

COMMENT

MOORE V. THE REGENTS OF THE UNIVERSITY OF CALIFORNIA: BALANCING THE NEED FOR BIOTECHNOLOGY INNOVATION AGAINST THE RIGHT OF INFORMED CONSENT

BY MAUREEN S. DORNEY[†]

Table of Contents

I.	INTRODUCTION	334
II.	THE TECHNOLOGY	335
III.	DISPUTES OVER THE OWNERSHIP OF CELL-LINES	338
	A. Cases Prior to <i>Moore</i>	338
	B. Facts and Procedural History of <i>Moore</i>	339
IV.	PROPERTY RIGHTS IN THE HUMAN BODY	342
	A. Intangible Property Rights in Human Tissue	342
	B. Tangible Personal Property Rights	343
	C. Quasi-Property Rights in the Human Body	349
V.	INFORMED CONSENT	355
	A. The Treating Researcher/Physician's Duty of Informed Consent	355
	B. Statutory and Regulatory Treatment of Informed Consent	361
VI.	SHOULD INDIVIDUALS BE ALLOWED TO SELL THEIR TISSUE?	363
	A. Doctrinal Treatments of the Commodification of Personhood	364
	B. Existing Regulation of the Sale of Human Tissue and Body Parts	365

© 1990 Maureen S. Dorney

[†] Associate, McCutchen, Doyle, Brown & Enerson, Intellectual Property Group. J.D., Boalt Hall School of Law, University of California, Berkeley, 1990; Senior Articles Editor, High Technology Law Journal, 1989-90; A.B., Oriental Languages, University of California, Berkeley, 1979. The author acknowledges with appreciation the encouragement and constructive suggestions of Michael Traynor.

C. Commodification of the Individual for Biotechnology Research	367
VII. CONCLUSION	368

I. INTRODUCTION

In just a few short years, advancements in the science of biotechnology¹ have made it possible to derive new medicines from human tissue. The potential profitability of these medicines has sparked great debate over whether the donors of these tissues must be informed that a commercial product may be developed using their cells and whether they have any right to compensation for such use.

The controversial case of *Moore v. The Regents of the University of California*² has become the focus of this debate. Unfortunately, the opinion of the California Court of Appeals was narrowly focused on the issue of whether or not the law should treat human body parts and other human tissue as a form of tangible personal property.³ This narrow focus obscured the three crucial issues raised by the *Moore* case: 1) Should the scope of the doctrine of informed consent be modified to include the right to be informed of any potential use of one's excised tissue to create commercial products?; 2) Do individuals have the right to refuse to consent to the use of their bodily tissue in this manner?; and 3) Should persons whose tissues are used to create a commercially valuable product have the right to compensation for such use?

The California Supreme Court properly turned the focus of the *Moore* case to these issues when it held that although there was no cause of action for conversion of human tissue, Mr. Moore could maintain an action against his treating physician for lack of informed consent to the use of his tissue for biotechnical research.⁴ This Comment will suggest,

1. The term "biotechnology" has been defined to include "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses." OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHONOLOGY: AN INTERNATIONAL ANALYSIS, U.S. CONG., PUB. NO. OTA-BA-218, at 3 (1984).

2. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990), *reh'g denied*, *Moore v. The Regents of the Univ. of California*, No. S006987 (Cal. Supreme Ct. Aug. 30, 1990) (1990 CAL. LEXIS 3975, States library, Cal file). See *infra* Section III for a discussion of the facts and the procedural history of the case.

3. The Appellate Court merely held that Mr. Moore had adequately stated a cause of action for conversion and remanded to the trial court for consideration of the remaining causes of action. *Moore v. The Regents of the Univ. of California*, 215 Cal. App. 3d 709, 722, 249 Cal. Rptr. 494, 502 (1988), *rev'd*, 51 Cal. 3d 120, 128, 793 P.2d 479, 483, 271 Cal. Rptr. 146, 150 (1990).

4. *Moore*, 51 Cal. 3d at 147, 793 P.2d at 497, 271 Cal. Rptr. at 164.

however, that the court's holding provides only a partial resolution of these issues.

Section II will describe the technology underlying the science of biotechnology because understanding the technology is crucial to understanding the issues presented by the *Moore* case. Section III of this Comment will discuss the facts and the procedural history of the *Moore* case in order to illustrate how the case squarely presents these three issues. In addition, this section will suggest that many other cases will be affected by the outcome of *Moore*. Section IV will analyze various sources of "property" rights in the human body in order to demonstrate that there are several reasons why it is inappropriate to treat human body parts as tangible personal property, and to explain why the California Supreme Court expressly refused to do so. Section V will analyze the doctrine of informed consent and why the Supreme Court held that it applies to the *Moore* case. In addition, this section will demonstrate that further modifications of the doctrine of informed consent to medical treatment and of existing guidelines for informing research subjects of the risk and benefits of research that is conducted on them are needed in order to respond to the use of human tissue in biotechnology research and product development. Finally, Section VI will briefly address the complicated issue of whether or not the initial source of the tissue should receive compensation for the use of that tissue.

