. See S. REP. NO. 96-480, at 34 (1979) (“‘March-in’ is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that in most cases complaints from third-parties will be the basis for the initiation of agency action.”).

pened in the case of the CellPro Petition. On March 3, 1997, CellPro wrote to the Secretary of the Department of Health and Human Services seeking march-in and stating its rationale why march-in was warranted.

II. THE NIH DETERMINATION ON THE CELLPRO MARCH-IN PETITION

The march-in provision was invoked by CellPro, which sought to obtain a license to practice a certain stem-cell separation technology²² that was invented by a researcher at The Johns Hopkins University ("Johns Hopkins") under a grant from the National Institutes of Health ("NIH"). CellPro, having failed to obtain a license to practice the invention from Johns Hopkins or the ultimate sublicensee, Baxter Healthcare Corporation ("Baxter"), was found liable for infringement of the Johns Hopkins patents, subsequently determined to be willful infringement.²³

In its petition under the Bayh-Dole Act, CellPro argued, *inter alia*, that march-in was warranted because Johns Hopkins and Baxter failed to take reasonable steps to commercialize the technology.²⁴ Alternatively, CellPro asserted that government action to grant CellPro a license was necessary "to alleviate health or safety needs" that were not being met by Baxter, since, infringement or not, CellPro had an FDA-approved product on the U.S. market.²⁵

CellPro sought government march-in under subparagraphs (a) and (b) of section 203(1).²⁶ On August 1, 1997, after several months of informal

22. Stem cell separation is the process of isolating and purifying a certain type of blood cell, the stem cell, from the bone marrow or peripheral blood. Purified stem cells are infused into a patient during bone marrow transplantation as a means of helping the patient regenerate the patient's blood supply after cancer chemotherapy or radiation therapy. Newer means of stem cell separation, such as the antibody/device process at issue in the present case, allow such efficient purification that they are also being studied for their potential ability to prevent metastatic recurrences by screening out the microscopic cancer cells that typically remain with older isolation methods.

23. See *Johns Hopkins Univ. v. CellPro*, 978 F. Supp. 184, 184 (D. Del. 1997).

24. Letter from Lloyd N. Cutler and former Senator Birch Bayh, attorneys for CellPro, to Donna Shalala, Secretary, U.S. Department of Health and Human Services 13 (Mar. 3, 1997) (on file with authors) [hereinafter Petition].

25. The CellPro Ceparate SC device was approved for use in the United States by the U.S. Food and Drug Administration in December 1996. See Petition, *supra* note 24, at 4-5.

26. The criteria for march-in authority under subparagraphs (c) and (d) are applicable only in very narrow and specific circumstances, and were not relevant to the CellPro Petition. The "public use" criterion of subparagraph (c) only applies when such use is mandated by regulation. Subparagraph (d) applies narrowly to cases involving a procedural failure when an exclusive licensee has failed to agree (or obtain a waiver) that any

fact-finding pursuant to 37 C.F.R. § 401.6(b),²⁷ the NIH declined to initiate march-in proceedings, although the agency left open such a possibility if new facts arose.²⁸ The NIH based its determination on a voluminous public administrative record, consisting of the filings and responses of the parties, letters from Members of Congress,²⁹ letters from biotechnology companies and funding recipient universities³⁰ and other members of the public, as well as other information compiled by the agency. Of primary concern to the third party university and industry commenters was the potential for exercise of march-in authority to undermine their licensing rights under the Bayh-Dole Act.

The NIH evaluated the administrative record with regard to the two relevant subparagraphs of the march-in provision: sections 203(1)(a) and (b). First, the NIH examined whether Baxter failed to take, or was not expected to take within a reasonable time, “effective steps to achieve practical application” of the subject inventions.³¹ “Practical application” refers to the manufacture, practice, or operation of an invention under conditions such that it is being utilized and its benefits are “available to the public on reasonable terms.”³² The NIH concluded that practical application had been achieved since Baxter was manufacturing, practicing, and operating a medical device based on the technology, called the Isolex 300.³³ The de-

products embodying the invention or produced through its use will be manufactured substantially in the United States.

27. Procedures governing the exercise of march-in rights by federal agencies are provided at 37 C.F.R. § 401.6.

28. See Office of the Director, National Institutes of Health, Determination in the Case of Petition of CellPro, Inc., (Aug. 1, 1997), available at <<http://www.nih.gov/news/pr/aug97/nihb-01.htm>> [hereinafter NIH Determination].

29. NIH received many letters from Congress resulting initially from CellPro’s, and subsequently from Johns Hopkins’s and Baxter’s, public relations campaigns in support of their respective positions. In total, NIH heard from 37 members in favor of CellPro’s position and 40 members in favor of Johns Hopkins and Baxter.

