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# Federally Funded Stem Cell Research: A Good Deal for the Taxpayer and Consumer?

Don Allen Resnikoff\*

On August 9, 2001, President Bush announced that he would allow federal taxpayer money to be used for medical research on stem cells from human embryos. He limited research to cells previously extracted from embryos and said that he would not support the destruction of new embryos.

The public debate that followed the President's announcement has focused mainly on the ethical issues of research using cells from human embryos, and whether the President's limitation of research to previously extracted stem cells will make enough stem cell "lines" available to researchers at a reasonable price. There is relatively little discussion in the media of pragmatic taxpayer and consumer issues. Is federal funding likely to be efficiently used? Is it likely to create medical benefits for the public? More specifically, will government owned or funded patents result from stem cell research, and should private companies get exclusive rights to develop the government patents? If companies get exclusive rights, should the prices for the resulting privately marketed medicines and procedures be regulated? Should companies with exclusive rights be regulated to assure they do a good job developing and commercializing patented inventions?

There has been some media discussion of whether federal funding will be well used. In an Op-Ed piece in the August 31, 2001 edition of the *New York Times*, computer entrepreneur Jim Clark said that the limitations President Bush has put on federal financing of stem cell research will cause harm, and urged that federal financing be offered with fewer restrictions:

Denying financing for this biomedical [stem cell] research will drive the formation of a new pharmaceutical industry outside the United States. Federally funded research helped create America's economic leadership in the Internet and computer technology. It led to the formation of companies like Silicon Graphics, Sun Microsystems, Cisco and Netscape. Restricting stem cell research for even a few years simply means that scientists in the United States will not be pioneers. Others will own the patents and claims, and a new pharmaceutical industry will thrive elsewhere. I believe our country risks being thrown into a dark age of medical research.<sup>1</sup>

Mr. Clark wants the federal government to provide research seed money to promote segments of the American pharmaceutical industry. He believes this is a wise investment in American economic leadership.

But is Mr. Clark right? Will American taxpayers and consumers really benefit from the government investment in industry that Mr. Clark advocates?

Mr. Clark's views represent one side of a broader set of taxpayer and consumer issues concerning the wisdom of the government's funding of research and development that aids the U.S. biotechnology industry (as well as other industries). Controversy surrounds the current U.S. government policy of patenting medically significant biological inventions developed by government scientists or funded with federal money, and then frequently turning them over to private companies for development, often on an exclusive basis.

One reason for controversy is that private companies that receive exclusive rights to exploit government owned or funded patents may charge high prices for the resulting medical products. Critics of private exploitation of publicly funded biotech inventions say that taxpayers may pay twice, first to sponsor the invention and then to

buy the patented medication or device. Another reason for controversy is that companies that receive exclusive rights may find it in their interests to develop and commercialize the government patent very slowly. Where rights are exclusive, there are no competing companies to challenge the laggard's protected market position.

The main defense for the government policy is that commercial development of medically significant biological inventions is expensive, so private companies would not perfect important medical advances unless the government turned over valuable patent rights. The argument is that exclusive rights create social benefit by encouraging private companies to develop technologies that would otherwise languish.

Debate about patents and private exploitation of government owned or sponsored medical inventions often is between experts and excludes the general public. The debaters are most often specialists in government biotech research policy or law. The debate takes place largely in academic journals and at scholarly meetings, and sometimes in Congressional hearings. Occasionally, activists like Ralph Nader and his colleague James Love (head of the Consumer Project on Technology--an advocacy group founded by Ralph Nader) do get involved and the debate becomes more public.

To better understand the debate about private exploitation of government owned or sponsored inventions and to draw the connection to stem cell research, a non-specialist should know something about the basics of stem cell research, and the laws that are the basis for the U.S. government policy of patenting its inventions and turning them over to private industry for exploitation. Also, knowledge of past controversies aids understanding.

