

HOPKINS V. CELLPRO:
AN ILLUSTRATION THAT PATENTING AND EXCLUSIVE
LICENSING OF FUNDAMENTAL SCIENCE IS NOT ALWAYS IN
THE PUBLIC INTEREST

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I. INTRODUCTION

“Publish an invention freely and it will almost surely die from lack of interest in its development. It will not be developed and the world will not be benefited. Patent it and it will be taken up and developed into a business.”¹ This admonition, attributed to Elihu Thomson in 1920, underlies the logic of today’s government technology transfer program. Publication, by itself, is becoming an insufficient reward for scientific achievement. Instead, the patent race has taken its place, and the great halls of America’s research universities are now the inventor’s track.

The concept of the university as a haven for development and dissemination of basic scientific research has changed greatly since the arrival of the Bayh-Dole Act in 1980.² The Bayh-Dole Act’s use of patents to stimulate technology transfer of federally funded research has had a profound impact on fundamental early stage research and its subsequent usage. Because the prestige and royalties associated with patents have replaced the traditional reward of publication and recognition in the furtherance of science, the university is starting to resemble commercial research laboratory, “like a corporation engaged

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This Note is dedicated to my uncle Moufid Ragheb, who died of cancer after spending his life treating others, and to my friend and classmate Dan Desevo, who died of cancer at a very young age. May those of us versed in science and the law endeavor to make the law work for the advancement of technology and humankind.

1. Lynne J. Bowers & Vickie Leon, *Patent Policies of 65 Educational Institutions: A Comparison*, SOC. RES. ADMIN. J., Spring 1994, at 7, 7.

2. See Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200–11, 301–07 (1994)).

in the relatively profitable business of producing ideas that it licenses to the highest bidders.”³

This regime, which has flourished under the Bayh-Dole Act, raises unexplored economic and political questions with respect to biology, as a field fundamentally tied to the well-being of the human race. Of the basic sciences — such as biology, chemistry, and physics — biology has traditionally been the most isolated from the commercial world. From the inception of the patent system, applications stemming from chemistry and physics have been the subject of patents. However, only since the Supreme Court’s 1980 decision in *Diamond v. Chakrabarty*⁴ have practical applications of biology — in the form of manipulation of living organisms or biotechnology — been recognized as patentable inventions.⁵

In August 1998, the United States Court of Appeals for the Federal Circuit decided a case involving potentially life-saving technology derived from publicly funded basic biological research developed and patented at a university.⁶ Through the lens of this case, *Johns Hopkins University v. CellPro, Inc.*, and its history, I will illustrate how the patenting of basic research as a tool of technology transfer has strayed from the principle of using public research dollars to maximize public welfare.

II. A SHORT HISTORY OF TECHNOLOGY TRANSFER POLICY

At about the same time the Supreme Court was opening the door to the Patent and Trademark Office (“PTO”) for the biotech field in *Chakrabarty*, Congress paved a path from the door of the university to the door of the PTO. In 1980, Congress passed the Bayh-Dole Act, allowing universities to patent and hold title to inventions developed with government funding, with the objective of “us[ing] the patent system to promote the utilization of inventions arising from federally supported research or development”⁷ The federal government has fostered

3. Wade L. Robison & John T. Sanders, *The Myths of Academia: Open Inquiry and Funded Research*, 19 J.C. & U.L. 227, 231 (1993).

4. 447 U.S. 303 (1980).

5. See *id.* at 310 (“Here . . . the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under [35 U.S.C.] § 101.”).

6. See *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998), *aff’g* 978 F. Supp. 184 (D. Del. 1997), *aff’g in part and vacating in part* 931 F. Supp. 303 (D. Del. 1996).

7. 35 U.S.C. § 200 (1994).

the development of the U.S. biotechnology industry by subsidizing much of the industry's basic research⁸ — that is, research that underlies later practical innovations, but which may have no applied value itself — much of which takes place in universities. The Act granted title to inventions based on government-funded research to any university with an established technology office, without requiring the university to seek a waiver of government retention to title on a case-by-case basis. By contrast, previous policy and legislation required governmental funding agencies either to retain title to government-funded inventions or to dedicate the findings to the public domain.⁹ A brief review of past technology policy reveals the underlying arguments and rationale of the Bayh-Dole Act.

In the Roosevelt era, the National Patent Planning Commission created a policy that combined public dedication and private ownership of discoveries reached with government funding.¹⁰ Although the Commission felt that the government should generally “make the inventions covered by its patents available for commercial [development]” by all interested parties, it recommended that the government “issue exclusive licenses in cases where it seems evident that otherwise the inventions in question will not come into general use.”¹¹ By contrast, the Attorney General at the time recommended that the government generally should maintain full ownership of government inventions and license them non-exclusively to the public or dedicate them to the public domain. In cases where non-exclusive licenses would not attract appropriate investment to commercialize the invention, the Attorney General recommended that the government itself should directly invest in the required development rather than grant an exclusive license.¹² One of the primary concerns of the Attorney General was the right of the public to reap the fruit of publicly funded discoveries, without having to sustain the additional costs posed by placing exclusive licenses in the hands of particular corporate intermediaries.