II. THE TECHNOLOGY

The science of biotechnology encompasses several new and different scientific technologies that enable researchers to solve the mysteries of our genetic make-up, and develop novel new drugs which have the potential to benefit many people.⁵ As with other developments in technology,⁶ biotechnology has created new legal, public policy, and ethical dilemmas which can only be solved satisfactorily if one understands the underlying techniques used in biotechnology research, and is familiar with the various types of human tissue which are used in such research.⁷

5. For a general discussion of the state of the biotechnology industry, see OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 1, at 119-253.

6. For example, the legal issues surrounding the use of fetal tissue in research can also only be understood if the underlying technology is first explained. See Terry, *Politics and Privacy: Redefining the Ethical and Legal Issues in Fetal Tissue Transplantation*, 66 WASH. U.L.Q. 523 (1988).

7. The types of tissue that are used in various forms of biotechnology research are important because any new rights or remedies created to deal with the issues raised by the *Moore* case must be integrated with an already complex system for the regulation of the use of human tissue or organs in research or medical treatment. See *infra* Section VI.

There are three main types of technologies that are employed in the science of biotechnology.⁸ The first, and most basic, is cell culture technology.⁹ Most established cell cultures are derived from cancerous tissue samples.¹⁰ Developing immortal human cell cultures is a difficult and time consuming process. Still, scientists do not fully understand why any particular culture is successful.¹¹ These cell cultures are essential in many types of commercial and non-commercial research. For example, they can be used as a "biological factory to produce large or small quantities of a substance," or to test the toxicity of various compounds.¹² It is the patenting of such a cell culture that is at issue in the *Moore* case.¹³

The second technique is known as hybridoma technology. As the name suggests, hybridomas are cells that are created by the fusion of two different types of cells, usually a tumor cell and a cell that is an efficient producer of certain antibodies.¹⁴ Hybridomas are used to produce individual antibodies in a greater quantity than possible by other means.¹⁵ The results of the hybridoma process are more commonly known as monoclonal antibodies.¹⁶

The third type of technology is known as recombinant DNA technology.¹⁷ This is perhaps the most dramatic of these techniques, because it usually involves the direct manipulation of the genetic material

8. OFFICE OF TECHNOLOGY ASSESSMENT, *NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS*, U.S. CONG., PUB. NO. OTA-BA-337, at 31 (1987) [hereinafter *OWNERSHIP OF HUMAN TISSUES AND CELLS*].

9. A cell culture is defined as a continuous culture of cells that can survive in a laboratory, independent of the source of the cells, for an indefinite period of time. *Id.* at 31-35. Hence, they are referred to as "immortal."

10. *Id.* at 33.

11. *Id.* at 32-34.

12. *Id.* at 35.

13. An examination of the patent granted for the "Mo cell-line" shows both the efforts that were expended to establish the cell-line, and the unique properties of the cell-line. *Moore v. The Regents of the Univ. of California*, 215 Cal. App. 3d 709, 754-68; 249 Cal. Rptr. 494, 516-30 (1988) (U.S. Patent No. 4,438,032 reproduced in Appendix A), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

14. A tumor cell is usually fused with a B lymphocyte that has been isolated from spleen or lymph node tissue. The B lymphocyte is a specialized type of white blood cell that secretes one specific kind of antibody in response to the presence of a specific foreign substance. When the B lymphocyte is fused with the immortal tumor cells, the resulting hybridoma is capable of continuously producing the beneficial antibody proteins. *OWNERSHIP OF HUMAN TISSUES AND CELLS*, *supra* note 8, at 37-38.

15. E. ANTEBI & D. FISHLOCK, *BIOTECHNOLOGY STRATEGIES FOR LIFE* 74 (1986).

16. For a detailed discussion of the development of monoclonal antibodies and related subjects, see *id.*, ch. 6.

17. In 1953, Francis Crick, James Watson and Maurice Wilkens discovered the double helix structure of the DNA (deoxyribonucleic acid). DNA contains the genetic code for all living creatures and is comprised solely of combinations of a four letter chemical "alphabet." For a detailed description, see E. ANTEBI & D. FISHLOCK, *supra* note 15, at 43.

(the DNA) of the cell.¹⁸ Recombinant DNA technology uses a variety of techniques to isolate a single piece of DNA and insert it into a rapidly growing cell, thereby creating large amounts of that DNA segment of interest.¹⁹

Currently, the human tissue needed for the various types of biotechnology research is derived from a number of different sources. Patients receiving medical treatment are a common source of tissue. This tissue may be removed incident to medical treatment, or solely for research purposes.²⁰ In addition, replenishing tissue and other bodily fluids may be obtained from healthy individuals according to accepted research principles.²¹ Finally, of course, cadavers are the only possible source of tissue from many organs, both healthy and diseased.²²

This brief discussion of the science of biotechnology illustrates several important factors that must be kept in mind when determining what judicial and legislative action should be taken to regulate the use of human tissue in biotechnology research. First, it takes an enormous skilled effort on the part of the researchers, as well as a certain amount of luck, to produce a successful commercial product. A significant amount of research is done on tissue that has no particular commercial value.²³ Second, unlike the *Moore* case, it is common for a successful product to be developed from multiple sources of tissue.²⁴ Third, since the tissue needed for biotechnology research comes from many types of sources, any permanent solution to the issues posed by the *Moore* case must be integrated with existing statutory schemes to regulate the sale of blood, procurement of organs for transplant, research protocols, etc.²⁵ For example, society must decide if it is desirable to allow the sale of organs for biotechnology research but not for transplant. Finally, it must be remembered that patients undergoing treatment for cancer are a crucial source of tissue for biotechnology research.²⁶ What rights do they have to be informed of the uses to which their excised tissue is put, and do they have any right to compensation for its use?

18. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 8, at 41.

19. *Id.* at 41-44.

20. *Id.* at 51. As suggested above, the cells from cancer patients are an indispensable source of tissue.

21. *Id.* For a discussion of the limits of current research guidelines, see *infra* Section V, Part B.

22. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 8, at 51.

23. *Id.* at 55.

24. *Id.*

25. See *infra* Section VI.

26. See *infra* Sections V and VI.

III. DISPUTES OVER THE OWNERSHIP OF CELL-LINES

As long as there is the potential for economic profit from genetically engineered cell-lines, there will be lawsuits over the right to profit from those cell-lines. Although the *Moore* case was the first to go to trial, it was not the first dispute over the ownership of cell-lines. Nor is it likely to be the last. At least one lawsuit has been on hold awaiting the ruling of the California Supreme Court.²⁷

A. Cases Prior to *Moore*

Prior to *Moore*, there were at least three other reported disputes over the ownership of cell-lines that were all settled out of court.

The first two disputes did not involve the actual tissue donors. In the first case, a researcher at Stanford University claimed the ownership of a cell-line which he created.²⁸ The case was settled without resolving the ownership of the cell-line.²⁹

The second dispute arose between the University of California and the pharmaceutical company of Hoffman-LaRoche. The dispute was over the use of a cell-line developed by researchers at UCLA Medical Center, which was subsequently used by Genentech (under contract to Hoffman-LaRoche) to isolate large quantities of the interferon gene.³⁰ In 1983, this dispute was also settled out of court.³¹

Prior to *Moore*, there was at least one case where a claim to the ownership of a patented cell-line was based on the tangible contribution of human tissue from which the cell-line was developed. This case also involved the development of a patented cell line by researchers at the University of California. In 1981, Dr. Hagiwara suggested that researchers at the University of California, San Diego use the lymph cells of his mother, who was being treated for cervical cancer.³² Mrs. Hagiwara's cells were used to develop a hybridoma cell-line that secreted

27. Following the Appellate Court's reinstatement of Mr. Moore's suit, a woman named Gina Potts filed a complaint in Superior Court for Santa Clara County alleging that Genentech, Inc., The Regents of the University of California, her doctors and her hospital used her blood and placenta without her consent in the development of the drug TPA (tissue plasminogen activator). Complaint, Potts v. Genentech, Inc., (Cal. Sup. Ct., County of Santa Clara, filed Nov. 1, 1988) (No. 670331). This complaint was filed but not formally served on the defendants. The parties were awaiting the ruling of the California Supreme Court on the *Moore* case before taking further action. Interview with Gary H. Ritchey, Esq., Cooley Godward Castro Huddleson & Tatum, Palo Alto, California (Apr. 16, 1990).

28. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 8, at 25.

29. *Id.*

30. *Id.*

31. *Id.* at 26.

32. *Id.*

anti-tumor antibodies.³³ In a subsequent dispute, the Hagiwaras asserted tangible personal property rights in the cell line. In 1983, the Hagiwaras and the University reached a settlement whereby the University retained all patent rights and the Hagiwaras were given an exclusive license to exploit the patent in Asia.³⁴ The dispute between the University of California and the Hagiwaras serves to illustrate that the dispute over the rights to a human cell-line in the *Moore* case is not unique and can be expected to arise again as the development of genetically engineered pharmaceuticals increases.

B. Facts and Procedural History of *Moore*

In 1976, John Moore was referred to the UCLA Medical Center for treatment of a relatively rare form of blood cancer known as hairy cell leukemia.³⁵ At the Medical Center he was seen by Dr. Golde, who recommended that Mr. Moore's spleen be removed. This was the only known treatment for the disorder.³⁶ Mr. Moore signed a standard surgical consent form for the therapeutic procedure. This consent form did not include any mention of research being performed on the excised tissue.³⁷ However, Mr. Moore's third amended complaint alleged that Dr. Golde noted in his medical record, before the surgery, "his desire to have a portion of plaintiff's fresh spleen placed in a sterile container and removed from the operating room for his independent research purposes."³⁸

Apparently, the operation was a success and Mr. Moore's condition "stabilized."³⁹ Over the next seven years, Mr. Moore traveled to the UCLA Medical Center from his home in Seattle approximately twelve times for follow-up visits.⁴⁰ During each visit, blood samples were

33. *Id.* It is important to note that, unlike the cell-line in the *Moore* case, hybridoma cell-lines are always created from cells from more than one donor. This makes it much harder for a plaintiff to prove that his or her tissue was the source of the cell-line. In fact, it is usually the case that the cells in a commercially valuable cell-line were obtained from multiple donors. See *infra* Section III.

34. *Id.* at 26.

