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### The Commercialization of Human Tissue—The Source of Legal, Ethical and Social Problems: An Area Better Suited to Legislative Resolution

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# THE COMMERCIALIZATION OF HUMAN TISSUE—THE SOURCE OF LEGAL, ETHICAL AND SOCIAL PROBLEMS: AN AREA BETTER SUITED TO LEGISLATIVE RESOLUTION

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## I. INTRODUCTION

Progress in the scientific techniques of genetic engineering<sup>1</sup> has sparked unprecedented interest in industrial applications<sup>2</sup> using living organisms.<sup>3</sup> Scientists have developed techniques that use human tissue to produce commercial products.<sup>4</sup> These biotechnology products carry great potential for treating many human diseases,<sup>5</sup> including, possibly, Acquired Immune Deficiency Syndrome (AIDS). In response to this increased interest in biotechnology products, many biotechnology firms have been formed with the goal of commercially exploiting biotechnology techniques for profit.<sup>6</sup> Consequently, companies are battling over

1. See *infra* notes 79-93 and accompanying text for a discussion of genetic engineering.

2. Industrial applications include the production of new drugs, food, and chemicals, the degradation of toxic wastes, and the improvement of agricultural products. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-BA-218, *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS* 3 (1984) [hereinafter *COMMERCIAL BIOTECHNOLOGY*].

3. *Id.*

4. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-BA-337, *NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUE AND CELLS* 23 (1987) [hereinafter *OWNERSHIP OF HUMAN TISSUE*].

5. See *id.* at 45.

6. *COMMERCIAL BIOTECHNOLOGY*, *supra* note 2, at 3. Private sector investment to commercialize biotechnology products exceeded one billion dollars in 1983 alone. *Id.* In addition, there are currently approximately 100 commercial biotechnology companies developing human therapeutic products. *OWNERSHIP OF HUMAN TISSUE*, *supra* note 4, at 56.

the enormous potential profits these products may generate.<sup>7</sup>

In 1980, two landmark events accelerated industry-sponsored research in human tissue and cells.<sup>8</sup> First, the United States Supreme Court, in *Diamond v. Chakrabarty*,<sup>9</sup> held that human-made life forms are patentable.<sup>10</sup> After *Chakrabarty*, scientists have been able to patent developed tissue.<sup>11</sup> Second, Congress passed the Patent and Trademark Amendment Act<sup>12</sup> with the objective of commercializing government-sponsored inventions.<sup>13</sup> This act encourages patenting inventions which result from government-sponsored projects.<sup>14</sup>

Researchers' abilities to patent biotechnology products, coupled with Congress' policy of promoting the placement of new products into the marketplace, has greatly stimulated commercial interest in biotechnology. As a result, scientists can now transform diseased human tissue into valuable therapeutic products.<sup>15</sup> Should the sources of this tissue be entitled to compensation?<sup>16</sup>

This issue burst upon the scene in *Moore v. Regents of the University of California*.<sup>17</sup> In *Moore*, the plaintiff, John Moore, entered the University of California, Los Angeles (UCLA) Medical Center with a rare form of cancer that caused his spleen cells to develop unique characteristics.<sup>18</sup> Moore's spleen cells were unique in that they could produce a wide variety of valuable therapeutic products.<sup>19</sup> After surgically removing

7. One author estimates a market of \$100 billion for biotechnology products by the beginning of the twenty-first century. Tompkins, *Capitalizing in Life*, Sci. Dig., June 1986, at 35.

8. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 49.

9. 447 U.S. 303 (1980).

10. *Id.* at 309-10.

11. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 215 Cal. App. 3d 709, 754-68 app. A, 249 Cal. Rptr. 494, 516-30 app. A (1988) (patent of "Mo" cell line derived from human spleen), *aff'd in part and rev'd in part*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990); see also Biggart, *Protecting Exclusivity in Biotechnology Developments*, in BIOTECHNOLOGY PATENT PRACTICE 7 (1986).

12. Pub. L. No. 96-517, 94 Stat. 3019 (1980) (codified as amended at 35 U.S.C. §§ 200-211 (1988)). The law allows nonprofit institutions, including universities, to apply for patents on federally funded inventions, and the federal agency which sponsored the project retains a nonexclusive license. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 50.

13. 35 U.S.C. § 200 (1988); see also OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 50.

14. 35 U.S.C. § 200. "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . ." *Id.*

15. See *infra* notes 39-62 and accompanying text.

16. As Justice Mosk stated, "The issue is as new as its source—the recent explosive growth in the commercialization of biotechnology." *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 161, 793 P.2d 479, 507, 271 Cal. Rptr. 146, 174 (1990) (Mosk, J., dissenting).

17. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

18. *Id.* at 125-27 & n.2, 793 P.2d at 481 & n.2, 271 Cal. Rptr. at 148 & n.2.

19. *Id.* at 126-27, 793 P.2d at 481-82, 271 Cal. Rptr. at 148-49.

Moore's spleen, Dr. David Golde, Moore's physician, developed a cell line from Moore's tissue without Moore's consent.<sup>20</sup> Dr. Golde patented the cell line, as well as the by-products derived therefrom, and entered into development contracts with biotechnology companies for significant profit.<sup>21</sup> Moore claimed that he should have a right to share in the profits from these products.<sup>22</sup>

In *Moore*, the California Supreme Court held that individuals do not have a property right in their surgically removed body tissue.<sup>23</sup> The court did hold, however, that patients have the right to informed consent to the commercial use of their tissue.<sup>24</sup> Under this theory, a doctor has a fiduciary duty to disclose to his or her patients the prospect of potential commercial gain from the use of their tissue.<sup>25</sup>

The court's holding in *Moore* creates many more questions than it answers. First, how will courts apply traditional informed consent doctrine in these cases? Second, will this right to informed consent, perhaps difficult to apply in practice, adequately protect the patient? Third, will doctors and biotechnology companies be forced to contract with patients for the right to use tissue commercially if patients consent only to their tissue's surgical removal and not to its subsequent commercial use? Fourth, will the legislature intervene to give patients more rights than did the *Moore* court? Finally, if so, how should the legislature intervene?

This Comment analyzes why the court's holding in *Moore* does not provide an adequate solution to the problems created by the commercial use of human tissue. Specifically, this Comment demonstrates that: (1) the court's expansion of the doctrine of informed consent does not adequately protect patients' rights, nor promote research; (2) to protect those rights, advance product development, and avoid an inequitable economic return by doctors and biotechnology companies, a system involving compensation to tissue sources is necessary; (3) an uncontrolled system under which tissue sources freely and independently contract for the rights to their tissue would create legal uncertainties and public policy problems; and (4) legislative intervention to define, control and limit patients' rights to compensation for use of their tissue is necessary to balance the competing interests of the patient, the physician, the scientific community and the public. Balancing these interests is difficult be-

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20. *Id.* at 127, 793 P.2d at 481-82, 271 Cal. Rptr. at 148-49.

21. *Id.* at 127-28, 793 P.2d at 481-82, 271 Cal. Rptr. at 148-49.

22. *Id.* at 135, 793 P.2d at 487, 271 Cal. Rptr. at 154.

23. *Id.* at 147, 793 P.2d at 497, 271 Cal. Rptr. at 164.

24. *Id.*

25. *Id.* at 131-32, 793 P.2d at 485, 271 Cal. Rptr. at 152.

cause these novel issues are complex and no single body of law, policy, or ethics exists.<sup>26</sup>

This Comment proposes a Uniform Tissue Source Compensation Act to resolve the many problems involved in this area. Under the proposed system, sources would be paid a flat fee and would relinquish all present and future economic rights in their tissue.

The legislation would adequately balance the interests of the individual tissue source, biotechnology companies and the public. The sources would be fairly compensated for the right to commercially use their tissue. The biotechnology companies would be contracting with sources for the right to their tissue at a fixed cost, without the threat of future lawsuits. Finally, the public's interest would be advanced, because such an act would encourage research and development of human tissue-derived products, minimize research costs and prevent delays in the development of therapeutic products.

## II. BACKGROUND: THE SCIENTIFIC TECHNOLOGIES

Biotechnology involves the creation of new plant varieties, new breeds of animals, new microorganisms,<sup>27</sup> and by-products<sup>28</sup> (human therapeutic agents)<sup>29</sup> through the application of engineering and technological principles.<sup>30</sup> Most of the technological principles used to produce valuable therapeutic products from human tissue and cells involve three main techniques:<sup>31</sup> tissue and cell culture technology,<sup>32</sup> hybridoma technology<sup>33</sup> and recombinant DNA technology.<sup>34</sup> It is through the use of tissue and cell culture techniques that scientists in *Moore v. Regents of the University of California*<sup>35</sup> transformed the plaintiff's tissue into valuable therapeutic products.<sup>36</sup> Advancements in these biotechnologies have also created many social, medical, economic, legal and ethical issues.<sup>37</sup> Thus, the nature of the techniques and how they can be used to manipu-

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26. See OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 23.

27. Bent, *Invention in Biotechnology: A Conceptual Approach*, in BIOTECHNOLOGY PATENT PRACTICE, *supra* note 11, at 1.

28. *Id.*

29. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 31.

30. MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 162 (1974) [hereinafter DICTIONARY].

31. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 31.

32. See *infra* notes 39-62 and accompanying text.

33. See *infra* notes 63-78 and accompanying text.

34. See *infra* notes 79-93 and accompanying text.

35. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

36. *Id.* at 127, 793 P.2d at 481-82, 271 Cal. Rptr. at 148-49.

37. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 31.

late human tissue into valuable commercial products must be understood to appreciate the novel issues involved.<sup>38</sup>

In the context of this Comment, knowledge of the basic techniques is necessary for several reasons: (1) to recognize that the law should encourage the commercial use of human tissue; (2) to discern the value of the tissue source's contribution to product development relative to the highly skilled and technical work of scientists in the discovery and development of marketable therapeutic products; (3) to recognize why limiting compensation is not unfair to tissue sources; and (4) to comprehend fully the novel legal problems that would be raised if tissue sources could freely contract for the rights to their tissue.

The following sections discuss the three main biotechnology techniques and the advantages of using human tissue and cell cultures to develop products over employing the other two biotechnology techniques.

#### A. Tissue and Cell Culture Technology

Tissue culture<sup>39</sup> is not a new technique; it was first devised in 1907 for the purpose of studying physiological behavior of animal cells *in vitro*.<sup>40</sup> Scientists theorized that by studying the behavior of tissue and cells kept alive *in vitro* they could understand their functioning *in vivo*.<sup>41</sup>

Tissue cultures can be established from a human tumor biopsy,<sup>42</sup>

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38. *Id.* Justice Mosk in his *Moore* dissent stated, "I dissociate myself completely from the amateur biology lecture that the majority impose on us throughout their opinion . . . because [as] they have no background in molecular biology[,] the majority may simply misunderstand what they are reading . . ." *Moore*, 51 Cal. 3d at 182, 184, 793 P.2d at 521, 523, 271 Cal. Rptr. at 188, 190 (1990) (Mosk, J., dissenting). Justice Mosk believes that in order to begin solving the problems created by the commercial use of human tissue, an independent and unbiased explanation of the scientific technology is essential. *Id.* at 184-85, 793 P.2d at 523, 271 Cal. Rptr. at 190 (Mosk, J., dissenting). This background is designed to present an objective and thorough explanation of the biotechnology techniques involved.

39. Technically there is a distinction between a tissue culture, a cell culture and a cell line; however, the term "tissue culture" is often used generically to include tissue culture, cell culture and cell line. R. FRESHNEY, *CULTURE OF ANIMAL CELLS: A MANUAL OF BASIC TECHNIQUES* 366 (2d ed. 1987). Tissue culture properly means the maintenance of a fragment of tissue, whereas, a cell culture is a growth of cells dissociated from the parent tissue. *Id.* at 363, 366. A cell line is a propagated culture derived from a primary cell culture. *Id.* at 363. A primary culture is defined as the culture established directly from cells, tissue or organs of the biological source. *Id.* at 365.

40. R. FRESHNEY, *supra* note 39, at 1. *In vitro* pertains to biological reactions which take place in artificial apparatuses; by contrast, *in vivo* pertains to biological reactions taking place in living cells or organisms. *DICTIONARY, supra* note 30, at 773.

41. Nardone, *Cell Culture Methodology from Donor to Cell Lines*, 5 *BIOTECHNIQUES* 122, 122 (1987). See *supra* note 40 for a definition of *in vivo*.

42. Nardone, *supra* note 41, at 124.

solid human tissue or blood.<sup>43</sup> When culturing tissue, scientists want to create an established cell line.<sup>44</sup> An established cell line is a sample of cells that are capable of continuous and indefinite growth.<sup>45</sup> Most normal cells do not give rise to established cell lines,<sup>46</sup> unless scientists employ some type of genetic engineering.<sup>47</sup>

The discovery that cultures from human tumors could give rise to established cell lines sparked scientists' interest in human tissue.<sup>48</sup> Cultured tumor cells are valuable because they have the capability of producing a wide variety of commercially useful therapeutic proteins.<sup>49</sup> Thus, by creating a cell line that is capable of continuous growth, the ability of scientists to produce marketable therapeutic products is greatly enhanced.

In *Moore*, the scientists' goal was to develop an established cell line derived from the plaintiff's leukemic spleen cells.<sup>50</sup> This was because the spleen cells were producing a number of therapeutically useful proteins.<sup>51</sup> In achieving their goal, the scientists created an incessant source of these proteins.

Although human tumor cells have the potential to develop into an established cell line, it is important to note that immortalization does not result in all cases.<sup>52</sup> The successful culturing of human tissue and cells is considered an art.<sup>53</sup> The process of successfully developing a cell line requires a great deal of highly skilled work involving many complex and difficult techniques.<sup>54</sup> Although there have been many advancements in

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43. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 33.

44. *See id.*

45. *Id.*

46. R. FRESHNEY, *supra* note 39, at 9.

47. *Moore v. Regents of the Univ. of Cal.*, 215 Cal. App. 3d 709, 756 app. A, 249 Cal. Rptr. 494, 518 app. A (1988) ("Mo" cell line patent), *aff'd in part and rev'd in part*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990). *See infra* notes 79-93 and accompanying text for an explanation of genetic engineering.

48. R. FRESHNEY, *supra* note 39, at 1. The first established human cell line was called HeLa (named after the patient-source Henrietta Lacks) and originated from a biopsy of a cancerous cervical tumor. Hsu, Schacter, Delaney, Miller, McKusick, Kennett, Bodmer, Young & Bodmer, *Genetic Characteristics of the HeLa Cell*, 191 SCIENCE 392, 392 (1976).

49. *See Moore*, 215 Cal. App. 3d at 756 app. A, 249 Cal. Rptr. at 518 app. A ("Mo" cell line patent).

50. *See id.* ("Mo" cell line patent).

51. *See id.* ("Mo" cell line patent).

52. R. FRESHNEY, *supra* note 39, at 289. Human mammary tumors can be cultured with only about a ten percent success rate. Lasfargues, *Human Mammary Tumors*, in *TISSUE CULTURE: METHODS AND APPLICATIONS* 45, 49-50 (1973).

53. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 33.

54. *See generally* R. FRESHNEY, *supra* note 39; *METHODS IN ENZYMOLOGY VOLUME LVIII CELL CULTURE* (W. Jakoby & I. Pastan eds. 1979); *TISSUE CULTURE: METHODS AND*



biotechnology, the probability of establishing a cell line from human tissue is low.<sup>55</sup> Why one particular cell line will grow continuously and another does not is unclear.<sup>56</sup> Consequently, cancerous tissue whose cells are capable of developing into a cell line is rare and can be extremely valuable.

Tissue is classified as rare if an extremely small percentage of the population has tissue with certain unique characteristics.<sup>57</sup> Many people, however, may have tissue with such characteristics but discovery of this tissue is rare.<sup>58</sup> Truly rare tissue, by definition, is tissue that not only exists within an extremely small percentage of the population, but also is impossible to identify except by chance discovery.<sup>59</sup>

A systematic method of identifying rare human tissue does not exist.<sup>60</sup> As a result, it is infrequent that a scientist does, in fact, discover that a person has a rare type of tissue. Once a characteristic is identified in one person's tissue, however, it usually can be detected in other tissue with those same characteristics.<sup>61</sup> Thus, the value of that tissue is not as great as truly rare tissue.<sup>62</sup>

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APPLICATIONS (P. Kruse & M. Patterson eds. 1973). For example, when cultures are derived from solid samples (tissue, tumors or organs), the samples must be minced and exposed to enzymes for disaggregation. R. FRESHNEY, *supra* note 39, at 113-24. Only certain cells which survive the process form the basis of the primary culture. *Id.* at 7. Special complex nutrients must be provided in order to sustain the human cells. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 32. In addition, scientists must strictly maintain the temperature of the culture environment and keep the culture free from contaminants. *Id.* Because scientists are only interested in certain special cells, such as cells which produce therapeutic proteins, selective overgrowth of unspecialized cells is a major problem. R. FRESHNEY, *supra* note 39, at 137. To overcome this problem, scientists must attempt to employ the often unsuccessful technique of cloning to select specific cell types. *Id.* Cloning means that the entire population of cells is derived from continual growth of a single cell. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 34. Finally, once the cell line is established and the specialized cells are producing the proteins of interest, these proteins must be isolated by using various separation techniques. *Moore*, 215 Cal. App. 3d at 758 app. A, 249 Cal. Rptr. at 520 app. A ("Mo" cell line patent).

55. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 32.

56. R. FRESHNEY, *supra* note 39, at 9. The ability of a cell line to grow may be due to its capacity for genetic variation. *Id.*

57. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 55.

58. *Id.*

59. *Id.* at 56.

60. *Id.* at 55.