During the Nixon administration, the Commission on Government Procurement proposed, as an alternative, a new, government-wide

8. See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1667 (1996); see also Kevin W. McCabe, *Implications of the CellPro Determination on Inventions Made with Federal Assistance: Will the Government Ever Exercise its March-In Right?*, 27 PUB. CONT. L.J. 645, 668 (1998).

9. See Eisenberg, *supra* note 8, at 1663–64.

10. See *id.* at 1672.

11. *Id.* (citation omitted).

12. See *id.* at 1673.

system allowing private corporations to retain title to patents, subject to a system of government march-in rights.¹³ The government could “march in” if the corporation failed to make use of the patent and force the patent owner to grant a licence to another entity. In contrast to the later Bayh-Dole Act, the Commission would reserve the presumption in favor of granting patent rights to corporations, but would not make such a presumption in the case of universities.¹⁴

Likewise, President Carter’s Industrial Advisory Subcommittee on Patent and Information Policy recommended that the private sector either be given title or awarded an exclusive license to inventions derived from government-funded research. The subcommittee generally objected to government ownership of patents, on the grounds that this system would give the private sector too little incentive to perform government-funded research.¹⁵ At around the same time, Senators Bayh and Dole offered a different approach, which, in a break with past recommendations, sought to grant universities and small businesses patent rights in government-funded research developments.¹⁶

III. OBJECTIVES AND RATIONALE OF THE BAYH-DOLE ACT

A look at the Bayh-Dole Act and the congressional debate that led to its passage reveal a number of policy objectives. This Section compares these policy objectives to the Act’s results.

A. Reducing Delays and Uncertainties in Technology Transfer

Until the passage of the Act, universities were forced to deal with a myriad of different policies regarding research funding and ownership of inventions. In total, twenty-six different agency regulations existed, all of them presumptively granting the government title to federally funded inventions.¹⁷ It was difficult, time-consuming, and risky for universities to overcome the presumptions of federal title. Although at least one university structured an Institutional Patent Agreement with two different funding agencies, allowing the university to shift the

13. *See id.* at 1687.

14. *See id.* (internal quotes omitted).

15. *See id.* at 1689.

16. *See id.* at 1691.

17. *See* Kenneth Sutherlin Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 FOOD & DRUG L.J. 453, 460 (1997).

presumption of title,¹⁸ not all universities had such resources. Prior to the Bayh-Dole Act, licensing an invention held by the federal government also presented substantial bureaucratic hurdles, and as a result few companies sought to license technology from the government.¹⁹ Smaller corporations, often viewed as more innovative, were even less likely to have resources to spare to navigate such government bureaucracy. Thus, the government was its own worst enemy in the dissemination and transfer of the work it was funding.²⁰ The Senate recognized these shortcomings when it reported that:

It has been well demonstrated over a number of years that Federal agencies are not as successful in delivering new products and inventions to the marketplace as the private sector. The result is that the public is not receiving the full benefits of the research and development efforts that it is supporting. It is in the public interest to see that new discoveries are commercialized as quickly as possible without the artificial restraints caused by unnecessary delays and uncertainties of the present Government patent policies which only serve to make an already risky attempt to develop new products more of a burden on interested companies.²¹

In response to these concerns, the Bayh-Dole Act created a uniform policy that presumptively granted title to patents developed with public money to universities and eliminated over twenty statutory provisions previously governing technology transfer.²²

B. Spurring Innovation

By facilitating technology transfer, the Bayh-Dole Act made cultivating the fruits of such research more enticing to companies and universities. It was hoped that the greater expected return to

18. See *id.* at 460 (discussing the agreements between the Wisconsin Alumni Research Foundation and the Department of Health, Education, and Welfare, and the National Science Foundation).

19. See Howard W. Bremer, *Testimony on the Effectiveness of the Bayh-Dole Act*, 5 J. ASS'N U. TECH. MANAGERS (1993), available at <<http://128.200.222.12/pubs/journal/93/testimony93.html>>.