30. Chiron, Genentech, Medtronic, Inc., and Research Corporation Technologies, among others, wrote to NIH expressing concern about the prospect of an NIH determination in favor of march-in, as did Harvard, Stanford, Emory, Vanderbilt, the University of Washington, Columbia University, University of Utah, University of Maryland System, University of Maryland at Baltimore, the Association of American Universities, and The Council on Governmental Relations. Only one funding recipient, the Fred Hutchinson Cancer Research Center, wrote in favor of march-in. CellPro held an exclusive license from the Fred Hutchinson Center on antibodies at issue in the infringement litigation.

31. NIH Determination, *supra* note 28, at 3-4.

32. 35 U.S.C. § 201(f) (1994).

33. The Isolex 300 was Baxter’s competing product to accomplish stem cell separation and filtering. The device relied on the antibody technology that is the subject of the Johns Hopkins patents.

vice was commercially available abroad³⁴ (having received regulatory approval in Europe), and it was in widespread clinical research use in the United States, although approval for commercial sale in the United States was still pending.³⁵

Second, the NIH examined whether there existed a health or safety need that was not reasonably satisfied by Johns Hopkins or Baxter under section 203(1)(b). The NIH found that the first factor needed to satisfy this criterion, in this case, the demonstration of a health need, had been met.³⁶ In reaching this conclusion, the NIH sidestepped a *de novo* review of the scientific or health data, about which the NIH found there to be considerable uncertainty and disagreement.³⁷ Instead, the NIH concluded that the very existence of CellPro's FDA-approved medical device was sufficient to meet the health need prong of section 203(1)(b), and that it would be "premature, and inappropriate for the NIH to substitute its judgment for that of clinicians and patients seeking to avail themselves of an FDA-approved medical device."³⁸ In other words, the NIH assumed a health need, since the Ceprate SC was the only device available for sale in the United States for selecting stem cells from autologous bone marrow for hematopoietic reconstitution. As stated in the NIH determination: "it fulfills a health need for those who wish to use it."³⁹

Although the NIH determined that there was a health need for the device, the NIH found it was "reasonably satisfied by the licensee."⁴⁰ In

34. The statute and regulations do not address whether practical application must be in the United States, or whether the health or safety needs relate to a domestic or an international population.

35. See Letter from Donald R. Ware, Foley, Hoag & Eliot, LLP and Frederick G. Savage, Office of the V.P. and General Counsel, Johns Hopkins University to Wendy Baldwin, Ph.D., Deputy Director, Office of Extramural Research, National Institutes of Health 17 (May 7, 1997) (on file with authors) [hereinafter Response].

36. See NIH Determination, *supra* note 28, at 3.

37. The NIH found considerable debate among scientists and clinicians as to whether immunoselection of stem cells with selection devices prior to transplantation provided a clinically significant benefit to patients over standard hematopoietic transplantation techniques. The clinical benefit upon which the CellPro Ceprate SC device was approved by the FDA was a reduction of infusional toxicity associated with the administration of bone marrow cells prepared with standard techniques. At the time of the agency's deliberation, neither CellPro nor Baxter had presented to the FDA any studies documenting that their cell separation devices improved stem cell engraftment, disease-free survival, or overall patient survival. The NIH found that it was premature to claim patient benefit from the use of either device. See NIH Determination, *supra* note 28, at 4.

38. *Id.*

39. *Id.*

40. *Id.* at 4-5.

making the determination, the NIH relied on the injunction entered by the United States District Court for the District of Delaware in the patent infringement litigation.⁴¹ The injunction allowed the continuing sale of the Ceparate SC until the Baxter product was approved for sale by the FDA, and for three months thereafter.⁴² In addition, the provision of products solely for use in clinical trials was authorized.⁴³ The NIH also relied on the pledge of Baxter to increase patient access to the Baxter stem cell separation device in the event CellPro reduced its support to clinical research sites.⁴⁴ Because it determined that the health need was being reasonably satisfied, the NIH concluded that march-in proceedings under 35 U.S.C. § 203(1)(b) were not warranted.⁴⁵

III. MARCH-IN AUTHORITY AND PUBLIC POLICY: ISSUES ILLUMINATED BY THE CELLPRO CASE

The CellPro Petition provides a vehicle to examine the march-in statute and its implementing regulations. Some of the problems encountered by the NIH in the CellPro Petition may be unique, such as how to make an agency determination about granting rights to an invention to a company that was simultaneously being sanctioned by a federal court for the practice of the same invention. Other problems are likely to recur, such as the lengthiness of the process. In this section, we illustrate some of the potential conflicts between federal agency authorities and between executive and judicial authorities that arose or could have arisen in the case of the CellPro Petition. In addition, we consider the unwieldiness of the march-in administrative process and the potential for misuse of the march-in authority.

