


## One Man's Trash is Another Man's Treasure, Bioprospecting: Protecting the Rights and Interests of Human Donors of Genetic Material

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**ONE MAN'S TRASH IS ANOTHER MAN'S TREASURE,  
BIOPROSPECTING: PROTECTING THE RIGHTS AND  
INTERESTS OF HUMAN DONORS OF  
GENETIC MATERIAL**

Leaders of the publicly funded human genome project and the private company, Celera Genomics of Rockville, Maryland, announced in February 2001 that the human genome has been mapped, marking a significant achievement in the history of modern science and medicine.<sup>1</sup> While researchers have already developed diagnostic tests for several diseases of genetic origin, it is not far fetched to predict that it will soon be possible to test for or treat hundreds of devastating genetic diseases.<sup>2</sup> The result: the biotechnology revolution has become modern alchemy, aiming to transmute diseased biological material into gold, and to find the panacea of human genetic illness. Researchers are racing to advance scientific knowledge and cash in on the enormous financial potential of their discoveries. Market forces and scientific advances in genetic research have merged, creating an uncomfortable tension between the goals and expectations of the market (profit) on the one hand, and the goals and expectations of science (freely shared knowledge) on the other.<sup>3</sup>

At the same time, the donors from whom is harvested the raw material of these discoveries are not compensated for their contributions.<sup>4</sup> This new "alchemy" raises urgent ethical and policy questions concerning the rights and interests of those individuals who donate their biological material to researchers who seek to develop useful diagnostic tests and successful treatments and to profit from their discoveries. The real profit and medical potential of raw human genetic material, specifically diseased genetic material, injects important equity considerations into a discussion of how the financial and thera-

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1. See Rick Weiss, *Life's Blueprint in Less Than One Inch: Only a Small DNA Segment Makes Human*, WASH. POST, Feb. 11, 2001, at A1.

2. See Rick Weiss, *A New Genetic Window on Curing Diseases*, WASH. POST, Feb. 11, 2001, at A10. See generally Margaret Graham Tebo, *The Big Gene Profit Machine*, A.B.A.J., ¶ 5 (Apr. 2001), available at <http://www.abanet.org/journal/apr01/fgene.html>.

3. See generally Sheldon Krinsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15 (1999); see also Julia D. Mahoney, *The Market for Human Tissues*, 86 VA. L. REV. 163 (2000). See Tebo, *supra* note 2, at ¶ 27-38.

4. See generally Gina Kolata, *Sharing Profits Is Debated As the Value of Tissue Rises*, N.Y. TIMES, May 15, 2000, at A1; see also Justin Gillis, *Gene Research Success Spurs Profit Debate*, WASH. POST, Dec. 30, 2000, at A1.

peutic benefits derived from successful research should be apportioned.

The case of Dan and Debbie Greenberg provides significant insight into the issues raised by the development of successful diagnostic testing for genetic diseases.<sup>5</sup> The Greenbergs had two children afflicted by Canavan disease, a rare but fatal genetic disorder.<sup>6</sup> They sought out and convinced Dr. Reuben Matalon to research Canavan disease; they raised money for his research, provided him with tissue samples from their afflicted children, and found other families to participate in the research.<sup>7</sup> The Greenbergs were shocked when Miami Children's Hospital, the institution supporting Dr. Matalon's laboratory, was awarded a patent for his successful Canavan research, and then began restricting use of the diagnostic test and charging a fee.<sup>8</sup> In October 2000, the Greenbergs, joined by several other families who had contributed tissues from diseased children to Dr. Matalon's research, filed suit against Miami Children's Hospital for breach of fiduciary duty, fraudulent concealment, conversion, misappropriation of trade secrets, unjust enrichment, and breach of informed consent.<sup>9</sup>

I argue that the interests and rights of individual donors of genetic material and the aggregate community of donors need to be protected. In addition, donors are entitled to a share in the fruits of successful research. These fruits include: access to diagnostic tests and useful treatment, public and legal acknowledgement of their contribution, and the rights to control that preserve the best interest of the other patients similarly situated or the public, and profit. Apportioning the fruits of genetic research is a formidable challenge, but it is imperative that we attempt to address these issues.

This paper consists of four parts. Part I provides an elementary explanation of genetic disease as it relates to the Greenberg case. Part II examines the Constitutional and statutory authority for our patent system. Part III explores the legal basis for patient rights in the Greenberg case. Part IV analyzes the effects of genetic patents and their profit potential on donors of the biological material necessary for research and discovery. This section of the paper begins by raising questions about whether genetic compounds should be patentable. Conceding that the current law allows these patents, the paper goes

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5. See *supra* note 4.

6. See *id.*

7. See *id.*

8. See *id.*

9. See *generally* Petitioner's Opening Brief, *Greenberg v. Miami Children's Hospital and Reuben Matalon*, No. 00C 6779 (D. Ill. filed Oct. 30, 2000).

on to assess ways to protect donors' rights and interests through informed consent, apportioning the benefits of successful genetic research, and creating patient advocacy groups.

### I. A PRIMER ON GENETIC DISEASE

Genetic diseases result from genetic mutations. In addition, sometimes genetic factors will combine with environmental factors to produce genetic disease.<sup>10</sup> Before scientists knew anything about gene mapping, genetic diseases were recognized through family histories of certain diseases. Today, many genetic diseases can be identified from a sequence alteration in the map of one or more genes.<sup>11</sup>

Genetic diseases are complex. Their diagnosis is complicated by a number of factors which results in clinical heterogeneity, that is, there is variability in the expression of a particular disease among those affected.<sup>12</sup> Different mutations in different genes can cause an identical or similar phenotype.<sup>13</sup> These complexities lead to varying levels of uncertainty underlying diagnosis and prognosis derived from genetic testing.<sup>14</sup>

Populations that have remained somewhat isolated and that share the same ancestors are relatively homogeneous genetically.<sup>15</sup> This homogeneity assists researchers with the difficult task of identifying a

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10. See generally Monique K. Mansoura & Francis S. Collins, *Medical Implications of the Genetic Revolution*, 1 J. HEALTH CARE L. & POL'Y 329 (1998).

11. See *id.* at 334. For example, currently predictive genetic tests are available for disease such as sickle-cell anemia, cystic fibrosis, achondroplasia, Down syndrome, Huntington disease, Tay Sachs, colon cancer, obesity, and some forms of breast cancer. See *id.* at 332, 334, 340.