20. See Dueker, *supra* note 17, at 459.

21. S. REP. NO. 96-480, at 19 (1979).

22. See Dueker, *supra* note 17, at 462.

government-funded researchers would encourage riskier or more innovative research endeavors. Senator Bayh succinctly expressed this sentiment in Congress:

Simply put, American efforts at innovation, in which we were once the undisputed world leader, were stagnating

[C]learly the United States needed to develop a more effective overall technology transfer program We came to the realization that this failure to move from abstract research into useful commercial innovation was largely a result of the government's patent policy and we sought to draft legislation which would change this policy in a way to quickly and directly stimulate the development and commercial realization of inventions.²³

C. Patenting Versus Public Domain: A Preference for Domestic Industry

A natural question at this point in the discussion, in light of prior regimes and the transactional costs of licensing and patent prosecution, is why patenting was preferred to dedication to the public domain. After all, the traditional academic procedure of publishing one's findings would make the invention readily accessible to interested companies without the high cost of patenting and licensing. In addition, prompt publication would provide proof of early discovery, precluding anyone other than the inventor himself from patenting the invention.²⁴ Therefore, to reduce costs to an absolute minimum, the federal government could have required prompt disclosure of all federally funded research.

The most important element lacking in such a policy is one of control. Once information is in the public domain, the government has little control over subsequent commercial exploitation of the technology. A patent, however, gives the patentee the exclusive, alienable right to

23. *The Bayh-Dole Act, A Review of Patent Issues in Federally Funded Research: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Senate Judiciary Comm.*, 103d Cong. 10 (1994) (prepared statement of Senator Birch Bayh).

24. This follows from the requirement that one can only patent one's own invention. See 35 U.S.C. § 102(f) (1994). In fact, one year after publication, not even the inventor can patent an invention. See *id.* § 102(b).

make, use, and sell the patented invention.²⁵ Thus, by restricting the licensing of patents springing from federally funded research, the government can control who ultimately develops and commercializes these inventions. The Bayh-Dole Act capitalizes on this opportunity by limiting licensing to companies that will manufacture the licensed inventions within the United States.²⁶ Thus the Act seeks to utilize tax dollars to maximize public welfare *through domestic industry*. The issue is then what degree of licensing exclusivity is optimal within domestic industry.

IV. THE PUBLIC INTEREST AND LICENSING EXCLUSIVITY

Within a system where universities have title to patents sponsored by government-funded research, we must ask whether the way universities license these patents comports with the public interest. Our policy preference as to exclusive or multiple licensing should balance industry interests in invention commercialization with the public interest in receiving the benefits of research. The National Institutes of Health ("NIH"), for instance, has articulated two goals for technology transfer: to disseminate knowledge and to rapidly incorporate biomedical research into clinical applications.²⁷

It would seem that the public interest plays little role in the market interaction between a licensor and licensee, where each tries to strike the best deal possible. A corporate licensee will seek an exclusive license if it believes that the monopoly profits — adjusted for the premium paid for exclusivity — exceed the profits it can gain with a non-exclusive license and the resulting competition. Exclusive licensing is a major benefit to corporations seeking to capitalize on patented university research. Patents, or an exclusive license to patents, are virtually a requirement in order for a start up company to gain venture capital financing.²⁸ On the other hand, it would only be in the best interest of a university to grant an exclusive license if the price received

25. *See id.* § 154.

26. *See id.* § 204.

27. *See The National Institutes of Health and Its Role in Creating U.S. High-Technology Industry Growth and Jobs: Hearing Before the Subcomm. on Regulation, Business Opportunities, and Energy, 102d Cong. 8 (1991) (statement of Bernadine Healy, Director, NIH).*

28. Venture capital is the predominant method of financing in the biotech startup industry — an industry that has seen strong venture capital investment levels for some time. *See* Craig W. Johnson, *Recent Developments in Venture Capital Financing for Biotechnology Companies*, in ALI-ABA COURSE OF STUDY, BIOTECHNOLOGY: BUS., L. & REG., Nov. 18, 1993, available in WESTLAW, C886 ALI-ABA 1, 3.

for exclusivity appears to be greater than the sum of multiple license proceeds.

In a 1979 congressional hearing prior to the enactment of the Bayh-Dole Act, Representative Jack Brooks criticized the awarding of patent rights to universities as giving away rights belonging to the taxpayers who funded the research.²⁹ Representative Brooks argued that granting the rewards of patenting is appropriate in the case of private investment, where a corporation bears the risk of failure. However, with public funding, the risk is borne by the taxpayers, and so the rewards should likewise be awarded to the public.³⁰

Under the Bayh-Dole Act, the government has no input as to whether the license should be made available to one or many, unless the licensee(s) fail to achieve practical application within a reasonable time.³¹ This limitation of government action may grease the wheels of technology transfer, but undue delay in government intervention may jeopardize the public interest. Some damage — for instance, the unavailability of medical treatment — may occur before the government can intercede on the public's behalf. It is noteworthy that neither the NIH nor any other agency has ever exercised its march-in rights.³²

However, universities do not always opt for exclusive licensing. One of the most profitable and well known technology transfer success stories is a set of broadly licensed patents on gene-splicing jointly developed by the University of California and Stanford University — the Cohen-Boyer gene-splicing patents — which had generated over \$155 million for the universities as of 1996.³³ The decision for multiple licensing was based at least in part on the fundamental, far-reaching, and revolutionary nature of the gene-splicing patents.