61. *Id.*

62. It has been stated that "the issue of rarity in human biologicals used in biotechnological research takes the form of a pyramid." *Id.* at 56. The vast majority of biological materials are readily obtainable, representing the bottom two-thirds of the pyramid; higher on the pyramid is an intermediate level, where particular tissues may have some uncommon characteristics or occur in low frequency; and at the top of the pyramid are the truly rare biological materials which occur in only a few cases. *Id.*

*B. Hybridoma Technology*

It is rare to develop a cell line directly from human tissue; therefore, as an alternative, scientists may employ hybridoma technology to produce therapeutic proteins. Hybridomas are new cells created from the fusion of two different cell types.<sup>63</sup> Hybridomas are made by fusing tumor cells, called myeloma cells, with either T lymphocytes (T-cells)<sup>64</sup> or B lymphocytes (B-cells).<sup>65</sup> Myeloma cells have the ability to grow continuously in culture.<sup>66</sup> T lymphocytes produce a variety of proteins, called lymphokines,<sup>67</sup> whereas B lymphocytes produce antibodies.<sup>68</sup> Both of these cells produce therapeutically useful substances,<sup>69</sup> but they are incapable of sustained growth and cultivation.<sup>70</sup> Hence, by fusing tumor cells with either of these cells, scientists create an immortal cell line that will become a continuous source of proteins or antibodies.<sup>71</sup>

The culture conditions and techniques employed for hybridomas are essentially the same as those previously described for tissue and cell cul-

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63. *Id.* at 157. The method was first described by Kohler and Milstein in 1975. Casali, Inghirami, Nakamura, Davies & Notkins, *Human Monoclonals from Antigen-Specific Selection of B Lymphocytes and Transformation of EBV*, 234 *SCIENCE* 476, 476 (1986) [hereinafter Casali].

64. *OWNERSHIP OF HUMAN TISSUE*, *supra* note 4, at 40. T lymphocytes are also called T-cells. *Id.*

65. *Id.* at 38. B lymphocytes are also called B-cells. *Id.* at 37.

66. *Id.* at 38.

67. *Id.* at 39. Lymphokines are essential in regulating the immune response and act in concert with antibodies in order to effectuate an immune response. *Id.* The immune response protects the body against disease. *Id.* at 37; see also *infra* note 68.

68. *OWNERSHIP OF HUMAN TISSUE*, *supra* note 4, at 37. The B lymphocytes in the human body produce antibodies in an immune response to invasions of foreign substances, called antigens, in order to protect the body against disease. *Id.* Each B lymphocyte is capable of producing antibodies which can counteract only one specific antigen. *Id.* To obtain B lymphocytes, scientists inject a chosen antigen (e.g., a virus) of interest into an animal source and isolate the B lymphocytes which produce the specific antibody. *Id.* at 38.

69. *Id.* at 37-40. B lymphocytes produce a variety of antibodies. *Id.* at 37-38. T lymphocytes produce an assortment of lymphokines with therapeutic potential, including interferon, interleukin-1 (IL-1 or lymphocyte activation factor), interleukin-2 (IL-2 or T-cell growth factor), interleukin-3 (IL-3), interleukin-4 (IL-4), colony stimulating factors (CSF), B-cell growth factor, macrophage activity factor, T-cell replacing factor, and migration inhibition factor. *Id.* at 40. Also, some lymphokines stimulate B lymphocytes to produce antibodies. *Id.* at 39.

70. *Id.* at 38.

71. *Id.* at 38-40. See *supra* note 69 for an example of therapeutic proteins produced by T lymphocytes. Each particular B-cell hybridoma cell line is capable of producing only a single specific type of antibody called a monoclonal antibody. *OWNERSHIP OF HUMAN TISSUE*, *supra* note 4, at 38. Although B lymphocytes, by themselves, produce a variety of useful antibodies that can be isolated from blood, it was not until scientists were able to create monoclonal antibodies through the use of cell lines that the antibodies could be therapeutically useful. *Id.* at 37-38.

ture.<sup>72</sup> However, virtually all monoclonal antibodies<sup>73</sup> currently used therapeutically in humans are derived from mice.<sup>74</sup> When using monoclonal antibodies derived from mice in humans there is always the danger that an allergic response will result.<sup>75</sup> Attempts to extend the technology to the production of human monoclonal antibodies have not been very successful.<sup>76</sup> In addition, although isolated lymphokines have potential therapeutic value,<sup>77</sup> the T-cell hybridoma cell lines produced so far have not been capable of generating sufficient quantities of lymphokines for widespread therapeutic use.<sup>78</sup>

### C. Recombinant DNA Technology

Genes are the basic units of heredity.<sup>79</sup> Chromosomes, which carry genes,<sup>80</sup> are composed of deoxyribonucleic acid (DNA).<sup>81</sup> DNA, which is present in every cell of living organisms, directs the functions of that cell.<sup>82</sup>

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72. *Id.* at 38; see *supra* note 54 and accompanying text. For example, scientists must isolate and separate the proteins or monoclonal antibodies from the hybridoma cell line. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 38-40.

73. Monoclonal antibodies are identical antibodies that recognize a single specific antigen. *Id.* at 157; see also *supra* note 71.

74. Pinsky, *Monoclonal Antibodies: Progress is Slow But Sure*, 315 NEW ENG. J. MED. 704, 704 (1986).

75. *Id.*

76. Casali, *supra* note 63, at 476. However, a promising new method has been developed which produces large quantities of human monoclonal antibodies. *Id.*

77. See *supra* note 69 for a list of lymphokines with therapeutic value.

78. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 40. However, human T-cell hybridoma cell lines are still valuable because they provide a source of lymphokine genes which may be used in other genetic engineering techniques for continuous large scale production of the proteins. *Id.*

79. DICTIONARY, *supra* note 30, at 613. In 1865, Gregor Mendel identified this basic mechanism of heredity. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 41.

80. DICTIONARY, *supra* note 30, at 266.

81. Ord & Stocken, *The Nucleus*, in CELL BIOLOGY IN MEDICINE, 151, 155 (E. Bittar ed. 1973).

82. COMMERCIAL BIOTECHNOLOGY, *supra* note 2, at 34. In the late nineteenth century, DNA was discovered to be within the nucleus of the cell. Ord & Stocken, *supra* note 81, at 155. The nucleus of a cell is a small mass of proteins surrounded by a membrane, found in most animal and plant cells, and functions in metabolism, growth and reproduction. DICTIONARY, *supra* note 30, at 1021. In 1953, James Watson and Francis Crick proposed that the structure of DNA was a double-stranded helix. T. SOLOMON, ORGANIC CHEMISTRY 991-93 (1976). Watson and Crick's proposal was verified by Wilkens using X-ray analysis. *Id.* at 991. The DNA double helix structure is formed by a series of four predictably pairing chemical subunits called bases. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 41. The four bases are guanine, adenine, thymine and cytosine. *Id.* Normally, guanine always pairs with adenine and cytosine with thymine. *Id.* The unique ordering of these bases in the helix encodes for the particular function of the gene. *Id.*

Recombinant DNA technology involves the use of complex techniques to manipulate genetic material to develop biological compounds.<sup>83</sup> Two general types of genes exist: structural genes which encode for products, such as proteins, and regulatory genes which command the production and quantity of substances.<sup>84</sup> The specific product which results and its amount can, therefore, be manipulated by altering the DNA of genes.

Scientists discovered that naturally occurring enzymes produced by bacteria, called restriction enzymes, recognized and cut DNA at specific points.<sup>85</sup> Once cut, the exposed ends attach to other strands of DNA.<sup>86</sup> The resulting strand of DNA is called "recombinant DNA."<sup>87</sup> This discovery allowed scientists to clone genes.<sup>88</sup> Gene cloning is the process of joining segments of DNA in a particular sequence to manufacture multiple copies of a particular piece of DNA.<sup>89</sup>

A major goal of recombinant DNA techniques is to implant recombinant DNA for a specific purpose into an organism, usually a bacterium, under conditions which will cause the cloned gene to be replicated more abundantly than the native gene.<sup>90</sup> The genetically engineered organism will produce potentially valuable therapeutic proteins.<sup>91</sup> For example, if the gene responsible for production of human insulin is engineered by producing the recombinant DNA molecule, it can be introduced into a host organism and will copy itself many times; as a result, the host will produce large amounts of human insulin.<sup>92</sup> The process requires employment of a group of recombinant DNA technological methods.<sup>93</sup>

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83. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 41. The term "genetic engineering" is synonymous with the term "recombinant DNA." *Id.*

84. *Id.*

85. *Id.* at 42-43.

86. *Id.* at 43.

87. *Id.*

88. *Id.* at 42.

89. *Id.*

90. Abelson, *Biotechnology: An Overview*, 219 SCIENCE 611, 611 (1983).

91. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, 44-45. Three commercial products created by recombinant DNA technology have been approved by the Food and Drug Administration (FDA) for therapeutic use in humans (human growth hormone, human insulin, and human alpha interferon). *Id.* at 45.

92. PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL RESEARCH, *SPLICING LIFE* 33 (1982).

93. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 42. Recombinant DNA technology generally works as follows: Donor DNA is cut by restriction enzymes into several fragments. *Id.* at 43. Once cut, the exposed ends attach to other DNA fragments known as vector DNA and result in recombinant DNA. *Id.* Vectors can be derived from many sources, bacterial, viral, etc. *Id.* Different vectors are capable of performing various functions. *Id.* For example,

#### D. *The Advantages of Using Human Tissue Cultures*

Using human tissue culture techniques to produce therapeutic products can be more cost-effective and more feasible than employing other biotechnologies. This is because while human cell lines produce a wide variety of proteins,<sup>94</sup> hybridomas or recombinant DNA hosts typically produce single products.<sup>95</sup> In addition, not only can scientists produce multiple products using human cell lines, but, because the cell directly produces the proteins of interest, they also can save costs by avoiding the numerous steps required for genetic engineering.<sup>96</sup> For example, the purification of a protein is greatly simplified when the protein is secreted from a cell directly into a medium.<sup>97</sup> This is how the cell line used in *Moore* produces its proteins.<sup>98</sup> When using recombinant DNA techniques, however, the proteins typically must be purified away from all other cellular components.<sup>99</sup> Also, any recombinant DNA technique requires the discovery of the appropriate gene probe,<sup>100</sup> and since this is the most difficult part of the genetic engineering process,<sup>101</sup> significant cost savings result from using a human cell line.

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some vectors are capable of maintaining the stability of a large piece of foreign DNA, whereas others reproduce rapidly and in high copy number. *Id.* In commercialization of recombinant DNA products, it is critical that the vector have the ability to achieve high product expression. *Id.* The recombinant DNA is then introduced into a host, which is an organism, often the bacterium *Escherichia coli*. *Id.* Human cells, yeasts and other cells may also be used as hosts. *Id.* The host provides an optimum environment for increasing the number of copies of the cloned DNA, thereby producing large amounts of a gene, its product, or both. *Id.* Only some host cells will accept the recombinant DNA. *Id.* The host cells that accepted the recombinant DNA are identified by adding antibiotics that kill those host cells that did not take up the recombinant DNA. *Id.* Finally, the small number of hosts containing the recombinant DNA of interest are detected by a gene probe. *Id.* A gene probe is one of a variety of different proteins which specifically binds to the desired gene. *Id.* at 43-44. The most difficult part of the process is discovering a suitable probe. COMMERCIAL BIOTECHNOLOGY, *supra* note 2, at 37.

94. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 215 Cal. App. 3d 709, 756 app. A, 249 Cal. Rptr. 494, 518 app. A (1988) ("Mo" cell line patent), *aff'd in part and rev'd in part*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

95. See OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 38; see also *Moore*, 215 Cal. App. 3d at 756 app. A, 249 Cal. Rptr. at 518 app. A ("Mo" cell line patent).

96. *Moore*, 215 Cal. App. 3d at 756 app. A, 249 Cal. Rptr. at 518 app. A ("Mo" cell line patent).

97. COMMERCIAL BIOTECHNOLOGY, *supra* note 2, at 38.

98. See *Moore*, 215 Cal. App. 3d at 767 app. A, 249 Cal. Rptr. at 529 app. A ("Mo" cell line patent).

99. COMMERCIAL BIOTECHNOLOGY, *supra* note 2, at 38. It is possible to perform additional recombinant DNA techniques that will direct the cell to secrete the protein. *Id.* However, even if it is possible, the additional steps would increase the cost.

100. See *supra* note 93.

101. See *supra* note 93.

Human tissue culture technology also has advantages over hybridoma technology. A human cell line can produce therapeutically valuable lymphokines, such as IL-2, interferon, and colony-stimulating factor (CSF),<sup>102</sup> in isolatable amounts.<sup>103</sup> This may be of great value since sufficient quantities of lymphokines can be produced for widespread therapeutic use, whereas hybridoma cell lines cannot produce such quantities.<sup>104</sup> Another advantage of using human cell lines over hybridomas is that products are derived directly from human tissue as opposed to rodent cells.<sup>105</sup> This significantly reduces the possibility of an allergic reaction occurring when the products are used to treat humans.<sup>106</sup> The likelihood of allergic reactions in humans could be of great concern to a company considering potential product liability risks and, as a result, may deter potentially valuable research.

Truly unique human tissue may be extremely valuable.<sup>107</sup> If a biotechnology company does not reach an agreement with a particular tissue source, it may never again have the opportunity to obtain such tissue. In light of the speculative commercial value of products derivable from the tissue, a biotechnology company confronted with this situation may be forced to consider several factors, including: (1) whether other techniques may be developed which allow for detection of this rare characteristic in other sources,<sup>108</sup> and (2) whether other biotechniques, such as recombinant DNA, can be used to reproduce the uniqueness without need of the tissue itself.<sup>109</sup>

### III. STATEMENT OF THE PROBLEM

Scientists have developed technology whereby human tissue may provide one of the most promising sources of valuable therapeutic prod-

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102. See, e.g., *Moore*, 215 Cal. App. 3d at 762 app. A, 249 Cal. Rptr. at 524 app. A ("Mo" cell line patent).

103. See *id.* at 756 app. A, 249 Cal. Rptr. at 518 app. A ("Mo" cell line patent); see also OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 35.

104. See *supra* note 78 and accompanying text. Lymphokines are typically present in human blood in only parts per billion. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 39. For example, interferon, which is one of the most abundant lymphokines, is in such low levels in blood that it takes about 65,000 liters of blood to produce 100 milligrams of interferon. *Id.* at 39-40. "A comparable task would be the search for less than one-eighth of a teaspoon of salt in a swimming pool." *Id.* at 40.

105. Compare *supra* notes 48-51 and accompanying text with *supra* notes 73-76 and accompanying text.

106. See *supra* note 75 and accompanying text.

107. See *supra* notes 57-62 and accompanying text for a discussion of the rarity of human tissue with potential therapeutic value.

108. See OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 56.

109. See *id.*

ucts. The problem in formulating an appropriate legal right in bodily tissue is balancing the many interests involved.

There is a significant public interest in encouraging research and development of products that can potentially treat many human diseases, including AIDS.<sup>110</sup> The federal government has an interest in advancing patent law policy designed to encourage research.<sup>111</sup> Biotechnology companies have an interest in gaining access to unique tissue in order to develop therapeutic products for commercialization and profit.<sup>112</sup> On the other hand, individual tissue sources maintain strong economic and privacy interests which must be balanced against the extraordinary public interests and the interests of the biotechnology industry.

In attempting to balance these competing interests in *Moore v. Regents of the University of California*,<sup>113</sup> the California Supreme Court has created much uncertainty. In *Moore*, the court held that patients do not have a property right in their bodily tissue.<sup>114</sup> One of the court's goals in denying such a right was to advance research and product development by ensuring that biotechnology companies would not be held liable under conversion for using human tissue.<sup>115</sup> The court, however, did offer some protection for unconsenting patients. Based on previously developed concepts, the court held that a patient's right to informed consent<sup>116</sup> includes disclosure of information regarding potential commercialization of his or her bodily tissue.<sup>117</sup> The *Moore* court believed that such a right would adequately protect a person's rights of privacy and autonomy.<sup>118</sup>

In practice, however, it may be difficult to apply traditional in-

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110. See *infra* notes 176-84 and accompanying text.

111. See *infra* notes 191-201 and accompanying text.

112. See *infra* notes 166-70 and accompanying text. In addition, these companies have an interest in being able to use human tissue for commercial development absent fear of future liability. See *infra* notes 171-75 and accompanying text.

113. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

114. *Id.* at 147, 793 P.2d at 497, 271 Cal. Rptr. at 164.

115. *Id.* at 143, 793 P.2d at 493, 271 Cal. Rptr. at 160. Conversion is the unlawful exercise of dominion and control over another's personal property, to the exclusion of or inconsistent with the rights of the owner. BLACK'S LAW DICTIONARY 300 (5th ed. 1979); see also W.P. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER AND KEETON ON THE LAW OF TORTS § 15 (1984).

116. Under traditional informed consent doctrine, a physician has a duty to disclose to patients all facts necessary to make an informed decision on whether to undergo the proposed treatment. *Cobbs v. Grant*, 8 Cal. 3d 229, 245, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972). See also *infra* notes 151-57 and accompanying text for a discussion of the right to informed consent.

117. *Moore*, 51 Cal. 3d at 131-32, 793 P.2d at 485, 271 Cal. Rptr. at 152.

118. *Id.* at 144, 793 P.2d at 494, 271 Cal. Rptr. at 161.

formed consent doctrine to the *Moore*-type situation because the main purpose of the doctrine is to allow patients to decide whether to consent to treatment<sup>119</sup> and not whether to consent to the subsequent use of their tissue.<sup>120</sup> Consequently, the *Moore* court's holding may not adequately protect patients' rights. On the other hand, if patients may consent only to their tissue's surgical removal and not to its subsequent commercial use, product development may be hindered because scientists may lose a unique opportunity to acquire therapeutically valuable tissue.

The *Moore* decision also left unclear whether, under freedom of contract principles,<sup>121</sup> a doctor or biotechnology company can compensate otherwise unconsenting patients for the right to commercial use of their tissue. Due, however, to the complex technology required to develop human tissue-derived products, as well as the unique subject matter and circumstances upon which parties would be contracting, enforceability of tissue contracts remains uncertain.<sup>122</sup>

Another problem is that some form of compensation may be necessary to provide an incentive for patients to consent, and thereby increase the amount of available tissue. However, if sources may freely negotiate for the highest price for the commercial rights to their tissue, such negotiation will cause delay in product development and increase the cost of the therapeutic products.<sup>123</sup> Such consequences are against the public interest.