12. See *id.* at 335.

13. See *id.* at 336.

14. See *id.* at 336-42. Clinical heterogeneity can be classified into two major categories: 1) allelic heterogeneity, referring to different mutations at one locus or gene, and 2) locus heterogeneity, referring to the fact that for many diseases, more than one gene can be involved in disease onset. Another concept fundamental to predictive genetic testing is *penetrance*. See *id.* This concept is an all or none phenomenon that refers to clinical expression, or lack of it, of mutant genes. See *id.* It addresses the likelihood that a given sequence alteration will actually result in disease. See *id.*

15. See ALICE WEXLER, *MAPPING FATE: A MEMOIR OF FAMILY, RISK, AND GENETIC RESEARCH* 182-210 (1995) (stating that in the early 1980's, researchers began studying inhabitants in the Lake Maracaibo region of Venezuela. These inhabitants were found to have a high occurrence of Huntington's disease and because of the founders effect, this community became invaluable to researchers in its search for the gene responsible for Huntington's.); see also Eliot Marshall, *Whose DNA Is It Anyway?*, 278 SCIENCE, Oct. 24, 1997, at 564-67 (providing researchers' hope that a tightly knit group of islanders who suffer a high incidence of asthma and who settled on Tristan de Cunha in the south Atlantic over 2000 years ago will provide valuable genetic information concerning the asthma gene.)

specific genetic mutation.<sup>16</sup> The “founders effect” describes a population or community of people, descended from a single ancestor or a small group of ancestors, in which any expression of a genetic disease would stem from the same original genes, located at the same spot on the same chromosome.<sup>17</sup> For instance, Ashkenazi Jews (Jews who trace their origins to Central and Eastern European descent) exhibit the founder’s effect. This population has remained relatively isolated in their genetic ancestry, and therefore genetic mutations are easier to identify than in members of the general population. Ashkenazi Jews make up 90% of the more than six million Jews in the United States.<sup>18</sup> In the case of the Canavan gene, one in 33 people of Ashkenazi heritage is likely to be a carrier.<sup>19</sup> If both parents are carriers, a couple has a 25% chance of producing a baby with the disease.<sup>20</sup>

## II. THE CONSTITUTIONAL AND STATUTORY BASIS FOR PATENTS

The next section of this paper offers a cursory glimpse at the complicated area of patent law and considers how patents affects the rights and interests of donors of genetic material.

Patent law derives from Article I, Section 8, Clause 8 of the United States Constitution, which grants Congress the power to legislate to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discourse.”<sup>21</sup> Current statutory authority defining *what* is patentable comes from Title 35 of the United States Code, section 101, which provides: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the requirements of this title.”<sup>22</sup> The statute requires that the invention be novel.<sup>23</sup> In addition, the invention must be non-obvious: “A patent may not be obtained . . . if . . . the subject matter as a whole would have been obvious at the time

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16. See WEXLER *supra* note 15.

17. See WEXLER *supra* note 15, at 189-90.

18. See Steven Greenhouse, *Doctor's Urge Screening for Disorder*, N.Y. TIMES, Apr. 27, 1999, at F6; see also Robert Lipsyte, *A Postcard from Morgan's Twilight World*, N.Y. TIMES, Apr. 14, 1996, Sec. 13, 1.

19. See *supra* note 18.

20. See *id.*

21. U.S. CONST. art. I, § 8, cl. 8.

22. 35 U.S.C. § 101 (1984).

23. See 35 U.S.C. § 102 (1984).

the invention was made to a person having ordinary skill in the art to which said subject matter pertains."<sup>24</sup>

Patent seekers must meet a three part "utility" test in determining whether the item for which they seek a patent is "useful."<sup>25</sup> They must show: 1) specific utility (usefulness must be specific to the subject matter claimed); 2) substantial utility (patent seeker must define a "real world" use); and 3) credible utility (the utility of the subject matter must be well-established).<sup>26</sup>

Our founding fathers developed patents as an incentive system for inventors to innovate and ultimately reveal their discoveries.<sup>27</sup> Patent rights are exclusionary rights and not ownership rights.<sup>28</sup> In exchange for making their inventions public, inventors receive the right to exclude the public from using their invention, as well as control use of their invention for a term of twenty years.<sup>29</sup> Control is managed through a system of licensing and fees.<sup>30</sup>

Congress intended the patent statute to include "anything under the sun that is made by man."<sup>31</sup> This did not mean there were no limits on statutory subject matter. The Patent and Trademark Office determines what is patentable, and its decisions must withstand the scrutiny of the courts. For instance, one who discovers a previously unknown law of nature, a physical phenomenon, or an abstract idea has no legal claim to a monopoly.<sup>32</sup> A newly discovered mineral or a new plant found in the wild is not patentable.<sup>33</sup> Likewise, "Einstein could not have patented the natural law of  $E = mc^2$  and Newton could not have patented the law of gravity."<sup>34</sup> These examples are part of

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24. 35 U.S.C. § 103 (1984).

25. Stephen Walsh, Associate Solicitor, U.S. Department of Commerce, Patent and Trademark Office, Address at a forum, *Patentability of Gene Sequences*, at the University of Maryland School of Law (Apr. 5, 2001).

26. *See id.*

27. *See* U.S. CONST. art. I, § 8, cl. 8.

28. *See* 35 U.S.C. § 154(a)(1) (1984).

29. *See id.*

30. *See* 35 U.S.C.A. § 154 (1984) (providing that "such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.").

31. *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (citing Committee Reports accompanying the 1952 Patent Act).

32. *See Chakrabarty*, 447 U.S. at 309.