## I. Stem Cell 101

The National Institutes of Health (“NIH”) provides a primer to help the public understand the medical potential of stem cell research.<sup>2</sup> The primer explains that so-called human “pluripotent” stem cells (cells capable of self-renewal, as well as differentiation into one or more subsets of mature, specialized cells) are important to science and to advances in health care:

At the most fundamental level, pluripotent stem cells could help us to understand the complex events that occur during human development. A primary goal of this work would be the identification of the factors involved in the cellular decision-making process that results in cell specialization. We know that turning genes on and off is central to this process, but we do not know much about these ‘decision-making’ genes or what turns them on or off. Some of our most serious medical conditions, such as cancer and birth defects, are due to abnormal cell specialization and cell division. A better understanding of normal cell processes will allow us to further delineate the fundamental errors that cause these often deadly illnesses.<sup>3</sup>

The NIH primer explains that stem cell research could improve therapeutic drug development and testing.<sup>4</sup> New methods could be developed for testing new medications using human cell lines, something that is already done in a limited way.<sup>5</sup>

A more ambitious goal of stem cell research is the generation of cells and tissue that could be used for so-called “cell therapies.”<sup>6</sup> The NIH primer explains that stem cells “offer the possibility of a renewable source of replacement cells and tissue to treat a myriad of diseases, conditions, and disabilities including Parkinson’s and Alzheimer’s diseases, spinal cord injury, stroke, burns,

heart disease, diabetes, osteoarthritis and rheumatoid arthritis.”<sup>7</sup> An example is development of healthy heart muscle cells from stem cells for transplant into the failing heart muscles of patients with chronic heart disease.<sup>8</sup> According to the NIH primer, “preliminary work in mice and other animals has demonstrated that healthy heart muscle cells transplanted into the heart successfully repopulate the heart tissue and work together with the host cells. These experiments show that this type of transplantation is feasible.”<sup>9</sup>

The stem cell research described in the NIH primer could lead to new medical procedures or medications of commercial value to drug companies. Where the new medical procedures or medications are owned or funded by the U.S. government, federal laws apply which provide for private commercial exploitation of the biotech inventions. For the purposes of those laws, stem cell research is the same as other biotechnology research which may lead to new medical procedures or medications.

## II. The Law of Technology Transfer

Maria C. Freire, Ph.D., Director of the NIH Office of Technology Transfer, briefly outlined some basic relevant federal laws when she testified to a Senate Subcommittee in January, 1999.<sup>10</sup> She explained that Congress enacted a series of laws that encourage government owned and funded research laboratories to pursue the commercialization of the results of their research. The laws are the Bayh-Dole Act of 1980, the Stevenson-Wydler Innovation Act of 1980, and the Federal Technology Transfer Act of 1986 (“FTTA”).<sup>11</sup> The “Bayh-Dole Act addresses intellectual property rights in federally funded grants, contracts, and cooperative agreements, while Stevenson-Wydler and the FTTA address intellectual property of government laboratories.”<sup>12</sup> Ms. Freire explained that “these laws allow government laboratories

and the recipients of government funding to elect to retain title to their inventions. They also impose certain obligations: promoting utilization, encouraging commercialization and ensuring public availability of these technologies."<sup>13</sup>

When Jack Brock of the U.S. General Accounting Office discussed the relevant law in Congressional testimony in July, 2001,<sup>14</sup> he explained that the Bayh-Dole Act has evolved over time. In its early years it was applicable to small rather than large businesses, as well as universities and other nonprofit organizations.<sup>15</sup> Not until February, 1983 was the Act extended to large businesses by a Presidential memorandum issued by Ronald Reagan.<sup>16</sup> In 1984, Congress amended the Bayh-Dole Act to cover outside contractors operating government-owned laboratories as well.<sup>17</sup> In April, 1987, the President issued an Executive Order which, among other things, required agencies to promote commercialization in accordance with the 1983 Presidential Memorandum.<sup>18</sup>

In her Congressional testimony, Maria Freire illustrated how the Bayh-Dole Act works, using the example of the stem cell lines licensed by Wisconsin Alumni Research Foundation ("WARF") to the Geron company.<sup>19</sup> (Both entities have been prominent in recent headlines because of their commercial control of many of the human cell lines President Bush wishes to be used for stem cell research.) Ms. Freire explained that early work at the University of Wisconsin on developing stem cell lines from non-human primates was federally funded, so that the patent on the procedure for developing and maintaining the cells fell under the rules of the Bayh-Dole Act.<sup>20</sup> As required by the Act, the invention of the procedure for developing stem cell lines was disclosed to the NIH. A patent application was filed by the University of Wisconsin through WARF, and WARF licensed the technology to Geron.<sup>21</sup> Ms. Freire explained that:

Because federal funds were used for this non-human primate work, the government has a non-exclusive, royalty-free right to use the patented cells by or on behalf of the of the government. This would allow the government laboratories and contractors the right to use the patented cells for further research. In addition, in handling this invention the University must ensure that the goals of the Bayh-Dole Act utilization, commercialization, and public availability are implemented.<sup>22</sup>

Ms. Freire pointed out that when research is funded entirely by the private sector, Bayh-Dole rules do not apply, so the government has no license, and availability to the government of patented information is strictly a matter of private discretion.<sup>23</sup> That is the case for the Geron sponsored work on human stem cell lines derived from human fetuses.<sup>24</sup>

### III. The AZT Controversy

AZT, a drug for fighting the AIDS virus, is perhaps the best known “poster child” story for those who believe private commercialization of government funded research leads to drugs that are too scarce and too costly, and who advocate government price regulation as a response.

Critics have excoriated patent holder Wellcome (now Glaxo because of a corporate acquisition) for years for profiting excessively from a medical patent that depended to a significant extent on government effort and protection. The September 15, 1989 *Wall Street Journal*<sup>25</sup> reported that activists in San Francisco, London and New York staged demonstrations attacking Burroughs Wellcome and its parent, London-based Wellcome PLC, as corporate extortionists. The *Journal* article explained that “[t]he company is accused by activists and some health-care providers of reaping

unseemly profits from AIDS patients and federally funded Medicaid by keeping the price of AZT, or azidothymidine, at a level that makes it one of the most expensive drugs ever sold—about \$8,000 for a year's supply per patient."<sup>26</sup>

With regard to the federal government's role in inventing AZT, the Journal reported that critics believe that AZT profits are a windfall for the company.<sup>27</sup> Critics say Wellcome "didn't create the compound, it wasn't the first to discover its effectiveness against AIDS-type 'retroviruses,' it didn't uncover its effectiveness against AIDS itself and it didn't conduct the first human tests." Much of that work was done by federally financed NIH scientists.<sup>28</sup>

Representative Waxman, a California Democrat, held Congressional hearings on AZT's price in early 1987.<sup>29</sup> A few years later he reportedly wrote to Wellcome, saying that the continued high price of the drug "appears to be an attempt to charge whatever patients, governments and insurers can scrape together because they are desperate and have no alternative."<sup>30</sup> He said that was inappropriate in light of all the government help Wellcome received, and warned that his subcommittee on health and the environment might reopen hearings into AZT's price.<sup>31</sup>

Complaints about AZT pricing have continued through the years. Reporter Gregory Palast, writing in the July 27, 2000 issue of the Guardian about drug company pricing policies toward poor Africans, had harsh words about Wellcome, saying that "Glaxo [Wellcome] was inventive, all right, but not in discovering AZT."<sup>32</sup> In recent years arguments directed against AZT's high prices have expanded to include new anti-AIDS drugs, such as the drug stavudine, a Bristol-Myers product sold under the brand name Zerit. The Seattle Times for June 13, 2001, reported that:

James Love, a Seattle native and head of the Consumer Project on Technology—an advocacy group founded by Ralph Nader—is pushing for the creation of a nonprofit company to license the rights to make and sell a low-cost version of d4T [stavudine], a widely used AIDS drug sold by Bristol-Meyers, for \$10 a day in the U.S. Known as Zerit, it was discovered by government-sponsored research at Yale, which has a deal with the company.<sup>33</sup>

Love reportedly argues that “a provision of the 1980 Bayh-Dole Act, which regulates a private company’s use of federally funded research, requires the federal government to issue a compulsory license when a company’s profits are deemed excessive in the face of people’s needs, provided tax money was used in the research.”<sup>34</sup>

The long range goal of a group associated with Mr. Love, Public Citizen, is broader government price regulation of drugs that benefit from government funding. Public Citizen’s July 23, 2001 publication called “Rx R&D Myths: The Case Against The Drug Industry’s R&D ‘Scare Card’” argues for price regulation for private company drugs that have benefited from taxpayer-funded research.<sup>35</sup>