This Comment contends that existing statutory and common-law concepts are inappropriate to apply to the unique problems involved in using human tissue to produce commercial therapeutic products. There is no discrete body of law that deals specifically with such use of human tissue, and biotechnology has advanced beyond existing law.<sup>124</sup> Relying on common law to solve these problems is misguided because common

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119. See *Cobbs*, 8 Cal. 3d at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515.

120. See *infra* notes 234-37 and accompanying text for a discussion of the problems applying traditional informed consent doctrine in the context of *Moore*.

121. See E. FARNSWORTH, *CONTRACTS* § 1.7 (2d ed. 1990); *OWNERSHIP OF HUMAN TISSUE*, *supra* note 4, at 9.

122. See *infra* notes 300-61 and accompanying text. A great part of the problem lies in the fact that it is difficult to determine a fair value for raw tissue. If a contract is executed and the products subsequently developed from the tissue become much more valuable than anticipated, the source may be able to rescind the contract. The source may then be able to sue in quasi-contract. Under quasi-contractual liability a scientist or biotechnology company receiving a benefit which would be unjust to retain must pay the reasonable value of the benefit to the tissue source. The threat of quasi-contractual liability may discourage research and development of human tissue-derived products, since companies could not adequately estimate their costs and would be uncertain as to whether they might be subject to future litigation.

123. See *infra* notes 266-73 and accompanying text.

124. *OWNERSHIP OF HUMAN TISSUE*, *supra* note 4, at 9.



law merely reacts to injuries only after they have occurred and does not anticipate developing interests.<sup>125</sup> Because the *Moore* ruling is controlling only in California, other state courts faced with these problems may make their own decisions. As the court expressed in *Moore*, however, such complex policy decisions are more appropriately the subject of legislative deliberation and resolution.<sup>126</sup> Accordingly, in order to advance product development and avoid inequities, Congress or a state legislature should develop a system whereby sources are compensated for the rights to use their tissue. However, such a system should not allow for a free market in human tissue. Instead, a Uniform Tissue Source Compensation Act should be enacted that limits a source's compensation.

#### IV. THE CALIFORNIA SUPREME COURT'S FAILED ATTEMPT TO DEFINE A RIGHT IN A PERSON'S BODILY TISSUE

##### A. *The Facts of Moore*<sup>127</sup>

In *Moore v. Regents of the University of California*,<sup>128</sup> Dr. Golde diagnosed the plaintiff, John Moore, as having hairy-cell leukemia.<sup>129</sup> Moore's form of cancer was rare.<sup>130</sup> Moore's spleen was removed at UCLA Medical Center as part of his cancer treatment.<sup>131</sup>

Before the surgery, Moore signed a standard surgical consent form to remove his spleen, as well as some other tissue and blood.<sup>132</sup> For almost seven years subsequent to the surgery, Dr. Golde continued to take blood and semen samples from Moore.<sup>133</sup>

Moore brought an action for conversion against Dr. Golde, a UCLA research technician, the Regents of the University of California (Regents), Sandoz Pharmaceuticals (Sandoz) and Genetics Institute Inc. (Genetics) claiming misappropriation of his tissue and cells.<sup>134</sup> However,

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125. *Id.*

126. *Moore*, 51 Cal. 3d at 136, 793 P.2d at 488, 271 Cal. Rptr. at 155.

127. The facts are based on unproven allegations of the complaint. *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 125, 793 P.2d 479, 480, 271 Cal. Rptr. 146, 147 (1990).

128. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

129. *Id.* at 125, 793 P.2d at 480, 271 Cal. Rptr. at 147.

130. Only an estimated 250 Americans per year contract hairy-cell leukemia. *Biopharmaceuticals: New Technology Unlocks the Body's Medicine Cabinet*, MED. WORLD NEWS, Mar. 25, 1985, at 45.

131. *Moore*, 51 Cal. 3d at 126, 793 P.2d at 481, 271 Cal. Rptr. at 148.

132. *Id.*

133. *Id.*

134. *Id.* at 125, 793 P.2d at 480-81, 271 Cal. Rptr. at 147-48. Moore eventually filed a third amended complaint alleging causes of action for: (1) conversion; (2) lack of informed consent; (3) breach of fiduciary duty; (4) fraud and deceit; (5) unjust enrichment; (6) quasi-contract; (7) breach of implied covenant of good faith and fair dealing; (8) intentional infliction of emotional

Moore's complaint alleged that prior to the surgery, Golde and the other defendants knew of the value of Moore's unique tissue and bodily substances, and without his consent formed the intent to establish cell lines and by-products therefrom.<sup>135</sup> Moore was never informed by the defendants of the commercial value of potential products derivable from his cell line.<sup>136</sup> This value was estimated to be three billion dollars.<sup>137</sup>

After the surgery, defendants took a portion of Moore's spleen to establish a cell line<sup>138</sup> which produced a variety of valuable therapeutic proteins.<sup>139</sup> The defendants obtained a patent on the plaintiff's cell line (designated "Mo" cell line) and nine products derived from the cell line.<sup>140</sup> Golde entered into contracts with Sandoz and Genetics to commercialize the "Mo" cell line.<sup>141</sup> Genetics transferred to Golde 75,000 shares of its stock at a nominal price and, in addition, paid the Regents and Golde \$330,000 over three years.<sup>142</sup> Sandoz paid the Regents and Golde \$110,000.<sup>143</sup>

Moore claimed that the use of his splenic tissue led to the "Mo" cell line and its products.<sup>144</sup> Moore further alleged that he should share in profits gained from the commercial use of his cells and any products derived from his biological material.<sup>145</sup>

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distress; (9) negligent misrepresentation; (10) interference with prospective advantageous economic relationships; (11) slander of title; (12) accounting; and (13) declaratory relief. *Id.* at 128 n.4, 793 P.2d at 482 n.4, 271 Cal. Rptr. at 149 n.4.

135. *Id.* at 125-26, 793 P.2d at 481, 271 Cal. Rptr. at 148.

136. *Id.* at 126, 793 P.2d at 481, 271 Cal. Rptr. at 148.

137. *Id.* at 127, 793 P.2d at 482, 271 Cal. Rptr. at 149.

138. See *supra* notes 42-56 and accompanying text for a discussion of cell lines.

139. *Moore*, 51 Cal. 3d at 127 & n.2, 793 P.2d at 481-82 & n.2, 271 Cal. Rptr. at 148-49 & n.2.

140. See *id.* at 127, 793 P.2d at 481-82, 271 Cal. Rptr. at 148-49. Products from the "Mo" cell line included (1) Colony-Stimulating Factor (CSF); (2) Erythroid-Potentiating Activity (EPA); (3) Immune Interferon (Type II); (4) Neutrophil Migration-Inhibitory Factor (NIF-T); (5) T-cell Growth Factor (TCFG, Interleukin II); (6) Macrophage-Activating Factor (MAF); (7) Factor-Stimulating Fibroblast Growth; (8) Factor-Stimulating Human Pluripotent Hematopoietic Stem Cell; (9) Factor-Stimulating Human Leukemic Cells *in vitro*. *Moore v. Regents of the Univ. of Cal.*, 215 Cal. App. 3d 709, 719 n.6, 249 Cal. Rptr. 494, 501 n.6 (1988), *aff'd in part and rev'd in part*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990); *id.* at 762 app. A, 249 Cal. Rptr. at 524 app. A ("Mo" cell line patent).

141. *Moore*, 51 Cal. 3d at 127-28, 793 P.2d at 482, 271 Cal. Rptr. at 149.

142. *Id.* at 127, 793 P.2d at 482, 271 Cal. Rptr. at 149.

143. *Id.*

144. *Id.* at 126-27, 793 P.2d at 481-82, 271 Cal. Rptr. at 148-49.

145. *Id.* at 135, 793 P.2d at 487, 271 Cal. Rptr. at 154.

### B. The Moore Court's Holding

In *Moore v. Regents of the University of California*,<sup>146</sup> the California Supreme Court could have concluded that patients have a property right in their tissue and that, based on that right, Moore had stated a cause of action in conversion. Instead, the court held that patients do not have a property right in their surgically removed tissue.<sup>147</sup> The court, however, also held that individuals do have a right to informed consent before a doctor may commercially use their tissue.<sup>148</sup> The court determined that in soliciting a patient's consent to surgery, a physician has a fiduciary duty<sup>149</sup> to disclose any potential economic gain that the doctor may realize from the post-operative use of the patient's tissue.<sup>150</sup>

The doctrine of informed consent is based on principles of individual autonomy and the special relationship between the doctor and patient.<sup>151</sup> Informed consent doctrine developed out of the concept that all human beings have the right to determine what shall be done with their bodies.<sup>152</sup>

According to traditional disclosure rules, the doctor has a duty to disclose all information which is "material."<sup>153</sup> Material information is that which a reasonable person in the patient's position would find significant.<sup>154</sup> Thus, the *Moore* court concluded that "material" information includes any potential commercial gain that a doctor may realize from the use of a patient's tissue.<sup>155</sup>

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146. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

147. *Id.* at 147, 793 P.2d at 496-97, 271 Cal. Rptr. at 163-64. Accordingly, the court held that the plaintiff could not state a cause of action in conversion. *Id.*

148. *Id.* at 131-32, 793 P.2d at 485, 271 Cal. Rptr. at 152.

149. A fiduciary duty arises when there is a relationship of trust and confidence, and the placing of reliance by one person upon the judgment of another. *Vai v. Bank of America*, 56 Cal. 2d 329, 337-38, 364 P.2d 247, 252, 15 Cal. Rptr. 71, 76 (1961); BLACK'S LAW DICTIONARY 564 (5th ed. 1979). A person having a fiduciary duty must act in scrupulous good faith primarily for another's benefit. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, app. C at 157.

150. *Moore*, 51 Cal. 3d at 131-32, 793 P.2d at 485, 271 Cal. Rptr. at 152.

151. PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: A REPORT ON THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 16-17, 51 (1982).

152. *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 126, 105 N.E. 92, 93 (1914), *overruled on other grounds in* *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1947).

153. *See* *Cobbs v. Grant*, 8 Cal. 3d 229, 245, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972).

154. *Truman v. Thomas*, 27 Cal. 3d 285, 291, 611 P.2d 902, 905, 165 Cal. Rptr. 308, 311 (1980).

155. *See Moore*, 51 Cal. 3d at 131-32, 793 P.2d at 485, 271 Cal. Rptr. at 152. The Office of Technology Assessment (OTA) stated that such disclosure requirements should include: the nature and purpose of using the human tissue; the probable benefits flowing from obtaining the

Under a typical application of the doctrine, the physician has a duty to disclose to the patient all facts necessary to allow the patient to formulate an informed decision on whether to undergo the proposed treatment or surgery.<sup>156</sup> Generally, such disclosure should include the nature of the diagnosed condition, the risks associated with the proposed treatment or surgery, the availability of alternatives and associated risks, an explanation of probable complications and discomforts, and the risks associated with not undergoing any treatment.<sup>157</sup> The informed consent doctrine in the medical treatment context, therefore, mainly focuses on the risks of treatment and not the disposition of human tissue. Unfortunately, the majority in *Moore* did not identify how its newly-created doctrine will apply.

## V. ANALYSIS OF COMPETING INTERESTS

One major concern involved in developing a legal right in a person's bodily tissue is that the right must adequately balance the interests of the individual, the biotechnology industry, the federal government and the public. An analysis of these interests and policy concerns reveals that the right to informed consent as developed by the *Moore* court will not significantly advance all of these interests.

### A. *The Interests of the Individual Tissue Source*

A person should have the right to decide what will be done with his or her own body.<sup>158</sup> Patients, not their doctors, should possess the right to determine the use to which their body parts will be put after removal.<sup>159</sup> The majority in *Moore* believed that one policy of overriding importance is the protection of a person's right to make autonomous

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tissue and probable beneficiaries; the possible commercial gain that may result from developing the tissue; the right to withdraw consent to the tissue's use. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 105-06.

156. *Cobbs*, 8 Cal. 3d. at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515.

157. F. ROZOVSKY, *CONSENT TO TREATMENT: A PRACTICAL GUIDE* 41-52 (1984). Laws also exist that require disclosure of far more information for consent of human research subjects to be valid. See CAL. HEALTH & SAFETY CODE § 24179 (West Supp. 1986); 45 C.F.R. § 46.116 (1990).

158. *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 126, 105 N.E. 92, 93 (1914), *overruled on other grounds in* *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1947).

159. *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 151, 793 P.2d 479, 499, 271 Cal. Rptr. 146, 166 (1990) (Broussard, J., concurring and dissenting). Justice Broussard argued that the Uniform Anatomical Gift Act makes it quite clear that patients have the right to decide, before their tissue is removed, the permissible uses to which their tissue may be put after removal. *Id.* at 154, 793 P.2d at 501, 271 Cal. Rptr. at 168 (Broussard, J., concurring and dissenting); see CAL. HEALTH & SAFETY CODE §§ 7150-7156.5 (West 1970 & Supp. 1990).

medical decisions.<sup>160</sup> The court agreed that "[a] patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress."<sup>161</sup>

The right to privacy also recognizes that individuals have a right to determine whether to give to the public something which is theirs.<sup>162</sup> Accordingly, this privacy interest is violated if individuals are denied the opportunity to decide whether to grant consent to their tissue becoming part of the public domain. This interest includes the right to be compensated if human tissue is used commercially.<sup>163</sup>

In support of this financial interest, Justice Broussard argued that the majority failed to mention the tissue source's interest in obtaining the economic value of his or her own body parts.<sup>164</sup> "Although such economic value may constitute a fortuitous 'windfall' to the patient, the fortuitous nature of the economic value does not justify the creation of a novel exception . . . which sanctions . . . misappropriation of that value from the patient."<sup>165</sup>

### *B. The Interests of the Biotechnology Industry*

The potential profits that can be obtained from human tissue-derived therapeutic products are enormous.<sup>166</sup> Consequently, the biotechnology industry has a financial interest in gaining access to unique human tissue in order to develop these commercially valuable products.

It has been stated that "[t]he path leading from the concept for a drug to a marketable product is arduous, costly, and extremely speculative."<sup>167</sup> The process leading to commercialization of a human tissue derived product can require efforts for a period of eighty years.<sup>168</sup> The cost

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160. *Moore*, 51 Cal. 3d at 129, 143, 793 P.2d at 483, 493, 271 Cal. Rptr. at 150, 160.

161. *Id.* at 139-40, 793 P.2d at 491, 271 Cal. Rptr. at 158 (quoting *Moore v. Regents of the Univ. of Cal.*, 215 Cal. App. 3d 709, 730, 249 Cal. Rptr. 494, 508 (1988)). However, the *Moore* majority did not believe that a cause of action in conversion was necessary to protect privacy and dignity since that could be accomplished by the right to informed consent. *Id.* at 140, 793 P.2d at 491, 271 Cal. Rptr. at 158.

162. Warren & Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 199 (1890).

163. See OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 115.

164. *Moore*, 51 Cal. 3d at 159, 793 P.2d at 505, 271 Cal. Rptr. at 172 (Broussard, J., concurring and dissenting).

165. *Id.* (Broussard, J., concurring and dissenting).

166. See *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 127, 793 P.2d 479, 482, 271 Cal. Rptr. 146, 149 (1990); see also *supra* note 7.

167. COMMERCIAL BIOTECHNOLOGY, *supra* note 2, at 150.

168. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 60-61 (case history of development of a human tumor derived product, angiogenin). The Food and Drug Administration (FDA) requires a human therapeutic product to undergo research, development and regulatory

of putting a single product through this process has been estimated to be sixty-five to one hundred million dollars.<sup>169</sup> Furthermore, whether a source's tissue or cells ever result in a marketable product is highly speculative—only about twelve percent of the products which enter human clinical trials ever reach the market.<sup>170</sup>

Another significant interest of the biotechnology industry is the elimination of uncertainty.<sup>171</sup> An important policy consideration for the *Moore* court was that it “not threaten with disabling civil liability innocent parties who are engaged in socially useful activities, such as researchers . . . .”<sup>172</sup> All of the effort, time, money and risk involved in commercializing a human tissue-derived therapeutic product is borne by the biotechnology company. Adding a threat of liability would likely discourage biotechnology companies, especially small companies, from investing in the development of “socially useful” human tissue-derived therapeutic products.<sup>173</sup> Uncertainty about how courts would resolve disputes between biotechnology companies and sources could be detrimental to the biotechnology industry.<sup>174</sup> Consequently, resolving the current uncertainty is important to the future of the biotechnology industry.<sup>175</sup>

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processes before it can be marketed. Generally the product development process includes the following steps:

1. Research: Scientists must identify, purify and characterize the natural protein. The product may be produced by use of one of the biotechnology techniques.
2. Research and Development: The product must be improved and laboratory tested.
3. Development: The product is formulated into a therapeutic form. The formulation must be prepared and the process scaled-up for manufacture.
4. Preclinical Testing: The product must be tested for toxicity and efficacy in animals.
5. Clinical Testing—Physician IND (Investigational New Drug): A physician, rather than the corporation, sponsors human patient testing of the product at one or more clinics.
6. Clinical Trials Phases I-III: The product goes through a series of phases to determine safety, dosage and efficacy in human patients.
7. Product License Approval Filing: The company files information for FDA approval of sale to patients. *Id.* at 61.

169. *Id.*

170. *Id.* at 60.

171. See *Moore*, 51 Cal. 3d at 143, 793 P.2d at 494, 271 Cal. Rptr. at 160-61; Schlicher, *Some Thoughts on the Law and Economics of Licensing Biotechnology Patent and Related Property Rights in the United States*, 29 J. PAT. TRADEMARK OFF. SOC'Y 263, 284 (1987).