33. *See id.*

34. *Id.*

the storehouse of knowledge of all men, and therefore not patentable.<sup>35</sup>

As a fundamental matter, there are strong arguments supporting the contention that genetic materials should not be and, in fact, are not patentable. Sir Isaac Newton once said, "if I have seen farther than other men, it is because I stood on the shoulders of giants."<sup>36</sup> Essentially, one could assert that scientific knowledge is cumulative and that an isolated genetic disease marker is a "product of nature." But because the patent regime is a complicated area of law and because genetics is a complex science, I will advance my argument concerning the rights and interests of individuals within the existing framework of today's patent regime.<sup>37</sup> Modern courts have upheld patents on genetic probes, or cloned gene sequences that identify certain characteristics or disease.<sup>38</sup>

### III. INFORMED CONSENT, CONVERSION, CONCEPTION, AND THE GREENBERG CASE

In 1990, the Supreme Court of California decided the important case of *Moore v. Regents of California*, which held that physicians have a fiduciary duty to inform patients of any personal interest, including research or economic, that is unrelated to the patient's health.<sup>39</sup> This case will be influential in the Greenberg case against Miami Children's Hospital, as the issues of the two cases are parallel. In *Moore*, the plaintiff, John Moore, underwent treatment for hairy-cell leukemia at the Medical Center of the University of California at Los Angeles.<sup>40</sup> The plaintiff's physician took blood, bone marrow aspirate, and other tissue samples for diagnostic purposes.<sup>41</sup> In addition, the physician recommended the removal of the plaintiff's spleen as part of a treatment plan.<sup>42</sup> The plaintiff conceded that the defendants had disclosed "they were engaged in strictly academic and purely scientific medical research"; however he claimed that the defendants had dis-

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35. See *id.*

36. Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 Nw. U.L. REV. 77, 90 (1999) (explaining the scientific norm that promotes sharing information, in which the equity of the individual scientist is limited to professional recognition and esteem).

37. See *infra* notes 91-146 and accompanying text.

38. See generally U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C.A. § 101 (1984); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Amgen v. Chugai Pharmaceuticals*, 927 F.2d 1200 (Fed. Cir 1991).

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

40. See *id.* at 125-26.

41. See *id.*

42. See *id.* at 126.

avowed any financial interest in the research.<sup>43</sup> During the course of the plaintiff's treatment and without his knowledge, the defendants established, then patented a cell line from the cells taken from the plaintiff's spleen and other body tissue samples.<sup>44</sup> The plaintiff claimed breach of fiduciary duty and informed consent, as well as conversion.

### A. *Informed Consent*

The doctrine of informed consent developed out of a strong judicial deference toward individual autonomy. Essentially, it holds that an individual has a right to be free from nonconsensual interference with his or her person.<sup>45</sup> In addition, the doctrine functions to protect a patient's status as a human being, avoid fraud and duress, encourage physicians to weigh decisions carefully, foster rational decision making in a patient, and involve the public in medicine.<sup>46</sup> Traditionally, before providing any kind of treatment a physician must disclose to the patient the diagnosis, the nature and purpose of a proposed treatment, the risks of treatment and non-treatment, and the alternatives to the proposed treatment.<sup>47</sup> In some jurisdictions, the scope of the duty to disclose is measured by the knowledge a reasonable patient needs to make an informed choice. In other words, all information material to a patient's decision should be given.<sup>48</sup> In other jurisdictions, the scope of the duty is measured by a reasonable medical practitioner, similarly situated.<sup>49</sup>

The court in *Moore v. Regents* expanded the physician's duty to include a *fiduciary duty* to disclose information that is material to a patient's decision.<sup>50</sup> The court examined the principles of informed consent: A person of adult years and in sound mind has the right to determine whether or not to submit to lawful medical treatment.<sup>51</sup> Further, "[i]n soliciting informed consent, a physician has a fiduciary duty to disclose all information material to the patient's decision."<sup>52</sup>

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43. *Id.* at 132. (citing Moore's allegations that his doctor "concealed an economic interest in the postoperative procedures.")

44. *See id.* at 127.

45. BARRY R. FURROWS ET AL., *HEALTH LAW CASES, MATERIALS, AND PROBLEMS* 397 (3d ed. 1987).

46. *See id.*

47. *See id.* at 107-08.

48. *See id.* at 429 (citing *Truman v. Thomas*, 27 Cal.3d 285 (Cal. 1980)).

49. *See id.* at 406.

50. *See Moore*, 51 Cal.3d at 129.

51. *See id.* (citing *Cobbs v. Grant*, 8 Cal.3d 229, 242 (Cal. 1972)).

52. *Id.*



The court observed that there are conflicting interests a physician must balance when she both treats and maintains a research interest in a patient.<sup>53</sup> Any interests extraneous to the health of a patient that may affect a physician's judgment are material, and a reasonable patient would likely want to know of those interests before consenting to a proposed course of treatment.<sup>54</sup> Ultimately, the court held, "[a] physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and obtain the informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."<sup>55</sup>

### B. Conversion

The plaintiff in *Moore* also asserted that the defendants interfered with his ownership interest in the cells that were removed from his body, and that he had a proprietary interest in the products created from his cells.<sup>56</sup> After balancing relevant policy considerations, the court declined to extend the tort of conversion to cases such as the one at bar, concluding that patients are sufficiently protected by the informed consent doctrine.<sup>57</sup> In its analysis, the court observed that there was no precedent for extending conversion liability to the use of human cells in medical research.<sup>58</sup> In addition, existing statutory laws limit patients' continuing interest in their excised cells.<sup>59</sup> Human tissue, transplantable organs, blood, fetuses, corneal tissue, dead bodies, and other human biological materials are considered by the law as *sui generis*; their disposition is regulated in deference to public policy consideration, rather than "abandoning them to the general law of personal property."<sup>60</sup> And lastly, the court held that the plaintiff had no possessory claim over the patented cell line because it "is factually and legally distinct from plaintiff's cell line."<sup>61</sup>

Another important policy consideration precluded the court from extending the tort of conversion to excised human cells. The court stated that innocent parties, such as medical researchers, who

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53. *See id.* at 130.

54. *See id.*

55. *See Moore v. Regents of California*, 51 Cal. 3d 120 at 131-32 (Cal. 1990). Certain personal interests may effect a physician's professional judgement. *See id.* at 132, n.10.

56. *See id.* at 134.

57. *See id.* at 142.

58. *See id.* at 137.

59. *See generally* Ann. Cal. Health & Safety Code § 7150 - 7158 (1994).

60. *Moore v. Regents of California*, 51 Cal. 3d 120, 137 (Cal. 1990).

