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# THE PROFIT OF SCIENTIFIC DISCOVERY AND ITS NORMATIVE IMPLICATIONS

SHELDON KRIMSKY\*

## INTRODUCTION

Until the late nineteenth century, the profession of scientist in Western societies was comprised almost exclusively of men from the propertied classes or bourgeoisie who were educated at the elite European universities. It was a calling of sorts, not unlike the ministry, for those with means and pedigree who could afford the luxury of investigating the workings of the universe by expanding and challenging their intellect. There was no vast wealth to be made—maybe a comfortable living at the peak of one's career.

With the rise of federal land grant colleges in the United States and the expansion of free national universities throughout the world, new scientific career options were created for people of diverse socio-economic status. Through much of the early twentieth century a career in academic science was much like a monastic order. The pursuit of knowledge, the sharing of its fruits, the gratification of self-enlightenment and mentoring students were all the reward one required to sustain and nurture a career.

The goals of science were already being recast during the Baconian period in the seventeenth and eighteenth centuries when the distinction was made between “experiments of light” that seek to discover the causes of things, and “experiments of fruit” that apply the knowledge to practical ends.<sup>1</sup> The new European nation states began to recognize the practical significance of scientific discovery in areas such as weaponry, mining and transportation. Building on the

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1. See HANBURY BROWN, *THE WISDOM OF SCIENCE: ITS RELEVANCE TO CULTURE AND RELIGION* (1986).

European experience with science and technology, the framers of the U.S. Constitution established intellectual property as a fundamental right and conferred to Congress the powers to make laws fostering the “useful arts.”

A second transformation in science took place in its purest and most unfettered form during post-World War II American economic expansion. Scientific research was now a matter of public policy.

The image of the lone scientist, broadly educated with the grasp of the large picture, working tirelessly in a makeshift laboratory furnished with hand-crafted equipment, and pursuing a path to knowledge according to some ineffable sixth sense, was undergoing a great transformation. The new image was for a strategically planned science consisting of teams of investigators working on large scale projects, competing for limited funds and positioning themselves in a social structure that would ensure the continuity of funding through volatile political times.<sup>2</sup>

In addition to the areas of academic science and engineering that became beneficiaries of state funding, industrial science also expanded significantly during this period. The American industrial system had become fully converted to the need for continuous technological innovation. Chemistry, chemical engineering, electronics, geology and material sciences were among the academic fields to which industry developed close working ties. By the late 1940s, over 300 U.S. companies funded research in universities through fellowships and direct grants.<sup>3</sup> According to Porter and Malone, “[i]n the decades after World War II, connections between academia and industry slowly weakened, reaching a low point in the early 1970s.”<sup>4</sup> As federal government support of basic research increased, the connections between academia and industry declined. In the mid-1950s, the federal government provided about fifty-five percent of the support for university research, industrial firms supplied eight percent of the funds and the remaining thirty-seven percent came from foundations and state governments.<sup>5</sup> By the late

2. See Sheldon Krimsky, *Science, Society, and the Expanding Boundaries of Moral Discourse*, in SCIENCE, POLITICS AND SOCIAL PRACTICE 113, 113 (K. Gavroglu et al. eds., 1995).

3. See ROGER J. PORTER & THOMAS E. MALONE, BIOMEDICAL RESEARCH: COLLABORATION AND CONFLICT OF INTEREST 49 (1992).

4. *Id.*

5. See R.C. Lewontin, *The Cold War and the Transformation of the Academy*, in THE COLD WAR AND THE UNIVERSITY 1, 1-34 (N. Chomsky et al. eds., 1997).

1960s, the government share expanded to more than seventy percent while the industry's share fell to under three percent.<sup>6</sup> Industry support for universities began to rise again with rising budget deficits and the leveling of science funding in the 1980s.<sup>7</sup>

Until shortly after the World War II, biology was largely a science in the classical pre-Baconian tradition. We studied how things worked rather than how we could improve on nature. The Green Revolution provided the first significant post-war agricultural application of advances in plant biology.<sup>8</sup> The innovations were based on methods of plant breeding and developing hybrid plant varieties that were most efficient when used with chemical inputs.<sup>9</sup> Yields of staple crops were dramatically increased.<sup>10</sup> It is reported that in 1985 the average yield for corn was six times the 1930s figure.<sup>11</sup> Those innovations, however, were not a consequence of a fundamental transformation in the biological sciences. That transformation took place in 1973 with the discovery of recombinant DNA ("rDNA") technology.<sup>12</sup> In that monumental discovery, the biological sciences had made the transition from an analytic to a synthetic science. It was now possible to rearrange the basic architecture of living things by transplanting genes. There were some prior attempts at creating a synthetic biology through discoveries like the hybridization of crops or the cross breeding of animals.<sup>13</sup> But the changes one could make in animals and plants through those procedures were limited by the constraints nature imposed on sexual and asexual reproduction. These constraints were rooted in the genomes of these organisms.

The introduction of rDNA technology established the absolute fungibility of genes, opening up possibilities for synthesizing new organisms and establishing revolutionary methods for mass producing biological products. The commercial opportunities of this discovery

6. *See id.*

7. *See* Richard Florida, *The Role of the University: Leveraging Talent, Not Technology*, ISSUES IN SCIENCE AND TECHNOLOGY, Summer 1999, at 67, 68.

8. *See* DAVID GOODMAN ET AL., FROM FARMING TO BIOTECHNOLOGY: A THEORY OF AGRO-INDUSTRIAL DEVELOPMENT 45 (1987).

9. *See* AL GORE, EARTH IN THE BALANCE: ECOLOGY AND THE HUMAN SPIRIT 138 (1992).

10. *See* JACK DOYLE, ALTERED HARVEST: AGRICULTURE, GENETICS, AND THE FATE OF THE WORLD'S FOOD SUPPLY 255-63 (1985).

11. JACK RALPH KLOPPENBURG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY 1492-2000 (1988).

12. *See* SHELDON KRIMSKY, GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY 72 (1982).

13. *See* GOODMAN ET AL., *supra* note 8, at 37.

were recognized immediately by scientists.<sup>14</sup>

Seven years after the discovery of rDNA technology, the journal *Nature* published its cover page with the headline *Setting Up In Biology Business*.<sup>15</sup> The issues' editorial raised the conflicts that arise when academic biologists and industry become "partners in progress."<sup>16</sup> There was an uneasiness expressed about the rapid and aggressive commercialization of the biological sciences.