172. *Moore*, 51 Cal. 3d at 143, 793 P.2d at 493, 271 Cal. Rptr. at 160.

173. See *id.*, 793 P.2d at 493-94, 271 Cal. Rptr. at 160-61.

174. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 27.

175. *Id.* (“resolving the current uncertainty may be more important to the future of biotechnology than resolving it in any particular way”); see also *Moore*, 51 Cal. 3d at 143, 793 P.2d at 493, 271 Cal. Rptr. at 161.

### C. *The Public Interest*

The public has a significant interest in gaining access to life-saving therapeutic products.<sup>176</sup> In *Moore*, the majority declined to grant individuals a property right in their surgically removed body tissue because "[t]o impose such a duty . . . would affect medical research of importance to all of society . . . ."<sup>177</sup> Thus, an overriding concern was to encourage research and product development.<sup>178</sup> To effectuate this policy, the *Moore* court declined to expand conversion liability to protect individual's rights because to do so would "threaten [researchers] with disabling civil liability" for using human tissue.<sup>179</sup> Such potential liability, the majority reasoned, would create uncertainty that could adversely affect product development.<sup>180</sup>

This interest is consistent with Congress' interest in enacting patent laws to foster research and development, as well as economic growth.<sup>181</sup> The public would suffer if patent goals are not advanced because therapeutic products would not become available.<sup>182</sup>

The public also has an interest in new treatments becoming available as quickly as possible. If researchers do not have available tissue to develop products, then they must instead attempt to develop alternative technologies.<sup>183</sup> Since the technology now exists for using human tissue to produce therapeutic products, this delay could cost many lives.

Finally, therapeutic products should not only become readily available, but their costs should not be so high as to become prohibitive.<sup>184</sup> Consequently, the public has an interest in keeping the price of these products affordable. If not, only the wealthy would benefit from product development.

### D. *The Interests of the Federal Government*

The interests of the federal government are evidenced by patent

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176. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 115.

177. *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 135, 793 P.2d 479, 487, 271 Cal. Rptr. 146, 154 (1990).

178. *Id.* at 143, 793 P.2d at 494, 271 Cal. Rptr. at 161.

179. *Id.*, 793 P.2d at 493, 271 Cal. Rptr. at 160.

180. *Id.*, 793 P.2d at 494, 271 Cal. Rptr. at 161.

181. See *infra* notes 191-201 and accompanying text.

182. In addition, investments to commercialize biotechnology products exceeded one billion dollars in 1983 alone. See *supra* note 6. Therefore, any decrease in research activities may reduce investment activity in biotechnology which, in turn, may have a detrimental effect on the economy.

183. See *supra* notes 63-93 and accompanying text for a discussion of these alternative technologies.

184. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 115.

laws. To ascertain what actions the law should encourage, an awareness of the policy concerns of intellectual property is essential. These policies also encompass the public interest in encouraging research and development, as well as the biotechnology industry's interest in protecting its inventions. An analysis of patent laws and policies reveals that the right to informed consent as developed in *Moore* will not adequately advance these interests.

Knowledge of patent law is necessary for another reason. Before the advent of the commercial potential of biotechnology, researchers were not motivated to seek patent protection.<sup>185</sup> This is because it was regarded as being against scientific norms to claim exclusive rights in research discoveries.<sup>186</sup> Consequently, commercial potential of recent advances in biotechnology has created a conflict between traditional policies of patent law and scientific research.<sup>187</sup> This commercial potential has also created the issues raised in the *Moore* case. The fact is that scientists are entrepreneurs<sup>188</sup>—"scientists for profit." Hence, their motivations are not purely altruistic. In addition, congressional interest in reforming patent laws is to foster economic well-being.<sup>189</sup> If both the scientists' and the government's motivations are financial, why should

185. See R. MERTON, *The Normative Structure of Science*, in *THE SOCIOLOGY OF SCIENCE* 267, 275 (N. Storer ed. 1973) [hereinafter *Normative Structure*].

186. *Id.* at 275-77. Traditionally, the foremost goal of science has been to extend certified knowledge through empirical research. *Id.* at 267. The scientist's motivation in advancing certified knowledge was to benefit humanity. M. KENNY, *BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX* 32 (1986). Scientific discoveries were thought to be a product of the scientific community as a whole because all new discoveries were the result of previous ones and future discoveries would be built upon them. *Normative Structure*, *supra* note 185, at 273-75.

Scientists should be motivated by a desire to seek knowledge and not to further their own financial interests. *Id.* at 275-77. Professional recognition should be the motivation for researchers to add to the wealth of scientific knowledge. R. MERTON, *Priorities in Scientific Discovery*, in *THE SOCIOLOGY OF SCIENCE*, *supra* note 185, at 286, 293-96. As a result, such recognition should provide scientists with an incentive to publish their discoveries. R. MERTON, *Behavior Patterns of Scientists*, in *THE SOCIOLOGY OF SCIENCE*, *supra* note 185, at 325, 325.

Once published, the findings become part of the public domain and cannot be patented. 35 U.S.C. § 102(a), (b) (1988); see also I. COOPER, *BIOTECHNOLOGY AND THE LAW* § 1.03, at 1-19 (1985). Because publication interferes with the acquisition of patent rights, intellectual property law has been thought to conflict with traditional scientific research policy. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 *YALE L.J.* 177, 184 (1987).

187. See also Eisenberg, *supra* note 186, at 178-79. Today, some scientists fear that commercial incentives may interfere with and undermine traditional norms of scientific research. See *id.* at 177.

188. See generally Eisenberg, *supra* note 186 (scientists have become more interested in protecting the commercial value of their research than in benefiting society).

189. Bent, *supra* note 27, at 27. One reason for this interest is that because a patent protects



the law expect the tissue sources' motivation to be solely altruistic? The fact is that tissue sources may demand payment before consenting to the commercial use of their tissue. Compensation to tissue sources, therefore, may be necessary to advance the interests of the federal government and others. Because compensation to tissue sources may be necessary, fair value of the tissue becomes an issue. Therefore, in order to analyze the value of a source's contribution, knowledge of patent laws is also important to understand what is patentable and what degree of work<sup>190</sup> is required by scientists before they can patent human tissue and cell products.

### 1. Patent law policy

According to the United States Constitution, patent laws were enacted for the purpose of promoting the "[p]rogress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."<sup>191</sup> A patent grants the exclusive right to make, use and sell the invention<sup>192</sup> for a period of seventeen years.<sup>193</sup>

The four traditional objectives upon which modern patent legislation is based were formulated by Fritz Machlup in his well known historical and economic analysis of the patent system.<sup>194</sup>

According to these widely accepted "patent theories" patents are granted:

To recognize the intellectual property of the inventor; To reward the inventor for his useful services as "teacher of the nation"; To encourage inventors and industry to invent, invest and innovate; and finally; To further the early disclosure and wide dissemination of technical knowledge.<sup>195</sup>

The policy rationale behind granting exclusivity is that of encouraging disclosure of the invention to the public, thereby "adding to the sum of

an invention, it provides inventors and investors with an incentive to risk time and money. COMMERCIAL BIOTECHNOLOGY, *supra* note 2, at 385.

190. See *supra* notes 52-56 and accompanying text for an illustration of the amount of technical work required to produce a patentable product using tissue culture technology.

191. U.S. CONST. art. I, § 8, cl. 8. The term "useful Arts" has been interpreted to include applied technology. See, e.g., *In re Bergy*, 596 F.2d 952, 958-59 (C.C.P.A. 1979), *aff'd sub nom. Diamond v. Chakrabarty*, 477 U.S. 303 (1980).

192. 35 U.S.C. § 271(a) (1988).

193. *Id.* § 154.

194. Beier & Straus, *Patents in a Time of Rapid Scientific and Technological Change: Inventions in Biotechnology*, in BIOTECHNOLOGY AND PATENT PROTECTION: AN INTERNATIONAL REVIEW 15, 17 (1985).

195. *Id.*

human knowledge."<sup>196</sup> The desired result is an increase in technical innovation and industrial development.<sup>197</sup>

If biotechnology companies could not prevent competitors from using or capitalizing on the results of their research and development efforts, many new and speculative projects would not be undertaken.<sup>198</sup> Addressing this concern, the United States patent law system was designed to provide the best form of protection for biotechnological inventions.<sup>199</sup> The policy emphasis, however, has shifted to economic growth,<sup>200</sup> and recognizing and rewarding intellectual efforts is no longer an important objective of current legislation.<sup>201</sup> Consequently, since the federal government has an economic interest in research and development, arguably tissue sources, whose tissue helps advance that interest, should have an interest in being compensated.

## 2. Patent law requirements

High technology industries have traditionally relied on utility patents in order to obtain exclusivity and competitive advantage.<sup>202</sup> An invention must be within patentable subject matter,<sup>203</sup> and must be new,<sup>204</sup> useful<sup>205</sup> and unobvious.<sup>206</sup> Additionally, in order to qualify for a utility patent, an inventor must file an application with the United States Patent and Trademark Office (USPTO).<sup>207</sup>

Prior to 1980, patent protection was not available for "living" sub-

196. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933).

197. *Beier & Straus*, *supra* note 194, at 15. Existing patent law, which was developed in the nineteenth century is outdated because many potentially valuable biotechnology inventions are either excluded or insufficiently protected by current patent law. *Id.*

198. *COMMERCIAL BIOTECHNOLOGY*, *supra* note 2, at 17.

199. *Id.* at 16.

200. *See id.* at 385; *Bent*, *supra* note 27, at 27.

201. *Beier & Straus*, *supra* note 194, at 20. Another indication of this shift in policy is evidenced by the fact that patent holders are generally having much greater success in the federal court system in litigation arising from patent infringement. *Id.*

202. *Biggart*, *supra* note 11, at 5. A "utility" patent is one which is obtainable by inventors when the subject matter of the invention is a "new or useful process, machine, manufacture or composition of matter." 35 U.S.C. § 101 (1988). Biotechnology utility patents may be categorized as product patents, for example, nutrient media, organisms, cultures, and by-products thereof; process patents, for example, fermentation methods, cultivation methods, and syntheses using enzymes; and use patents, for example, using a previously known substance for a new purpose. *I. COOPER*, *supra* note 186, § 1.03.

203. 35 U.S.C. § 101.

204. *Id.*

205. *Id.*

206. *Id.* § 103.

207. *Id.* § 111.

ject matter such as microorganisms, cell lines and plants.<sup>208</sup> The United States Supreme Court's decision in *Diamond v. Chakrabarty*<sup>209</sup> changed this view.<sup>210</sup> It is now clear that tissue and cells that are manipulated by scientists are patentable subject matter.<sup>211</sup> Before a patent can be issued, however, cells must be deposited in a recognized independent depository.<sup>212</sup>

A significant requirement of patentability is that the invention be developed through human intervention.<sup>213</sup> Patents are not obtainable on products of nature.<sup>214</sup> Although a scientist, through the use of biotechnology, can transform human tissue and cells into a patentable invention,<sup>215</sup> tissue sources, such as the plaintiff in *Moore*, cannot patent their own unique tissue or cells.

Furthermore, sources that simply contribute tissue and cells to scientists cannot be regarded as inventors.<sup>216</sup> To be considered an inventor, one must be the first to conceive of the idea.<sup>217</sup> Because, however, it is improbable that a source would even be aware of his or her tissue's potentially useful characteristics,<sup>218</sup> nearly all sources could not be considered inventors.

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208. Biggart, *supra* note 11, at 6.

209. 447 U.S. 303 (1980). The Court ruled that a man-made genetically engineered microorganism which was capable of breaking down components of crude oil was patentable. *Id.* at 305.

210. The Court determined that the mere fact that the invention was a living organism did not preclude the possibility of obtaining patent protection. *Id.* at 318.

211. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 71. The USPTO currently issues patents on man-made organisms, cell lines and hybridomas on a routine basis. Biggart, *supra* note 11, at 7.

212. *In re Lundak*, 773 F.2d 1216, 1220-22 (Fed. Cir. 1985). A deposit is required to meet the Patent Law Enablement Act, which is designed to allow the public to practice freely the claimed invention when the patent expires, and to be able to improve upon the technology during the seventeen-year period. Benson, *Biotechnology Patent Pitfalls*, 4 BIOTECHNOLOGY 118, 120 (1986). See *supra* note 194 and accompanying text for an explanation of the seven-year period.

213. Biggart, *supra* note 11, at 11.

214. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). The underlying rationale involved is that naturally occurring products are available to the public free from restrictions. Biggart, *supra* note 11, at 11.

215. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 71. It is important to note that biotechnology products which are identical to counterparts which exist naturally, such as microorganisms, cannot be patented. Biggart, *supra* note 11, at 11. But, hybridomas, recombinant DNA and parts of cells, developed through genetic engineering are patentable, either as a composition of matter or an article of manufacture. *Id.* Also, any novel processes, such as a novel process for genetically engineering a cell and altering its DNA or a novel method for tissue culture, can be the basis of a utility patent. *Id.*

216. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 71.

217. 35 U.S.C. § 102 (1988).

218. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 71.

Thus, tissue sources, under existing patent law, could not patent their own unameliorated tissue. Therefore, absent scientific intervention, the uniqueness of the tissue is worthless to the source. This is an important factor in determining the fair value of the tissue source's contribution.

### 3. Rights granted to patent holders

A patent holder of a human tissue-derived biotechnology invention holds legally protected intellectual property rights.<sup>219</sup> The exclusive rights granted through patents are considered personal property.<sup>220</sup> The patent holder enjoys an exclusive property right in the intangible subject matter of an invention.<sup>221</sup> It is important to distinguish that the actual physical embodiment of the invention, such as a human cell line, is not the subject matter of the patent; rather, the mental concept allowing for its creation is the protected property.<sup>222</sup> Because, however, a patent grants an exclusive right to make, use and sell the invention, it implicitly vests exclusive tangible property rights in all products derived from the intangible subject matter of the invention.<sup>223</sup>

#### *E. The Right to Informed Consent Does Not Advance All Interests*

According to the majority in *Moore v. Regents of the University of California*,<sup>224</sup> individuals have the right to informed consent regarding whether their tissue can be used commercially after its removal.<sup>225</sup> This right, however, will not advance all of the competing interests.

The *Moore* court stated that it was very concerned with protecting an individual's autonomy.<sup>226</sup> The right it developed, however, falls short of granting such protection under at least four circumstances.

First, under the traditional doctrine of informed consent, doctors may avoid liability if the doctors can prove that their patients would have consented to the surgery even if they had disclosed all material information.<sup>227</sup> If the patient, fully informed, would have consented to the surgery, the doctor's nondisclosure could not have caused the patient's

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219. See 35 U.S.C. § 261 (1988).

220. See *id.*

221. See *id.*

222. See *Dubilier Condenser Corp.*, 289 U.S. at 188.

223. These rights are assignable; therefore, inventors may transfer their rights through a license. See 35 U.S.C. § 261.

224. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

225. *Id.* at 131-32, 793 P.2d at 485, 271 Cal. Rptr. at 152.

226. *Id.* at 143, 793 P.2d at 493, 271 Cal. Rptr. at 160.

227. *Cobbs v. Grant*, 8 Cal. 3d 229, 246, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972).

injury. In *Moore*, Justice Broussard, concurring in part and dissenting in part, and Justice Mosk, dissenting, disagree on how the court would resolve this situation. Justice Mosk believed that a doctor would be able to avoid all liability unless a patient proved that he or she would not have had the medically necessary surgery.<sup>228</sup> Justice Broussard, on the other hand, maintained that for there to be a breach of the right to informed consent, patients need to establish only that they would not have consented to the commercial use of their tissue, not that they would not have had the surgery at all.<sup>229</sup> According to Justice Broussard, tissue sources could then prove that the doctor's failure to disclose information caused them some type of compensable damage.<sup>230</sup> The majority, however, failed to address this issue. Thus, how courts would resolve this type of situation is unclear.

Second, the *Moore* court was ambiguous regarding whether patients, once fully informed of the potential commercial value of their tissue, can consent only to surgery and not to the tissue's subsequent use. In virtually all cases concerning human tissue with potential commercial value, the patient will have an insufferable disease so the choice to undergo surgery will be a life or death decision.<sup>231</sup> As a result, the patient invariably wants the surgery, but he or she may not want the removed tissue to be used to develop a cell line. The court's holding could be interpreted to mean, once fully informed, a patient must decide between either: (1) consenting to surgery and to the tissue's subsequent commercial use or (2) not consenting to the surgery at all. If so, this infringes on the patient's interest in making autonomous medical decisions. For example, a patient with a rare form of cancer may want to have the world's most prominent doctor perform the surgery, yet that doctor may also desire to use the removed tissue commercially. If the patient is unwilling to consent to the tissue's commercial use, the patient would be forced to seek another doctor. In contrast to the majority opinion, Justice Broussard's position in this regard is clear. According to Justice Broussard, a patient has the right, prior to surgery, to control the use of the tissue after its

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228. *Moore*, 51 Cal. 3d at 179-80, 793 P.2d at 519, 271 Cal. Rptr. at 186 (Mosk, J., dissenting).

229. *Id.* at 152, 793 P.2d at 500, 271 Cal. Rptr. at 167 (Broussard, J., concurring and dissenting).

230. *Id.* at 158, 793 P.2d at 504, 271 Cal. Rptr. at 171 (Broussard, J., concurring and dissenting).

231. *See, e.g., id.* at 126, 793 P.2d at 481, 271 Cal. Rptr. at 148 (patient had leukemia). Human tissue becomes therapeutically valuable due to a chance abnormality caused by cancer. *See supra* notes 48-51 and accompanying text.

removal.<sup>232</sup> Accordingly, a patient could consent to surgical removal of the tissue, but not to its commercial use.<sup>233</sup>

Third, according to the majority, if a doctor has no plans to use commercially a patient's tissue at the time of the surgery, then the patient's interests have not been impaired.<sup>234</sup> This would allow a doctor to perform the surgery and later perform research on the tissue to determine whether it is unique and potentially valuable. If a doctor then uses the tissue commercially, the tissue source would have no rights in the tissue. Justice Broussard, however, would disagree with this proposition because he contends that the doctor's fiduciary duty also encompasses postoperative conduct.<sup>235</sup>

Finally, parties other than the patient's doctor, such as biotechnology companies, unless they are joint venturers, do not owe a fiduciary duty to the patient.<sup>236</sup> As a result, such parties could commercially use a source's tissue without liability.