61. *Id.* at 142.

engage in socially useful activities, should not be threatened with civil liability.<sup>62</sup> Allowing a patient, who is a specimen source, a cause of action in conversion could hinder research and product development by restricting access to necessary raw material.<sup>63</sup> The legislature, not the court, should make the decision as to whether liability for conversion should be extended.<sup>64</sup>

### C. Conception

Courts have held that people cannot contract for things to which they are not entitled. This is true in patent law, as is illustrated by the following case, *Brown v Regents of the University of California*.<sup>65</sup>

In 1994, the court held in *Brown v Regents of the University of California* that patent law does not recognize the contributions of individuals who provide the raw material for a patent.<sup>66</sup> The plaintiff supplied researchers with cats she suspected to have feline immunodeficiency virus (F.I.V.), the feline form of human immunodeficiency virus (H.I.V.). The court considered whether the plaintiff had made sufficient contribution to the "conception" that led to a patent award as to be named a joint inventor.<sup>67</sup>

The plaintiff, an animal health technician, had observed immunodeficiency symptoms in several of the cats in the shelter she maintained for them.<sup>68</sup> She made detailed observations and records of the cats' illnesses and had a veterinarian test them for a number of diseases, which turned up no diagnoses.<sup>69</sup> Ultimately, the plaintiff brought the cats to the defendant, a well-known animal virologist and told him she suspected that the cats suffered from a virus similar to H.I.V.<sup>70</sup> The defendant did extensive laboratory work, which led to an award of a patent on methods for identifying F.I.V. in a pure and non-naturally occurring form, and of detecting F.I.V. in cats and immunizing them against it.<sup>71</sup>

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62. See *id.* at 143.

63. See *id.* at 144.

64. See *id.* at 145.

65. See 866 F.Supp. 439 (N. Dist. Cal. 1994); see also *infra* notes 63–71 and accompanying text.

66. See *Brown*, 866 F.Supp. at 440.

67. See *id.*

68. See *id.*

69. See *id.*

70. See *id.*

71. See *Brown v. Regents of California*, 866 F.Supp. 439 (N. Dist. Cal. 1994).

The court found that the plaintiff, a “nonscientist,” played no role in the lab work involved in isolating the virus.<sup>72</sup> Despite the value of her research leads, the plaintiff did not contribute to the conception of the inventions covered by the patents held by the defendant.<sup>73</sup> The court held that to qualify as a joint inventor, the plaintiff must have contributed to the conception of the invention.<sup>74</sup>

#### D. *The Greenberg Case*

In the early 1980's, Dan and Debbie Greenberg discovered that two of their children were afflicted by a devastating genetic disorder, Canavan disease.<sup>75</sup> Canavan disease, which occurs most commonly in Ashkenazi Jews, is a form of leukodystrophy, a rare degenerative neurological disease that is fatal, usually by the time affected children reach their teens.<sup>76</sup> Children born with Canavan disease have poor vision and abnormally low muscle tone; they do not have normal motor coordination and will not learn to crawl, feed themselves, walk, or talk.<sup>77</sup> The way the Canavan genetic mutation works is by preventing production of an enzyme needed to metabolize an acid found in the brain.<sup>78</sup> Unmetabolized acids destroy myelin, the insulation that allows nerves in the brain to function normally.<sup>79</sup>

In an effort to produce something good from their tragedy, the Greenbergs recruited Dr. Reuben Matalon in 1987 to research the genetic cause of their children's disease.<sup>80</sup> They contacted other families worldwide to acquire more blood, urine and tissue samples from other children affected by disease.<sup>81</sup> The Greenbergs also provided seed money and raised cash to establish a foundation to help fund Dr. Matalon's research.<sup>82</sup> Dr. Matalon quickly and successfully identified

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72. *Id.* at 445.

73. *See id.*

74. *See id.* at 442 (explaining that conception is “the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice.”)

75. *See supra* note 4.

76. *See* Reuben Matalon et al., *Canavan Disease: From Spongy Degeneration to Molecular Analysis*, 127 J. PEDIATRICS 1995, 511–17; *see also* Steven Greenhouse, *Doctor's Urge Screening for Disorder*, N.Y. TIMES, Apr. 27, 1999, at F6.

77. *See* Matthew Hay Brown, *Hope in a New Treatment For a Fatal Genetic Flaw*, N.Y. TIMES, Oct. 29, 1996, at Sec. 13CN, 1.

78. *See id.*

79. *See id.*

80. *See supra* note 4.

81. *See id.*

82. *See id.*

the gene that caused Canavan Disease, opening up the possibility of prenatal testing.<sup>83</sup>

In 1991, Dr. Matalon moved his research laboratory to Miami Children's Hospital Research Institute, bringing his Canavan research with him.<sup>84</sup> In early 1993, Dr. Matalon announced his success in cloning the gene responsible for Canavan disease.<sup>85</sup> As a result, academic labs began offering early prenatal testing for the disease based on Dr. Matalon's papers.<sup>86</sup> Miami Children's Hospital Research Institute filed a patent application in the fall of 1994 and the institution was awarded the patent in the fall of 1997, at which point it began restricting use of the test and charging a fee.<sup>87</sup>

After failed attempts at dialogue, the Greenbergs, other parents and allied groups filed suit against Miami Children's Hospital in Illinois federal court for breach of duty, unjust enrichment, and breach of informed consent.<sup>88</sup> Among the concerns they raised was the fear that research on Canavan disease would be slowed because access to available information and testing would be severely limited by exorbitant fees.<sup>89</sup> The fees would make it difficult for other interested researchers to do new investigations, and for people who needed diagnostic testing to get it.<sup>90</sup>

#### IV. EQUITY CONSIDERATIONS AND THE MEANS TO PROTECT DONORS

The genetic revolution has created opportunities to improve human health dramatically, to perform acts of enormous generosity, and to realize great financial returns on investment.<sup>91</sup> The law and policy in place inadequately address the equity considerations that emanate from this movement. Informed consent begins to address issues of fairness and justice by alerting donors to all the interests in a given research endeavor. Although informed consent is an important tool for protecting donors, it falls short of addressing the issue of prin-

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83. See Justin Gillis, *Gene Research Success Spurs Profit Debate*, WASH. POST, Dec. 30, 2000, at A1, ¶ 41.

84. See *id.*

85. See Petitioner's Opening Brief at 9, *Greenberg v. Miami Children's Hospital and Reuben Matalon*, No. 00C 6779 (D. Ill. filed Oct. 30, 2000); see also R. Kaul et al., *Cloning of the Human Aspartoacylase cDNA and a Common Missense Mutation in Canavan Disease*, 5 NAT. GENET. at 118-23 (1993).

86. See *supra* note 4.

87. See *id.*

88. See *id.*

89. See generally Petitioner's Opening Brief, *Greenberg v. Miami Children's Hospital and Reuben Matalon*, No. 00C 6779 (D. Ill. filed Oct. 30, 2000).