Problems and acrimony have arisen between the biologists and industry, and among the biologists, particularly over the question of confidentiality. Scientists with one foot in the academic and one in the business world would have felt a conflict between the need to publish fast and first in the former, and to keep secrets and respect patent law in the latter . . . . It is an interesting moment for biologists: they have great power in their hands. Do they let the entrepreneur guide them, willy nilly, to the fastest return? Or do they, if ever so slightly, change his priorities.<sup>17</sup>

The scientific grounds for this transformation in the biological sciences are well studied and understood. But there is much to learn about the symbiosis between academic biology and industry. How is the field of biology changing as a result of the commercial interests in its discoveries? What has been the response of government to the new technological revolution in molecular genetics? What conflicts have arisen in the engagement of two cultures that have pursued a partnership of mutual interests? This paper discusses the factors responsible for and the manifestations of the intense commercialization of the biological sciences and their impact on the normative structure of science. What are the consequences for science and society of the commodification of scientific knowledge and the growth of entrepreneurship in scientific research? I shall begin with a discussion of the historical background.

## I. THE RAPID COMMERCIALIZATION OF MOLECULAR GENETICS

The excitement in 1973 was palpable. Biology, it appeared, had just come of age. Chemists had been creating new molecules for over 100 years and were responsible for tens of thousands of new compounds that became the signature of our industrial world.

14. See SHELDON KRIMSKY, *BIOTECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS* 30-33 (1991).

15. 283 *NATURE* at cover page (1980).

16. Alexander G. Bearn, *The Pharmaceutical Industry and Academe: Partners in Progress*, 71 *AM. J.L. & MED.* 81, 81-88 (1981).

17. *Biotechnology Back in the Limelight*, 283 *NATURE* 119, 119 (1980).

Physicists split the atom and unleashed a form of energy that transformed the concept of war and created new forms of mass destruction. In the mid-1970s, developments in the cutting and splicing of genes brought immediate applications in therapeutic drugs, agriculture and food sciences.<sup>18</sup> Savan reports that “industrial funding of academic research and development in the United States quadrupled between 1973 and 1983, increasing from \$84 million to \$370 million.”<sup>19</sup> Unlike other fields where scientists left academia to create their own for-profit business to exploit new discoveries, most of the leading molecular biologists retained their academic positions while pursuing their commercial interests.<sup>20</sup>

In March 1981, the front cover of *Time* reflected the new trend in academic biology.<sup>21</sup> It pictured the disembodied head of scientist-entrepreneur Herbert Boyer set within a background of strands of deoxyribonucleic acid (“DNA”) bursting from a cell.<sup>22</sup> Boyer, a co-patent holder of the Cohen-Boyer rDNA technique, was described as a new breed of millionaire-scientists, who commercialized their discoveries and helped establish a new industrial sector. While a professor at the University of California, Boyer was a co-founder in 1976 of Genentech, a first generation biotechnology company formed to apply genetic engineering applications for drug development.<sup>23</sup> Five years after Boyer became involved with Genentech, his personal stock in the company was valued at about \$40 million in a volatile biotech securities market. His university salary at the time was \$50,000.<sup>24</sup> The lure of rapid financial success ran through the field of biology like an infectious virus.

A report of the Congressional Research Service, released in 1982, described the differences between the academic industrial relations in biology with that of other academic fields. The report indicated that the commercialization of biological techniques occurred at a more accelerated rate than similar instances in physics and chemistry, involved a broader spectrum of disciplines in its participation, and had a much wider range of applications than the

18. See KRIMSKY, *supra* note 14, at 21-30.

19. BETH SAVAN, SCIENCE UNDER SIEGE: THE MYTH OF OBJECTIVITY IN SCIENTIFIC RESEARCH 73 (1988).

20. See MARTIN KENNEY, BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX 35 (1986); see also PHILIP J. HILTS, SCIENTIFIC TEMPERAMENTS 185 (1982).

21. *Shaping Life in the Lab*, TIME, Mar. 9, 1981, at cover page.

22. See *id.*

23. See Frederic Golden, *Shaping Life in the Lab*, TIME, Mar. 9, 1981, at 50, 52.

24. See *id.* at 51.

commercialization of discoveries in the physical sciences.<sup>25</sup>

By the mid-1980s, hundreds of new venture capital companies had colonized faculty from the leading universities.<sup>26</sup> Following that trend, according to Kenney, “[b]y 1983 every large chemical and pharmaceutical company had made a multi-million dollar investment in biotechnology” and established major funding partnerships with universities.<sup>27</sup>

The climate for research in the biological sciences, particularly molecular genetics, both within the universities and throughout the federal government, changed dramatically. In describing the changes, a 1980 editorial in *Nature* commented that “a new breed of molecular biologist is emerging which concerns itself not so much with understanding basic mechanisms as with manipulating them to reach desired goals.”<sup>28</sup> Meanwhile, U.S. government budget deficits began to take their toll on scientific funding.<sup>29</sup> The rapid expansion of universities and federal funding for science that had taken place in the 1960s and early 1970s had appeared to come to an abrupt end before and during the Reagan presidency. Fears had spread throughout academia that the Halcyon years of abundance for scientific research would not continue.<sup>30</sup> To retain their leadership in research, many of the elite research universities began to consider private sources of funding for filling the shortfalls resulting from declining federal budgets.<sup>31</sup>

As the decade of the 1970s came to an end, American business analysts reported declines in productivity and global markets of major industries like steel and microelectronics. They attributed the problem to the failure of American industry to maintain an innovative climate and make use of scientific breakthroughs. The obstacle, they argued, was not in America’s scientific leadership, but in the time lapse between discovery and application. It was, in effect,

25. See generally JUDITH A. JOHNSON, *BIOTECHNOLOGY: COMMERCIALIZATION OF ACADEMIC RESEARCH* (1982).

26. See Sheldon Krimsky et al., *Academics-Corporate Ties in Biotechnology: A Quantitative Study*, 16 *SCI., TECH. AND HUMAN VALUES* 275, 275-87 (1991).

27. MARTIN KENNEY, *BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX* 199 (1986).

28. *Biotechnology Back in the Limelight*, *supra* note 17, at 119.

29. See KRIMSKY, *supra* note 14, at 66-67.

30. See Barbara J. Culliton, *Biomedical Research Enters the Market Place*, 304 *NEW ENG. J. MED.* 1196, 1197 (1981).

31. See R.M. ROSENZWEIG, *THE RESEARCH UNIVERSITIES AND THEIR PATRONS* 15-21 (1982).

as MIT's President Paul Gray wrote, a problem of technology transfer.<sup>32</sup> Congress responded favorably to this explanation of the United States' declining competitive edge. A series of legislative acts and executive orders were premised on the concept of technology transfer and university-industry partnerships.