35. *The Use of Human Biological Materials in the Development of Biomedical Products: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 99th Cong., 1st Sess. 241 (1985) (statement of John Moore) [hereinafter Hearings].*

36. *Id.* At the time of the surgery, Mr. Moore's spleen weighed approximately 22 pounds whereas a normal spleen weighs around half of a pound.

37. *Id.* Exhibit A at 267.

38. Third Amended Complaint, *Moore v. The Regents of the University of California*, (Cal. Sup. Ct., County of Los Angeles, filed in 1984) (No. 513755). [hereinafter Third Amended Complaint].

39. *Hearings, supra* note 35, at 241.

40. *Id.*

obtained. Mr. Moore claims that when he asked if he could have the blood samples taken in Seattle and sent to Dr. Golde (in order to save money), Dr. Golde said that would not be a good idea and that he would be able to find grant money to pay Mr. Moore's expenses.⁴¹

In September of 1983, during one of these follow up visits, Mr. Moore was asked to sign a form consenting to the use of his blood for research purposes.⁴² The consent form included a portion where the individual was to circle either "I do", or "I do not" "voluntarily grant to the University of California any and all rights I, or my heirs, may have in any cell-line or any other potential product which might be developed from the blood and/or bone marrow obtained from me."⁴³

Mr. Moore has testified before the House of Representatives Subcommittee on Science and Technology that, during this visit, he formed the impression that he was being given "vague" and "patronizing" answers to his questions about whether there were any ongoing efforts to commercialize his tissue. Mr. Moore claims that this treatment led him to circle the "I do not consent" option on the consent form.⁴⁴ Mr. Moore has stated that, after he left UCLA Medical Center, Dr. Golde and his secretary made repeated efforts to get him to re-sign the consent form "correctly" and that this fact finally caused him to see an attorney who commenced the investigation which led to the filing of the current lawsuit.⁴⁵

On March 20, 1984, Dr. Golde and his researcher, Shirley Quan, received a patent for the "Mo cell-line"; this cell-line was developed solely from Mr. Moore's tissue.⁴⁶ The patent was assigned to the University of California.⁴⁷ The University and Dr. Golde also entered into agreements with Genetics Institute and Sandoz Pharmaceutical to develop commercial products from the Mo cell-line.⁴⁸ As of the date of the patent, nine potential products had been developed from the Mo cell-line.⁴⁹

41. *Id.*

42. Mr. Moore did sign an identical consent form on an earlier visit in April of 1983. *Id.*

43. *Moore v. The Regents of the Univ. of California*, 215 Cal. App. 3d 709, 769, 249 Cal. Rptr. 494, 531 (1988) (quoting from a copy of the consent form reproduced in Appendix B of the opinion), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

44. *Hearings, supra* note 35, at 242.

45. *Id.* at 242-43.

46. *Moore*, 215 Cal. App. 3d at 757, 249 Cal. Rptr. at 519 (U.S. Patent No. 4,438,032 reproduced in Appendix A).

47. *Id.* at 755, 249 Cal. Rptr. at 517.

48. *Hearings, supra* note 35, at 243-44.

49. *Moore*, 215 Cal. App. 3d at 762, 249 Cal. Rptr. at 524.

The complaint alleges that, in addition to the payment of fees to the University, part of which were used to pay Dr. Golde's salary, Dr. Golde received options to acquire 75,000 shares of Genetics Institute stock for a total of \$750 in exchange for his consulting services.⁵⁰

In 1984, Mr. Moore filed a Third Amended Complaint in Superior Court for the County of Los Angeles, alleging causes of action for conversion, lack of informed consent, breach of a quasi-contract, breach of the implied covenant of good faith and fair dealing, intentional infliction of emotional distress, negligent misrepresentation, interference with prospective advantageous economic relationships, and slander of title, and requesting an accounting and declaratory relief.⁵¹

The first trial court to hear a motion to dismiss sustained the joint demurrers of the Regents, Dr. Golde and Ms. Quan on the first cause of action for conversion.⁵² In addition, the court held that, because the first cause of action was incorporated into the remaining causes of action, the demurrers to the remaining causes of action were sustained as well.⁵³

The court gave four reasons for its ruling. First, that the complaint failed to allege that Mr. Moore did not know or have reason to know that any tissue removed incident to treatment at UCLA Medical Center might be used for research.⁵⁴ Second, that the complaint failed to allege that the defendants knew of the potential commercial value of Mr. Moore's cells and "had formed the intent to commercially exploit such substances" prior to the surgery.⁵⁵ Third, that Mr. Moore failed to allege that he had consented only to the removal of his spleen for therapeutic purposes.⁵⁶ Fourth, that Mr. Moore had failed to attach either a copy of the consent form for the splenectomy or the September 1983 consent form as exhibits to the complaint.⁵⁷

The Court of Appeals reversed the trial court and held that the demurrer to the conversion cause of action had been improperly

50. Third Amended Complaint, *supra* note 38. The value of this stock has been estimated to be approximately two million dollars.

51. *Id.*

52. Note that the second trial court later sustained the demurrers of Genetics Institute and Sandoz under a similar rationale. *Moore*, 215 Cal. App. 3d at 720-21, 249 Cal. Rptr. at 501.