90. See *id.*

91. See generally Julia Mahoney, *The Market for Human Tissue*, 86 VIR. L. REV. 163 (2000).

cipled apportionment of the benefits of successful research. Apportioning the benefits of genetic research is a formidable challenge, but it is imperative that we try to address it.

### A. *A Critique of the Patent Regime*

The profit potential of raw human genetic material, particularly diseased genetic material, injects important equity considerations into a discussion of how the financial and therapeutic benefits derived from successful research using this material should be apportioned.<sup>92</sup> As argued below, the individual donors of genetic material and the aggregate community of donors are entitled to a share in the fruits of successful research.<sup>93</sup> These fruits include access to any diagnostic test or any useful treatment, public and legal acknowledgement of their contribution, any rights to control that preserve the best interest of the other patients similarly situated or the public, and of course, profit.<sup>94</sup> Nevertheless, the patent regime does not recognize the contributions of donors.<sup>95</sup>

The Patent and Trademark Office's issuance of patents in this area, as well as court decisions in such cases as *Diamond v. Chakrabarty* and *Amgen v. Chugai* support the presumption that such patents are legal.<sup>96</sup> While genes are products of nature, scientists have convinced the Patent and Trademark Office, the courts, and, to some extent the legislature as demonstrated by its inaction, that modifying genes alters their natural molecular sequence enough such that the result is a "new composition of matter" that is patentable.<sup>97</sup> Despite widespread support, there are compelling arguments to be made against the patentability of gene sequences;<sup>98</sup> however, a comprehensive illustration of these analyses is beyond the scope of this paper.

On the topic of genetic advances and legal institutions, United States Supreme Court Justice Stephen G. Breyer has asserted that judicial decisions need to be grounded in realistic, "not fanciful," predic-

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92. See *infra* notes 110–57 and accompanying text.

93. See *id.*

94. See *id.*

95. See *supra* notes 65–74 and accompanying text.

96. See Sheldon Krinsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15, 23 (1999).

97. See *id.* at 26.

98. See generally Arthur L. Caplan & Jon Merz, *Patenting Gene Sequencing: Not in the Best Interest of Science or Society*, 312 BRIT. MED. J. 926 (Apr. 13, 1996); Jon Merz, *Diseased Genes Are Not Patentable*, 7 CAMBRIDGE Q. OF HEALTHCARE ETHICS 425 (1998); Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 239 SCIENCE 698 (May 1, 1998).

tions of what science will do.<sup>99</sup> He asserts that it is imperative that judges have a sense of the likely social and economic consequences of their decisions before they act.<sup>100</sup> He has questioned how well the patent system has responded to the latest developments in genetics: for instance, does the patenting of naturally occurring genes and disease-causing mutations fulfill the objectives of the patent regime?<sup>101</sup> Has it allowed for financial incentives that will “encourage useful discovery and disclosure without unduly restricting the dissemination of those discoveries, hindering circulation of important scientific ideas, or scattering ownership to the point where it inhibits use of the underlying genetic advance?”<sup>102</sup> If not, he posits, “How should the law be changed?”<sup>103</sup> Justice Breyer’s questions appear to reflect a willingness on his part, or perhaps on behalf of the Supreme Court, to entertain the notion that at least some (if not all) gene sequences should *not* be patentable. He reveals his sense that the issue is, at least, ambiguous, “[c]loning a previously unknown DNA sequence is a little like the ‘discovery’ of a pre-existing part of the human body, it is also something like the expensive, time-consuming and novel, isolation of a previously unknown molecule.”<sup>104</sup>

Justice Breyer’s questions reflect some of the criticisms of the patent system in the context of genetic sequences. Answers to these questions have serious implications for donors of genetic material and patients who could benefit from the advances in diagnostic and treatment options for genetic diseases. Beyond the fact that the patent regime does not recognize the contributions of specimen donors, other aspects of patent law have an adverse impact on patient access to useful diagnostic or treatment options.<sup>105</sup> For instance, the length of a patent, which reserves to the holder seventeen to twenty years of the rights of exclusive use and control, is probably out of line with the magnitude of investment and the speed of advances in genetics.<sup>106</sup>

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99. Justice Stephen G. Breyer, Genetic Advances and Legal Institutions, Remarks at the Whitehead Policy Symposium, Plenary Session (May 10, 2000), in 28:4 J. OF L. & MED., Dec. 22, 2000 at S23.

100. *See id.*

101. *See id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. *See generally* American College of Medical Genetics: *Position Statement on Gene Patents and Accessibility of Gene Testing*, <http://www.faseb.org/genetics/acmg/pol-34.htm> (visited Apr. 8, 2001).

106. Michael S. Watson, Executive Director, American College of Medical Genetics & ACMG Foundation., address at a forum, *Patentability of Gene Sequences*, at the University of Maryland School of Law (Apr. 5, 2001).

The effect of this is that the monopoly created by a given patent can limit access to diagnostic testing, as well as further research.<sup>107</sup> Licensing has resulted, in some cases, in exorbitant fees and limitations on which laboratories are authorized to perform diagnostic testing.<sup>108</sup> This in turn reduces or even eliminates competition, causes quality to suffer, keeps prices high, and deters innovation.<sup>109</sup>

Further, as the Greenberg case illustrates, the patent system and the manner in which it is employed by researchers and the biotechnology industry compromises future donor participation in research because of a deeply felt sense of exploitation. While the patent system rewards researchers for their discoveries and innovations, there is no analogous regime that provides an incentive for donors to participate. Likewise while discoveries and innovations are rigorously protected, the interests of the research participants are not subject to the same security. Instead donors are expected to subscribe to an altruistic scheme in which their "reward" is the feeling of having contributed to the betterment of the human condition. Only limited rights are associated with that contribution. Clearly, the intersection of the profiteering norms with altruistic norms creates a clash of expectations that ought to be addressed.