This was a boon to the public; however, multiple licensing also proved wise with respect to the universities' financial interests. One patent attorney and professor of patent law claims that the success of the Cohen-Boyer patents can be attributed to a licensing fee "so pitifully low that even foreign companies signed on as licensees, even though they would never need to take a license to do work in their home

29. See H.R. REP. NO. 96-1307, at 2 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6487.

30. See *id.*

31. See 35 U.S.C. § 203.

32. See *Underreporting Federal Involvement in New Technologies Developed at Scripps Research Institute: Hearing Before the Subcomm. on Regulation, Business Opportunities, and Technology*, 103d Cong. 29 (1994) (statement of Wendy Baldwin, Deputy Director of Extramural Research, NIH).

33. See Dueker, *supra* note 17, at 492 tbl.12.

countries.”³⁴ The \$10,000 per year license fee is roughly on par with the cost of a non-infringement opinion, and so, “[t]he Cohen-Boyer patents had become the ‘bambi’ of the university community; nobody wanted to shoot bambi; it was a good will gesture to make out a \$10,000 per year ‘donation’ to Stanford.”³⁵ Moreover, the patents may have been invalid from the start because the invention was disclosed to a group of industry experts at a research conference more than one year prior to the filing of the first patent application.³⁶ Thus, one can argue that multiple licensing was a necessity, and not motivated by the public interest in widespread availability. Indeed, another commentator believes that licensing these patents

ha[s] done [nothing] to promote product development that would not have occurred if the patented technology had instead been placed in the public domain. The reason universities count these patents as successes is not that they have helped move the technology out to the private sector for commercial development, but rather that they have generated a lot of revenue for the institutions that own them.³⁷

The stakes for the public in technology-transfer policy are raised in cases such as the Cohen-Boyer patents, where a patent can catalyze more developments than a single licensee could reasonably exploit.

V. FUNDAMENTAL RESEARCH AND “RESEARCH TOOLS”

Licensing of scientific research has recently become the subject of much criticism. The increasing number of patents covering discoveries with widespread potential laboratory usage has led to increasing interference with the dissemination and utilization of what have been labeled “research tools.” The NIH Working Group on Research Tools has defined these to include: “cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs

34. Harold Wegner, *The Research Tool “Reach Through” Patent License: Billion Dollar Rainbow or Simply Fool’s Gold?* 10 (Apr. 14, 1999) (class materials for Comparative Patent Law at the Georgetown University Law Center, on file with the *Harvard Journal of Law & Technology*).

35. *Id.* at 10.

36. *See id.* (citing MARTIN J. ADELMAN ET AL., *PATENT LAW* § 4.2 (1998)).

37. Eisenberg, *supra* note 8, at 1710.

and drug targets, clones and cloning tools, methods, laboratory equipment and machines, databases and computer software.”³⁸

In June 1998, the NIH Working Group promulgated guidelines in response to problems in obtaining access to patented research tools — including refusals to license — encountered by NIH-funded investigators.³⁹ The issue of granting proprietary rights on fundamental research tools is of great concern not only to researchers but also to industry and the general public. If industry is precluded from using such basic and fundamental tools, development of products beneficial to the public will be slowed or delayed. “Research tools” may have applications not limited to research; and, as upstream discoveries, they “might ultimately prove to be therapeutic or diagnostic products in their own right, marketable to consumers for use outside the laboratory.”⁴⁰

Chief among the group’s recommendations were that the NIH should promote free dissemination of research tools without legal agreements whenever possible, especially when the prospect of commercial gain is remote, and that the NIH should develop and disseminate for recipients of NIH funds guidelines as to what terms in licenses and contracts are reasonable for the use of tangible materials in research.⁴¹

VI. *HOPKINS V. CELLPRO*

A. *The Science*

Hopkins v. CellPro concerned certain technology related to stem cells, a type of undifferentiated blood cell found in the bone marrow from which all the various blood cells found in the bloodstream arise. In the early 1980s, Dr. Curt Civin was studying the maturation, differentiation, and isolation of blood cells to learn about diseases related

38. NATIONAL INSTITUTES OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS 3 (1998), *available at* <<http://www.nih.gov/news/researchtools/index.htm>> [hereinafter NIH WORKING GROUP REPORT].

39. The problem is not limited to licensing practices; some members of the Working Group believe that “the problem of proprietary restrictions on the availability of research tools has been aggravated by the issuance of excessively broad patent claims.” *Id.* at 4. Broader patentability issues were left for another day, although two members of the working group expressed considerable dissatisfaction with the operation of the patent system in biomedical research in areas such as the research exemption to infringement and the utility and nonobviousness requirements. *See id.* at 23.