Already in gestation during the Carter administration, several pieces of legislation were enacted in 1980 to create more cooperation between industries and universities. The Stevenson-Wydler Technology Transfer Act of 1980<sup>33</sup> encouraged interaction and cooperation among government laboratories, universities, big industries and small businesses. In the same year, Congress passed the Bayh-Dole Patent and Trademark Laws Amendment,<sup>34</sup> which gave intellectual property rights to research findings to institutions that had received federal grants. Discoveries and inventions from public funds could be patented and licensed, initially to small businesses, with exclusive rights of royalties given to the grantee. The Economic Recovery Tax Act of 1981<sup>35</sup> gave companies a twenty-five percent tax credit for sixty-five percent of their direct funding to universities for basic research. In 1983, by executive order, President Reagan extended the Bayh-Dole Act to all industry. To close the circle of research partnerships among industry, universities and government, Congress passed the Federal Technology Transfer Act of 1986,<sup>36</sup> which expanded science-industry collaboration to laboratories run by the federal government. Governmental standards for keeping an arm's length from industry were being turned on their head. Through this act, a government scientist could form a "Cooperative Research and Development Agreement" ("CRADA") with a company as a route to commercializing discoveries made in a federal laboratory.<sup>37</sup> Government scientists could accept royalty income up to a given amount, fifteen percent of the National Institutes of Health (the "NIH") share, to supplement their salaries. At the time this policy was enacted, there was virtually no public discussion about the blatant conflicts of interest that this would introduce. The CRADA required government scientists to keep

32. See Paul E. Gray, *Advantageous Liaisons*, ISSUES IN SCIENCE AND TECHNOLOGY, Spring 1990, at 40, 40-46.

33. 15 U.S.C. § 3701 (1994).

34. 35 U.S.C. §§ 200-212 (1994).

35. 26 U.S.C. § 1 (1994).

36. 15 U.S.C. § 3701 (1994).

37. See PORTER & MALONE, *supra* note 3, at 216.



company data confidential and impeded the sharing of information in government laboratories.<sup>38</sup>

The new federal initiatives on technology transfer and academic-industry-government collaborations were responsible for a marked rise in university patents.<sup>39</sup> In 1980, American university patents represented one percent of all U.S. origin patents.<sup>40</sup> By 1990, the figure rose to 2.4%.<sup>41</sup> Within that decade, the number of applications for patents on NIH-supported inventions increased by nearly 300%.<sup>42</sup>

The legislative and executive branches of government have invested in the idea that the ivory tower of academic science and the insulated domains of federal laboratories had to build bridges to the industrial sector. The operative term for these new arrangements was "mutualism." Industry, universities and government had something to offer one another. If carefully planned and consummated, the concerns and impediments to these partnerships could be overcome, and the American society would be the big winner. The engine of innovation was re-ignited, and in its wake universities would have to make adjustments and compromises.

But there was one additional national sector that could connect all the institutional pieces and give the fledgling field of applied genetics the boost it had so aggressively lobbied for. The courts laid the groundwork for establishing intellectual property rights over a broad spectrum of genetic discoveries, creating the new concept of "life patents."<sup>43</sup>

## II. ORGANISMS, ANIMALS AND GENES AS INTELLECTUAL PROPERTY

Supporters of technology transfer incentives as a means to jump start the lagging U.S. economy and establish the country's global leadership in biotechnology and information technology were faced

38. See Barbara Culliton, *NIH, Inc: The CRADA Boom*, 245 *SCIENCE* 1034, 1034-35 (1989).

39. See *Business Opportunities, and Technology of the Committee on Small Businesses: Hearing on S. Doc. No. 103-5 Before the Subcomm. on Regulation House of Rep.*, 103rd Cong., 70 (1993) (statement of Bernadine Healy, M.D., Director, National Institutes of Health) [hereinafter *Business Opportunities*].

40. See *id.*

41. See *id.*

42. See *id.*

43. *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice, H.R. Comm. on the Judiciary*, 100th Cong. (1987).

with a legal obstacle to the fulfillment of the vision. Unless the discoveries and innovations in molecular genetics and software could be protected under patents or copyrights, the new products could easily be replicated by foreign companies and produced more cheaply. Two solutions to this problem were the establishment of trade barriers to prevent foreign products from competing with American goods or extending patent/copyright protection. As the new economic philosophy of free markets took a foothold in United States' policy, trade barriers were out of fashion. Transnational agreements like the North Atlantic Free Trade Agreement were opening up markets and eliminating tariffs. Patent and property right protection became the choice solution for protecting the United States' competitive position in a global economy. Decisions by the Supreme Court and the U.S. Patent Office, and non-decisions by Congress, established the final element of an economic policy that fully incorporated life forms and their parts into the market system. By establishing property rights over discoveries in biology, the courts and the U.S. Patent Office turned scientific knowledge into an invention, thereby creating new opportunities for scientists to acquire wealth, establishing new incentives for product development, and, downstream, adding to the costs of consumer goods and medical care.<sup>44</sup>

In June 1980, a single vote on the Supreme Court transformed the social and legal matrix within which science and the nascent biotechnology industry operated.<sup>45</sup> In a 5-4 decision, the Supreme Court overturned the Patent and Trademark Office's (the "PTO") denial of a patent for a microorganism, thereby paving the way for the use of the patent system for all sorts of life forms and their parts, including human genes.<sup>46</sup> The Court ruled that a human-modified microorganism can be classified as a product of manufacture, and thus falls under patent protection.<sup>47</sup>

At the time the Court reviewed *Diamond v. Chakrabarty*, there was a backlog of 114 patent applications of living organisms, with an

44. See LINDA MARSA, PRESCRIPTION FOR PROFITS 202 (1997); Azra T. Sayeed, *Consumers Pay Billions for Patent Extensions on Medications*, in THE OWNERSHIP OF LIFE: WHEN PATENTS AND VALUES CLASH 48, 48 (Martin Teitel et al. eds., 1997); see also Jonathan King & Doreen Stabinsky, *Patents on Cells, Genes, and Organisms Undermine the Exchange of Scientific Ideas*, THE CHRON. OF HIGHER EDUC., Feb. 5, 1999, at B8.

45. See OFFICE OF TECH. ASSESSMENT, 101ST CONG., NEW DEVELOPMENTS IN BIOTECHNOLOGY, NO. 5, PATENTING LIFE 7 (1989).

46. See *id.*

47. See *id.*

estimated fifty applications added per year.<sup>48</sup> The Court was well aware of the commercial interests in this case. Biotechnology trade organizations were growing rapidly and the financial publications were replete with investment opportunities in new capital venture companies.