### B. *Informed Consent*

In his article *The Profit of Scientific Discovery and Its Normative Implications*, Sheldon Krimsky points out that new financial opportunities in molecular genetics have a profound effect on the relationship between scientists and their work.<sup>110</sup> Arguably, the new profit motives in genetic research also have a penetrating effect on the relationship between researchers and doctors, on the one hand, and donors and pa-

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107. *See id.*

108. *See id.*; *see also* Letter from Anna Schissel et al. to the editor, NATURE, *Survey Confirms Fear About Licensing of Genetic Tests*, 402 NATURE 118 (Nov. 11, 1999) (claiming exclusive rights to several patents are being used to monopolize testing services, or restricting performance of testing services by other labs. Public institutions (including NIH) should not grant exclusive licenses for "upstream" technologies, particularly when discovered using public funds. Patents should be available to all. Licensees should be permitted to perform patented tests non-exclusively and to sublicense to other researchers/labs. Collection of a reasonable royalty will ensure that the financial rewards and incentives of the patent system are maintained.); *see also* Arthur L. Caplan & Jon Merz, *Patenting Gene Sequencing: Not in the Best Interest of Science or Society*, 312 BRIT. MED. J. 926 (Apr. 13, 1996) (arguing that while investment is good, limiting access is unlikely to lead to maximal intellectual exploitation of the resource. If there is not persuasive reason to forbid the patenting of human genes, the argument must then turn to consequences.)

109. *See supra* note 102.

110. *See* Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV 15, 27 (1999).

tients, on the other. "Bioprospecting" for new cell lines is infused with many of the same dangers of exploitation of the body and human dignity as the Great California Gold Rush, which ravaged land, broke spirits, decimated populations of indigenous people, and made some people grossly wealthy. The researching community is walking a very fine line as it risks alienating the patient population on whom it depends for the raw material at the center of their research. Patients, if alienated, may refuse to participate in genetic research, fearing exploitation.

### 1. *Comparing Moore and Greenberg: Similarities*

There are fundamental similarities between the *Moore* case and the *Greenberg* case that demonstrate why informed consent is a valuable and necessary tool in protecting the rights and interests of donors of genetic materials. The *Moore* case reveals how the disclosure of a physician's financial interest through informed consent might have protected the *Greenbergs*.<sup>111</sup>

The intersection of the new profiteering model of scientific research with the altruistic model imposed on human tissue donation creates a disturbing clash between the often aggressive profit goals of researchers and institutions, on the one hand, and the charitable expectations of donors, on the other. Not-for-profit institutions are no longer what they appear. Their dependence on profit-making individuals and corporations and their creation of profit-making "spin-offs" produces great financial complexity. Research, in both the *Moore* and *Greenberg* cases, was done at a not-for profit institution. In both cases, the donors and their families were aware that academic research was being performed on their cells.<sup>112</sup> Nevertheless, both *Moore* and the *Greenbergs* were not informed of the researchers' intent to file a patent or that there was the prospect of profit resulting from the research.<sup>113</sup> These hidden profit motives suggest some level of fraud committed against the donors, leaving them feeling misled or exploited, their expectations violated. Informed consent would put donors on notice that they could exercise a choice about who should benefit from their gift.

If researchers were required to disclose profit incentives, donors would learn of the potential financial value of their donated biological materials and the researchers' and institutions' intentions to capitalize

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111. See *infra* notes 112–157 and accompanying text.

112. See *Moore v. Regents of California*, 51 Cal.3d 120, 132 (Cal. 1990); *supra* note 4.

113. See *Moore*, 51 Cal.3d at 126–27; *supra* note 4.



on their gift. Given that our current public policy does not allow donors of genetic material to realize any profit from their diseased tissue, at the very least they will not be misled as to the beneficiary of their gratuitous transfer.<sup>114</sup> This may avert the disturbing clash between altruistic expectations of donors and the aggressive profit-making goals of researchers and the institutions for whom they work.<sup>115</sup>

Allowing researchers and institutions to convert gifts into profit transforms the gift. As Lewis Hyde writes, "Gifts are a class of property whose value lies only in their use and which literally ceases to exist as gifts if they are not constantly consumed. When gifts are sold, they change their nature as much as water changes when it freezes, and no rationalist structure can replace the feeling that is lost."<sup>116</sup> Adequate informed consent should disclose any profit potential to protect individuals from the exploitation inherent in transforming a valuable and intimate gift into a profit for an unintended beneficiary.

## 2. *Comparison of Moore and Greenberg: Differences*

Individuals and institutions involved in genetic research have many different goals, which may include: contributing to a diagnosis or cure of a disease to benefit one's self, contributing to benefit the health of others, making life-saving and health-saving medical services available, making a significant profit on an investment of labor or capital, gaining public recognition, or contributing to the world's knowledge and understanding of a particular disease.<sup>117</sup> Examining the *Moore* and the *Greenberg* cases reveals the spectrum of expectations.<sup>118</sup>

First, John Moore sought and received medical treatment for his disease.<sup>119</sup> Research on his cells was incidental to his treatment.<sup>120</sup> Although he knew he was participating in academic research, he stood to benefit, potentially, from the medical treatment he received. The Greenbergs, on the other hand, actively pursued a researcher who would study Canavan, not a physician who would treat their children.<sup>121</sup> The Greenbergs actively participated in supporting the research by raising money to fund it and sought other participants for

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114. See generally 42 USCA § 274e (West 1987).

115. See generally Julia Mahoney, *The Market for Human Tissue*, 86 VIR. L. REV. 163 (2000).

116. LEWIS HYDE, *THE GIFT: IMAGINATION AND THE EROTIC LIFE OF PROPERTY* 21 (1983).

117. See *infra* notes 118–132 and accompanying text.

118. See *id.*

119. See *Moore v. Regents of California*, 51 Cal.3d 120, 125 (Cal. 1990).

120. See *id.* at 125–28.

121. See *supra* note 4.

the studies.<sup>122</sup> The Greenberg's children who donated specimens expressly for the purpose of research were not likely to benefit from research done on their cells.<sup>123</sup> Given the short life span of children with this rare disease, and given that little was known about Canavan disease, their participation would likely benefit only people other than themselves.<sup>124</sup> However, the Greenbergs were able to conceive two children who were not afflicted with Canavan disease because of the predictive testing that resulted from research.<sup>125</sup>

Second, the researchers in the *Moore* case developed their cell line from John Moore's cells exclusively, not from an aggregation of many donor cells.<sup>126</sup> While researchers had learned much about hairy cell leukemia from studying cells other than John Moore's cells, his cells were of great value to them because they overproduced certain proteins that had potential therapeutic value.<sup>127</sup> It is unusual that the cells from one individual would be the exclusive source for a cell line used in diagnosis and treatment of a particular disease. More often, information is aggregated from many individuals and leads to the development of a genetic probe that can be used to detect genetic mutations. This was the case with the Canavan research, which developed its cell line from several individuals. In addition, therapeutic value was less certain at the early stage in research on Canavan disease.