53. *Id.* at 720, 249 Cal. Rptr. at 501.

54. *Id.*

55. *Id.* Note that paragraphs 8 through 15 of the complaint do allege that the defendants were in a position to recognize the unique properties of Mr. Moore's cells during pre-operative testing, that such testing did take place and that, prior to surgery, the defendants arranged to obtain a portion of Mr. Moore's spleen without his consent. See Third Amended Complaint, *supra* note 38.

56. *Moore*, 215 Cal. App. 3d at 720, 249 Cal. Rptr. at 501.

57. *Id.* The majority of the Appellate Court held that there is no authority requiring documents be attached to a complaint. *Id.* at 736, 249 Cal. Rptr. at 512.

sustained and that Mr. Moore had properly stated a cause of action for conversion.⁵⁸ In support of its holding, the court stated that:

The rights of dominion over one's body, and the interests one has therein, are recognized in many cases. These rights and interests are so akin to property interest that it would be subterfuge to call them anything else.⁵⁹

The California Supreme Court granted review of the case.⁶⁰ The Supreme Court subsequently held that "the allegations of Moore's third amended complaint state a cause of action for breach of fiduciary duty or lack of informed consent, but not conversion."⁶¹

Until this ruling, the debate engendered by the *Moore* case had concentrated on the issue of whether Mr. Moore could state a cause of action for the conversion of human tissue. The opinion of the Supreme Court demonstrates, however, that the fundamental issue in the *Moore* case is whether a person has the right to be informed of how tissues that are removed from his or her body will be used and disposed of.

IV. PROPERTY RIGHTS IN THE HUMAN BODY

A. Intangible Property Rights in Human Tissue

The patent in the Mo cell-line is an intangible property right.⁶² In *Diamond v. Chakrabarty*, the United State Supreme Court for the first time held that certain living cells that met the standard of novelty, unobviousness and usefulness qualified for patent protection.⁶³

It is important to realize that patent rights are only available to the inventor who reduces his idea to practice.⁶⁴ "Products of nature," no matter how exceptional, cannot be the subject of patent protection.⁶⁵ Thus, patent protection is not available for human tissue in its unaltered form, and the fact that patent protection has been granted to the inventor of a cell-line (or other genetically engineered substance) has no bearing on what rights the source of the original tissue may possess in that tissue.⁶⁶

58. *Id.* at 722, 249 Cal. Rptr. at 502.

59. *Id.* at 725, 249 Cal. Rptr. at 505.

60. 252 Cal. Rptr. 816, 763 P.2d 479 (1988).

61. *Moore v. The Regents of the Univ. of California*, 51 Cal. 3d 120, 147, 793 P.2d 479, 497, 271 Cal. Rptr. 146, 164.

62. Intangible assets such as patents are defined as "property that is a right." BLACK'S LAW DICTIONARY 808 (6th ed. 1990).

63. 447 U.S. 303, 309-10 (1980). For an overview of the requirements for patenting biotechnology inventions see I. COOPER, BIOTECHNOLOGY AND THE LAW, ch. 2 (1985).

64. 35 U.S.C. § 102(g) (1988).

65. I. COOPER, *supra* note 63, § 3.02.

66. Wagner, *Human Tissue Research: Who Owns The Results?*, 3 COMPUTER & HIGH TECH. L. J. 233, 236 (1987).

B. Tangible Personal Property Rights

The California Court of Appeals faced a difficult task when it was forced to rely upon existing legal doctrine to rule on the novel questions presented by the *Moore* case.⁶⁷ It appears that one reason the Court turned to property law to define the rights and obligations of the parties in *Moore* is that few legal concepts are potentially as broad in their application as the concept of property.⁶⁸

In keeping with a broad definition of property, the California Civil Code defines property in the following manner: "The ownership of a thing is the right of one or more persons to possess and use it to the exclusion of others. In this Code, the thing of which there may be ownership is called property."⁶⁹ In defining tangible personal property, the California Civil Code provides, "Every kind of property that is not real is personal."⁷⁰

The Court of Appeals used both the common law concept of the expansive bundle of rights associated with property interests, as well as the all-encompassing definition of property contained in the California statutes, to support its holding that there is a tangible personal property right in human tissue.⁷¹ The Appellate Court opinion makes clear that the underlying principle guiding the Court of Appeals is that human beings must have the right to control the disposition of their tissue and bodily parts. The court stated 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."⁷²

However, as will be discussed below, creating tangible personal property rights in human tissue will have legal consequences that go beyond merely granting individuals the right to exert dominion and control over their excised tissue.

67. See *infra* Section V for a discussion of the problems encountered by the court when trying to apply the doctrine of informed consent in the context of the *Moore* case.

68. For example, the court noted that "As a matter of legal definition, 'property' refers not to a particular material object but to the right and interest or domination rightfully obtained over such object, with the unrestricted right to its use, enjoyment and disposition. In other words, [in] its strict legal sense ... 'property' is nothing more than a collection of rights." *Moore v. The Regents of the Univ. of California*, 215 Cal. App. 3d 709, 725, 249 Cal. Rptr. 494, 504 (1988) (citing 63A AM. JUR. 2D, *Property*, § 1, at 228 (1984)), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

69. CAL. CIV. CODE § 654 (West 1982). These general property statutes were enacted in 1872 and have not been amended since.