41. *Johns Hopkins Univ. v. CellPro*, No. 94-105-RRM (D. Del. Jul. 24, 1997) [hereinafter Order].

42. The Order states in pertinent part:

CellPro may continue to make, have made, use and sell SC Systems and disposable products (including the 12.8 antibody) for use with SC Systems, within the United States, until such time as an alternative stem cell concentration device, manufactured under a license under the '204 and '680 patents, is approved for therapeutic use in the United States by the United States Food and Drug Administration ... and for a period of three months thereafter.

Id. at 5.

43. *See id.* at 5, 7.

44. *See* Letter from Vernon Loucks, Chairman and Chief Executive Officer, Baxter Healthcare Corporation to Donna Shalala, Secretary, U.S. Department of Health and Human Services (June 12, 1997) (on file with authors).

45. *See* NIH Determination *supra* note 28, at 6-7.

A. Potential Conflicts Between Sister Agencies

The CellPro Petition demonstrates that the statute's "health or safety" criterion may give any funding agency presented with a march-in petition the ability to inadvertently undermine another executive branch agency's statutory authorities. Federal agencies are hesitant to work at cross-purposes with other agencies, since it can confuse the public and generate tension and inconsistency within the executive branch.

In the CellPro Petition, the NIH was called upon to determine whether a "health need" existed for a medical device, and, if so, whether a competing device "reasonably" satisfied that need under a complex factual situation implicating FDA regulatory authorities. As described above, the NIH avoided a complex and controversial factual inquiry by determining that because the FDA approved the Ceprate SC as safe and effective for selecting stem cells from autologous bone marrow for hematopoietic reconstitution, and because, at that time, the Ceprate SC was the only device available for sale in the United States *for that purpose*, the device did fulfill a health need for those who wished to use it, until such time as a comparable alternative product became available for sale.⁴⁶ In essence, the NIH used the "safe and effective" approval standard for drugs set forth in the U.S. Food, Drug and Cosmetic Act as a proxy for a health need.⁴⁷

Although convenient to use the FDA "safe and effective" standard as a proxy for the Bayh-Dole Act's "health or safety" criterion, the two are not interchangeable. FDA approval does not involve an assessment of need, instead leaving judgments as to the value of a particular product to the physician and patient. This case, therefore, neither sets a precedent nor offers guidance on the meaning of the health or safety criterion of 35 U.S.C. § 203(1)(b). The CellPro Petition illustrates that in the absence of further regulations, funding agencies apparently have discretion to determine what constitutes a health or safety need for the purposes of march-in, based on any reasonable criteria they deem suitable. The NIH's reliance on FDA approval as a proxy for a health need shows a prudent reluctance to place two agencies of HHS at potential odds with each other, even though a *de novo* determination of a health need would presumably be more in the NIH's area of expertise than any in other federal agency's. Other federal agencies, called upon to make a health need determination

46. *See id.* at 4.

47. 21 U.S.C. § 355(a), (b) & (j). (1994).

merely because they happened to be the source of funding for a particular invention, may face even greater challenges.⁴⁸

The NIH also sidestepped a more subtle problem presented by unique facts in the CellPro Petition. Although CellPro's Ceprate SC device was FDA-approved, it was *not* approved for the use for which the device was primarily being used. The device was approved for use in processing bone marrow for autologous (self) transplants, based on evidence that it reduced infusional toxicities associated with bone marrow prepared with standard techniques.⁴⁹ This use was neither the most prevalent, nor that which CellPro sought to preserve by seeking march-in.⁵⁰ The more prevalent and clinically important use, immunoselection of stem cells prepared from peripheral blood (rather than bone marrow), was at that time experimental and practiced only by medical practitioners using the device "off-label" or within the context of FDA-approved clinical trials.⁵¹

By seeking a license under the march-in authority for an unapproved use, CellPro put the NIH in an awkward position. The NIH was being asked to make a finding on whether a health need existed for an off-label, unapproved use of an experimental medical device, which nonetheless showed great anecdotal clinical promise. Had the NIH determined that march-in was warranted, two agencies—in this case in the same department of the executive branch—might have been working at cross-purposes. Due to the very public nature of the proceedings, a determination by NIH declaring a public health need for the device would have

48. There is nothing in the Bayh-Dole Act or its implementing regulations that requires or precludes federal agencies called upon to make "health or safety" determinations outside the scope of their technical expertise from consulting with appropriate sister agencies, or nonfederal parties for that matter, in order to make the march-in determination. While such consulting might increase the likelihood of consistent and appropriate findings, it will add to the burdensome and time-consuming nature of march-in authority. *See infra* Part IV.C.