In the 1980s, and more recently, the result of public agitation alleging price gouging in the sale of AZT and other anti-AIDS drugs has been some moderation in drug prices. Recently large drug companies have effectively lowered the price of AIDS drugs sold to people in poor nations in Africa and elsewhere.<sup>36</sup>

The AZT story illustrates the debates about drug company pricing that could erupt should federally financed stem cell research lead to patented medical products. Fairness requires the observation that the limited nature of Glaxo-Wellcome’s role as inventor of AZT is not so plain as critics suggest. As a matter of patent law (as opposed to broader equitable argument), the courts have

decided that for the most part the role of government scientists did not give them (or their employer, the U.S. government) the rights of co-inventors.<sup>37</sup>

#### **IV. The Cellpro Controversy**

The Cellpro controversy involved narrow but bitterly contested patent disputes. It also involved argument about the need for government regulation of companies that hold exclusive rights to government owned or funded patents, and which are alleged to be laggards in developing the patents.

The patent dispute in Cellpro concerned rights to rival procedures for separating immature from mature stem cells. The immature cells were useful for the purpose of replacing damaged bone marrow in cancer patients who had received radiation treatments. The mature cells caused rejection problems, so procedures were developed for separating them. Federal funding contributed to one of the two rival procedures.

The separation procedure that was first to be patented was a federally funded invention made by a scientist at Johns Hopkins University. The patent for the invention was owned by the University and licensed exclusively to Baxter Healthcare Corporation (Baxter). The patents owned by Cellpro were issued later. Simply stated, the argument of the Hopkins/Baxter patent infringement lawsuit against Cellpro was that because the Hopkins/Baxter patents had priority in time, and were overlapped by the Cellpro patents, Cellpro's use of its separation procedures infringed the Hopkins/Baxter patent and should be stopped. To a large extent, Hopkins/Baxter prevailed in the courts over Cellpro's patent law arguments.<sup>38</sup>

Cellpro supplemented its defense of the Hopkins/Baxter patent litigation by complaining to the federal government and requesting that the government use its authority against Hopkins/Baxter under the Bayh-Dole

Act. Cellpro wanted the government to “march in” and require that the federally funded Hopkins/Baxter stem cell separation technology be made more freely available to others, including itself. Cellpro asserted that federal action was necessary to alleviate health and safety needs, because the federal court had enjoined sale of the commercially available Cellpro stem cell separation device at a time when the equivalent Hopkins/Baxter device was not yet widely available for purchase. Cellpro alleged that Hopkins/Baxter had failed to take reasonable steps to commercialize their device, so that Cellpro was the only one of the two that had a commercially available FDA approved device.

In 1997, the NIH, which was responsible for deciding the Cellpro petition, decided against “marching in.”<sup>39</sup> It reasoned there was no threat to patient health or safety because Baxter had pledged in the course of patent infringement litigation to refrain from fully enforcing patent rights.<sup>40</sup> The Court had entered an order making unlikely the “loss of availability of the Cellpro product.”<sup>41</sup> Any possible loss of availability would be only for the brief period until the Hopkins/Baxter product was approved by the FDA.<sup>42</sup> Moreover, medical efficacy of the separation devices was unclear, so availability of separation devices was of questionable value to patient well being.<sup>43</sup>

With regard to the allegation that Baxter had failed to commercialize the cell separation technology, the NIH found that Baxter had proceeded with reasonable speed, even if it lagged behind Cellpro.<sup>44</sup>

The NIH decision articulated an enforcement philosophy of avoiding Bayh-Dole march-in for fear of discouraging private company exploitation of government inventions:

We are wary, however, of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-

reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies. . . . In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.<sup>45</sup>

The NIH did not exercise its Bayh-Dole march in authority in the Cellpro matter and, indeed, scholars that have studied the question say that NIH has never used its march in authority in any matter.<sup>46</sup>

The Cellpro story suggests the possibility of future debates where government sponsored stem-cell based medical research results in a patent. Where patent rights are given to a private company on an exclusive basis, disputes may arise about whether the company is diligently developing and commercializing the patent. Competitors or consumers may argue that exclusivity has made the beneficiary company lazy and slow to develop and commercialize a patented product or process. Complainants may argue that the exclusivity should be broken by the sponsoring government agency and the patent shared with other companies.