Under these circumstances patients would be denied the right to decide what should be done with their bodily tissue. Consequently, "the existence of a breach-of-fiduciary-duty cause of action does not provide a complete answer"<sup>237</sup> and does not adequately protect individuals' privacy rights.

The *Moore* court's right to informed consent will not advance the biotechnology industry's interest in eliminating uncertainty. Consequently, the interests of the federal government and the public in encouraging research and product development are hindered.

Uncertainty exists for doctors and biotechnology companies as to their potential liability under each of the four circumstances, discussed above, because: (1) when a reasonable person with an insufferable disease, if informed, would have consented to the surgery, but not to the

232. *Moore*, 51 Cal. 3d at 155, 793 P.2d at 502, 271 Cal. Rptr. at 169 (Broussard, J., concurring and dissenting).

233. *See id.* at 158, 793 P.2d at 504, 271 Cal. Rptr. at 171 (Broussard, J., concurring and dissenting) (patient can donate tissue and reserve right to approve how used).

234. *Id.* at 131, 793 P.2d at 484, 271 Cal. Rptr. at 151.

235. *See id.* at 152, 793 P.2d at 500, 271 Cal. Rptr. at 167 (Broussard, J., concurring and dissenting).

236. *See id.* at 133-34, 793 P.2d at 486-87, 271 Cal. Rptr. at 53-54. In addition, according to Justice Broussard, a patient may consent to the use of his or her tissue and reserve the right decide how that tissue would be used. *Id.* at 158, 793 P.2d at 504, 271 Cal. Rptr. at 171 (Broussard, J., concurring and dissenting). Accordingly, if another biotechnology company misappropriated the tissue and used it in an unauthorized manner for its own economic gain, there would not be a breach of a fiduciary duty and consequently no cause of action would be available to vindicate the tissue source's rights. *Id.* (Broussard, J., concurring and dissenting).

237. *Id.* (Broussard, J., concurring and dissenting).

tissue's commercial use, it is unclear whether doctors would be liable for nondisclosure of potential commercial gain; (2) when a patient is fully informed of the tissue's potential commercial value, doctors are uncertain as to whether consent to the surgery allows them to use the tissue even though the patient is opposed to its commercial use; (3) when a doctor discovers a tissue's potential value after surgery, there is disagreement among the justices concerning whether a doctor breaches a fiduciary duty by commercially using the tissue without the source's consent; and (4) when biotechnology companies work in conjunction with doctors, they are unsure whether they would be considered joint venturers and therefore liable for any breach of a fiduciary duty by the doctors.

In addition, Justice Broussard believes that patients could grant consent to commercial use of their tissue, and at the same time reserve the right to disapprove the research projects for which their tissue would be used.<sup>238</sup> If so, this creates uncertainty for biotechnology companies because they would never be sure whether sources would approve their proposed projects.

Finally, the *Moore* court left indeterminate whether interested parties can compensate patients for consent to use their tissue commercially. This becomes an important issue if patients are permitted to consent only to the surgical removal of their tissue and not to its commercial use.<sup>239</sup> Applying the principles of freedom of contract,<sup>240</sup> there seems to be no reason why parties could not make compensation arrangements. The *Moore* court apparently failed to recognize how rare and potentially valuable certain tissue can be and that biotechnology companies working jointly with doctors may be so interested in obtaining such tissue that they would be willing to pay for it. It is apparent, however, that the *Moore* court's motive for not expanding conversion liability was its opposition to allowing tissue sources to share profits.<sup>241</sup> Nevertheless, the majority may have overlooked that the right to informed consent to commercial use of tissue may create the possibility that interested parties will contract for that right. Contracts between scientists and tissue

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238. *Id.* at 158, 793 P.2d at 504, 271 Cal. Rptr. at 171 (Broussard, J., concurring and dissenting).

239. See *supra* notes 231-33 and accompanying text.

240. See E. FARNSWORTH, *supra* note 121, § 1.7. In the absence of definitive laws, the sale of tissue is generally permissible, unless the sale would pose a threat to the public health. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 9. Under the circumstances of biotechnological use of human tissue, no law prohibits the sale of human tissue. *Id.*

241. Since body tissue is not property, it follows that tissue sources cannot share in the profits from its commercial use. Shapiro, *Who Profits from Selling Human Body Parts?*, L.A. Daily J., Aug. 23, 1990, at 7, col. 1.

sources may be subject to unconscionability problems and threats of rescission.<sup>242</sup>

As illustrated, it is very unclear how the California courts will resolve many types of situations involving the commercial use of human tissue. The court in *Moore* wanted to eliminate uncertainties to protect researchers from liability and to encourage research and product development.<sup>243</sup> The majority narrowly interpreted conversion law to achieve its objectives.<sup>244</sup> Ironically, the *Moore* court's holding has not only failed to resolve many uncertainties, but has created new ones. Consequently, the interests of eliminating uncertainty and promoting research and product development are not advanced.

## VI. DEVELOPING AN APPROPRIATE SOLUTION TO THE PROBLEMS RAISED BY THE COMMERCIAL USE OF HUMAN TISSUE

To resolve the many problems created by using a person's tissue commercially, an appropriate balance of the competing interests must be achieved. The individual's right in the disposition of his or her body tissue must be protected. At the same time, however, any law designed to protect that right must not discourage research and product development, nor create public policy problems or legal uncertainties.

### A. *Compensation to Tissue Sources Will Advance Interests*

Compensation to tissue sources for the right to use their tissue commercially would advance several interests. Compensation would preserve the individual's rights and avoid windfalls to researchers. More importantly, compensation would provide incentive for potential sources to allow their tissue to be used in the development of therapeutic products.

Currently, a majority of states allows tissue donors legally to contract to sell parts of their bodies.<sup>245</sup> In addition, although the National Organ Transplant Act of 1984 (NOTA)<sup>246</sup> prohibits the sale of organs through interstate commerce,<sup>247</sup> that prohibition does not apply to sales of human tissue for research, commercial or other nontransplantation

242. See *infra* notes 300-58 and accompanying text.

243. *Moore*, 51 Cal. 3d at 143, 793 P.2d at 493-94, 271 Cal. Rptr. at 160-61.

244. See *id.* at 151, 157-58, 793 P.2d at 499, 504, 271 Cal. Rptr. at 166, 171. It is difficult to believe that a part of a person's body is not his or her property. In order to advance its policies, the majority should have instead concluded that the tissue was property and that an exception to conversion liability exists, such as abandonment.

245. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 75.

246. 42 U.S.C. §§ 273-274e (1988).

247. *Id.* § 274e.



purposes.<sup>248</sup>

1. Compensation to sources will protect the interests of patients

The law must protect a patient's privacy and autonomy rights, including the right to decide what will be done with his or her surgically removed body tissue.<sup>249</sup> In addition, sources have an interest in obtaining the economic value of their tissue.<sup>250</sup> If sources are not compensated for the commercial use of their tissue, they sacrifice part of their self-determination and lose a prospective financial advantage.<sup>251</sup> Consequently, compensation for the right to use a person's tissue commercially would preserve these interests.

2. Compensation to sources will avoid windfalls to researchers

Allowing researchers to profit from the use of a person's tissue without compensation would permit them to realize an inequitable return on their services and products. The profits obtained through the commercial use of human tissue would not exist without the tissue source's contribution. Compensating sources for their necessary contribution would eliminate the potential windfall to biotechnology companies and doctors.<sup>252</sup>

3. Compensation will advance product development

After *Moore v. Regents of the University of California*,<sup>253</sup> it is uncertain whether interested parties will have to compensate sources for consent to use their tissue commercially.<sup>254</sup> Patients in California now have a right to informed consent for the commercial use of their tissue;<sup>255</sup> accordingly, those willing to give up that right should be entitled to compensation. As a result, payment may be necessary to motivate sources to consent to transfer their rights.<sup>256</sup> For example, blood donors have traditionally been motivated primarily by altruism.<sup>257</sup> However, when there has been an insufficient supply by altruistic donors, payment to donors

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248. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 76.

249. See *supra* notes 158-62 and accompanying text.

250. See *supra* notes 163-65 and accompanying text; see also OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 16.

251. See Comment, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 227 n.99 (1986).

252. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 124-25.

253. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

254. See *supra* notes 239-42 and accompanying text.

255. *Moore*, 51 Cal. 3d at 128-32, 793 P.2d at 483-85, 271 Cal. Rptr. at 150-52.

256. See OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 118.

257. *Id.*

increased the supply.<sup>258</sup> Also, in the case of organ donations, patients are dying because of the shortages of certain organs.<sup>259</sup> Payments for organs would be virtually certain to increase the supply of organs for transplant.<sup>260</sup> Similarly, such payment to sources should advance research and development of human tissue products because it would likely increase the available supply of tissue.<sup>261</sup>

Payments to sources may be necessary especially because the developers, who commercially use the tissue, may realize tremendous profits.<sup>262</sup> As *Moore* confirms, however, the tissue source who made those profits possible may receive nothing. The prospect that researchers will be gaining massive profits through the use of tissue may override many sources' altruistic motivations for donating their tissue. Compensation would overcome this by providing an economic incentive for patients to consent to the use of their tissue.<sup>263</sup>

Providing impetus for consent is especially important because truly unique tissue with potential therapeutic value is extremely rare.<sup>264</sup> Unless another biotechnique can be used as an immediate alternative,<sup>265</sup> failure to obtain the consent of even one potential source may result in a significant detriment to the public health.

### *B. Problems Created by Compensating Tissue Sources*

Allowing tissue sources to seek payment for their tissue on the open market raises many concerns. Payments to tissue sources carry both economic and policy implications. Allowing sources to negotiate freely for their tissue's highest price may adversely affect all of the interested parties, including the individual source.

258. *Id.*

259. *Id.*

260. *Id.*

261. See *id.* at 118; Note, *Source Compensation for Tissues and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628, 638 (1989).

262. The potential market for products obtained from *Moore's* tissue is approximately three billion dollars. *Moore*, 51 Cal. 3d at 127, 793 P.2d at 482, 271 Cal. Rptr. at 149.

263. Comment, *supra* note 251, at 233.

264. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 56. Cases of true uniqueness are not only few in number, but are difficult, if not impossible, to identify except by chance discovery. *Id.* The condition that caused *Moore's* spleen to develop unique characteristics occurs in only 250 Americans per year. See *supra* note 130. In addition, only a small percentage of this tissue will have the capability of developing into a cell line. See *supra* notes 52-56 and accompanying text.

265. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 56.

### 1. Added costs of research and development

The United States Congress Office of Technology Assessment (OTA) has stated that a central issue concerning payments to sources is the added cost of research and development of therapeutic products.<sup>266</sup> Two types of additional costs are associated with payments to sources: (1) the actual compensation to sources, and (2) transaction costs, which are the costs of administering a payment program.<sup>267</sup> If tissue sources can freely negotiate for the rights to their tissue, then a bidding war between companies for rare tissue could significantly increase the cost of the tissue. According to the OTA, however, transaction costs "are likely to dwarf the costs of actual payments to the sources."<sup>268</sup> These costs will most likely be passed on to the public in the form of higher product prices.

Transaction costs would be high because a number of cell lines from different sources may be responsible for the creation of any single commercial product.<sup>269</sup> Since research and development takes many years,<sup>270</sup> this would significantly increase the transaction costs involved in tracking the origin of all the sources.<sup>271</sup> Furthermore, these costs would be incurred regardless of the success of the research.<sup>272</sup> Consequently, transaction costs would significantly increase the price of commercial products regardless of the benefit provided by the individual source's tissue.

### 2. Delaying product development

Allowing sources to freely negotiate for the rights to their tissue would cause delays in the commercial availability of therapeutic products. Due to the complex nature of biotechnology, sources may seek to retain knowledgeable consultants, similar to stocks and bonds brokers, in assessing the commercial value of their tissue.<sup>273</sup> The resulting negotiations would delay development, as well as further increase transaction costs. These delays would retard the development of products that could potentially cure many fatal diseases.

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266. *Id.* at 115.

267. *Id.* at 116.

268. *Id.*

269. *See id.*

270. *See supra* notes 167-68 and accompanying text.

271. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 116.

272. *Id.*

273. *Id.* at 117.

### 3. Conflict with encouraging research

If the price researchers pay for tissue is too high, biotechnological research may be discouraged,<sup>274</sup> especially if the tissue is used solely for research by scientists with no profit motive.<sup>275</sup> For example, the price of human tissue could become prohibitively high due to bidding wars between biotechnology companies. Researchers may instead concentrate on developing alternative techniques to human tissue culture.<sup>276</sup> Furthermore, if sources can contract for the rights to their tissue, the enforceability of such contracts may be uncertain.<sup>277</sup> The uncertainty would dampen research and development.<sup>278</sup> This undermines the patent goal of encouraging research. Consequently, discovery of new therapeutic products would be hindered also because of the resulting decrease in dissemination of technical knowledge.<sup>279</sup>

### 4. Ethical concerns

There is widespread moral repugnance to the idea of developing a market in human tissue.<sup>280</sup> Ethicists are concerned that a market in human tissue unacceptably alters the meaning of the human body.<sup>281</sup> "The effect on human dignity of a marketplace in human body parts [is

274. See Danforth, *Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits*, 6 YALE L. & POL'Y REV. 179, 200 (1988).

275. For example, graduate students at universities typically perform research without a profit motive. The traditional goals of scientific research are exclusively knowledge oriented and not commercially motivated. Placing a monetary value on human tissue or cells in the research context seems in direct conflict with these traditional policies. See *supra* notes 186-87 and accompanying text for a discussion of scientific research policies.

276. See *supra* notes 94-109 and accompanying text for a discussion of the advantages of using human tissue cultures.

277. See *infra* note 300-61 and accompanying text for a discussion of contract law problems.

278. See *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 143, 793 P.2d 479, 494, 271 Cal. Rptr. 146, 161 (1990).

279. See *supra* note 186. Because, under patent law deposit requirements, cells must be made available in order to be used for research, see *supra* note 212 and accompanying text, a decrease in these deposits may frustrate new discoveries.

280. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 117; Sherman, *The Selling of Body Parts*, Nat'l L.J., Dec. 7, 1987, at 32, col. 2.

281. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 16. For example, Justice Arabian in *Moore* stated:

Plaintiff has asked us to recognize and enforce a right to sell one's own body tissue *for profit*. He entreats us to regard the human vessel—the single most venerated and protected subject in any civilized society—as equal with the basest commercial commodity. He urges us to commingle the sacred with the profane. He asks much.

*Moore*, 51 Cal. 3d at 148, 793 P.2d at 497, 271 Cal. Rptr. at 164 (Arabian, J., concurring).

greatly feared] . . . ."<sup>282</sup> Many believe that if the body is to be considered part of the basic dignity of human beings, then trade in human tissue should be limited.<sup>283</sup>

### 5. Concerns for the individual

The prospect of financial gain could have an undue influence on patients. There is a concern that tissue sources may harm themselves in an effort to realize a pecuniary gain.<sup>284</sup> Tissue sources may expose themselves to unacceptable risks to profit from their tissue.<sup>285</sup>

Very often a patient's tissue is valuable because of a disease, such as cancer. If tissue sources are negotiating for the highest price for their tissue, they will be delaying their surgery. Attention to maximizing their profit could distract them from the more important aspect of treating their condition. Such a distraction could be life-threatening.

### 6. Contract law uncertainties

As previously discussed, to advance all of the interests involved, it may be permissible and necessary to compensate tissue sources for the rights to use commercially their tissue.<sup>286</sup> In fact, the right to informed consent may be a right for which parties can contract,<sup>287</sup> or possibly Congress or a state legislature may intervene by creating a free market in human tissue.<sup>288</sup>

Examination of the application of traditional contract law doctrines to possible tissue contracts reveals several dilemmas. During the development of common-law principles, recent advances in biotechnology were unimaginable. The parties would be contracting for unique subject matter under exceptional circumstances. Consequently, an unrestricted right to contract for consent would create additional legal uncertainties due to the lack of relevant law in this area. Uncertainty about how a court would resolve a dispute between the parties to a tissue contract could discourage the development of human tissue-derived therapeutic

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282. *Moore*, 51 Cal. 3d at 149, 793 P.2d at 498, 271 Cal. Rptr. at 165 (Arabian, J., concurring).

283. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 13; Sherman, *supra* note 280, at 32.

284. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 11.

285. *Id.*

286. See *supra* notes 245-65 and accompanying text.

287. See *supra* notes 239-42 and accompanying text.

288. See OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 16.

products.<sup>289</sup> This is a result the *Moore* majority had hoped to avoid.<sup>290</sup>

Before doctors and biotechnology companies attempt to draft a tissue consent contract, they must consider (1) whether the Uniform Commercial Code (U.C.C.), which governs commercial transactions, including contracts for the sale of goods, should apply to sales of tissue; and (2) how contracts between sources and research companies should be drafted to avoid enforceability problems. Although a cleverly drafted contract can arguably avoid uncertainties,<sup>291</sup> under these unique circumstances that may not be the case.

*a. applicability of the U.C.C.*

The provisions of Article Two of the Uniform Commercial Code—Sales<sup>292</sup> apply to “transactions in goods.”<sup>293</sup> If the sale of tissue is treated as a sale of goods, then the U.C.C. should apply. However, if the courts characterize the transfer of human tissue as a service,<sup>294</sup> then the U.C.C. will not apply.