40. *Id.* at 4.

41. *See id.* at 18.

to them.⁴² This research at Johns Hopkins was funded in part by the NIH. Civin located an antigen named My-10, found only on stem cells.⁴³ He further developed an antibody, also called My-10, the first of its kind that was stage specific and detected immature cells such as stem cells.⁴⁴ The My-10 antigen and antibody are also known as the CD34 antigen and antibody. This basic biological research formed the basis for the patents at issue in *Hopkins v. CellPro*: one for the antibodies to the CD34 antigen (patent 4,965,204, the “204 patent”); one for a purified suspension of stem cells (patent 4,714,680, the “680 patent”); one for a method of creating a purified suspension of stem cells using CD34 antibodies (patent 5,035,994, the “994 patent”); and one for a method of using the purified suspension of stem cells in bone marrow transplants (patent 5,130,144, the “144 patent”).⁴⁵

These patents had potential application to the treatment of cancer — specifically, as an alternative medium for bone-marrow transplants. The bone marrow is often damaged by radiation and chemotherapy, so that a cancer patient can no longer generate new blood cells — a constant need for any patient, since blood cells have a lifespan of only a few days.⁴⁶ However, the two traditional approaches to bone-marrow transplants carry dangers of their own. Grafting bone marrow from another individual can result in Graft Versus Host Disease (“GVHD”), in which white blood cells produced by the transplanted marrow attack the patient’s body.⁴⁷ On the other hand, grafting the patient’s own pre-radiation bone marrow runs the risk of transplanting cancerous cells back into the body.⁴⁸ Using purified stem cells avoids the hazards of both of these courses of action.

CellPro manufactures two devices to purify stem cells, the Ceprate LC and the Ceprate SC.⁴⁹ In 1986, researchers at the Fred Hutchinson Cancer Research Center produced the 12.8 antibody, which recognizes a different element of the My-10 antigen on CD34 cells than does Civin’s antibody.⁵⁰ The 12.8 antibody has the advantage of being able to link physically to baboon CD34 cells in addition to human cells,

42. See *Johns Hopkins Univ. v. CellPro, Inc.*, 931 F. Supp. 303, 308 (D. Del. 1996).

43. See *id.* at 309.

44. See *id.* at 309–10.

45. See *id.* at 310–12.

46. See *id.* at 308.

47. See *id.* at 309.

48. See *id.*

49. See *id.* at 312.

50. See Eliot Marshall, *Varmus to Rule in Fight Over Cell-Sorting Technology*, 276 Sci. 1488 (1997).

which was essential in paving the way to human clinical trials. In order to develop methods to prepare purified stem cell suspensions, several scientists at the Hutchinson Center formed CellPro, Inc.⁵¹ In December 1996, CellPro obtained FDA approval for use of the process of isolating and separating stem cells in the United States, before Hopkins, its licensee Becton Dickinson and Co., or its sublicensee, Baxter Healthcare Corp., had done so.⁵²

B. The Litigation

In March 1994, Hopkins sued CellPro in the federal court in Delaware, alleging that CellPro had willfully infringed the '204 patent (for CD34 antibodies).⁵³ CellPro denied infringement and asserted that the '204 patent was invalid and unenforceable.⁵⁴ CellPro also counterclaimed, alleging violations of antitrust law and for a declaratory judgment that the '204 patent, as well as the '680 patent, the '994 patent, and the '144 patent, were invalid, unenforceable, and not infringed.⁵⁵

In the district court, a jury found that Hopkins's patents were invalid in view of the prior art, and therefore there was no possibility of infringement.⁵⁶ Following the trial, the judge held, as a matter of law, that CellPro infringed the '680 patent (stem cell suspension) and that Baxter, Hopkins' licensee, was entitled to a new trial.⁵⁷ At the second trial, the jury, charged only with determining willfulness, found that CellPro's infringement was in fact willful.⁵⁸

However, the court did not immediately enjoin CellPro to cease marketing its 12.8 antibody. Although the jury had found willful infringement, the district court ordered that "CellPro may continue to make, have made, use, and sell [the 12.8 antibody] until such time as an alternative stem cell concentration device . . . is approved for therapeutic use in the United States by the United States Food and Drug

51. *See Johns Hopkins Univ. v. CellPro, Inc.*, 978 F. Supp. 184, 187 (D. Del. 1997).

52. *See id.* at 186.

53. *See* 931 F. Supp. at 306.

54. *See id.*

55. *See id.*

56. *See id.* at 307.

57. *See id.* at 328.

58. *See* 978 F. Supp. at 185.