Third, Moore's hairy cell leukemia is more common than Canavan disease. This difference most likely has an impact on the respective patent holders' expectations for a profitable return on their discovery. The potential market for the Moore cell line was predicted to be as high as three billion dollars.<sup>128</sup> No predictions are available for the Canavan discovery.

Finally, Moore's doctor assisted the Regents of California in developing the commercial value of the cell line and any products derived from it.<sup>129</sup> A private biotechnology company, Genetics Institute (G.I.), was given exclusive access to the materials and research performed.<sup>130</sup> Consequently, Moore's doctor became a paid consultant to G.I., acquired rights to G.I. stock, and received other payments and

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122. *See id.*

123. *See id.*

124. *See supra* note 4.

125. *See* Justin Gillis, *Gene Research Success Spurs Profit Debate*, WASH. POST, Dec. 30, 2000, at A1.

126. *See Moore v. Regents of California*, 51 Cal.3d 120, 127 n.2 (Cal. 1990).

127. *Id.*

128. *See id.* at 127.

129. *See id.*

130. *See id.*

fringe benefits from the company.<sup>131</sup> The Greenbergs' researcher, on the other hand, claims to have received no financial benefits from his discovery, even though Miami Children's Hospital has attempted to move ahead with finding a company to which it would give exclusive licensing rights.<sup>132</sup>

### 3. *The Apportionment Dilemma*

The current regime of allocating the duties, rights and entitlements associated with the use of human biological materials is inadequate.<sup>133</sup> In designing a better system of apportionment, we need to examine the rationale for our current public policy that disallows a donor, the human repository of valuable cells, from realizing any profit and allows only very limited control of those tissues. The policy seems to be contradicted by the fact that commerce plays a central role in the distribution and allocation of human biological material, which may be exploited for its financial value once it has been taken from the donor and stored in a secondary repository.<sup>134</sup>

Current public policy limiting donor rights' emerges from concerns that granting individuals property rights in their own tissue will commodify the human body.<sup>135</sup> Also, offering compensation may lead to exploitation of the poor who may be willing to assume great health risks for payment.<sup>136</sup> In their book *Body Bazaar*, Lori Andrews and Dorothy Nelkin introduce the prospect that giving people property rights in their own tissue will prompt other people to treat it as property.<sup>137</sup> They raise the specter of chilling possibilities: a man is denied welfare because his kidney is worth \$20,000; a woman is denied a student loan because her eggs are worth \$2,000 to \$50,000; a comatose woman's eggs are harvested to pay for her hospital bill.<sup>138</sup> And finally, allowing donors property interests in their own tissue may serve as a disincentive to researchers to do such research.

Nevertheless, commerce already plays a central role in the allocation of human biological materials; human biological materials have

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131. *See id.*

132. *See generally* Justin Gillis, *Gene Research Success Spurs Profit Debate*, WASH. POST, Dec. 30, 2000, at A1.

133. *See generally* Julia D. Mahoney, *The Market for Human Tissues*, 86 VA. L. REV. 163 (2000).

134. *See id.* at 165.

135. *See id.*

136. *See id.*

137. *See* LORI ANDREWS & DORTHY NELKIN, *BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE* 165 (2001).

138. *See id.*

been commodified.<sup>139</sup> Body parts are bought and sold throughout the medical industry, once they have been donated; property rights in body parts vest only in secondary individuals and institutions though, not the original donor.<sup>140</sup> In tort suits, the court is authorized to compensate individuals for the value of a severe injury, considering a variety of factors in the calculus (for example: earning potential, lost opportunity, life expectancy).<sup>141</sup> Athletes and models are compensated for physical attributes. Tina Turner can insure her legs for two million dollars.<sup>142</sup> Robert Parker, the famous wine critic, can insure his taste buds for one million dollars.<sup>143</sup> The images of famous people are awarded property status.<sup>144</sup>

It is easy to understand how property rights serve as an incentive for researchers and institutions to do work that will prove commercially successful. Medical options that improve health clearly have commercial value. Conceding these points, though, does not support the argument that individuals should be denied property interests in their own tissue. In fact, one could argue that a similar incentive system would be effective in encouraging more people to participate in research. By acknowledging an individual's property interest in human biological materials, we may be better able to protect the rights and interests of donors. Precluding individuals from access to the same or similar incentive system has the potential to alienate people from participating in valuable research because of the perception that they may be exploited.

In addition, the point can be made that value already exists in the raw human biological materials before they are submitted to any scientific processes. Consider the following hypothetical: An individual owns a rock embedded with sapphires. Clearly, this person owns something of value, though admittedly, the value of the sapphires will increase if they are extracted, cut into gems, and perhaps mounted in a setting. The process, which the individual who owns the rock does not have the skill to perform, adds more value to the stones. Nevertheless, the process does not spontaneously create the value.

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139. See generally Julia D. Mahoney, *The Market for Human Tissues*, 86 VA. L. REV. 163 (2000).

140. See generally ANDREWS *supra* note 137.

141. See generally RICHARD A. EPSTEIN, *CASES AND MATERIALS ON TORTS* 873-74, 882-83, 482-88 (6th ed. Aspen Law & Business Panel Publishers 1995).

142. See Erica Garcia, *Insure This* <http://www.business2.com/articles/mag/0,1640,10385,FF.html> (visited Nov. 23, 2001).

143. See John Vankat, *Straight Talk About Wine*, <http://www.winepocketlist.com/columns/whoisexpert.html> (visited Nov. 23, 2001).