The Supreme Court saw as its task the determination of whether living organisms fit under U.S. patent law.<sup>49</sup> Without explicit statutory language, the Court sought to interpret the intention of Congress by examining the language and intent of historical documents such as congressional reports and revisions of the patent laws.<sup>50</sup>

In 1973, biologist Ananda Chakrabarty, while working for General Electric Corporation, modified a microorganism by transporting extra-chromosomal elements, called plasmids, from several organisms into one bacterium.<sup>51</sup> Each plasmid was capable of degrading a component of crude oil.<sup>52</sup> The patent application was for both the process of cleaning up oil spills and for the bacterium containing multiple plasmids.<sup>53</sup> The PTO accepted the process application, but rejected the application for a patent on the organism *sui generis*, claiming that microorganisms were products of nature and therefore not patentable.<sup>54</sup> The decision of the PTO was appealed to the Patent and Trademark Office Board of Appeals, which claimed that Chakrabarty's microorganism was man-made and not found in nature, but upheld the lower court on the claim that living things are not patentable subject matter.<sup>55</sup> The next appeals court, the Court of Customs and Patent Appeals, argued that a key section of the U.S. Patent Act<sup>56</sup> did not preclude man-made living organisms, dismissing the lower court's interpretation of the patent laws.<sup>57</sup> Its decision, upheld by the Supreme Court, extended the concept of intellectual property and provided a liberal interpretation of the terms

48. 447 U.S. 303 (1980).

49. *See id.* at 307.

50. *See id.* at 308.

51. *See* OFFICE OF TECH. ASSESSMENT, 97TH CONG., IMPACTS OF APPLIED GENETICS: MICRO-ORGANISMS, PLANTS, AND ANIMALS 240 (1981).

52. *See* Sheldon Krimsky, *Patents for Life Forms Sui Generis: Some New Questions for Science, Law and Society*, 4 RECOMBINANT DNA TECHNICAL BULL. 11, 11 (1981).

53. *See id.*

54. *See Diamond*, 447 U.S. at 306.

55. *See id.*

56. 35 U.S.C. § 101 (1994).

57. *See Diamond*, 477 U.S. at 306.

“manufacture” and “composition of matter” within the meaning of the statute.<sup>58</sup>

On what legal grounds did the five Supreme Court justices base their decision? The justices could find no explicit language in the Act on the issue of whether living things were or were not patentable.<sup>59</sup> They reviewed two statutes on plant patents, one passed in 1930 and the other in 1970.<sup>60</sup> These statutes were used as evidence against the interpretation of blanket congressional intent to include living things as patentable material, because if that were so, Congress would have not chosen to enact two pieces of legislation that extended intellectual property ownership to plants.<sup>61</sup> Moreover, the 1970 plant patent statute explicitly excluded microorganisms from patent protection.<sup>62</sup>

The Court did find in a 1952 recodification of the patent statutes a congressional report that stated that patentable subject matter may include “anything under the sun made by man.”<sup>63</sup> It was this phrasing that persuaded the majority of the justices of the congressional intent to include living things as patentable subject matter.<sup>64</sup> How much of the Court’s decision was based on the practical considerations of the nascent biotechnology industry is left for interpretation by legal historians.

The dissenting four justices were persuaded by the passage of the two plant protection acts of quite a different congressional intent. For the minority, Justice Brennan wrote: “[B]ecause Congress thought it had to legislate in order to make agricultural ‘human-made inventions’ patentable and because the legislation Congress enacted is limited, it follows that Congress never meant to make items outside the scope of the legislation patentable.”<sup>65</sup> Several years later, in 1987, a patent was awarded for a multicellular organism (polyploid oysters), and, in 1988, the first animal patent was approved for a transgenic mouse.

Meanwhile, patents on human gene fragments were issued by the U.S. Patent Office not as living things, but as compositions of matter. Human genes are not manufactured or modified, and therefore could

58. *Id.* at 313.

59. *See id.* at 307-08.

60. *See id.* at 310.

61. *See id.* at 313.

62. *See id.*

63. *Id.* at 308.

64. *See id.* at 313-14.

65. *Id.* at 320.

not receive a patent on the criteria of intellectual property. There were two strategies open to patent applicants. They could claim that the isolation of the genes within the genome of the organism was novel and therefore deserving of a patent, or that the form of the gene for which a patent was sought was not derived from nature.

Strictly speaking, genes cannot be patented because, like proteins, they are products of nature. Scientists argued before the PTO that their modification of the genes could qualify for patents because the natural molecular sequence has been altered and a new composition of matter replaced it. To make this argument, scientists used the version of a genetic sequence called copy or complementary DNA ("cDNA"). Typically, a gene that codes for a protein has many redundant or irrelevant nucleotides in the sequence that are not essential for the synthesis of a protein. When the extraneous sequences (called introns) are removed, the version of the gene is called copy DNA. Because this version of the gene is not present in the cell and can be created by using certain enzymes, it was considered patentable under section 101 of the U.S. Patent Act where the subject matter must be novel, useful, and non-obvious. Following the Court's reasoning, the term cDNA is described in books on genetics as "a man-made copy of the coding sequences of a gene."<sup>66</sup>

In extending intellectual property rights to genes, the PTO had ostensibly created a future's market in gene sequences and spurred a competitive frenzy among scientists in molecular biology.<sup>67</sup> The PTO's decision, in effect, meant that natural DNA sequences when modified as cDNA, were considered "artificial products" and therefore patentable.<sup>68</sup> Anyone involved in sequencing genes was encouraged by their colleagues and institution to apply for patents on the grounds that a competitor group will do so and control licensing fees. Patents were awarded to sequences whose functional role in the genome was not yet understood. The patent application usually covered broad uses of the gene sequence. Ostensibly, the human genome was under colonization. Universities, private companies, and, for a while, even government agencies sought intellectual

66. THE CODE OF CODES: SCIENTIFIC AND SOCIAL ISSUES IN THE HUMAN GENOME PROJECT 376 (Daniel J. Kevles & Leroy Hood eds., 1992).

67. See Eliot Marshall, *Companies Rush to Patent DNA*, 275 SCIENCE 780, 780 (1997); see also TO PROFIT OR NOT TO PROFIT 176-182 (Burton A. Weisbrod ed., 1998).

68. Evelyn Fox Keller, *Nature, Nurture and the Human Genome Project*, in THE CODE OF CODES: SCIENTIFIC AND SOCIAL ISSUES IN THE HUMAN GENOME PROJECT 281, 313 (Daniel J. Kevles et al. eds., 1992).

property protection over segments of the genome.<sup>69</sup> Amgen, Inc. of California is credited with holding the most valuable patent of a human gene with estimated earnings of one billion dollars a year.<sup>70</sup> Its patent is for the human erythropoietin gene, which codes for a hormone needed by kidney disease patients.<sup>71</sup> In 1991, the Supreme Court ruled favorably on the validity of Amgen's 1987 patent of this human gene.<sup>72</sup>

Merz notes that the PTO has been awarding an increasing number of patents on methods for detecting disease-related genes.<sup>73</sup> The patent holder has exclusive rights to develop and perform diagnostic tests that detect specific genetic mutations.<sup>74</sup> By patenting genes that are responsible for disease, the authors argue that physicians are faced with serious conflicts of interests.<sup>75</sup> "The profit motive may lead to unwarranted promotion of genetic tests which are still in many ways experimental."<sup>76</sup>

The implications of the new financial opportunities in molecular genetics were profound because they contributed to a new set of relations between scientists and their work.<sup>77</sup> First, the time lapse between scientific discovery and commercial use, which had traditionally buffered scientists from the lure of pecuniary affairs, was now very short. This meant that almost any discovery of a new gene had potential commercial value. Second, scientists internalized a new set of values. Added to the traditional value in academia of the "pursuit and dissemination of knowledge" was the responsibility to use that knowledge for the development of marketable products.<sup>78</sup> A new ethos emerged in the biological sciences that meant balancing interests between two independent and potentially conflicting premises.<sup>79</sup> The first states that knowledge is part of the common human heritage, while the second treats knowledge as possessing

69. See Rebecca S. Eisenberg, *Patent Rights in the Human Genome Project*, in GENE MAPPING: USING LAW AND ETHICS AS GUIDES 226, 226 (George J. Annas et al. eds., 1992).