49. Evidence of reduced infusional toxicities is reported in Meeting of the FDA Center for Biologics Evaluation and Research: Biological Response Modifiers Advisory Committee (February 28, 1996) (on file with authors). At that public meeting, Richard Champlin, M.D. of the Anderson Cancer Center, introducing the CellPro device on behalf of CellPro, stated to the Committee, "again, one has to remember this is not a treatment for cancer. This is a means to enrich stem cells for a variety of purposes. It has again been shown to be reproducible, safe, and effective for that purpose. And this technology is really critical to allow us to develop the field in a number of other very important applications." *Id.* at 21-22. For documentation of FDA pre-market approval based on this evidence, see Letter from FDA to Monica Krieger, Ph.D., CellPro, Inc. (Dec. 6, 1996) (on file with authors).

50. *See* Petition, *supra* note 24, at 13.

51. *See* Response, *supra* note 35, at 5-6.

placed pressure on the FDA to approve the as-yet unapproved uses of the CellPro or the competing Baxter devices.⁵²

The NIH dilemma illustrates a serious concern with implementation of the health or safety criterion of the march-in authority. Funding agency determinations under this criterion may implicate the authorities of other agencies, resulting in conflicting or duplicative agency actions, since there is no statutory or regulatory directive under Bayh-Dole to defer to sister agencies. In addition, agencies may make decisions under the march-in authority in areas in which they have no expertise. Even when the funding agency defers to pertinent findings made by the applicable agency, anomalies may result. Such was the case here, where the FDA-approved use of the technology was declared to meet a "health need," notwithstanding the fact that the approved use was not how the device was actually being used. Further, the coordination that took place in the case of the CellPro Petition between the FDA and the NIH can in part be attributed to the fact that although the agencies have different missions, they are both agencies within the U.S. Public Health Service, Department of Health and Human Services. One can imagine examples where such overlapping expertise and ability to coordinate would not occur.

B. Potential Conflicts Between the Funding Agency and the Courts

A march-in petition may also put an executive branch agency considering the petition at odds with the judiciary. The petitioner, simultaneously before the funding agency and a court, both of which have authority to affect the petitioner's license rights, could obtain conflicting remedies. The facts of the CellPro Petition, although perhaps unusual, illustrate this problem. CellPro initially attempted to obtain rights to practice the technology the traditional way: by seeking a license.⁵³ CellPro was offered essentially the same terms as two other companies, Systemics, Inc. and Applied Immune Sciences, Inc.⁵⁴ While these companies accepted licenses,⁵⁵ CellPro refused the offered terms and instead, in April 1992, initiated a suit seeking a declaratory judgment that Johns Hopkins' patents were in-

52. As with any promising, but unproven medical advance, the device had a devoted following among cancer patients and advocates, many of whom called upon the NIH to ensure that issues of statutory interpretation and patent infringement not inhibit their access to the device.

53. See Petition, *supra* note 24, at 8; see also Response, *supra* note 35, at 18.

54. See Response, *supra* note 35, at 18.

55. See *id.* The acceptance of a license to the technologies by two other companies suggests that Baxter's terms were not commercially unreasonable. CellPro may have made a business decision weighing the costs of the license against the potential liability for infringement.

valid and that, in any event, CellPro did not infringe them. That suit was dismissed on jurisdictional grounds, and further license negotiations ensued. Again, license negotiations failed, and ultimately, the patent holder, Johns Hopkins, and its licensee and sublicensee, Becton Dickinson and Baxter, sued CellPro in U.S. District Court for the District of Delaware in March 1994, for patent infringement.⁵⁶

CellPro's defense in litigation was largely unsuccessful. The district court determined that CellPro's product infringed the Johns Hopkins' patent, and the jury's award of over \$2.3 million from CellPro's willful infringement was then trebled by the court.⁵⁷ Having failed to achieve the right to practice Johns Hopkins' patents through conventional negotiation of a license, and having failed to undo Johns Hopkins' rights through litigation, CellPro sought the intervention of a federal government agency under the power of the Bayh-Dole Act.⁵⁸ Although this was an understandable strategy by CellPro—one that potentially could obtain for the company a sought-after license or at least generate some pressure on Baxter to resolve the matter by executing a license with the company directly—the circumstances of the petition created a tension between the executive and judicial branches because of their overlapping jurisdiction.