144. See, e.g., *White v. Samsung Elecs. America, Inc.*, 971 F.2d 1395 (9th Cir. 1992).

While apportioning the benefits of research presents a significant challenge, certain goals ought to be met. First, researchers and their funding institutions should be reimbursed for most of their expenses associated with the research. Second, the researcher and/or the funding institution should be able to receive some percentage of any money received in excess of recouped expenses as an incentive to do further research. After this, the criteria for an apportionment scheme become harder to define. One patient advocacy group has attempted to develop such a scheme through its foundation, PXE International, Inc., including a private agreement between and collaborative efforts of PXE International and the researchers at the University of Hawaii.<sup>145</sup>

### C. *Grassroots Advocacy: A Collaborative Model*

Sharon and Patrick Terry established a foundation, PXE International, Inc., after discovering that two of their children had a genetic disease called pseudoxanthoma elasticum, a disease that causes the connective tissue in the skin, eyes, and arteries to calcify.<sup>146</sup> The foundation serves as a repository to store blood and tissue samples of individuals with the disease, and in addition, raises money to fund research on the disease.<sup>147</sup> To protect their donors' interests, PXE required that researchers who wanted to use samples from their repository agree to joint possession of any intellectual property rights, shared profits resulting from any discoveries. PXE also required that any genetic test that were developed be made available to the foundation.<sup>148</sup> Researchers at the University of Hawaii agreed to PXE's stipulations and used the specimens in the PXE repository to isolate the gene responsible for the disease.<sup>149</sup> In an unprecedented move, PXE and the University filed a joint patent application.<sup>150</sup> Both the University and the donor advocacy group seem to have similar goals in mind: that the tests and treatments be widely accessible and available at an affordable price.

Given that the courts have held that people cannot contract for things to which they are not entitled,<sup>151</sup> the agreement between PXE

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145. See *infra* notes 146–57 and accompanying text.

146. See Paul Smaglik, *Tissue Donors Use Their Influence in Deal Over Gene Patent Terms*, 401 NATURE 821 (Oct. 19, 2000); see generally [www.pxe.org](http://www.pxe.org) (last visited Nov. 20, 2001).

147. See Gina Kolata, *Sharing Profits Is Debated As the Value of Tissue Rises*, N.Y. TIMES, May 15, 2000, at A1.

148. See *supra* note 146.

149. See *id.*

150. See *id.*

151. See *supra* notes 65–74 and accompanying text.

and researcher at the University of Hawaii may not withstand the scrutiny of the Patent Trademark Office. As in *Brown*, PXE may not be a co-inventor within the statutory requirements for conception.<sup>152</sup>

PXE International serves an important function for potential donors. Universities, such as the University of California, and some hospitals, such as Miami Children's Hospital, are no longer unambiguously not-for-profit institutions. PXE International on the other hand, is clearly a not-for-profit foundation, which acts with the best interest of individuals who have pseudoxanthoma elasticum. Understanding the forces at play in the genetic revolution is essential to being able to mobilize resources to protect donors' interests and rights, and balance competing interests.

It is interesting to note that the PXE International's blood donation informed consent form does not disclose that a patent application has been filed.<sup>153</sup> Under "financial considerations" the form explains that a donor is not charged, nor does he/she receive payment for participating in the research.<sup>154</sup> It behooves the foundation to reveal that a patent application has been filed on the informed consent form. Donors should be informed not only that therapeutic benefit may be derived from their donations, but also that the pending patent application, if successful, will result in financial benefit to those named on the patent. Donors should be able to control who will derive any financial benefit resulting from their donations.

In October of 1999, the Alliance of Genetic Support Groups and the American Society of Human Genetics Ad Hoc Committee on Consumer Issues delivered a consensus statement recognizing the important role genetic support groups play in the research of genetic diseases.<sup>155</sup> But not everyone agrees that patient advocacy groups

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152. See *Brown v. Regents of the University of California*, 866 F. Supp. 439, 440 (N. Dist. Cal. 1994).

153. See the PXE informed consent form (describing what will happen with blood samples: "Blood will be used in research projects that isolate the gene(s) for pseudoxanthoma elasticum and its mutations, and which have been approved by PXE International." It also describes benefits: "There is no direct benefit to the blood donor, but the hope of the foundation is that information gained from the bank will help in the treatment of pseudoxanthoma elasticum." (on file with the author).

154. *Id.*

155. Genetic Alliance statement of position on collaborative research at <http://www.geneticalliance.org/aboutus/researchmodel.html>, (visited Apr. 4, 2001). The statement reads as follows:

Research in Human Genetics is a shared enterprise that involves investigators, subjects, and ancillary agencies, including funding organization and regulatory boards. The cultures of these groups often differ and these differences create a dynamic tension between shared and divergent interests. When divergent interests interfere with recruitment of subjects to research and compromise mutual

have a role in balancing the competing interests that emerge in the context of the research. Some believe that if tissue donors demand any control over the results of research or a cut of the profits, "a long standing and noble tradition in this country of voluntary and charitable donations to medical research" will be undermined.<sup>156</sup> In addition, donors could influence the design of studies and the direction of research to the detriment of the greater good.<sup>157</sup> Balancing competing interests in the context of genetic research is a complex and challenging undertaking; the profit potential has changed the scientific paradigm and donors' relationship to it. As a result and for lack of a better alternative, patient advocacy groups are an essential mechanism for protecting donors' interests and rights.

## V. CONCLUSION

The Greenberg case represents a compelling reason to expand informed consent to include profit incentive in the disclosures researchers and institutions must make before proceeding with their investigations. Their case also presents an opportunity to delve more deeply into how we should apportion the therapeutic and financial benefits resulting from successful research. The patent system and public policy do not sufficiently address the problems inherent in exchanges between donors of genetic material and researchers. As the *Greenberg* and *Moore* case, illustrate, the current system threatens to alienate potential donors from the research process. There is an ur-

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understanding of goals of both parties, it is important to identify mechanisms to create or recognize these shared goals. Genetic support groups are an important agency in this enterprise. These groups have diverse objectives: creation of community, advancement of education for members and professional and sponsorship and encouragement of research. To the extent that successful support groups have created active involvement in research, their activities provide models for future collaborative relationships. The key activities at the level of support groups include education of members about expectations for research, elements of the consent process, and the nature of research as well as education of investigators with respect to many of these same elements. Support groups can best broker the successful relationships between investigators and participants where the cultural differences are clearly delineated. As the Human Genome Project reaches its objective of a complete sequence and the emphasis in Human Genetics research evolves from gene finding to characterization of disease mechanisms, the role of support groups in recruitment of subjects will be increasingly important. The change, i.e., to search for successful therapies, will require an even more active interaction of investigators, subjects, support groups, and other agencies to recruit the participants and to explain the objectives of the research process. Active collaboration among investigators, subjects, and support groups will be the catalyst for future research productivity in human genetic disorders.

156. Matt Fleischer, *Patent Thyself*, THE AMERICAN LAWYER, June 2001, at 87.

157. *See id.*

gent need to design and implement new legal and policy regimes that better regulate the commerce of human biological materials. Doing so will promote human health and reward the generosity of the human spirit.

ANNE NICHOLS HILL