70. See *id.* at 239.

71. See *id.*

72. See Marshall, *supra* note 67, at 780-81.

73. Jon F. Merz, *Patenting Genetic Tests: Putting Profits Before People*, GENE WATCH (Council for Responsible Genetics, Cambridge, Mass.), Oct. 1998, at 1, 6.

74. See *id.*

75. See *id.*

76. *Id.*

77. See TO PROFIT OR NOT TO PROFIT, *supra* note 67, at 180.

78. See Sheldon Krimsky, *The New Corporate Identity of the American University*, 14 ALTERNATIVES 20, 20-29 (1987).

79. See *id.*

economic value that should be realized.<sup>80</sup> This change in the culture of the biological sciences brought with it a new set of social relations between academic research and private industry.<sup>81</sup> The question on everyone's mind was how would these new relations affect the practice and integrity of scientific work?

### III. THE GROWTH OF RESEARCHER FINANCIAL INTERESTS IN BIOMEDICAL RESEARCH

By the mid-1980s, genetic technology had spawned hundreds of new companies, many with academic scientists as officers, board members or consultants.<sup>82</sup> Small venture capital companies colonized the faculty of prestigious universities for building their intellectual capital.<sup>83</sup> Major corporations that had sector interests in drugs, therapeutics, and agriculture invested large sums into multi-year contracts with universities.<sup>84</sup> Several of the most notable examples of university-industry partnerships involved Monsanto Corporation. In 1974, Monsanto and Harvard University signed a contract after a year and a half of negotiations. Under the agreement, Monsanto gave Harvard \$23 million in research support, laboratory space, construction, and endowment money.<sup>85</sup> In return, Harvard gave Monsanto the patent rights to a substance called tumor angiogenesis factor ("TAF"), which was involved in the growth of cancerous tumors.<sup>86</sup>

Washington University entered into a five-year, \$23.5 million agreement with Monsanto in 1982.<sup>87</sup> The agreement involved the support of biomedical research at the university. It was renewed three times, most recently in 1989.<sup>88</sup> Monsanto's total investment with the university came to about \$100 million.<sup>89</sup> The agreement was widely publicized and became the subject of a federal subcommittee hearing.<sup>90</sup> According to the agreement, manuscripts and abstracts

80. See TO PROFIT OR NOT TO PROFIT, *supra* note 67, at 180.

81. See Henry Etzkowitz, *Entrepreneurial Science in the Academy: A Case of the Transformation of Norms*, SOCIAL PROBLEMS, Feb. 1989, at 14, 14-29.

82. See KRIMSKY, *supra* note 14, at 28-33.

83. See *id.*

84. See *id.*

85. See KENNEY, *supra* note 20, at 58.

86. See *id.*

87. See *id.* at 67-69.

88. See *id.*

89. See *id.*

90. See *id.*

resulting from Monsanto support would not be delayed for publication for longer than thirty days, during which time Monsanto had to make a decision about whether to patent a result.<sup>91</sup> Professors working under the Monsanto agreement had to give allegiance to the company, avoiding any relationships with other institutions that might create a conflict of interest for Monsanto.<sup>92</sup>

A number of studies published in the early 1990s began to shed some light on the extent to which the burgeoning field of biotechnology had begun to impact universities. One national study investigated faculty linkages to new biotechnology companies in the period 1985 to 1988.<sup>93</sup> At leading American universities, dozens of faculty in departments of medicine and biology developed formal relationships with venture capital companies.<sup>94</sup> At Harvard, the biotechnology faculty had ties to forty-three different firms, at Stanford twenty-five and at MIT twenty-seven.<sup>95</sup> For MIT, at least thirty-one percent of the faculty in its Department of Biology had commercial affiliations, while for Stanford and Harvard the figure for biotechnology faculty across several departments was nineteen percent.<sup>96</sup> The authors of the study reported that their methodology was likely to underestimate the academic-industry connections, and that the trend for faculty to develop a commercial outlet for their work was rising.<sup>97</sup>

During the early stages of the commercialization of academic biology, science writer Philip Hiltz wrote: "It is already apparently true that there is no notable biologist in this field anywhere in America who is not working in some way for business. I interviewed some two dozen of the best molecular biologists in the country and found none."<sup>98</sup>

The impact of university-industry relationships on the behavior and values of scientists began to emerge through a series of surveys of biomedical scientists taken by researchers from Harvard's School of Public Health between 1984 and 1994.<sup>99</sup> One of the clear outcomes of

91. *See id.*

92. *See id.*

93. *See* Krinsky et al., *supra* note 26, at 275-87.

94. *See id.*

95. *See id.* at 281.

96. *See id.* at 282.

97. *See id.* at 286.

98. PHILIP HILTZ, *SCIENTIFIC TEMPERAMENTS: THREE LIVES IN CONTEMPORARY SCIENCE* 185 (1982).

99. *See* David Blumenthal et al., *Relationship Between Academic Institutions and Industry*



these new arrangements that was revealed in the Harvard surveys was that they impeded the “free, rapid, and unbiased dissemination of research results.”<sup>100</sup> Biotechnology faculty with industry support were four times as likely as other biotechnology faculty to report that trade secrets had resulted from their research.<sup>101</sup> The vast majority of the faculty without industry support viewed the commercial relationships as undermining intellectual exchange and cooperation within departments.<sup>102</sup> The surveys also revealed that faculty believed the new relationships were responsible for skewing the research agenda in biology toward applied research.<sup>103</sup>

A 1994 survey of senior executives in 210 life science companies confirmed that the changes taking place in academia were not transitory.<sup>104</sup> Trade secrets and confidentiality for industry-supported faculty were becoming the norm.<sup>105</sup> The majority (fifty-eight percent) of the respondents in this survey reported that “their companies typically require academic investigators to keep information confidential for more than six months in order to file a patent application.”<sup>106</sup> The authors of the study also reported that eighty-eight percent of the respondents indicated that their funding agreements with universities require students and fellows to keep research confidential.<sup>107</sup>

In another study involving researchers at Harvard University and the University of Minnesota, over 2000 scientists were surveyed at fifty research intensive universities.<sup>108</sup> About forty-three percent of the respondents indicated that they receive private gifts for their research, which their universities do not regulate.<sup>109</sup> Of the 920 scientists who received gifts, one-third reported that their corporate

*in the Life Sciences—an Industry Survey*, 334 *NEW ENG. J. MED.* 368, 371 (1996) [hereinafter Blumenthal et al., *Relationship Between Academic Institutions*]; see also David Blumenthal et al., *University-Industry Research Relationships in Biotechnology: Implications for the University*, 232 *SCIENCE* 1361, 1361-66 (1986) [hereinafter Blumenthal et al., *University-Industry Research*].