Administration”⁵⁹ The district court granted treble damages, for a total of \$6.9 million in damages.⁶⁰

On appeal, in an opinion by Judge Lourie, the Federal Circuit held that both the ’204 and the ’680 patents (antibodies and stem cell suspension, respectively) were valid and infringed by CellPro.⁶¹ The Federal Circuit upheld the district court’s damage award.⁶²

C. CellPro’s Petition for a Government March-in

Before the second trial and the subsequent appeal to the Federal Circuit, CellPro petitioned Donna Shalala, Secretary of the Department Health and Human Services (“DHHS”), to exercise the government’s march-in rights under 35 U.S.C. § 203 against the Civin patents. Shalala forwarded the petition to NIH Director Harold Varmus because NIH, as the funding agency for the subject patents, is responsible for exercising the government’s march-in rights.⁶³

Section 203(1)(a) permitted the government to require Hopkins to grant CellPro a license if Baxter, Hopkins’ exclusive licensee, “ha[d] not taken, or [was] not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention”⁶⁴ Section 203(1)(b) likewise permits exercise of march-in rights if “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.”⁶⁵

CellPro argued that allowing Hopkins and Baxter to exercise their full patent right to exclude CellPro from making, using, or selling its cancer treatment device would create a public health need.⁶⁶ However, Varmus, responding eight days after the Federal Circuit made its decision, declined to exercise march-in rights, emphasizing “Hopkins’ licensing activities and Baxter’s manufacture, practice, and operation of

59. Harold Varmus, *National Institutes of Health, Office of the Director, Determination in the Case of Petition of CellPro, Inc.*, Aug. 1, 1997, at 4 (citing *Johns Hopkins Univ. v. CellPro, Inc.*, No. 94-105-RRM (D. Del. July 24, 1997) (order granting permanent injunction and partial stay of injunction)), available at <<http://www.nih.gov/news/pr/aug97/nihb-01.htm>> [hereinafter *NIH Determination*].

60. See 978 F. Supp. at 196.

61. See *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1357–62 (Fed. Cir. 1998).

62. See *id.* at 1362–64.

63. See Marshall, *supra* note 50, at 1488.

64. 35 U.S.C. § 203(1)(a) (1994).

65. *Id.* § 203(1)(b).

66. See *NIH Determination*, *supra* note 59, at 1.

the Isolex 300 [Baxter's cell-sorting device], as well as the pending applications for FDA approval."⁶⁷ Varmus also denied the existence of any exigent public health need.⁶⁸ In so doing, Varmus deferred to the courts and the failure of open market licensing:

It would be inappropriate for the NIH, a public health agency, to exercise its authority under the Bayh-Dole Act to procure for CellPro more favorable commercial terms than it can otherwise obtain from the Court or from the patent owners. CellPro's commercial viability is best left to CellPro's management and the marketplace.⁶⁹

VII. THE DECISION NOT TO EXERCISE MARCH-IN RIGHTS

NIH Director Varmus really had nothing to decide after the opinion and injunctions from the infringement litigation were issued. His job was considerably simplified because any possible harm that might result to the public under 35 U.S.C. §§ 203(1)(a) & (b) was alleviated by the District Court's order limiting Hopkins' and Baxter's full monopoly rights.

Consider that under section 203(1)(a), the government, acting through Varmus, only has the right to take action if it determines that "action is necessary" to require the contractor, assignee, or exclusive licensee to grant a license. Since the court effectively stayed CellPro's removal from the market and granted it a temporary license, no action on Varmus's part was necessary to protect public health.

CellPro's very presence in the marketplace alleviated any factors that might have led to the exercise of the government's march-in rights. In sum, because the court filled the gap that would have been created by vesting Baxter with its full rights, Varmus and the executive branch did not need to act according to either section 203(1)(a) or section 203(1)(b).

A. No Unmet Health Need?

In determining whether the CellPro Ceprate SC fulfills any health or safety needs not reasonably satisfied by the Baxter Isolex 300, the NIH

67. *Id.* at 9.

68. *See id.*

69. *Id.* at 8.

ignored the link between health needs and usage by hospitals. Although the Biological Response Modifiers Advisory Committee, on which Varmus relied in his response, found that Baxter's device can produce *successful* stem-cell engraftments, Varmus emphasized the lack of evidence of an *improvement* in overall clinical results:

To date neither party has presented to the Biological Response Modifiers Advisory Committee any studies documenting that cell separation devices improve stem cell engraftment, [the FDA-approved clinical benefit,] disease-free survival, or overall survival. Thus it is premature for either Baxter or CellPro to claim patient benefits (other than a decrease in infusional toxicities) from stem cell isolation and purification, T-cell, lymphocyte, and tumor cell purging, or other claimed uses.⁷⁰