The tension arises because although the march-in authority, under section 203(1)(b), gives the agency discretion to undo the exclusive rights of the patent holder when such action is merited by public health needs, the court also has that authority through its equitable powers.⁵⁹ If a petition for

56. See *Johns Hopkins Univ. v. CellPro Inc.*, 978 F. Supp. 184 (D. Del. 1997), *aff'd* 152 F.3d 1342 (Fed. Cir. 1998).

57. See *id.* at 196. On August 11, 1998 (more than one year after the NIH determined not to initiate march-in proceedings) the Federal Circuit upheld the district court's determination and damage award. See *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1365 (Fed. Cir. 1998). The Federal Circuit modified the district court's injunction in one minor regard, determining that CellPro was not required, as previously ordered, to return to the United States six vials of cells used to produce antibodies that had been shipped to Canada in 1993. See *id.* at 1367. On September 28, 1998, CellPro announced that it had settled its dispute with Johns Hopkins and Baxter and agreed to pay them \$15.6 million. Shortly thereafter, CellPro initiated voluntary Chapter 11 bankruptcy proceedings. See *In re CellPro, Inc.*, No. 98-13604 (Bankr. W.D. Wash., Nov. 6, 1998) (on file with author).

58. See *Petition*, *supra* note 24, at 1.

59. Injunctive relief invariably takes account of the public interest. See, e.g., *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982). There is clear, if dated, precedent for not enforcing patent rights to their fullest when such action would harm the public. See, e.g., *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation*, 146 F.2d 941 (9th Cir. 1944) (discussing suppression of patents against the public interest, in this case, in connection with a patent for irradiated margarine used to treat rickets); *City*

and determination to march-in *precedes* the issuance of an injunction by a court concurrently considering an infringement action, then the agency runs the risk of preempting the court's authority to strictly enforce the patent.⁶⁰ If the agency decided to exercise its march-in authority, it would presumably also be required to intervene in the district court case in order to bring the government's determination and interests before the court. It is not clear what would happen if the district court disagreed with the government's action and failed to recognize in its order any license granted by the government under march-in. Alternatively, if a court issued an injunction strictly enforcing a patent prior to an agency determination that march-in was warranted, the license granted under the march-in authority could be in direct conflict with the injunction. In such event, the licensee would be compelled to request the court to modify its injunction, or risk violating the injunction by practicing its rights under the license. Although these issues are likely resolvable, this overlapping jurisdiction creates procedural issues and tension between the executive branch and judiciary that may not have been anticipated by Congress when it enacted the march-in authority.

In the *CellPro* case, the injunction⁶¹ was issued only days before NIH's self-imposed deadline for making its determination.⁶² Although the language is vague, the regulations clearly intend that the consideration of a march-in petition be handled expeditiously and come to closure.⁶³ Each

of *Milwaukee v. Activated Sludge*, 69 F.2d 577, 592-93 (7th Cir. 1934) (denying injunctive relief when the requested relief would have closed the city's sewage treatment plant thereby causing public health concerns).

60. Clearly, if the agency decides not to march-in, the court may still assess the public interest and not strictly enforce the patent. In such a case, there would be no conflict between the agency's and the court's actions.

61. See Order, *supra* note 42, at 1-4.

62. See Letter from Robert B. Lanman, Legal Advisor, National Institutes of Health, to Donald R. Ware, Foley, Hoag & Eliot, L.L.P. (June 24, 1997) (on file with authors).

63. The regulations implementing the march-in process set forth a schedule for the agency's action, stating that:

[w]henver an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it

party involved in this dispute continued to brief issues for the NIH, which then triggered requests by the other party to respond. Eventually, in keeping with the intent of the regulations,⁶⁴ the NIH set a firm deadline for its determination.⁶⁵ Because the court did not order CellPro's product to be removed immediately from the market, no action was needed to alleviate health or safety needs, as the only FDA-approved technology was still available both for sale and for clinical research.⁶⁶ The outcome of the judicial decision was crucial information for the NIH to consider in making its march-in determination. However, the timing of the court's ruling was purely serendipitous. In the future, federal agencies faced with a march-in petition as well as the prospect of concurrent judicial jurisdiction may wish to consider notifying the contractor that "it will not pursue march-in rights on the *basis of the available information*,"⁶⁷ citing the pending judicial consideration, and subsequently open a new administrative action if warranted.⁶⁸

Although the problem did not arise in this dispute, yet another instance of overlapping jurisdiction could have arisen had NIH made a determination to exercise its march-in authority. If a determination to march-in is made by a funding agency, the statute provides that the adversely affected party may appeal to the U.S. Court of Federal Claims.⁶⁹ If the NIH had marched-in and required Johns Hopkins to license CellPro, presumably CellPro would have had to seek a modification of the injunction from the district court. Johns Hopkins would likely have contested any such modification and simultaneously appealed the march-in determination to the U.S. Court of Federal Claims. It is not clear how the conflicts would have been resolved if the U.S. Court of Federal Claims had upheld the march-in decision, but the district court refused to modify its injunction.