100. Blumenthal et al., *University-Industry Research*, *supra* note 99, at 366.

101. *See id.*

102. *See id.*

103. *See id.* at 1361-66.

104. *See* Blumenthal et al., *Relationship Between Academic Institutions*, *supra* note 99, at 368.

105. *See id.*

106. *Id.*

107. *See id.*

108. *See* Eric G. Campbell et al., *Looking a Gift Horse in the Mouth*, 279 *JAMA* 995, 995-99 (1998); see also Sheryl Gay Stolberg, *Gifts to Science Researchers Have Strings, Study Finds*, *N.Y. TIMES*, Apr. 1, 1998, at A17.

109. *See* Campbell et al., *supra* note 108, at 995.

benefactors expected to review their academic papers before publication, and nineteen percent indicated that the donors wanted the patent rights to commercialize discoveries arising from the gifts.<sup>110</sup>

Some have argued that the potential liabilities of federal policies designed to create university-industry partnerships and expand intellectual property rights for scientific discoveries were far outweighed by the benefits of the new social contracts in science.<sup>111</sup> They maintain that trade secrecy, at least for a period of time, was not going to disrupt the scientific agenda or impair the quality of research.<sup>112</sup> Universities would recalibrate their guidelines for sponsored research and establish some constraints for the more commercially adventurous faculty. However, two concerns flowing from the intense commercialization of science that could not be resolved by ethical standards established within universities were conflicts of interest and scientific bias. Cases of conflicts of interest were periodically highlighted in investigative journalistic reports.<sup>113</sup> As an example, in 1988, a federally-sponsored study published in the *Journal of the American Medical Association* reported that an anti-clotting medication to prevent heart attacks called tissue plasminogen activator ("TPA"), which is manufactured by Genentech, was significantly more effective than the drug currently in use called streptokinase.<sup>114</sup> Subsequently, it was reported widely in the print media that some of the study's investigators were long-term Genentech stockholders.<sup>115</sup> A journal that prided itself in its ethical standards for its contributors was criticized harshly for not disclosing the authors' conflicts of interests.

In another case, a conflict of interest at a university was connected with violations of federal regulations. It involved a University of Minnesota Medical School surgeon, who started a company in collaboration with his university to develop, manufacture and market an anti-rejection drug for use in organ transplants.<sup>116</sup>

110. *See id.*

111. *See The Ties that Bind or Benefit*, 283 NATURE 130, 130-31 (1980).

112. *See Biotechnology Back in the Limelight*, *supra* note 17, at 119.

113. *See, e.g., Zina Moukheiber, Science for Sale*, FORBES, May 17, 1999, at 136, 136-44; David Shenk, *Money + Science = Ethics Problems on Campus*, THE NATION, Mar. 22, 1999, at 11, 11-18; Daniel Zalewski, *Bind: Do Corporate Dollars Strangle Scientific Research*, LINGUA FRANCA, June/July 1997, at 51, 51-59.

114. MARSAs, *supra* note 44, at 199-222.

115. *See id.* at 201.

116. *See Christopher Anderson, Scandal Scars Minnesota Medical School*, 262 SCIENCE 1812, 1812 (1993).

Federal investigators discovered procedural violations in how the drug was used, including failure of the clinical faculty to report in proper fashion deaths and other serious adverse reactions. The investigators also determined that the faculty had illegally made profits from the sales.<sup>117</sup> The university was forced to stop its sales of the multimillion dollar drug.<sup>118</sup> Some have argued that universities should not be in a situation where they are producing products, even if they do not violate any laws. According to Porter and Malone, “[B]y 1991, more than 100 American universities had started financing new companies to exploit the research findings of their faculties for commercial advantage.”<sup>119</sup> Thus, in addition to conflicts of interests held by individual faculty, institutional conflicts of interest among universities present a special challenge.

Until 1996, there was little quantitative information on the extent to which the authors of scientific publications had a financial interest in the subject matter of their research. In that year, a study appeared in the journal *Science and Engineering Ethics* that examined leading biomedical journals for the financial interests of authored original papers.<sup>120</sup> The researchers used 1992 as a test year and selected Massachusetts-based authors of articles in fourteen journals selected from *Science Citation Index* for their high impact rating.<sup>121</sup> In the study, authors are said to “possess a financial interest” if they are listed as inventors in a patent or patent application closely related to their published work; serve on a scientific advisory board of a biotechnology company; or are officers, directors or major shareholders in a firm that has commercial interests related to their research.<sup>122</sup> Of the 789 articles and 1105 Massachusetts authors reviewed in the study, thirty-four percent of the papers met one or more of the criteria for possessing a financial interest.<sup>123</sup> Furthermore, none of the articles revealed the authors’ financial interests. Most of the journals examined did not have disclosure or conflict of interest requirements in their “Instructions to Authors”

117. See LAWRENCE C. SOLEY, *LEASING THE IVORY TOWER: THE CORPORATE TAKEOVER OF ACADEMIA* 49 (1995).

118. See *id.*

119. PORTER & MALONE, *supra* note 3, at 27.

120. Sheldon Krinsky et al., *Financial Interest of Authors in Scientific Journals: A Pilot Study of 14 Publications*, 2 *SCI. & ENGINEERING ETHICS* 395, 395-410 (1996).