Although conclusive evidence of *improvement* of stem cell engraftments may have been lacking, patient benefits still existed, as evidenced by public demand. As Dr. Varmus indicated himself, the CellPro device "fulfills a health need for those who wish to use it"⁷¹ The very fact that hospitals purchased millions of dollars of CellPro's stem cell separation equipment, the only equipment approved for sale in the United States, indicates that CellPro was fulfilling a health or safety need not satisfied by the licensee Baxter. Given the therapeutic benefits associated with the CellPro device, it is contradictory to award Hopkins and Baxter a royalty which is based upon commercial success, while completely ignoring commercial success in the determination of public need for section 203(1)(b) march-in rights. Commercial success and long-felt need are criteria that have long been utilized to determine the novelty and obviousness of an invention in determining patentability.⁷² Indeed, the jury was instructed to consider "the established profitability of the product made under the patent, its commercial success, and its current popularity" in determining a reasonable royalty.⁷³ These criteria, widely used to determine damages and eligibility, should also be utilized to determine if there is an unmet need according to section 203(1). If they can have

70. *Id.* at 5–6 (footnote omitted).

71. *Id.* at 6.

72. *See, e.g.,* *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

73. *Johns Hopkins Univ. v. CellPro, Inc.*, 894 F. Supp 819, 838 (D. Del. 1995).

the force of a sword when determining damages, they should have equal force in determining public need in the context of march-in rights.

Furthermore, focusing on the clinical benefit upon which the CellPro device was approved by the FDA — immunoselection of stem cells prior to transplantation — and relying on a lack of consensus among clinicians about its efficacy ignores the reality that the device was being used in cancer treatment. Although clinicians may have been debating whether a clinically significant benefit to patients was recognized as compared to standard hematopoietic transplantation techniques,⁷⁴ they were still buying and using millions of dollars worth of CellPro's equipment. While it may be that some of the demand was due to "off-label" uses not approved by the FDA, such uses are legal, and so should not detract from the "on label" benefits of the device.⁷⁵

B. The Free Market: Viability and Commercial Considerations

In addition to his ignoring the significance of hospitals' use of the Isolex 300, Dr. Varmus also made a lapse in his reasoning. He argued that the market had decided against CellPro, citing CellPro's failure to negotiate a license on its own. Yet this begs the question of whether the government should exercise its march-in rights, which by definition grant more favorable terms than are available in the marketplace.

Moreover, ignoring the viability of a provider of a public health benefit is imprudent considering the NIH's goal of improving the health of the citizenry. Viability is not strictly an economic determination left to the free market, but is an area that has been addressed by the legislature and the courts. Courts regularly make decisions concerning the future viability of companies found to infringe patents. The courts award treble damages in willful infringement cases, which often punishes an infringer to such a degree that it will no longer be viable.⁷⁶

Infringement, however blatant or willful it may be, should not be the yardstick of intervention in order to facilitate technology transfer. Indeed, a company will attempt to invoke march-in rights only after it believes that it will be found to infringe or if it already has infringed. Otherwise, it would be free to make, use, or sell its product without any restriction. It may be the case that multiple players best serve the public's needs — if not always, at least in the specific instance. Therefore, the issue becomes whether exercising march-in rights and

74. See *NIH Determination*, *supra* note 59, at 6.

75. See Marshall, *supra* note 50, at 1491.

76. See Judge Randall Rader, Lecture for Comparative Patent Law course at the Georgetown University Law Center (Apr. 14, 1999).

awarding a second license would have such adverse effects on investment that the effectiveness of technology transfer on the whole would be reduced to an unacceptable level. This is not something that should be left to the patent courts to decide. Invocation of the march-in rights should be based upon need — specifically the need for non-exclusive licensing to protect the public health. In this instance, the court went out of its way to manipulate the patent monopoly for the public well-being. However, the very presence of march-in rights in § 203 is evidence that the legislature intended that NIH, as the agency responsible for the public health, is the governmental entity best equipped to determine whether to march-in on the patentee's exclusive right.

VIII. REALIZATION OF TECHNOLOGY TRANSFER GOALS IN *HOPKINS V. CELLPRO*

The Hopkins patent and its exclusive license to Baxter in this case was not in the public interest and did not realize the intent of the Bayh-Dole Act. CellPro beat Baxter to the market, but was soon driven out by Baxter and Hopkins. Contrary to the intent of spurring innovation, the innovation that was taking place was prohibited by the technology transfer program. If not for Hopkins' and Baxter's voluntary limitation in exercising their full patent rights, a device used to treat cancer patients would have been taken from the public. The public voiced its interest in maintaining a competitive market — twelve U.S. senators and twenty-five representatives wrote letters to HHS Secretary Donna Shalala on CellPro's behalf.⁷⁷

Further, exclusive licensing reduces competition because of potential liability due to patent infringement. Fear of infringement and the uncertainties of patent litigation will surely dissuade development of beneficial technology, whether or not infringement is even likely to be found. CellPro was dependent upon an opinion of non-infringement by its patent counsel in raising capital to fund its organization.⁷⁸ Opinion of counsel in this case offered no protection in mitigating liability,⁷⁹ and in general, legal advice does little to reduce the uncertainty of patent litigation.