C. The Procedurally Burdensome Nature of the March-in Process

The CellPro Petition also highlights the unwieldy nature of the march-in administrative process. Under Department of Commerce regulations, an

will not pursue march-in rights on the basis of the available information.

37 C.F.R. § 401.6 (1998).

64. See 37 C.F.R. § 401.6(b) (1998).

65. See Letter from Robert Lanman to Donald Ware, *supra* note 62.

66. See Order, *supra* note 42, at 5.

67. 37 C.F.R. § 401.6(b) (1998) (emphasis added).

68. Neither the text nor legislative history of the Bayh-Dole Act indicates whether Congress anticipated this potential concurrent jurisdiction or considered it as a source of checks and balances between the Executive and Judiciary.

69. See 35 U.S.C. § 203(2) (1994).

agency that receives information it believes might warrant march-in may not initiate march-in proceedings without notifying the funding recipient and seeking informal comment.⁷⁰ After this notice and comment period, the agency may initiate march-in proceedings.⁷¹ While these proceedings are described in the regulation as "informal," in fact, they entail a full administrative fact-finding complete with the right to counsel, opportunity to call and confront witnesses, and to present documentary evidence.⁷² In the event that a determination adversely affects the funding recipient, inventor, assignee or exclusive licensee, that party may appeal to the U.S. Court of Federal Claims. In cases involving a funding recipient's failure to take steps to achieve practical application of an invention⁷³ or failure to meet requirements for public use specified by federal regulations,⁷⁴ the agency's determination is held in abeyance pending the exhaustion of appeals.⁷⁵

In the case of the CellPro Petition, the informal written comments from the grantee became an administrative process unto itself. CellPro submitted an extensive petition and Johns Hopkins responded in kind. The NIH, following a careful four-month review of all of the submissions related to the petition, determined that a march-in proceeding was not warranted. Had the NIH determined that a march-in proceeding was warranted because Johns Hopkins or Baxter could not reasonably alleviate the health need for the technology, it may easily have taken far longer to complete the full administrative process set forth in the regulations. In a case where march-in was justified by a health care emergency, the administrative process would likely not be expeditious enough to address the situation.⁷⁶ Although the march-in provision of the Bayh-Dole Act seeks, in part, to alleviate public health or safety needs for federally-funded inventions, the implementation of this authority hinders quick action.

70. See 37 C.F.R. § 401.6(b) (1998).

71. See *id.*

72. See 37 C.F.R. § 401.6(e) (1998).

73. See 35 U.S.C. § 203(1)(a) (1994).

74. See 35 U.S.C. § 203(1)(c) (1994).

75. See 35 U.S.C. § 203(2) (1994).

76. As in any judicial proceeding, issues beyond the merits of the case may be challenged and litigated, thereby extending the length of the case. For example, Hopkins reserved objections to NIH jurisdiction over the patents at issue. See Response, *supra* note 35, at 22 n.9. Johns Hopkins communicated to the NIH that Johns Hopkins and Baxter would challenge jurisdiction in federal court in the event that NIH initiated march-in proceedings: See *id.*

D. Use of March-in Petitions as a Weapon Against Competitors

It was recognized in the legislative history of the Bayh-Dole Act that interested third parties would probably generate most petitions for march-in.⁷⁷ However, there is nothing in the statute or its legislative history to indicate that use of the march-in authority should be for the direct benefit of such third parties. Rather, the march-in authority is intended to be an extraordinary remedy to be used to protect the public.⁷⁸ If funding agencies exercised their march-in authority frequently to allow third parties to compete with a bona fide licensee, federally-funded technology would be financially devalued by license applicants. In addition, frequent use of the march-in authority would chill the government's ability to license exclusively to applicants concerned about the certainty of their rights.

Fortunately, petitions for march-in in the biomedical arena are rare.⁷⁹ This is not surprising, because there are powerful economic incentives for the funding recipient, the licensee and the third party seeking a license to reach a commercial licensing arrangement. Patent owners generate revenue by licensing, and non-profit organizations, such as universities, have every incentive to license.⁸⁰ One of the criteria for marching in—lack of practical application—can be most effectively addressed by the funding recipient when the technology is licensed. For example, if an exclusive license is contemplated, a patent owner can negotiate specific fields of use (most often corresponding to different applications of the technology), and require applicants to submit commercial development plans with objective development benchmarks and milestones. These fields of use and development plans can, as part of the license, stipulate the loss of exclusivity or termination of the agreement if the licensee fails to develop the technology by meeting the benchmarks and milestones. There is little need to exercise march-in for non-use of such a license, because the funding recipient/licensor itself can modify or terminate the license in response to a

77. *See supra* note 21 and accompanying text.