## V. The Ongoing Debate

There plainly are problems with a government policy of patenting government owned or funded inventions and giving exclusive rights to the patents to private companies. Some comments by scholars help pinpoint the problems. Rebecca Eisenberg, a professor and frequent consultant to the government, offers an overview, explaining that:

Today, we have in place a system that pervasively promotes patenting federally-sponsored inventions

wherever they are made, whether in government, university, or private laboratories. Current law presumes that anyone involved in the research project who wants the discovery to be patented should prevail over the objections of anyone who thinks the discovery should be placed in the public domain, absent exceptional circumstances . . . . Only in exceptional circumstances does the statute acknowledge that there may be an affirmative case for putting a discovery in the public domain for the greater social good.<sup>47</sup>

Professor Eisenberg says that "this is a counterintuitive policy in a number of respects."<sup>48</sup> First, allowing private firms to hold exclusive rights to inventions that have been generated at public expense requires the public to pay twice for the same invention, "once through taxes to support the research that yielded the invention, and then again through higher monopoly prices and restricted supply when the invention reaches the market."<sup>49</sup> Second, giving companies exclusive rights in existing publicly funded inventions is something like giving patent rights on existing inventions, which results in a net social loss.<sup>50</sup> That is because giving exclusive rights to an existing invention may cause prices to go up but yields no beneficial new invention. Third, "by promoting the private appropriation of federally-sponsored research discoveries as a matter of routine, it calls into question the public goods rationale for public funding of research."<sup>51</sup> And fourth, "by providing incentives to patent and restrict access to discoveries made in institutions that have traditionally been the principal performers of basic research, it threatens to impoverish the public domain of research science that has long been an important resource for researchers in both the public and private sectors."<sup>52</sup>

Scholar Nathan Adams is similarly unenthusiastic about transfer of government patents to private compa-

nies. He complains that it is bad industrial policy and bad economics for the U.S. government to fund medical research and development that leads to patents for private firms.<sup>53</sup> He says that the policy will do more harm to the U.S. economy than good, for three reasons: (1) the policy causes the government to "choose commercial winners" and support some business efforts, but not others; (2) it creates opportunities for fraud and pork barrel politics, and (3) it encourages markets dominated by a few companies (an oligopoly) charging high prices.<sup>54</sup>

Adams' "choosing winners" complaint is similar to the observation made by Professor Eisenberg. By granting some corporations within an industry exclusive rights to public knowledge, in effect the federal government "blesses them twice at the expense of other corporations . . . once with funds for research and development and a second time with monopoly pricing rights."<sup>55</sup>

The "fraud and pork barrel politics point" is that many government grants are likely to be politically expedient rather than economically wise. Adams argues with regard to Bayh-Dole type grants that "federal laboratories tend to interact predominantly with only a few, interested private and public entities . . ."<sup>56</sup>

Adams' point about high prices charged by a few large companies is that Bayh-Dole type government largesse typically encourages only a small coterie of companies by giving them exclusive rights. Adams feels that leads to great market concentration, an oligopoly, in particular products and processes.

A recent National Research Council report commented wistfully on the problem of patenting of government inventions, even as the report strongly endorsed public funding of stem cell research and a strong focus on basic research.<sup>57</sup> The report says that "[e]ven patenting of publicly funded research need not be a deterrent to progress if such patented research is licensed with terms that enable broad dissemination . . ."<sup>58</sup> The report gives an example of certain patented DNA research that was

widely disseminated by a group of universities on a voluntary basis. Involuntary dissemination is seen as unlikely, because the government's limited Bayh-Dole authority to compel dissemination is "never exercised."<sup>59</sup>

The scholars teach us that there are two views on the current government policy of patenting the results of government research and often giving exclusive rights to private companies. One is the view pointedly noted by Adams: the policy causes the government to support some business efforts, but not others, and creates opportunities for non-objective decision making and favoritism toward a handful of large companies.