70. CAL. CIV. CODE § 663 (West 1982).

71. *Moore*, 215 Cal. App. 3d at 723-32, 249 Cal. Rptr. at 503-09.

72. *Id.* at 728, 249 Cal. Rptr. at 506.

1. CONVERSION

Conversion is defined as "any act of dominion wrongfully exercised over another's personal property in denial of or inconsistent with his rights therein."⁷³ It is interesting to note that, originally, intangible property rights could not be the subject of an action for conversion.⁷⁴ Currently, the law has developed to the point where intangible rights in a document (e.g. a check or stocks) can be the subject of a conversion.⁷⁵

However, the expansion of the doctrine of conversion has never been extended to include all types of personal property. Courts have refused to find conversion of an intangible personal property right, such as an ordinary debt, the good will of a business, or an idea.⁷⁶ California courts have followed this general rule and limited the types of personal property that could be subject to a cause of action for conversion. For example, in *Olschewski v. Hudson*,⁷⁷ the court held that, while a list of customers was protectible property, it was not tangible personal property and could not be the subject of an action for conversion.⁷⁸ Likewise, Prosser and Keeton state that, although commentators have urged that conversion be expanded to apply to all types of property, both tangible and intangible, it is preferable to fashion other remedies to "protect people from having intangible values used and appropriated in unfair ways."⁷⁹

The fundamental reason that conversion has not been extended to apply to intangible property is the harsh nature of the remedy for conversion. The rationale for protecting intellectual property rights is to encourage the development of new inventions, creations or commercial endeavors that will benefit society.⁸⁰ Hence, intangible property rights must balance the amount of protection needed to encourage innovation against the benefit to society of competition and of free access to the fruits of subsequent innovation.⁸¹

73. W. PROSSER & W. KEETON, PROSSER AND KEETON ON TORTS § 15, at 92 (5th ed. 1971); see also CAL. CIV. CODE § 1712 (West 1989).

74. W. PROSSER & W. KEETON, *supra* note 73, § 15, at 91.

75. *Id.*

76. *Id.* at 92.

77. 87 Cal. App. 282, 262 P. 43 (1927).

78. *Id.* at 286, 262 P. at 45; see also *Vuich v. Smith*, 140 Cal. App. 453, 35 P.2d 365 (1934) (leasehold interest); *Italiani v. Metro-Goldwyn-Mayer Corp.*, 45 Cal. App. 2d 464, 114 P.2d 370 (1941) (plagiarism of a literary composition is a separate tort and not the subject of a suit for conversion).

79. W. PROSSER & W. KEETON, *supra* note 73, at 92.

80. *Bonito Boats, Inc. v. Thunder Craft Boats*, 489 U.S. 141, 146 (1989).

81. A similar rationale is applied to determine the extent of patent and trademark protection. See, e.g., *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 522

It will be demonstrated below that, because the statutes for conversion were designed solely to provide a remedy for another's taking of a personal possession,⁸² conversion is not an appropriate cause of action for the wrongful use of human tissue in biotechnology research. This is due to the presence of important, competing public policy considerations in biotechnology research, such as encouraging beneficial technological innovation and protecting individual autonomy.⁸³ One example of this is found in the measure of damages for a conversion. The California Civil Code provides for the following damages:

[F]irst—The value of the property at the time of the conversion ... or, an amount sufficient to indemnify the party injured for the loss which is the natural, reasonable and proximate result of the wrongful act complained of and which a proper degree of prudence on his part would not have averted; and

Second—A fair compensation for the time and money properly expended in pursuit of the property.⁸⁴

This statute would appear to limit a plaintiff like Moore's recovery to whatever he or she could establish was the value of the removed organ or tissue at the time of its removal.

However, while it is true that, as the dissenting opinion of the Appellate Court suggests,⁸⁵ there are serious difficulties inherent in attempting to determine what value to place on diseased tissue in its unaltered state, it is not the case that, under an action for conversion, a person would be limited to the provisions of California Civil Code section 3336. Section 3336 merely sets forth a *presumption* of damages. Both the dissent and the majority for the Appellate Court opinion in the *Moore* case failed to note that the California Civil Code also provides for the remedy of specific performance when tangible property is wrongfully taken and made into a new product.⁸⁶

(1963) (Black, J., dissenting); *In re Morton-Norwich Pro Inc.*, 671 F.2d 1332, 1341 (C.C.P.A. 1982).

82. *Olschewski*, 87 Cal. App. at 287, 262 P. at 45. While it is certainly the case that a person's tissue is not analogous to the good-will of a business or a trademark, it is true that there are ethical and public policy concerns implicated by the commercial use of human tissue that could not have been contemplated in 1872 by the drafters of California's statutes on conversion.

83. Note that this section of the analysis deals only with the appropriateness of applying the doctrine of conversion to human tissue. Whether there should be a right to control the disposition of one's tissue is dealt with in Section VI, *infra*, under the doctrine of informed consent.