77. See Eliot Marshall, *NIH Nixes Appeal to Bypass Patent Law*, 277 Sci. 759 (1997).

78. See *Johns Hopkins Univ. v. CellPro, Inc.*, 978 F. Supp. 184, 187–88 (D. Del. 1997).

79. See *id.*

Of course, one example in which the Bayh-Dole Act failed to achieve its goals does not mean that the technology transfer system is not functioning properly. In fact, university statistics suggest that university technology transfer programs are an overall success. According to the Association of University Technology Managers ("AUTM"), 333 start-up companies were formed in FY 1997, and 2214 companies have been formed since 1980, that were based on a license to an academic invention.⁸⁰ Further, the AUTM concludes that academic licensing was responsible for \$28.7 billion of economic activity — and 245,930 jobs — in the United States in FY 1997.⁸¹ However, it is impossible to understand what development would have taken place without the exclusivity inherent to patent protection. Moreover, statistics indicating increased patenting may represent just that — simply that more patents are being issued as universities seek to increase their wealth, not that any more innovation and development is necessarily taking place.

The NIH has developed guidelines for the licensing of fundamental research which, if followed, would have served it well in *Hopkins v. CellPro*. Development of technology based upon stem cells is of such fundamental interest that exclusive licenses should not be permitted without any evaluation of the consequences. Patenting itself retards the dissemination of research results due to the need for secrecy before application. The resultant need for licensing further delays subsequent use of the invention. The combination of patenting and exclusive or unchecked free market licensing can foreclose research and development in a crucial field. The NIH has recognized this problem in the context of research tools, and the Working Group on Research Tools has recommended that the following alternatives be investigated:

1. developing a standard "term and condition" for grants requiring that recipients provide the NIH with samples of unique research resources upon request to facilitate the government use license;
2. replacing the current "encouragements" to recipients to disseminate unique research resources with stronger requirements to the same effect;
3. revising its policies with regard to election of title under the Bayh-Dole Act to ensure that NIH elects title to unique

80. See ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, LICENSING SURVEY FY 1997, Executive Summary, available at <<http://www.autm.net/pubs/survey/1997/execsumm.html>>.

81. See *id.*

research resources and takes necessary action to ensure that the research community is not blocked from using such resources, including dedication to the public domain or deposit in an appropriate repository; [and]

4. using its “exceptional circumstances” authority for particular funding agreements where the purpose of the grant is to generate unique research resources.⁸²

While it is clear that the NIH is seeking to protect free usage of unique research by other researchers, heightened scrutiny of funding recipients and increased dissemination of research tools would also benefit private industry.

These proposals are consistent with prior policies of technology transfer and better realize the intent of bringing research science to market effectively and responsibly. Such a policy would not be as drastic as the Roosevelt administration’s issuance of exclusive licenses only in cases where the invention would otherwise not come into use, but would resemble the Nixon administration’s proposal granting the contractor title only if it was determined that inventions likely to flow from a given contract will be promoted in a manner consistent with the objectives of utilization and maintenance of competition.⁸³ Although these proposals would increase bureaucracy, which the Bayh-Dole Act sought to reduce, exercising march-in rights sparingly and only in cases involving unique research resources should minimize the dissuasive effects on industry investment. If such criteria were utilized, Dr. Civin’s discoveries may never have been patented or exclusively licensed.

The NIH should adopt these proposals and, more importantly, must act upon them. Perhaps the NIH viewed CellPro as not deserving of ownership, or perhaps the NIH viewed as unduly great the chilling effect on future investment of exercising march-in rights. However, utilizing some combination of the above options should reduce the need to exercise the drastic and last-minute march in. Ensuring widespread dissemination and use of basic research fundamental to the development of beneficial human therapies would increase access by the public and mitigate potential conflicts such as that exemplified by *Hopkins v. CellPro*.

82. NIH WORKING GROUP REPORT, *supra* note 38.

83. See Eisenberg *supra* note 8, at 1672–87.

IX. CONCLUSION

While encouraging the private sector to develop federally funded basic research is an important goal, *Hopkins v. CellPro* illustrates that allowing a university to patent, hold title, and maintain unlimited control of the results is not without its shortcomings. This case indicates that policies intended to facilitate technology transfer to private industry for the benefit of the consuming public can actually retard innovation and competition when left unchecked.

While patents may serve a critical role in facilitating technology transfer, guidelines need to be established and enforced to regulate the licensing practices of inventions funded by the NIH. Much of the research funded at the university level by the federal government is fundamental in nature and forms the basis for an unknown range of further discoveries. Inhibiting developments based upon that research is antithetical to the very purpose of sponsoring university research. Science so basic and fundamental to the functioning and treatment of the human body should not be controlled solely by free market forces.