An analogy can be drawn to the sale of blood and semen. States allow the sale of blood or semen in amounts which are non-vital.<sup>295</sup> State laws usually treat these as transfers of services rather than as sales of

289. See *Moore*, 51 Cal. 3d at 143, 793 P.2d at 494, 271 Cal. Rptr. at 160-61. One commentator has stated that “[u]ncertainty is an ubiquitous feature of biotechnology licensing. Almost every provision is touched by this uncertainty. . . . Reducing this uncertainty is desirable.” Schlicher, *supra* note 171, at 284.

290. *Moore*, 51 Cal. 3d at 143, 793 P.2d at 494, 271 Cal. Rptr. at 160-61.

291. To protect itself against contract enforceability problems, a biotechnology company should take several steps during contract formation with a tissue source. First, the company should both make a full disclosure of all known facts relating to potential value of the tissue and acknowledge that the tissue may be more valuable than anticipated. Second, the company should have the source expressly agree, in light of this full disclosure, to relinquish all rights in the tissue, even in the event that some previously unknown value is discovered. The contract should also state that the compensation includes payment for possible unforeseen value. Third, the contract should address the form of consideration, for example, a lump sum payment or a royalty arrangement. A compensation scheme which accounts for variable values of derivative products, however, may provide more protection against future claims.

Nonetheless, it may be possible for a biotechnology company to completely avoid contracting with a source. A company may use a source's cell line only for research and not as part of the commercial production process. Once researchers discover the genetic properties responsible for the establishment of a cell line and its by-products, a company could use recombinant DNA techniques to synthesize that particular gene sequence. The recombinant form can be used for commercial production instead of the source's actual cells. Therefore, the commercial products would not be directly obtained from the source's tissue.

292. U.C.C. § 2-101 (1989).

293. *Id.* § 2-102.

294. Courts usually determine whether a transaction is a sale of goods or a service. *Triangle Underwriters, Inc. v. Honeywell, Inc.*, 604 F.2d 737, 742 (2d Cir. 1979).

295. Note, *The Sale of Human Body Parts*, 72 MICH. L. REV. 1182, 1193 (1974).

goods.<sup>296</sup> The main policy reason for characterizing these transactions as services is to avoid products liability under either common law or the U.C.C. implied warranty provisions.<sup>297</sup> In deciding whether to treat the transfer of tissue as a sale of goods or as a service, a court may look to state and federal laws which govern transactions involving blood and semen.

Nonetheless, tissue that is used as raw material for commercial products, arguably, is distinguishable from blood and semen in both form and substance. Blood and semen are replenishable, whereas tissue, such as a spleen, is not. One test used to determine whether a transaction is one in goods or services is whether the "predominant factor" is a sale, "with labor incidentally involved," or instead, the rendering of a service, "with goods incidentally involved."<sup>298</sup> Notwithstanding this distinction, the U.C.C. should not apply because the tissue contract should be viewed as involving intangible rights and not tangible goods. This is because under *Moore*, the right involved is based not on a tangible property right in the tissue, but on an intangible right in informed decision-making. As a result, the contract involves compensation for one's consent and not a sale of a good. Since in such a case no "transaction in goods" is involved, the U.C.C. should not apply to the contract.<sup>299</sup>

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296. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 76.

297. *Id.*

298. Bonebrake v. Cox, 499 F.2d 951, 960 (8th Cir. 1974).

299. If the U.C.C. applies to tissue contracts, then U.C.C. warranties may be applicable. The U.C.C. provides two implied warranties. The implied warranty of merchantability requires goods to be of fair average quality, within the seller's description, and fit for the good's ordinary purpose. U.C.C. § 2-314 (1989). The implied warranty of fitness requires goods to be suitable for the buyer's particular purpose to the extent that the seller knows this purpose. *Id.* § 2-315. Liability for breach of warranties is based on strict liability and not negligence. *See id.* §§ 2-314, 2-315. As a result, even careful examination of the tissue for contamination or genetic flaw would not relieve the providing entity from liability. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 77.

The implied warranty of merchantability applies only to merchants. *See* U.C.C. § 2-314 comment 3. A merchant is a person who deals in goods of the kind involved in the transaction. *Id.* § 2-104. If a tissue market is created, a middleman may contract with a tissue source and then sell the tissue to a biotechnology company. Such a middleman may be considered a merchant. *See id.*; OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 77. Although the warranty may apply to middlemen, it would not apply to the actual tissue source because sources would not generally be in the business of selling tissue.

In contrast, the warranty of fitness, applies not only to merchants, but also to occasional sellers. U.C.C. § 2-315 comment 4. Consequently, this warranty may apply to the tissue source. Upon learning of the prospect of commercial gain, a tissue source may not disclose certain medical or family history which would reveal that the tissue was not suitable for the buyer's purpose. *See* OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 104. If the tissue's derivative products cause injury, the tissue source may be held strictly liable.

Finally, under the U.C.C., specific performance is a possible remedy if goods are unique

*b. contract enforceability pitfalls*

When drafting contracts with tissue sources, biotechnology companies should be aware of potential problems in enforcing these contracts. Contracts may be subject to claims of unconscionability or rescission. Both doctrines are somewhat related,<sup>300</sup> but apply in slightly different contexts. Unconscionability is used as a defense to the enforcement of a contract, or to its unconscionable terms.<sup>301</sup> Therefore, problems arise before the transaction occurs. Rescission issues apply to situations where a party wants to avoid an initially valid contract.<sup>302</sup> A tissue source who has already relinquished his or her tissue may attempt to rescind the contract and make a claim under quasi-contract.<sup>303</sup> Damages in quasi-contract are measured as the reasonable value of the benefit received.<sup>304</sup> Under quasi-contract, tissue sources may be able to recover profits derived from their tissue.<sup>305</sup>

*i. unconscionability*

Section 2-302 of the U.C.C. covers unconscionability.<sup>306</sup> Although

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or where monetary damages are inadequate. U.C.C. § 2-716(1) (1989). Since the tissue involved would be unique and the profit potential highly speculative, specific performance should be an appropriate remedy for biotechnology companies to compel performance of a contract. At least one court, however, refused to force a person to donate bone marrow, even though he had initially agreed. *McFall v. Shrimp*, Case No. 78-17711 (Pa. filed July 26, 1978) ("forcible extraction of living body tissues causes revulsion to the judicial mind"). A court's repugnance to forced donations may apply with equal force to a repudiated contract for tissue. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 77.

300. To avoid a contract obligation due to mistake, there must be a showing that enforcing the contract would be "unconscionable." See, e.g., *Boise Junior College Dist. v. Matfeffs Constr. Co.*, 92 Idaho 757, 450 P.2d 604 (1969) (enforcement of contract pursuant to terms of bid would be unconscionable because contractor mistakenly failed to include sub-bid).

301. D. DOBBS, *REMEDIES* § 10.7 (1973).

302. G. PALMER, *MISTAKE AND UNJUST ENRICHMENT* 13 (1962) [hereinafter G. PALMER, *MISTAKE*].

303. *Id.* at 38. Quasi-contract refers to an implied-in-law contract that requires restitution to the plaintiff of some benefit that the defendant has received, but in equity and good conscience belongs to the plaintiff. D. DOBBS, *supra* note 301, § 4.2.

304. *Kossian v. American Nat'l Ins. Co.*, 254 Cal. App. 2d 647, 651, 62 Cal. Rptr. 225, 227 (1967); *McCaffrey v. Cronin*, 140 Cal. App. 2d 528, 534-35, 295 P.2d 587, 591 (1956); *DeRossier v. Vierra*, 109 Cal. App. 2d 291, 294, 240 P.2d 660, 662 (1952); CAL. CIV. CODE § 1621 (West 1985); E. FARNSWORTH, *supra* note 121, § 2.20.

305. See 1 G. PALMER, *THE LAW OF RESTITUTION* § 2.12 (1978) [hereinafter G. PALMER, *RESTITUTION*].

306. U.C.C. § 2-302(1) (1989). The section provides in part:

If the court as a matter of law finds the contract or any clause of the contract to have been unconscionable at the time it was made the court may refuse to enforce the contract, or it may enforce the remainder of the contract without the unconscionable clause, or it may so limit the application of any unconscionable clause as to avoid any unconscionable result.



technically the U.C.C. only covers "transactions in goods,"<sup>307</sup> section 2-302 has been applied by analogy to many types of contracts.<sup>308</sup> Furthermore, the unconscionability section of the *Restatement (Second) of Contracts* is based on section 2-302 of the U.C.C.<sup>309</sup> Therefore, irrespective of whether the U.C.C. would technically apply to tissue contracts, the unconscionability terms embodied in section 2-302 should apply.

Commentators have often stated that the term "unconscionability" is incapable of definition.<sup>310</sup> The basic test for unconscionability is "whether, in the light of the general commercial background and commercial needs of the particular trade or case, the clauses involved are so one-sided as to be unconscionable under the circumstances existing at the time of the making of the contract."<sup>311</sup> Unconscionability can be established without showing fraud, serious misconduct, misrepresentation, duress or undue influence.<sup>312</sup>

A potential problem with tissue right contracts may be that a source may decide that the initially agreed-upon consideration is inadequate. This may result if the source at the time of entering into the contract was not fully aware of the tissue's potential value. Traditionally, inadequacy of consideration alone was not grounds for granting equitable relief unless the inadequacy is such that it "shocks the conscience" of the court.<sup>313</sup>

Although inadequacy of consideration alone is generally not enough

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*Id.*

307. *Id.* § 2-102.

308. Section 1670.5 of the California Civil Code, which embodies section 2-302 of the U.C.C., applies to contracts in general and is not limited to sale of goods. *See* CAL. CIV. CODE § 1670.5 (West 1985); *see also* *Graham v. Scissor-Tail, Inc.*, 28 Cal. 3d 807, 623 P.2d 165, 171 Cal. Rptr. 604 (1981) (contract to promote concert tour); *Zapatha v. Dairy Mart, Inc.*, 381 Mass. 284, 408 N.E.2d 1370 (1980) (franchise agreement); *Ellsworth Dobbs, Inc. v. Johnson*, 50 N.J. 528, 236 A.2d 843 (1967) (real estate brokerage contract).

309. RESTATEMENT (SECOND) OF CONTRACTS § 208 reporter's note (1981).

310. *See* D. DOBBS, *supra* note 301, § 10.7; *see also* E. FARNSWORTH, *supra* note 121, § 4.28 (Professor Farnsworth comments that term's incapability of precise definition is a source of both strength and weakness).

311. U.C.C. § 2-302 comment 1.

312. *See* D. DOBBS, *supra* note 301, § 10.7; E. FARNSWORTH, *supra* note 121, § 4.27; 4 J. POMEROY, A TREATISE ON EQUITY JURISPRUDENCE AS ADMINISTERED IN THE UNITED STATES OF AMERICA § 1405a (5th ed. 1941).

313. *See* *Coles v. Trecothick*, 32 Eng. Rep. 592, 597 (1804). In one case, a twenty percent interest in property was given in return for a total consideration of \$12,225. *Marks v. Gates*, 154 F. 481, 483 (9th Cir. 1907). When the property acquired ultimately was worth over \$750,000, the court denied enforcement of the contract because the inadequacy of consideration was "so gross as to render the contract unconscionable." *Id.* at 483. Similarly, if a source promises to grant a company the rights to his or her tissue for consideration which is substantially less than its commercial value, the source may assert that the contract is unconscionable.

to make a contract unconscionable, at least one court has recognized that unconscionability includes "an absence of meaningful choice on the part of one of the parties . . . [and] unreasonably favorable [contract terms] to the other party."<sup>314</sup> When a person lacks education he or she is not afforded an opportunity to understand the contract terms and therefore make a "meaningful choice."<sup>315</sup> A tissue source will almost always lack the necessary education to make a meaningful decision since the technology involved in transforming tissue into commercial products is extremely sophisticated.<sup>316</sup> Furthermore, in a majority of cases, the tissue is valuable because the patient is suffering from a disease such as cancer. Often the tissue source will be dying and will require immediate surgery. Consequently, tissue sources may argue their lack of knowledge of sophisticated biotechnology coupled with time constraints when they made their decision created an "absence of meaningful choice" that resulted in "unreasonably favorable" contract terms for the company.

In determining whether a contract is unconscionable the relationship between the parties is also significant. The confidential relationship between sister and brother coupled with the gross inadequacy of price constituted unconscionability for a land sale contract.<sup>317</sup> Similarly, a court may emphasize the fiduciary relationship between a doctor and patient. Since the biotechnology companies are often joint venturers with the doctors, this relationship can also make biotechnology companies liable.<sup>318</sup>

A biotechnology company may defend itself from an unconscionability claim by asserting that the fairness of the contract is to be judged at the time the contract was made.<sup>319</sup> It may argue that the value of the tissue was determined fairly at the time the contract was made, and therefore subsequent developments are irrelevant. Even though courts have rejected this argument,<sup>320</sup> a company would have an opportunity to

314. *Williams v. Walker Thomas Furniture Co.*, 350 F.2d 445, 449 (D.C. Cir. 1965) (retail installment sales contract which reserved right to repossess all items ever purchased from seller for which buyer still owed money). The terms "substantive unconscionability" and "procedural unconscionability" have been used to refer to "unreasonably favorable" contract terms and "absence of meaningful choice" in the bargaining process, respectively. See Leff, *Unconscionability and the Code—The Emperor's New Clause*, 115 U. PA. L. REV. 485 (1967).

315. *Williams*, 350 F.2d at 449.

316. See *supra* notes 39-93 and accompanying text.

317. *Jackson v. Seymour*, 193 Va. 735, 739, 71 S.E.2d 181, 184 (1952).

318. See *Moore*, 51 Cal. 3d at 133-34, 793 P.2d at 487-88, 271 Cal. Rptr. at 154-55.

319. U.C.C. § 2-302(1); see also *Bradford v. Plains Cotton Coop. Ass'n*, 539 F.2d 1249, 1255 (10th Cir.) ("subsequent increase in price did not make contract unconscionable"), *cert. denied*, 429 U.S. 1042 (1976).

320. See, e.g., *Industrialease Automated & Scientific Equip. Corp. v. R.M.E. Enters.*, 58

present evidence as to its commercial setting, purpose and effect.<sup>321</sup> A biotechnology company should stress that the initially agreed-upon consideration is not unfair in light of the labor, investment costs and assumption of risk which it incurred. Furthermore, such a company should emphasize that the great public interest in developing new therapeutic products is a significant factor against rendering the contract unconscionable.

## ii. rescission

Another related contractual problem is whether a source could rescind an executed tissue contract and sue in quasi-contract.<sup>322</sup> There are several theories upon which a court may grant rescission of a contract in this context.<sup>323</sup> When a contracting party has knowledge of facts affecting the value of the transaction and does not disclose those facts to the innocent party, the innocent party may be able to rescind the transaction.<sup>324</sup>

Because of the fiduciary relationship between a patient and doctor,<sup>325</sup> it may not be difficult for a tissue source to establish grounds for rescission. Even when no fiduciary relationship exists, however, a party may be able to rescind a contract if one party made an innocent misrepresentation to the other or if the parties entered into the contract under

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A.D.2d 482, 396 N.Y.S.2d 427 (1977) ("we cannot divorce entirely the events which occur later").

321. U.C.C. § 2-302(2). The subsection states: "When it is claimed or appears to the court that the contract or any clause thereof may be unconscionable the parties shall be afforded a reasonable opportunity to present evidence as to its commercial setting, purpose and effect to aid the court in making the determination." *Id.*

322. See *Richardson Lumber Co. v. Hoey*, 219 Mich. 643, 189 N.W. 923 (1922); E. FARNSWORTH, *supra* note 121, § 2.20; G. PALMER, MISTAKE, *supra* note 302, at 131; 2 G. PALMER, RESTITUTION, *supra* note 305, § 11.5(a). See *supra* notes 303-05 and accompanying text for a discussion of quasi-contract and recoverable damages.

323. See CAL. CIV. CODE § 1689(b)(1) (West 1985). A contract may be rescinded if consent to the contract was given due to mistake, duress, menace, fraud, or undue influence. *Id.* See also the *Restatement (Second) of Contracts* which provides that contracts are voidable on the grounds of mistake, misrepresentation, abuse of a fiduciary relationship, duress, and undue influence. *RESTATEMENT (SECOND) OF CONTRACTS* §§ 153, 164, 173, 175, 177 (1981).

324. See, e.g., *Roberts v. Sears, Roebuck & Co.*, 573 F.2d 976 (7th Cir.) (plaintiff established grounds for rescission of contract assigning patent rights), *cert. denied*, 439 U.S. 860 (1978); *Clauser v. Taylor*, 44 Cal. App. 2d 453, 112 P.2d 661 (1941) (plaintiff established grounds for rescission of contract for real property).

325. See *Moore*, 51 Cal. 3d at 131-32, 793 P.2d at 485, 271 Cal. Rptr. at 157. See *supra* note 149 for an explanation of fiduciary duty. Biotechnology companies involved in joint ventures with doctors, when negotiating tissue contracts, may also be held to the same duty as doctors. See *Moore*, 51 Cal. 3d at 133-34, 793 P.2d at 486-87, 271 Cal. Rptr. at 153-54.

some mistaken belief.<sup>326</sup>

(a) *breach of fiduciary duty*

A party may rescind a contract due to a breach of a fiduciary or confidential relationship<sup>327</sup> that induces reliance to the prejudice of that party.<sup>328</sup> When a fiduciary relationship exists, and there is gross inadequacy in value of consideration, a court determining the validity of a transaction views it with "the most scrutinizing jealousy."<sup>329</sup> Furthermore, when a fiduciary relationship exists the burden of proof is on the party gaining the advantage to show that he or she acted with fairness.<sup>330</sup> This is the case even though the fiduciary did not have a fraudulent intent.<sup>331</sup> Therefore, it is possible for a party to make a statement which, in

326. See *infra* notes 334-58 and accompanying text for a discussion of establishing grounds for rescission in the absence of a breach of a fiduciary duty.

327. "'A confidential relation exists between two persons when one has gained the confidence of the other and purports to act or advise with the other's interest in mind. A confidential relation may exist [even though] there is no fiduciary relation . . .'" *Vai v. Bank of America*, 56 Cal. 2d 329, 337-38, 364 P.2d 247, 252, 15 Cal. Rptr. 71, 76 (1961) (quoting RESTATEMENT (SECOND) OF TRUSTS § 2 comment b (1959)).