121. See *id.*

122. *Id.*

123. See *id.*

during 1992, the target year of the study.<sup>124</sup> During that period, scientists seemed less concerned about conflicts of interest than government, journal editors, the media and the general public.<sup>125</sup>

Some scientists and journal editors scoffed at the idea that such relationships could compromise the integrity of their work.<sup>126</sup> They argued that professional rewards like tenure and promotion or leadership positions in professional societies were more important in influencing the behavior of scientists than consulting relationships or patent applications.<sup>127</sup> The new attention placed on financial conflicts of interest was compared by some to “witch trials,” where guilt was determined by association.<sup>128</sup> These critics are correct, however, in pointing out that there has never been a credible link found between cases of scientific misconduct and conflicts of interest, despite the effort by a congressional subcommittee report to draw the connection.<sup>129</sup>

Although many more journals have added financial disclosure and conflicts of interest requirements since 1992, some editors argue that, without evidence of a connection between possessing a financial interest and bias or misconduct in research, they have no need to require their authors to disclose any financial affiliations.<sup>130</sup> This position was highlighted in an editorial published by *Nature* that acknowledges the pervasiveness of conflicts of interest in science but sees no point in requiring disclosure of financial interests:

This journal has never required that authors declare such affiliations, because the reasons proposed by others are less than compelling. It would be reasonable to assume, nowadays, that virtually every good paper with a conceivable biotechnological relevance emerging from the west and east coasts of the United States, as well as many European laboratories, has at least one author with a financial interest—but what of it? . . . Such appeals for openness are selective—other pieces of information would be just as (ir)relevant to a paper’s content. . . . The work published (*Science and Engineering Ethics*)<sup>131</sup> makes no claim that the undeclared interests led to any fraud, deception or bias in presentation, and until there is evidence that there are serious risks

124. *Id.*

125. *See id.*

126. *See* Kenneth J. Rothman, *Conflict of Interest: The New McCarthyism in Science*, 269 JAMA 2782, 2782-83 (1993).

127. *See id.*

128. *See id.*

129. *See* H.R. REP. NO. 101-688 (1990).

130. *See* *Avoid Financial ‘Correctness’*, 385 NATURE 469, 469 (1997).

131. Krinsky et al., *supra* note 120, at 395.

of such malpractice, this journal will persist in its stubborn belief that research as we publish it is indeed research, not business.<sup>132</sup>

The conjecture that possessing a financial interest increases research bias or misconduct is empirically testable, but few rigorous and convincing studies have been published. In the mid-1980s, a study which appeared in the *Journal of General Internal Medicine* reported that clinical trials sponsored by pharmaceutical companies were much more likely to favor new drugs (an outcome beneficial to the sponsoring companies in this case) than studies not supported by the companies.<sup>133</sup>

A recent study that brought significant media attention was published in the wake of the controversy over the use of calcium channel blockers to treat obesity.<sup>134</sup> A University of Toronto research team reviewed seventy English language articles, reviews, and letters to the editor on the effectiveness and safety of the new generation of drugs for treating obesity.<sup>135</sup> The investigators classified each author's position (supportive, neutral or critical) on the use of the drugs and surveyed the authors, inquiring whether they had financial interests with drug manufacturers of calcium channel blockers or competing products.<sup>136</sup> The results of the study, published in the influential *New England Journal of Medicine*, indicated that those authors who were supportive of the obesity drugs were significantly more likely than the authors who were neutral or critical of the drugs to have a financial agreement with a manufacturer of a calcium channel blocker (ninety-six percent, sixty percent and thirty-seven percent respectively).<sup>137</sup> It was also found that critics of the obesity drugs were not more likely to have financial ties to manufacturers of competing products.<sup>138</sup> Since the interpretation of drug safety and efficacy evidence is hardly an exact science, it is highly plausible that the discretionary factors in one's interpretation can be weighted (whether consciously or unconsciously) toward the interests and values of the institutions that provide the support. Further confirmation of this effect could provide journal editors ample justification for requiring financial disclosure.

132. *Id.*

133. R.A. Davidson, *Source of Funding and Outcomes of Clinical Trials*, 3 J. OF GEN. INTERNAL MED. 155, 155-58 (1986).

134. See Henry T. Stelfox et al., *Conflict of Interest in the Debate Over Calcium-Channel Antagonists*, 338 NEW ENG. J. MED. 101, 101 (1998).

135. *See id.*

136. *See id.*

137. *Id.*

138. *See id.*

The relationship of funding sources to bias in research has been a matter of increasing concern among journal editors and federal funding institutions. A great effort is put into clinical drug trials, and the public trust in their outcome is crucial to rational drug policies. The National Academy of Sciences (the "NAS"), which convenes scientific panels on complex science-policy debates, has been faced with panel members who have private company affiliations. The NAS leadership has acknowledged concerns that a panelist's commercial ties could affect his or her scientific judgment.<sup>139</sup>

#### IV. THE PRIVATIZATION OF KNOWLEDGE

According to the Hippocratic Oath, physicians have an obligation to share their knowledge with others in the profession in the interest of the patient. The oath includes the phrase:

[A]nd to teach them this art—if they desire to learn it—without fee and covenant; to give a share of precepts and oral instruction and all other learning to my sons and to the sons of him who has instructed me and to the pupils who have signed the covenant and have taken an oath according to the medical law, and no one else.<sup>140</sup> The code of ethics of the American Medical Association contains the phrase, make available information to patients, colleagues, and the public. . . .<sup>141</sup>

Medical knowledge must serve the common good. This fundamental value which survived through millennia of medical practice, is superseded by the normative changes taking place in biomedical sciences. Because every biomedical discovery has potential monetary value, the new culture of science will seek to protect that discovery from becoming part of the "knowledge commons." Filing patent applications prior to publication establishes a proprietary interest in the discovery. Even after the patent application is filed, it is not in the interest of the applicant to disseminate too much information about the discovery in the event that a competitor will find a way to use the knowledge that avoids patent infringement. Scientists, instead of sharing their discoveries in a timely fashion, are protecting them as trade secrets. This has resulted in wasteful duplication of research, not for the sake of verifying results, but rather for establishing the

139. See Christopher Anderson, *Conflict Concerns Disrupt Panels, Cloud Testimony*, 355 NATURE 753, 753-54 (1992).

140. LEON R. KASS, TOWARD A MORE NATURAL SCIENCE: BIOLOGY AND HUMAN AFFAIRS 228 (1985).

141. *Id.* at 231.

unpublished data needed to secure intellectual property rights over the discovery. Writing in *Science*, Eliot Marshall noted, “[w]hile some duplication is normal in research, experts say it is getting out of hand in microbe sequencing. Tuberculosis, like *Staph aureus* and *H. Pylori* will be sequenced many times over in part because sequencers aren’t sharing data, whether for business reasons or because of interlab rivalries.”<sup>142</sup>

The concept of intellectual property in biomedical research has become so inclusive that it embraces genes, plants, animals, microorganisms, including viruses; and even medical procedures. Seth Shulman, in his book *Owning the Future*, tells the story of an eye surgeon who inadvertently discovered a method of making incisions in cataract surgery that can heal without sutures.<sup>143</sup> While eager to share this knowledge with his students and colleagues, to his amazement and dismay, the physician learned that the surgical procedure that he had developed quite independently had been patented.<sup>144</sup> Moreover, by not paying licensing fees to the patent holder when he used the procedure, he was guilty of patent infringement.<sup>145</sup> Shulman disclosed a startling trend: “In 1993 the Patent Office was already awarding scores of patents each month on medical procedures, and by early 1996 the number had reached an unprecedented one hundred per month.”<sup>146</sup>

Companies have taken out patents on disease causing bacteria and viruses, sometimes keeping confidential parts of the sequenced genome.<sup>147</sup> This may inhibit two companies competing in the search for a cure or treatment for a disease. Why should anyone own the natural sequence of a natural microorganism? Pharmaceutical companies can now exercise property ownership over both the drug to treat a disease and the microorganism that causes it. The intense privatization of biomedical knowledge that has evolved since the 1980s threatens the entire edifice of public health medicine.