Adams' view is, of course, contrary to the view of Jim Clark, the Op-Ed author, and others. They believe it is wise industrial policy for the government to fund research that results in patents that are often turned over to particular companies for development. Harold Varmus, who supported use of exclusive licenses as head of NIH, argued that "[i]t is well documented that technologies with potential as therapeutics are rarely developed into products without some form of [private company] exclusivity, given the large development costs associated with bringing the product to the market. No benefit accrues to the public if the technology is left to languish and no product reaches the marketplace." Dr. Varmus explained that while government licensing strategy gives preference to nonexclusive licenses so that market competition and broad distribution are fostered, "[e]xclusive licenses are granted when such rights are believed to be necessary to ensure product development."<sup>60</sup>

The difference between the two views is not one of black and white, but one of balancing any broad social benefits of exclusive licensing against any harm. Differences of opinion may turn on whether one trusts government people to analyze an undeveloped technology and predict that giving an exclusive license will create an important benefit to society and avoid the languishing of

technology that Dr. Varmus fears. Skeptics may doubt the value of such predictions, and think it better for the government to rely strongly on non-exclusive licenses that bring the beneficial forces of commercial competition into play.

The scholars' discussion reminds us that the AZT and Cellpro type issues of regulation of price and patent rights follow the most basic analytical question of whether government patents should be transferred to private companies for exclusive exploitation. It is only if the answer is "yes" that companies can rely on patent exclusivity and any resulting market power to charge high prices, as was alleged in the AZT controversy, or justify being overly cautious in commercially developing government patents, as was alleged in the Cellpro controversy. If the answer is "no," and companies get no exclusive rights, then there are diminished opportunities for companies to charge high prices and go slowly in developing products, largely because there may be competition between companies with non-exclusive rights. Rivalry among competitors should automatically provide incentives to low prices and rapid commercial development of valuable patents. In a competitive environment there is relatively little need for regulatory discussion about government control of pricing and patent rights of companies. That is important, because equitable government price regulation can be very difficult to accomplish. Government regulation of the timeliness of a company's product development and commercial exploitation is more difficult yet.

## **VI. Conclusion**

Stem cell research is part of a broader debate about the efficacy of federal funding for research that is often privately exploited for commercial gain. There is debate in some circles about whether it is wise industrial and economic policy for the government to selectively fund

research leading to patents that are turned over to particular companies for exclusive commercial development. Such funding may be bad economics and bad industrial policy, and generate troublesome regulatory issues of whether private companies that benefit from exclusive rights should be subject to government price controls and other remedies where commercialization is slow. Avoiding exclusivity and relying on competitive commercialization of patents should automatically lead to low prices and rapid commercial development of valuable patents, and make unnecessary government regulation of price and the pace of commercialization.

There is likely to be future debate about exclusive commercial exploitation of the results of stem cell research. The sooner and more public that debate, the better the chances for wise and balanced public policy.

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## Endnotes

\* DISCLAIMER: The views expressed do not purport to reflect those of the United States Department of Justice, where the author is employed.

1. Jim Clark, *Squandering Our Technological Future*, N.Y. TIMES, Aug. 31, 2001, at A19.

2. National Institutes of Health, *Stem Cells: A Primer*, at <http://www.nih.gov/news/stemcell/primer.htm> (last visited Oct. 15, 2001).

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. *Stem Cell Research: Patenting and Health Implications: Hearings before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, 106th Cong. (1999)* [hereinafter *Hearings: Freire*] (statement of Maria C. Freire, Director of the NIH Office of Technology Transfer).

11. Bayh-Dole University and Small Business Patent Act of 1980, 35 U.S.C.A. §§ 200-212; Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C.A. §§ 3701-3717; Technology Transfer Improvement Act, 15 U.S.C.A. § 3710a(b)(2).

12. *See* 35 U.S.C.A. §§ 200-212; 15 U.S.C.A. §§ 3701-3717.

13. *Hearings: Freire, supra* note 10.

14. *Toward Greater Public-Private Collaboration in Research and Development: How the Treatment of Intellectual Property Rights is Minimizing Innovation in the Federal Government: Hearings before the House Committee on Government Reform, 107th Cong. (2001)* [hereinafter *Hearings: Brock*] (statement of Jack Brock, Managing Director, Acquisition and Sourcing Management).