328. *Gold v. Los Angeles Democratic League*, 49 Cal. App. 3d 365, 373, 122 Cal. Rptr. 732, 738 (1975); *Odorizzi v. Bloomfield School Dist.*, 246 Cal. App. 2d 123, 129, 54 Cal. Rptr. 533, 539 (1966). In California such an action would be in constructive fraud. See CAL. CIV. CODE § 1573 (West 1982). The elements of constructive fraud are (1) breach of a duty, (2) without an actually fraudulent intent, (3) which allows a person at fault to gain an unfair advantage, (4) by misleading a victim to his or her prejudice or anyone claiming under the victim. *Id.*

329. *Herbert v. Lankershim*, 9 Cal. 2d 409, 426, 71 P.2d 220, 228 (1937).

330. *Boyd v. Bevilacqua*, 247 Cal. App. 2d 272, 290, 55 Cal. Rptr. 610, 622 (1966).

331. *In re Arbuckle*, 98 Cal. App. 2d 562, 568, 220 P.2d 950, 955 (1950); see also *Agair, Inc. v. Shaeffer*, 232 Cal. App. 2d 513, 517, 42 Cal. Rptr. 883, 886 (1965); *Efron v. Kalmanovitz*, 226 Cal. App. 2d 546, 559-60, 38 Cal. Rptr. 148, 157 (1964); CAL. CIV. CODE § 1573.

In *Roberts v. Sears, Roebuck & Co.*, the plaintiff was an eighteen year old Sears sales clerk who, during his off hours, designed and constructed a "quick-release" ratchet wrench. 573 F.2d 976, 978 (7th Cir.), *cert. denied*, 439 U.S. 860 (1978). The plaintiff submitted a prototype of his invention to Sears. *Id.* Sears took steps to ascertain that the design was useful and that the invention was, in fact, valuable. *Id.* at 978-79. Sears' lawyer contacted the plaintiff and told him that based on his invention's limited patentability and cost of production, the invention was only worth \$10,000. *Id.* at 979. Based on these representations, plaintiff entered into a contract assigning all of his rights in the invention to Sears for a royalty of two cents per unit up to a maximum of \$10,000. *Id.* Nine months after the assignment, Sears sold over a half-million wrenches and paid plaintiff his maximum royalty. *Id.* at 980. Within ten years, Sears had sold over nineteen million wrenches and realized millions of dollars in profits. *Id.*

Four years after the assignment of his rights, the plaintiff sued Sears in an attempt to rescind the contract. *Id.* at 980. The Seventh Circuit Court of Appeals, finding that a confidential relationship existed between the parties, held that Sears breached that relationship by failing to disclose vital information concerning the product's value. *Id.* at 980, 984. In misrepresenting the invention's value, Sears was found to have overestimated the cost of production to the plaintiff. See *id.* at 979-80. The court upheld the district court's finding that Sears

view of the known facts, is warranted, but due to the relationship between the parties, may establish grounds for rescission when the statement turns out to be false.

Based on this theory, a tissue source may seek to rescind a tissue contract by arguing that the consideration was grossly inadequate. A

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committed negligent misrepresentation concerning the invention's value, salability and public acceptance. *Id.* at 986.

The facts of *Roberts* may be analogous to factual situations surrounding tissue contracts. Assume a patient would go to a doctor concerning possible surgery. The doctor performs pre-surgery tests on the patient's tissue and determines that the tissue is unique and commercially valuable. *See, e.g., Moore*, 51 Cal. 3d at 125-26, 793 P.2d at 481, 271 Cal. Rptr. at 198. This is analogous to *Roberts*, whereby Sears determined that the plaintiff's wrench was valuable. The doctor may currently be involved in a joint venture with a biotechnology company and may then convey this information to his or her partner. The parties may decide to contract with the patient for the rights to the tissue.

During negotiations with a tissue source, the biotechnology company or doctor may underestimate or fail to disclose information relating to the potential therapeutic applications and market potential of products derived from the tissue. Full information regarding the tissue's potential value may be impossible to convey since the prospect is likely to be vague and speculative at the time the tissue sample is obtained. *See OWNERSHIP OF HUMAN TISSUE, supra* note 4, at 104. The source may be able to rescind the contract if he or she discovers, years after transferring tissue rights to the company, that the exchange in value was inadequate. For example, if a source assigns his or her tissue rights under a royalty agreement which is limited by a maximum amount, that contract may be rescinded if there was any material misrepresentations as to the tissue's potential value. Even if a royalty agreement is not limited by a maximum amount, a source may attempt to seek rescission if after the assignment the source concludes that the tissue was worth a greater percentage than represented by the biotechnology company. This can occur, if after the assignment, it becomes apparent that the biotechnology company did not have to expend as much skill and labor in transforming the tissue into commercial products as it represented during negotiations. In *Moore*, the plaintiff claims that defendants did not need to invent or employ any extraordinary scientific methodology in order to develop a cell line from his tissue and that the products derived therefrom were more a result of his tissue's unique quality. *Moore v. Regents of the Univ. of Cal.*, 215 Cal. App. 3d 709, 716, 249 Cal. Rptr. 494, 501 (1988), *aff'd in part and rev'd in part*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990). The fact that a fiduciary relationship existed, combined with other factors, such as the overestimation of research, development and production costs, may establish grounds for rescission, as the overestimation of production costs did in *Roberts*. *Roberts*, 573 F.2d at 979-80. This can occur even though the biotechnology company believed its estimates to be true. *See, e.g., Hayter v. Fulmor*, 92 Cal. App. 2d 392, 206 P.2d 1101 (1949) (person may make misrepresentation even though that person believes representation to be true).

Even if the biotechnology company claims that it acted in good faith, it would have the burden of proving that the applications and market potential of the tissue were unforeseeable at the time, and therefore, its projections were accurate at the time of disclosure. *See supra* note 330 and accompanying text. For example, in *Roberts*, the defendant's argument that part of the success of the "quick-release" ratchet was due to an unforeseeable boom in do-it-yourself repairs was unsuccessful. *See Roberts*, 573 F.2d at 980. This can be an onerous burden due to the lengthy and complex process of pharmaceutical product development. *See supra* notes 167-70 and accompanying text for a discussion of the industrial product development process. Consequently, estimating costs and predicting unforecasted additional therapeutic applications is extremely difficult.

biotechnology company may defend against such a suit, however, by arguing that its knowledge and skill resulted in the profitability of the tissue.<sup>332</sup> Conversely, a tissue source does not contribute any ideas or skill, nor perform any work and cannot patent his own tissue.<sup>333</sup> It is merely by chance that a source's diseased tissue, which requires surgical removal, has unique capabilities and, therefore, has potential value. While inside the source, tissue is not only valueless, but is life threatening as well. Furthermore, even after it is removed the tissue is of no value to the source absent the knowledge, skill and labor of scientists.

(b) *innocent misrepresentation and mistake*

Alternative theories under which a tissue source may seek rescission include innocent misrepresentation<sup>334</sup> or mistake.<sup>335</sup> These doctrines are related;<sup>336</sup> however, under innocent misrepresentation a party must make a false statement, whereas under mistake the defendant need not have performed any misleading acts.<sup>337</sup> It is more difficult to establish

332. In *Roberts*, however, the jury rejected the defendant's argument that the success of the wrenches was a function of advertising. See *Roberts*, 573 F.2d at 980. *Roberts* is distinguishable from cases involving assignment of tissue rights, however, because in *Roberts* the plaintiff conceived the idea and designed and constructed the subject matter of the invention. See *Roberts*, 573 F.2d at 978.

333. Patentable subject matter requires human intervention. See *supra* note 213.

334. See *Barrer v. Women's Nat'l Bank*, 761 F.2d 752, 757 (D.C. Cir. 1985); *Reliance Fin. Corp. v. Miller*, 557 F.2d 674, 680 (9th Cir. 1977); *Cousineau v. Walker*, 613 P.2d 608, 610 (Alaska 1980); *Crocker-Anglo Nat'l Bank v. Kuchman*, 224 Cal. App. 2d 490, 495, 36 Cal. Rptr. 806, 809 (1964). The essential elements of innocent misrepresentation are (1) a false statement, (2) concerning a material fact, (3) that was relied upon (4) justifiably by the party seeking rescission of a contract. *Barrer*, 761 F.2d at 758; *Cousineau*, 613 P.2d at 612; RESTATEMENT (SECOND) OF CONTRACTS § 164(1) & comment a.

335. *Reliance Fin. Corp.*, 557 F.2d at 679; *Wood v. Kalbaugh*, 39 Cal. App. 3d 926, 930, 114 Cal. Rptr. 673, 675 (1974); *Worsham v. Pierce*, 251 So. 2d 896, 898 (Fla. Dist. Ct. App. 1971); *Lenawee County Bd. of Health v. Messerly*, 417 Mich. 17, 26, 331 N.W.2d 203, 208 (1982). The essential elements of mistake of fact are (1) a mistake (2) that goes to a basic assumption on which the contract was made (3) that has a material effect on the agreed exchange of performances and (4) is not one of which the party bears the risk. *Lenawee*, 417 Mich. at 29-30, 331 N.W.2d at 209-10; RESTATEMENT (SECOND) OF CONTRACTS § 152.

336. Innocent misrepresentation is a type of mistake. *Crocker-Anglo Nat'l Bank*, 224 Cal. App. 2d at 495-96, 36 Cal. Rptr. at 809.

337. See *supra* notes 334-35. It is unclear whether an innocent non-disclosure will qualify. Under the *Restatement*, a person's non-disclosure of a fact is not treated as a misrepresentation when it is not known that disclosure (1) is necessary to prevent a previous assertion from being a misrepresentation or material, (2) would correct a mistake of the other party as to a basic assumption and non-disclosure amounts to failure to act in good faith and in accordance with reasonable standards of fair dealing, (3) would correct a mistake as to the contents or effect of a writing, or (4) where the other person is entitled to know the fact because of the existence of a confidential relationship. RESTATEMENT (SECOND) OF CONTRACTS § 161. Consequently, following the *Restatement* if a person is totally innocent as to any cure which disclosure could

grounds for rescission under a mistake theory than under an innocent misrepresentation theory.<sup>338</sup>

### (1) innocent misrepresentation

Under an innocent misrepresentation theory, a contract may be rescinded if the representation was "material,"<sup>339</sup> even though it was made innocently.<sup>340</sup> The rationale for the rule is that one should not benefit at the expense of another even though the false statement was made under an honest belief of its truth.<sup>341</sup>

Under the standards of materiality, statements relating to the tissue's value should be considered material since a reasonable person would attach importance to such a consideration in deciding whether to grant consent. Innocent misrepresentations relating to the value of land and stocks have been held to be material.<sup>342</sup> By analogy, should a tissue source assent to a particular compensation agreement under representations that the tissue was of a particular value, those representations should be considered material if its actual value turns out to be significantly more.

For a court to grant a source's request for rescission of a tissue contract based on innocent misrepresentation, that source must also show that the misrepresentation acted as an inducement.<sup>343</sup> Inducement is shown through actual reliance;<sup>344</sup> and the source must also establish that the reliance was justified.<sup>345</sup>

A biotechnology company may argue that a source should investi-

accomplish and is not in a confidential relationship with the other party, then non-disclosure of a known fact will not qualify as a false statement.

338. *Reliance Fin. Corp.*, 557 F.2d at 680.

339. A key requirement in establishing innocent misrepresentation is that the false statement is material. A misrepresentation is material if it would likely induce a reasonable person to assent to a transaction. *See id.*; *Wood*, 39 Cal. App. 3d at 930, 114 Cal. Rptr. at 676; RESTATEMENT (SECOND) OF CONTRACTS § 162 comment c.

340. *Barrer*, 761 F.2d at 757. It has been stated that "the good faith of the party who procures the assent of another to the making of a contract by material misrepresentations is of no moment." *Crocker-Anglo Nat'l Bank*, 224 Cal. App. 2d at 497, 36 Cal. Rptr. at 810 (quoting *Scott v. Delta Land & Water Co.*, 57 Cal. App. 320, 328, 207 P. 389, 392 (1922)).

341. *See Barrer*, 761 F.2d at 757; 1 G. PALMER, RESTITUTION, *supra* note 305, § 3.19.

342. *See Cousineau*, 613 P.2d at 612 (misrepresentation as to the amount of gravel on property which reduced its value); *Crocker-Anglo Nat'l Bank*, 224 Cal. App. 3d at 494-95, 36 Cal. Rptr. at 809 (misrepresentation as to the value of stock).

343. *See Barrer*, 761 F.2d at 759; *Reliance Fin. Corp.*, 557 F.2d at 680; *Cousineau*, 613 P.2d at 612.

344. *Barrer*, 761 F.2d at 759. However, comment a of section 167 of the *Restatement* states that this reliance need not be the sole or predominant factor influencing the decision. RESTATEMENT (SECOND) OF CONTRACTS § 167 comment a.

345. *Barrer*, 761 F.2d at 758; *see also supra* note 334.

gate, independently, facts concerning tissue value.<sup>346</sup> This argument would fail, however, because a biotechnology company has special skill in an area which is necessary to the formation of the tissue source's sound judgment. Therefore, the source's reliance on the company's assertion with respect to the potential value of the tissue would be justified.<sup>347</sup>

## (2) mistake

A tissue source may also rescind a contract under the theory of mistake. If a source enters into a contract with a biotechnology company, transfers the tissue to the company, and later claims that there was a "belief that was not in accord with the facts,"<sup>348</sup> the contract may be rescinded under the mistake doctrine.<sup>349</sup> Mistake consists of unconscious ignorance or forgetfulness of a material fact to the contract, or a belief in the past or present existence of a material thing which does not, or has not, existed.<sup>350</sup> In order to allow for rescission, the mistake must also go

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346. However, if a tissue source acts in good faith and according to reasonable standards of fair dealing, failure to discover facts does not make reliance unjustified. *Barber*, 761 F.2d at 759 (referring to RESTATEMENT (SECOND) OF CONTRACTS § 172 (1981)). Section 169 of the *Restatement (Second) of Contracts* may be even more applicable to situations involving tissue contracts. See RESTATEMENT (SECOND) OF CONTRACTS § 169 (applies when a party to the contract has a special skill in the area).

347. See RESTATEMENT (SECOND) OF CONTRACTS § 169 comment d (when a person has special skill in an area which is necessary to the formation of sound judgment, reliance on his or her assertion with respect to the subject matter is justified).

348. *Id.* § 151.

349. See *Hoey*, 219 Mich. at 649-50, 189 N.W. at 925; see also *supra* note 335.

350. CAL. CIV. CODE § 1577 (West 1982). A distinction is often made between mutual and unilateral mistake. A mistake is mutual if the mistaken assumption is shared by both parties. D. DOBBS, *supra* note 301, § 11.3; E. FARNSWORTH, *supra* note 121, § 9.3; G. PALMER, MISTAKE, *supra* note 302, at 69. If only one party was mistaken as to a given fact underlying the transaction, the mistake is unilateral. D. DOBBS, *supra* note 301, § 11.4; E. FARNSWORTH, *supra* note 121, § 9.3; G. PALMER, MISTAKE, *supra* note 302, at 62. Professor Palmer has declared that "[a]lthough it is commonly said that mutual mistake is a prerequisite of rescission, this is not the case." 2 G. PALMER, RESTITUTION, *supra* note 305, § 12.1. In California, neither section 1577 of the Civil Code nor section 1689, which govern mistake and rescission, require that the mistake be mutual. See CAL. CIV. CODE §§ 1577, 1689. Many cases in California have granted rescission for a unilateral mistake. *E.g.*, *Architects & Contractors Estimating Serv., Inc. v. Smith*, 164 Cal. App. 3d 1001, 211 Cal. Rptr. 45 (1985); *Brunzell Constr. Co. v. G.J. Weisbrod, Inc.*, 134 Cal. App. 2d 278, 285 P.2d 989 (1955); *Forest Lawn Memorial Park Ass'n v. De Jarnette*, 79 Cal. App. 601, 250 P. 581 (1926). Also, the *Restatement (Second) of Contracts* changed its previous position and provides for rescission based on unilateral mistake or when enforcement of the contract would be unconscionable. RESTATEMENT (SECOND) OF CONTRACTS § 153(a). Under the previous *Restatement of Contracts*, unilateral mistake allowed for rescission of a contract only if the other party had reason to know of the mistake or caused the mistake. RESTATEMENT OF CONTRACTS § 12 (1937). Professor Palmer



to a basic assumption upon which the contract was made.<sup>351</sup> Once the contract is rescinded,<sup>352</sup> a source may have a claim in quasi-contract.<sup>353</sup>

Researchers and biotechnology companies have two defenses to claims of mistake. First, mistakes as to quality or value, or mistakes about characteristics of the subject matter of the contract may not be compensable.<sup>354</sup> In such cases courts rule that a contract can be rescinded only if there was a mistake in identity.<sup>355</sup> Second, researchers

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advocates that most cases concerning mistake can be dealt with without using the terms. G. PALMER, *MISTAKE*, *supra* note 302, at 67.

351. *Lenawee*, 417 Mich. at 29, 331 N.W.2d at 209; RESTATEMENT (SECOND) OF CONTRACTS § 152.