It may be difficult for some to understand how turning federal research funds into discoveries that are privately controlled, how classifying scientific results of therapeutic significance as trade secrets,

142. Eliot Marshall, *Is Data-Hording Slowing the Assault on Pathogens?*, 275 *SCIENCE* 797, 797-80 (1991).

143. SETH SHULMAN, *OWNING THE FUTURE* 33-36 (1999).

144. *See id.*

145. *See id.*

146. *Id.* at 36.

147. *See* Marshall, *supra* note 67, at 780.

and how a publicly funded research enterprise in which conflicts of interest are endemic can serve the public interest. The answer may be found in the escalating price of pharmaceuticals and therapeutic tests. An investigative report in the *Boston Globe* noted that forty-eight of the fifty top-selling drugs approved by the FDA received money from the FDA or the NIH in discovery, development, or testing.<sup>148</sup> A drug called Proleukin, used for renal cell cancer, received a federal subsidy of nearly forty-six million dollars; the price for a typical course of treatment is \$19,900.<sup>149</sup> A second drug called Taxol, used for ovarian and breast cancer, was federally subsidized at nearly twenty-seven million dollars with a treatment cost of \$5500.<sup>150</sup> The effect of escalating pharmaceutical prices is explained by geneticist Jonathan King:

The patenting process, by granting a monopoly of seventeen to twenty years to the patent holders, allows a company to prevent other efforts to utilize the same information, genes or technology. As a result it offers the possibilities of superprofits to investors . . . . The profitability of these agents stems in part from the potential—lacking competition—to charge very high prices for the product.<sup>151</sup>

The cost of genetic screening tests may also be influenced by the private ownership of genetic sequences. The patent for the Tay-Sachs disease is held by the Department of Health and Human Services. A screening test costs about \$100.<sup>152</sup> In contrast, the patent for two breast cancer genes (BRCA1 and BRCA2) is held by Myriad Genetics and a screening test costs \$2400.<sup>153</sup>

The field of biomedical research has become so infused with profiteering that bioprospecting for cell lines has taken scientists to distant places to negotiate the retrieval of tissue or blood samples.<sup>154</sup> Some indigenous groups have become suspicious of cell line prospecting and consider it a form of Western thievery of Third World resources.<sup>155</sup> The Biodiversity Convention was designed to

148. Gerard O'Neill et al., *Public Handouts Enrich Drug Makers, Scientists*, BOSTON GLOBE, Apr. 6, 1998, at A1, A10-11; Gerald O'Neill et al., *Tax Dollars Fuel University Spinoffs*, BOSTON GLOBE, Apr. 7, 1998, at A1, A24.

149. *See id.*

150. *See id.*

151. Jonathan King, *Gene Patents Retard the Protection of Human Health*, GENE WATCH (Council for Responsible Genetics, Cambridge, Mass.), Oct. 1996, at 10, 10-11.

152. *See* Jon F. Merz, et al., *Patenting Genetic Tests: Putting Profits Before People*, GENE WATCH (Council for Responsible Genetics, Cambridge, Mass.), Oct. 1998, at 4, 4.

153. *See id.*

154. *See* Gary Taubes, *Scientists Attacked for "Patenting" Pacific Tribe*, 270 SCIENCE 1112, 1112 (1995).

155. *See* VANDANA SHIVA, MONOCULTURES OF THE MIND 151-84 (1993).



protect species-rich Third World nations from exploitation by the industrial nations.<sup>156</sup> There is no comparable treaty for the protection of human genes or tissue samples that have commercial value. An unusual antibody discovered in an isolated tribe in South America can be used to develop a drug against a rare disease. A Western company sequences and patents the gene for the antibody, manufactures the drug, and develops a global market that includes the nation in which the tribal group lives. It is probably true that the drug would not have been developed if there were no company willing to invest capital in the tribal antibody. But does the human host of the unusual antibody and the community that supported him have any entitlements to share the profits on his biological material? Should someone have the right to profit from someone else's cell line? A group called the Indigenous Peoples Coalition Against Biopiracy has been organized to address such questions. In a draft of its ethical guidelines, the Human Genome Diversity Project has committed itself to sharing the financial rewards it might receive from cell lines with the communities from whom the cell lines were obtained. These arrangements are beginning to address the equity considerations involving the commercialization of human genetic resources, but do not get at the root issue of the appropriation and privatization of scientific knowledge.

The U.S. courts have thus far ruled against individuals and in favor of surgeons who claimed ownership of cell lines removed during an operation.<sup>157</sup> A case of considerable significance involved the California Supreme Court and a cell line developed from patient John Moore's spleen.<sup>158</sup> The court denied to Moore ownership of the cells taken from his body.<sup>159</sup> The judges did not rule that his cells belonged to the common pool of human knowledge.<sup>160</sup> Instead, they transferred ownership of the cells to his medical care team and their institutions.<sup>161</sup>

It has been over fifty years since sociologist Robert Merton published two classic papers that articulated the normative conditions

156. *See id.*

157. *See* George J. Annas, STANDARD OF CARE: THE LAW OF AMERICAN BIOETHICS 167-80 (1993); *see also* Beth Burrows, *Second Thoughts About U.S. Patent #4*, GENE WATCH (Council for Responsible Genetics, Cambridge, Mass.), Oct. 1996, at 4, 4-7.

158. *See* Moore v. Regents of the Univ. of California, 51 Cal.3d 120 (Cal. 1990).

159. *See id.* at 141-42.

160. *See id.* at 142.

161. *See id.* at 137, 142.

of scientific practice.<sup>162</sup> Merton wrote that science consisted of an “emotionally toned complex of rules, prescriptions, mores, beliefs, values and presuppositions which are held to be binding upon the scientist.”<sup>163</sup> Among the norms Merton cited were communalism—open and free exchange and the shared fruits of knowledge, and disinterestedness—knowledge as the sole interest of research.<sup>164</sup> The commercialization of scientific research has compromised the traditional Mertonian norms on the dubious assumption that the appropriation of knowledge as intellectual property, and in its wake the erosion of communalism and disinterestedness, will yield a greater public good in the long run.

162. ROBERT K. MERTON, *SOCIAL THEORY AND SOCIAL STRUCTURE* 595 (1957).

163. *Id.*

164. See *SCIENCE IN CONTEXT* 16 (Barry Barnes & David Edge eds., 1982).