78. *See id.*

79. To the best of the authors' knowledge, the CellPro petition to the HHS is the only formal petition for march-in since the inception of the Bayh-Dole Act. There have been various inquiries to federal agencies from third parties regarding possible march-in, but all have been resolved informally.

80. The Bayh-Dole Act encourages commercialization and allows non-profit funding recipients to retain royalties and other consideration earned from the licensing of federally-funded technologies. *See* 35 U.S.C. §. 202(c)(7) (1994). These royalties are an important source of revenue for universities. *See generally* ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, 1998 SURVEY OF UNIVERSITY TECHNOLOGY TRANSFER ACTIVITIES.

march-in petition by a third party, thereby making the technology available to the third party or others.

There are also market incentives for an exclusive licensee to sublicense. Where a licensee has failed to bring the invention to practical application, either entirely or within particular fields of application, it will likely welcome sublicensing discussions with a third party as a means of extracting some value, or additional value, out of the technology. This is common practice in biotechnology, an industry having a proclivity for partnerships, mergers, and sublicensing. The parties in the *CellPro* case were no exception. Baxter sublicensed the technology to two other companies, and apparently would have sublicensed to CellPro as well had terms been consummated. Further, in the midst of the CellPro march-in case, Baxter initiated discussions with VIMRX Pharmaceuticals, Inc. and subsequently sold its entire Immunotherapy Division to this small company (which subsequently began doing business as Nexell).⁸¹ Indeed, market forces resolved the ostensible "health need," as interpreted by the NIH to require availability of at least one of the devices, without the exercise of the march-in authority, resulting in CellPro's withdrawal of its petition on September 28, 1998.⁸² When CellPro filed for bankruptcy, Nexell Therapeutics Inc. obtained judicial approval to acquire CellPro's intangible assets, including intellectual property rights, patents, antibodies and related cell banks, research, and license rights.⁸³ Thus, Nexell acquired the right to market and sell the CellPro Ceprate SC. In addition, Nexell obtained FDA approval for the Isolex 300 device.⁸⁴ Thus, although both devices were ultimately licensed to the same company, which may result in only the more promising of the two devices being developed, march-in authority was not required to ensure that the public retained access to the technology originally developed under the government grants.

81. See Letter from Loucks to Shalala, *supra* note 44. Soon thereafter, VIMRX and Baxter Healthcare Corporation formed a new company, Nexell Therapeutics Inc., as a collaboration to develop and market cell therapies. See Nexell Therapeutics Inc., *VIMRX Announces Restructuring and Name Change to Nexell Therapeutics Inc.* (Jan. 14, 1999) <<http://www.nexellinc.com/press/1999/99jan15NEX.htm>>. Nexell's lead products were the Isolex 300 Cell Selection Systems. See *id.*

82. See Stipulation by CellPro, Inc. and Johns Hopkins University, September 28, 1998, *In re* Petition of CellPro, Inc. (on file with authors).

83. See Nexell Therapeutics Inc., *Nexell Acquires CellPro Assets* (Feb. 1, 1999) <<http://www.nexellinc.com/press/1999/99FEB01%20nex.htm>>.

84. See Nexell Therapeutics Inc., *Nexell Therapeutics Receives FDA Approvable Letter for Isolex 300 and 300i Cell Selection System* (Jan. 8, 1999) <<http://www.nexellinc.com/press/1999/99jan08NEX.htm>>.

Despite economic incentives to license, there are times when march-in may be necessary because of market failure or when companies license technologies without intending to develop them. For example, a company may exclusively license certain patents primarily to raise capital or to block competitors. If the patent owner has licensed without milestones and benchmarks, it loses the ability to address problems of public availability of the technology. Perhaps, it is here that the march-in authority provides its greatest value. Because march-in authority is such a blunt and powerful means to ensure that a government-funded technology does not languish to the detriment of the public, it exerts an *in terrorem* effect on the conduct of funding recipients and exclusive licensees. Exclusive licensees, in particular, are deterred from shelving federally-funded technologies because they may lose rights that may be important to them. Thus, exclusive licensees are encouraged by the presence of the march-in authority to develop or sublicense a technology, both of which benefit the public.

IV. ALTERNATIVES TO GOVERNMENT USE OF THE MARCH-IN AUTHORITY

If march-in authority is an unwieldy safeguard of the public interest, one must ask if alternative powers of the government are better suited to the task.