352. Professor Palmer states that two elements are of central importance in determining whether a mistake is sufficiently basic to warrant rescission: (1) the way the mistake influenced the formation of the contract, especially the extent to which the mistake produced a discrepancy between the actual and the supposed subject matter of the contract; and (2) the effect of the mistake on the economic equivalence of the agreed exchange. 2 G. PALMER, *RESTITUTION*, *supra* note 305, § 12.2. Palmer suggests that the effect on the economic equivalent of exchange is important because a reasonable degree of equivalence is expected in business transactions. *Id.* Furthermore, Palmer declares that prevention of unjust enrichment is a principal reason for giving relief for mistake. *Id.* (citing as examples *Marker v. United States*, 43 F.2d 457 (D.C. Idaho 1930); *Worsham v. Pierce*, 251 So. 2d 896 (Fla. App. 1971)). In the famous case, *Sherwood v. Walker*, the plaintiff, a cow breeder, contracted to sell a purebred cow at a price which was based on the cow's value for beef. 66 Mich. 568, 576, 33 N.W. 919, 923 (1887). The parties assumed that the cow was barren and could no longer reproduce. *Id.* However, it turned out that the cow was pregnant at the time that the contract was made and worth ten times more than the agreed price. *Id.* The court held that the plaintiff could avoid the sale under the theory of mistake. The parties had reached a specific agreement at a specified price, without any misleading acts by the defendant, and the seller was allowed to rescind the contract because the values of the exchange were grossly disproportionate. See *Sherwood*, 66 Mich. at 577-78, 33 N.W. at 923-24.

Applying the facts of *Sherwood* to a tissue contract, if a source agrees to transfer the rights to his or her tissue under a particular compensation agreement and the parties were mistaken as to the actual value of the tissue, then such a mistake may be deemed to go to a basic assumption. See *Lenawee*, 417 Mich. at 29, 33 N.W.2d at 209. Such a mistake can occur if the tissue's cells produce significantly more therapeutic proteins than anticipated. Consequently, if the exchange in value was grossly disproportionate, a source may rescind the contract.

A defendant in a suit for rescission of a tissue contract may attempt to distinguish *Sherwood* by arguing that it was subsequent events, such as research and development, that gave the tissue its increased value and that such value did not exist at the time the contract was made. A court would then have to determine whether the tissue's newly discovered value was inherent at the time of contracting or whether its value was solely due to biotechnological development. In such a case the court should look at whether the tissue is truly unique in the sense that only a small percentage of the population has tissue with such capabilities, or whether it is the fact of discovery which was unique. See *supra* notes 57-62 and accompanying text for a discussion concerning the rarity of tissue. If the tissue itself is not truly unique then its subsequent value may be seen as being more the result of biotechnology than the tissue itself.

353. See *supra* note 322.

354. 2 G. PALMER, *RESTITUTION*, *supra* note 305, § 12.17.

355. *Id.* For example, in *Wood v. Boynton*, the plaintiff sold a stone for one dollar. 64 Wis.

and biotechnology companies may argue that the tissue source assumed the risk of uncertainty.<sup>356</sup> A seller is said to assume the risk of mistake where, for example, after the sale of land it is discovered that the land contains valuable mineral deposits.<sup>357</sup> The defendant in a tissue contract dispute can argue that the source assumed the risk of a mistake in the tissue's value. In tissue contracts, however, the hidden potential value of

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265, 268, 25 N.W. 42, 43 (1885). Both parties believed that the stone was topaz or some other stone of nominal value; however, the stone was actually an uncut diamond worth \$700. *Id.* The plaintiff was not allowed to rescind the contract because there was no mistake as to identity. *Id.* at 271, 25 N.W. at 44.

Rescission was also denied on the same grounds in *Costello v. Sykes*, where stock was sold at \$136 a share when, unknown to the parties, due to a coverup of an embezzlement in the books the stock was only worth \$60 a share. 143 Minn. 109, 110-11, 172 N.W. 907, 908 (1919). The court stated that "a mistake relating merely to the attributes, quality, or value of the subject of a sale does not warrant a rescission." *Id.* at 111, 172 N.W. at 908. Defendants in tissue contract disputes could argue, using these cases as support, that a mistake in value should not allow for rescission based on mistake.

Although the defendant in a tissue contract rescission case can argue that the mistake was one of value and not identity, such an argument may not succeed. The *Restatement of Contracts* used the facts of *Wood* as an example illustrating when a court should grant, not deny, rescission. RESTATEMENT OF CONTRACTS § 503 comment a, illustration 3 (1932). Furthermore, Professor Palmer suggests that the results in previous cases where rescission was denied would be the opposite today because of the recognition of the principle of avoiding unjust enrichment. See 2 G. PALMER, *RESTITUTION*, *supra* note 305, § 12.17. In these instances, unjust enrichment connotes that the transaction lacked economic equivalence. *Id.* § 12.2. Palmer also notes, however, that even today there is often little or no reference to an unjust factor. *Id.* (citing as example *Reliance Fin. Corp. v. Miller*, 557 F.2d 674 (9th Cir. 1977)). In many cases where there would be unjust enrichment, courts stretch to characterize the mistake as one in identity. *Id.* § 12.17. For example, in *Sherwood* it was held that because the cow was pregnant it "was not in fact the animal" which was intended to be sold. *Id.* (citing *Sherwood v. Walker*, 66 Mich. 568, 33 N.W. 919 (1887)). Ultimately, the court in *Lenawee* expressly ruled that the *Sherwood* holding, with respect to the material or the collateral nature of a mistake, is limited to its facts because such a distinction only impedes the analysis. *Lenawee*, 417 Mich. at 29, 331 N.W.2d at 209. Consequently, mere reliance on the fact that the mistake was only one of value may not prove successful.

356. See, e.g., *Nester v. Michigan Land & Iron Co.*, 69 Mich. 290, 37 N.W. 278 (1888) (timber sold at lump sum price, amount of timber was in controversy during negotiation, buyer held to have assumed risk of uncertainty). According to the *Restatement*:

A party bears the risk of a mistake when (a) the risk is allocated to him by agreement of the parties, or (b) he is aware, at the time the contract is made, that he has only limited knowledge with respect to the facts to which the mistake relates but treats his limited knowledge as sufficient, or (c) the risk is allocated to him by the court on the ground that it is reasonable in the circumstances to do so.

RESTATEMENT (SECOND) OF CONTRACTS § 154.

357. *Id.* § 154 comment a. Professor Palmer states that although putting the matter in terms of assumption of risk has appeal, that appeal is deceptive. 2 G. PALMER, *RESTITUTION*, *supra* note 305, § 12.5. "[A] decision that the risk on one party or the other is often merely another way of stating the conclusion." *Id.* Palmer believes that there should not be a relievable mistake because the matter was not the basis of the bargain. G. PALMER, *MISTAKE*, *supra* note 302, at 50. His opinion is influenced by the inherent uncertainty of the matter. *Id.*

the tissue is the basis of the bargain.<sup>358</sup>

### iii. summary of contract pitfalls

In summary, problems with tissue contracts may arise due to improper valuation because the subject matter is inherently uncertain and the knowledge of the parties may be incomplete.<sup>359</sup> Rescission of tissue contracts may be possible when there is a serious inequality in an agreed exchange of values. Courts consider the nature of the misrepresentation or mistake and surrounding circumstances—for example, whether there is a fiduciary relationship between the parties. In addition, courts will consider the nature in which a mistake interacts with the factor of unjust enrichment<sup>360</sup> or possibly unconscionability. Whether a court grants relief will often depend on policy considerations.<sup>361</sup> As a result, decisions in tissue contract cases could vary considerably.

## VII. PROPOSAL

Developing an appropriate solution to the problems raised by the commercial use of human tissue involves "complex policy decisions affecting all society."<sup>362</sup> As all of the justices advanced in *Moore v. Regents*

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358. The plaintiff, tissue source, may distinguish the mineral discovery case because the existence of minerals was totally unforeseen and therefore not the basis of the bargain. See *Lenawee*, 417 Mich. at 29, 331 N.W.2d at 209; G. PALMER, MISTAKE, *supra* note 302, at 50. In a tissue contract the tissue's potential value is the basis of the bargain. The defendant may rebut that, due to the complex nature of biotechnology, the potential value of the tissue is inherently uncertain, and therefore, the tissue source assumed the risk of a mistake. See *supra* notes 39-56 and accompanying text for a discussion of tissue culture technology.

This may lead to the issue of whether the parties' bargain included compensation for unforeseen therapeutic applications. In deciding this issue, an analogy can be drawn to personal injury release cases. In these cases, the injured party attempts to avoid a release by claiming the parties were mistaken as to the extent of the injuries. See, e.g., *Myers v. Fecker Co.*, 312 Minn. 469, 252 N.W.2d 595 (1977). To prevail, the plaintiff must show that the parties shared the basic assumption that the release did not include compensation for unknown injuries. *Id.* at 476, 252 N.W.2d at 600. Courts will look to the amount of the settlement compared to the magnitude of the known injuries to determine what was the basic assumption. See, e.g., *Reede v. Treat*, 62 Ill. App. 2d 120, 210 N.E.2d 833 (1965); *Boccarossa v. Watkins*, 112 R.I. 551, 313 A.2d 135 (1973). If the amount received in the settlement was close to the value for known injuries, it suggests that the release did not include compensation for unforeseen injuries and rescission may be granted. See *Reede*, 62 Ill. App. 2d at 132, 210 N.E.2d at 839. In deciding whether a source was compensated for unforeseen value a court may judge whether or not the payment received under the contract was close to the tissue potential value that was proposed at the time of the bargain.

359. See 2 G. PALMER, RESTITUTION, *supra* note 305, § 12.3.

360. *Id.* § 12.2.

361. *Id.* § 12.5.

362. *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 147, 793 P.2d 479, 496, 271 Cal. Rptr. 146, 163 (1990).

of the University of California,<sup>363</sup> the legislature should make such complex policy decisions because legislators have the ability to gather empirical evidence, solicit the advice of experts, and hold hearings.<sup>364</sup> Congress or a state legislature may decide that the right to informed consent does not provide adequate protection to the autonomy and privacy rights of patients.<sup>365</sup> The government may also decide that it cannot condone the windfalls researchers would receive if they did not compensate their tissue sources.<sup>366</sup>

There are several actions Congress or state legislatures may take, but any action must be consistent with governmental policies reflected in current federal patent laws.<sup>367</sup> Legislation may be enacted: (1) prohibiting commercialization of human tissue;<sup>368</sup> (2) allowing commercialization, but prohibiting compensation to tissue sources;<sup>369</sup> or (3) allowing both commercialization and compensation to tissue sources.<sup>370</sup>

Passing legislation prohibiting commercialization would be both a detriment to the public, since life-saving therapeutic products would not become available, and a detriment to the economy, since it would reduce investment activity in biotechnology. Any commercialization of human tissue should be accompanied by a system of compensation to tissue sources. Absent receipt of some compensation, tissue sources may be reluctant to consent to commercial use of their tissue. Consequently, any legislation enacted should allow both commercialization and compensation to sources.

A Uniform Tissue Source Compensation Act (the Proposed Act) should be enacted to allow commercialization of biotechnology products and compensate tissue sources, while avoiding the problems that would result if sources could freely negotiate tissue rights contracts. This compensation system would pay sources with unique tissue on a flat fee basis,<sup>371</sup> including the costs of surgery, regardless of whether subsequent research and development is successful. Once paid, sources would relinquish all present and future rights in their tissue. The Proposed Act

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363. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

364. *Id.* at 147, 793 P.2d at 493, 271 Cal. Rptr. at 163.

365. See *supra* notes 224-44 and accompanying text for a discussion of why the right to informed consent inadequately protects individuals' rights.

366. OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 124-25.

367. See *supra* notes 191-201 and accompanying text for a discussion of patent law policy.

368. See OWNERSHIP OF HUMAN TISSUE, *supra* note 4, at 15-19.

369. See *id.*

370. See *id.*

371. The fee should be somewhere between \$10,000 and \$20,000.

would also exempt tissue sources from any possible liability, such as strict products liability.

Flat fee compensation is a more appropriate system than awarding sources a fixed percentage of profits realized from the final product for several reasons.<sup>372</sup> First, since tissue sources do not have property rights in either their surgically removed tissue<sup>373</sup> or the resulting cell line,<sup>374</sup> it follows that sources should not share profits.<sup>375</sup> Second, it is contrary to patent law to allow sources, who do not contribute any ideas, skill or labor to product development, to share profits because they cannot be considered inventors.<sup>376</sup> Third, tissue sources should not share profits because it is the highly technical skill and labor of the scientist that transform the diseased tissue into patentable subject matter. Furthermore, sources do not share investment costs and risks associated with industrial product development.

The Proposed Act would reduce costs. Uniform compensation would eliminate the need for complex negotiations involving brokers and attorneys. Also, since sources are paid regardless of whether their tissue yields a commercial product, this approach minimizes record-keeping and eliminates the need for tracking.<sup>377</sup> Even if the tissue does not result in the production of a commercial product, the biotechnology company would still have derived useful research value from the tissue's use. Accordingly, the Proposed Act would minimize costs and delays in research and development.<sup>378</sup>

As a result of these benefits, the Proposed Act protects the interests of the tissue sources and biotechnology companies in other ways as well. The rights of sources are vindicated by compensation for their consent to commercial use of their tissue. The biotechnology industry's interest would be served because the system would allow companies to fix prod-

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372. One author, prior to the California Supreme Court's ruling in *Moore*, proposed legislation based on a fixed-rate of profit sharing. Danforth, *supra* note 274, at 199-200.

373. The sources are only being compensated for their consent, not their property.

374. *Moore*, 51 Cal. 3d at 135, 793 P.2d at 487, 271 Cal. Rptr. at 154. In addition to this legal distinction, the cells making up the patented cell line also are factually distinct from those taken from a source's body. This is because the cells that give rise to a continuous cell line undergo a genetic alteration called "transformation." R. FRESHNEY, *supra* note 39, at 9. The specific cells that ultimately gave rise to the cell line are not genetically the same as the source's and were not present initially in the original tissue sample. *Id.* For these reasons, as well, the patented cell line cannot be the source's property. *Moore*, 51 Cal. App. 3d at 141 & n.35, 793 P.2d at 492 & n.35, 271 Cal. Rptr. at 159 & n.35.

375. See Shapiro, *supra* note 241, at 7, col. 1.

376. See *supra* notes 216-18 and accompanying text.

377. See *supra* notes 269-71 and accompanying text.

378. See *supra* notes 266-73 and accompanying text.

uct development costs without having to share the profits, and without the threat of contract enforceability problems.<sup>379</sup>

Finally, the Proposed Act would advance public interest by eliminating delays and disincentives to research and development of valuable therapeutic products. Additionally, because the system would minimize transaction costs, the cost of the commercial products to the public would not be prohibitively high. Thus, the Proposed Act would assure availability of biotechnology products to the general public.

Although the source's contribution is necessary to product development, flat fee compensation is fair because the tissue has value only due to a chance abnormality. The source benefits from the surgery. It is the work of scientists that transforms the tissue into valuable therapeutic products. Flat fee compensation ensures payment to sources regardless of the commercial success of the project.<sup>380</sup> The tissue source's relative contribution, unique tissue discovered by chance, does not merit a share of the profits. The Proposed Act will compensate tissue sources fairly, particularly in light of the tremendous public interest involved in making the therapeutic products available and affordable. Any "personal sacrifice involved is part of the necessary contribution of the individual to the welfare of the public."<sup>381</sup>

## VIII. CONCLUSION

The development of powerful biotechnology techniques have made it possible to transform diseased human tissue into extremely valuable commercial products. These products are valuable to both the biotechnology industry, in the form of profits, and the public, in the form of therapeutic products. Recognition of the right to informed consent to commercial use of a patient's surgically removed tissue does not advance all of the interests involved and may even force entities to contract for these rights.

If compensation is disproportionate to the exchange in tissue value, under current laws, contract enforceability problems may arise. Companies will be discouraged from engaging in human tissue product develop-

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379. See *supra* notes 300-61 and accompanying text for a discussion of contract enforceability problems.

380. This is advantageous since the potential success of any product development project is highly speculative. See *supra* note 167. Therefore, under a licensing agreement, whereby patients shared profits, a source most likely would either end up with nothing or, even if product development was successful, profits might not be realized until after the death of the source. See *supra* note 168 and accompanying text for a discussion of the length of time involved in the industrial product development process.

381. *Blair v. United States*, 250 U.S. 273, 281 (1919).

ment. If sources are allowed to negotiate freely for the rights to their tissue, costs may become prohibitively high. Such results hinder advancement of patent law policy, which encourages research and dissemination of knowledge. Consequently, therapeutic products would not be developed or would become available only at increased costs. Ultimately, the public would suffer because these products carry great potential to treat many human diseases, possibly even AIDS.

Biotechnology industry researchers believe that new laws are needed to clarify the legal issues.<sup>382</sup> The problems created by the commercial use of human tissue, however, cannot be resolved adequately by the courts. Although courts often decide difficult legal issues even when they require a choice between competing social or economic policies, "[t]he difference here . . . lies in the nature of the conflicting moral, philosophical and even religious values at stake, and in the profound implications" of recognizing rights in human tissue.<sup>383</sup> "Where then shall a complete resolution be found? Clearly, the Legislature . . . is the proper deliberate forum."<sup>384</sup>

The legislature should create a Uniform Tissue Source Compensation Act. Such an act would eliminate many of the problems associated with payment to sources. Sources would be paid a flat fee, regardless of commercial success. The system would serve the interests of the individual and at the same time reduce transaction costs by eliminating the need for complex negotiations and tracking of sources. Biotechnology companies could fix their costs without the threat of future contract litigation.

Such a compensation system is fair because valuing a source's contribution must be analyzed in light of the scientific technologies, patent laws and policies, and industrial product development. Sources generally do not contribute any ideas, skill, labor or investment capital to development projects. Due to the high degree of technical skill and labor involved in developing therapeutic products and creating a patentable subject matter, along with extraordinary investment costs, limiting a source's compensation does not result in a windfall to biotechnology companies. Most importantly, a uniform compensation system fosters the development of human tissue products and their availability at re-

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382. Hamilton, *Who Told You Could Sell My Spleen*, BUS. WK., Apr. 23, 1990, at 38.

383. *Moore*, 51 Cal. 3d at 149, 793 P.2d at 498, 271 Cal. Rptr. at 165 (Arabian, J., concurring).

384. *Id.* (Arabian, J., concurring).

duced costs. As a result, such a system balances the interests of the individual source, the biotechnology industry and the public.

*John J. O'Connor\**

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