84. CAL. CIV. CODE § 3336 (West 1982).

85. *Moore v. Regents of the University of California*, 215 Cal. App. 3d 709, 747-48, 249 Cal. Rptr. 494, 536-37 (1988) (George, J., dissenting), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

86. "In all cases where one whose material has been used without his knowledge, in order to form a product of a different description, can claim an interest in such product, he

More importantly, conversion is a strict liability tort.⁸⁷ In other words, "[t]he foundation for the action of conversion rests neither in the knowledge nor the intent of the defendant."⁸⁸ If the California Supreme Court were to have allowed an action for conversion in the *Moore* case, the practical implication of strict liability under California Civil Code section 1032 would have been that the ownership of the Mo cell-line (and all products derived therefrom) would revert to Mr. Moore.⁸⁹ In other words, the researcher, Ms. Quan, and the pharmaceutical companies would be strictly liable, along with the treating physician and the hospital, no matter what knowledge they actually possessed concerning how the original tissue sample was obtained.

It has been suggested that the doctrine of accession would also apply to the *Moore* case.⁹⁰ Under California law:

If one makes a thing from materials belonging to another, the latter may claim the thing on reimbursing the value of the workmanship, unless the value of the workmanship exceeds the value of the materials, in which case the thing belongs to the maker, on reimbursing the value of the materials.⁹¹

However, Civil Code section 1028 is not applicable in a situation where the materials of another are willfully used without the owner's consent.⁹² Therefore, accession would not be a remedy in the *Moore* case, because the tissue was knowingly used without Mr. Moore's consent.⁹³

In other words, the application of tangible personal property law to the *Moore* case would not allow for any apportionment of the benefit among Moore (the owner of the tissue) and the researchers (in recognition of their contribution to value of the cell-line). This result would be directly contrary to the articulated policy of the Supreme Court of California to foster the creation of new prescription drugs. This policy

has an option to demand either restitution of his material in kind, in the same quantity, weight, measure, and quality, or the value thereof; or where he is entitled to the product, the value thereof in place of the product." CAL. CIV. CODE § 1032 (West 1982).

87. *Henderson v. Security Nat'l. Bank*, 72 Cal. App. 3d 764, 770-71, 140 Cal. Rptr. 388, 391 (1977); see generally 5 WITKIN, SUMMARY OF CALIFORNIA LAW, § 624 (4th ed. 1988).

88. *Moore*, 215 Cal. App. 3d at 722, 249 Cal. Rptr. at 503 (quoting *City of Los Angeles v. Superior Ct.*, 85 Cal. App. 3d 143, 149, 149 Cal. Rptr. 320 (1978)).

89. This is assuming that he succeeds in establishing that his tissue was taken without his consent, that there was no abandonment, etc.

90. Note, *Toward The Right Of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 253 (1986) (authored by Roy Hardiman) [hereinafter *Toward the Right of Commerciality*].

91. CAL. CIV. CODE § 1028 (West 1982).

92. "The foregoing sections of this Article are not applicable to cases in which one willfully uses the materials of another without his consent; but, in such cases, the product belongs to the owner of the material, if its identity can be traced." CAL. CIV. CODE § 1031 (West 1982).

93. See *supra* text accompanying note 38.

was articulated in the case of *Brown v. Superior Court*.⁹⁴ In *Brown*, the court reasoned that, because of the public interest in the "development, availability, and reasonable price of drugs," a drug manufacturer's liability for design defects should not be governed by a standard of strict liability.⁹⁵ Instead, the court held that the appropriate standard of liability is one of negligence, as is suggested in Comment k to section 402A of the Restatement (Second) of Torts.⁹⁶

In its opinion in the *Moore* case, the California Supreme Court held that both the policy considerations underlying the holding in *Brown* and the difficulty of assessing damages, made it inappropriate for the courts to extend liability for conversion to include taking human tissue.⁹⁷ The court stated:

Indeed, this is a far more compelling case for limiting the expansion of tort liability than *Brown*. In *Brown*, eliminating strict liability made it more difficult for plaintiffs to recover actual damages for serious physical injuries resulting from their mothers' prenatal use of the drug diethylstilbestrol (DES). In this case, by comparison, limiting the expansion of liability under a conversion theory will only make it more difficult for Moore to recover a highly theoretical windfall. Any injury to his right to make an informed decision remains actionable through the fiduciary-duty and informed-consent theories.⁹⁸

2. LIABILITY FOR PRODUCT DEFECTS

An additional reason for refusing to treat human tissue as property is the fear that the source of the tissue could be liable for defects in the tissue that cause injury. This concern has led states to enact laws that provide that other biological materials are not property. For example, concern over the possibility of strict liability being imposed on the sources of blood used for transfusions and various blood products, as well as on the third-party blood banks and blood product companies, has

94. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

95. *Id.* at 1061, 751 P.2d at 477, 245 Cal. Rptr. at 418.

96. *Id.* In general, Comment k provides that drug manufacturers should not be held liable for a drug's side effects if they could not have known of the defect, under the existing scientific knowledge that was available at the time the drug was distributed. *Id.* at 1058-59, 751 P.2d at 475-76, 245 Cal. Rptr. at 416-17. For a comprehensive analysis of the *Brown* opinion, as well as its application to biotech drugs, see Traynor & Cunningham, *Emerging Product Liability Issues In Biotechnology*, 3 HIGH TECH. L.J. 149 (1988).