A. 35 U.S.C. § 202(c)(4)

In addition to the march-in authority under section 203, the Bayh-Dole Act also protects the public's investment in government-funded research by reserving a license for the government. 35 U.S.C. § 202(c)(4) states, in part, that the federal funding agency has a nonexclusive license to practice or have practiced the invention for or on behalf of the United States anywhere in the world.⁸⁵

85. [W]ith respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights; including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

35 U.S.C. § 202(c)(4) (1994).

The government's license under section 202(c)(4) does not provide the same ability to use the invention as the march-in authority. It is limited to practice "for or on behalf of the United States," whereas march-in authority is not so limited.⁸⁶ The reach of a section 202(c)(4) license has not been litigated. The government clearly can practice the invention itself, and it is well established that anything the government can do itself, it can do by contract.⁸⁷ Accordingly, under section 202(c)(4) the government could enter into a contract for the production of a particular technology that required the practice of an invention, provided that the federal agency's contract was otherwise authorized. In theory,⁸⁸ the NIH could have exercised its license under section 202(c)(4) by entering into a contract with CellPro to manufacture the stem cell separator. However, the government's contract with CellPro could only have been for the production of the technology for authorized government purposes. The NIH has authority to "secure, develop and maintain, distribute and support the development and maintenance of resources needed for research."⁸⁹ It appears, therefore, that NIH had the authority to contract with CellPro to support clinical research, but not to support CellPro's broader commercial purposes.⁹⁰

Notwithstanding the limitations of section 202(c)(4), it has certain advantages over the march-in authority of section 203. For example, the government's license under section 202(c)(4) applies statutorily and no administrative process is required for the government to exercise its rights.⁹¹ This means that the government can exercise its license expeditiously.

86. *Id.*

87. See generally 2 U.S. GENERAL ACCOUNTING OFFICE, PRINCIPLES OF FEDERAL APPROPRIATIONS LAW ch.10, 10-11 (2d ed. 1992) (describing federal assistance in the form of grants and cooperative agreements).

88. We say "in theory" only because, due to the overlapping jurisdiction of the court and the federal agency as described *supra* Part III.B, once the injunction against CellPro issued, NIH would presumably have had to go to the court to obtain modification of the order.

89. 42 U.S.C. § 284(b)(1)(F) (1994).

90. It is an open question, we believe, whether the license "on behalf of the United States" at section 202(c)(4) can be extended to allow the use of the invention by federal grantees. Although grantees and contractors are treated the same for purposes of the Bayh-Dole Act, these two types of funding recipients are not identical. Contracts are used to fund research that is for the direct benefit or use of the government, while grants are awarded for investigator-initiated research that supports a public purpose. This issue, however, is beyond the scope of this Essay.

91. It is worth noting, however, the government's license constitutes protection against a claim of infringement but does not necessarily provide the government with the

B. 28 U.S.C. § 1498 as an Alternative to March-in Authority

In contrast to sections 202(c)(4), and 203, section 1498 gives the federal government the right to practice an invention or infringe a copyright without a license if that practice is “by or for the United States”⁹² whether such inventions or copyrights were generated with federal funding or not. Under section 1498, the owner’s only remedy is a suit for money damages after the government’s use has begun.⁹³

In the case of the CellPro Petition, had there truly been a public health need for the invention, particularly an immediate need, the logical recourse for the government would have been action under section 1498, not the initiation of march-in proceedings under section 203. March-in proceedings, as described, are burdensome and, more significantly, time-consuming. Compliance with the procedural requirements of the march-in authority would be a disaster in the face of a true public health need; lawyers would be arguing while the public was left waiting. If there truly is a public health need for a particular patented technology, the government, through the use of section 1498, can immediately practice the invention, or contract with another entity for the practice of the invention, and the wrangling over “reasonable compensation” may occur after the public health needs have been addressed.

ability to practice the invention. For instance, a funding recipient may make an invention involving a method of using certain biological materials. The government’s statutory license to practice the invention does not provide the government with the necessary materials or the know-how. Government agencies that anticipate a desire to practice inventions made under funding agreements would be advised to assure that the funding agreements provide that materials will be a deliverable under the contract or will be shared with the agency under a grant.

92. 28 U.S.C. § 1498 (1994).

93. Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.... For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

V. CONCLUSION

The march-in authority is cumbersome to invoke, duplicates, in part, existing authorities, and has the potential to undermine the process of federal technology transfer by disrupting the existing synergy between the academic community and the private sector. What, then, is its value? In the view of the authors, there is value in the *in terrorem* effect march-in has on federal funding recipients and their licensees. The greatest value of march-in may well be as the proverbial Sword of Damocles, suspended over the federally-funded invention licensing process, its very presence an incentive for parties to resolve privately would-be cases of march-in.