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.* (Mr. Brock appears to be referring to Executive Order 12,591 and Executive Order 12,618).

19. *Hearings: Freire, supra* note 10.

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. Marilyn Chase, *Pricing Battle: Burroughs Wellcome Reaps Profits, Outrage From Its AIDS Drug; Mounting Protests Over Cost Of AZT Tarnish the Firm and Intensify Regulation; Irony of Charitable Ownership*, WALL ST. J., Sept. 15, 1989, at A1.

26. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. Gregory Palast, *Keep Taking Our Tablets (No One Else's): The WTO's Response to Africa's Aids Crisis is a Chilling Reminder of Where Power Lies*, THE GUARDIAN, July 27, 2000.

33. Raquel Pontes de Campos, *AIDS: The great divide; Dispute over generic drugs pits the world's haves against have-nots*, THE SEATTLE TIMES, June 13, 2001.

34. *Id.*; see also Peter S. Arno and Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving In Whole Or In Part From Federally Funded Research*, 75 TUL. L. REV. 631, 647 (2001).

35. Public Citizen Congress Watch, *Rx R&D Myths: The Case Against The Drug Industry's R&D's Scare Card*, at <http://www.citizen.org/publications/release.cfm?ID=7065> (July 23, 2001).

36. Michael Waldholz, *Antitransmission Drug Provided Free By Boehringer, Axios; New Plan Helps Countries Get Needed Medication*, ASIAN WALL ST. J., Sept. 10, 2001 at N3; see also *Roche Concedes Discount to Protect Viracept Patent*, GENERIC LINE, Sept. 7, 2001 (Brazil won a 40 percent discount from Roche for the company's AIDS treatment Viracept in exchange for pledging not to make a generic version of the patent-protected drug).

37. *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1231 (Fed. Cir. 1994) (the court held as a matter of law that National

Institute of Health (NIH) scientists who confirmed that AZT was effective against HIV at request of the pharmaceutical manufacturer were not co-inventors with regard to patents encompassing compositions of methods of using AZT to treat acquired immunodeficiency syndrome (AIDS)).

38. *Johns Hopkins Univ. v. Cellpro, Inc.*, 931 F.Supp. 303 (D. Del. 1996) (where the court found infringement of two patents, notwithstanding a jury verdict for the competitor on one of the patents); 978 F.Supp. 184 (D. Del. 1997) (sustaining jury verdict on willfulness and assessing treble damages); 152 F.3d 1342, 1368 (Fed. Cir. 1998) (affirmed in part, vacated in part).

39. National Institute of Health, Office of the Director, *Determination in the Case of Petition of Cellpro, Inc.*, at <http://www.nih.gov/news/pr/aug97/nihb-01.htm> (last visited Oct. 15, 2001.)

40. *Id.*

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

45. *Id.*

46. See 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, 649 (1998); Arno, *supra* note 34, at 682; see also Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. Cellpro March-in Rights Controversy*, 8 TEX. INTELL. PROP. L.J. 211, 229 (2000).

47. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1666 (1996).

48. *Id.*

49. *Id.*

50. *Id.* at 1666-67.

51. *Id.* at 1667.

52. *Id.*

53. Nathan A. Adams IV, *Monkey See, Monkey Do: Imitating Japan's Industrial Policy in the United States*, 31 *TEX. INT'L L.J.* 527, 547 (1996).

54. *Id.* at 529.

55. *Id.* at 547.

56. *Id.* at 552.

57. Committee on the Biological and Biomedical Applications of Stem Cell Research, *STEM CELLS AND THE FUTURE OF REGENERATIVE MEDICINE*, 34 (National Academy Press 2001), *available at* <http://www.books.nap.edu/books/0309076307/html>.

58. *Id.*

59. *Id.*

60. Letter from NIH Director, Dr. Harold Varmus to Ralph Nader, James Love and Robert Weissman responding to their request calling on the NIH to provide the World Health Organization, (WHO,) access to US government funded medical inventions (October 19, 1999), *available at* <http://www.cptech.org/ip/health/savarmusletteroct19.html>.