97. *Moore v. The Regents of the Univ. of California*, 51 Cal. 3d 129, 142-47, 793 P.2d 479, 493-97, 271 Cal. Rptr. 146, 160-64 (1990). The California Supreme Court stated that the legislature was best suited to decide whether users of cell lines should be liable for "failing to investigate the consensual pedigree of their raw materials...." *Id.* at 147, 793 P. 2d at 496, 271 Cal. Rptr. at 163.

98. *Id.* (citation omitted).

motivated both the courts and most legislatures to label blood as a "service" instead of a "good" (i.e. a type of tangible property).⁹⁹

California law provides that:

The procurement, processing, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body shall be construed to be, and is declared to be, *for all purposes whatsoever*, the rendition of a service by each and every person, firm, or corporation participating therein, and shall not be construed to be, and is declared not to be, a sale of such whole blood, ... for any purpose whatsoever.¹⁰⁰

California courts have interpreted this statute to be a codification of the holding in *Perlmutter v. Beth David Hospital*,¹⁰¹ that a hospital's furnishing of blood to a patient was a service, not a sale, and thus not subject to strict liability on a warranty theory.¹⁰² At the time *Perlmutter* was decided, strict liability in tort did not exist.¹⁰³ However, in *Shepard v. Alexian Bros. Hosp.*, the court held that section 1606 applied to strict liability in tort as well.¹⁰⁴ Subsequent cases have held that section 1606 exempts both blood banks¹⁰⁵ and blood product manufacturers¹⁰⁶ from strict liability for defective blood or blood products.

The rationale behind section 1606 is the need to promote an adequate supply of blood.¹⁰⁷ As the California Supreme Court made clear in the *Brown* opinion,¹⁰⁸ there is an equally strong policy to promote the development and supply of new drugs. Therefore, in light of the fact that section 1606 makes no distinction between the person compensated for the use of her blood and the hospital or blood products company, the

99. See *infra* section VI for a discussion of the separate issue of whether the source of the blood, organ or other tissue is entitled to compensation.

100. CAL. HEALTH & SAFETY CODE § 1606 (West 1988) (emphasis added).

101. 308 N.Y. 100, 123 N.E.2d 792 (1954). For California cases interpreting *Perlmutter* and section 1606, see *McDonald v. Sacramento Medical Found. Blood Bank*, 62 Cal. App. 3d 866, 869, 133 Cal. Rptr. 444, 445 (1976); *Shepard v. Alexian Bros. Hosp.*, 33 Cal. App. 3d 606, 610, 109 Cal. Rptr. 132, 134 (1973).

102. *Perlmutter*, 308 N.Y. at 107, 123 N.E.2d at 795.

103. Note, *Hepatitis, AIDS and the Blood Product Exemption from Strict Product Liability in California: A Reassessment*, 37 HASTINGS L.J. 1101, 1108 n.49 (1986) (authored by Pamela T. Westfall).

104. *Shepard*, 33 Cal. App. 3d at 610, 109 Cal. Rptr. at 133.

105. *Klaus v. Alameda-Contra Costa County Medical Ass'n Blood Bank*, 62 Cal. App. 3d 417, 418, 133 Cal. Rptr. 92, 92-93 (1976).

106. *Fogo v. Cutter Laboratories*, 68 Cal. App. 3d 744, 752, 137 Cal. Rptr. 417, 422 (1977). For a criticism of the application of section 1606 to blood product manufacturers see Note, *supra* note 103, at 1119-29. Cf. Note, *Liability for Transfusion-Transmitted Disease*, 14 WM. MITCHELL L. REV. 141 (1988) (authored by Lynn Shodahl).

107. *Klaus*, 62 Cal. App. 3d at 419, 133 Cal. Rptr. at 92-93.

108. See *supra* notes 94-96 and accompanying text.

supply of blood for biotechnology research and product development should also be treated as a service and not as the sale of property.

California law also exempts the donor of a body part from liability for "any injury or damage that may result from the making or the use of the anatomical gift."¹⁰⁹ However, Health & Safety Code section 7155.5(d) does not apply to situations where the individual did not make a "gift" of her tissue.¹¹⁰ This suggests that, if human tissue is considered alienable property, an individual can be held liable for defects in that tissue.¹¹¹

In summary, the Supreme Court correctly refused to treat human tissue and body parts as a form of tangible personal property that can be subject to a cause of action for conversion. There is no precedent in either statutory or judicial law that supports doing so. Furthermore, the extension of the doctrine of conversion to parts of the human body would cause strict liability to be imposed on suppliers of genetically engineered drugs, a result that is directly contrary to the stated policy of both the California courts and legislature. Finally, treating the human body as property opens up difficult and largely unanswered questions regarding the nature of the liability of the "owner" of tissue to individuals who are injured by defects in that tissue.

C. Quasi-Property Rights in the Human Body

The California Supreme Court has stated that the "term property is sufficiently comprehensive to include every species of estate, real and personal, and everything which a person can own and transfer to another. It extends to every species of right and interest capable of being enjoyed as such upon which it is practicable to place a money value."¹¹²

It has been argued that, although it may be inappropriate to treat the human body as tangible personal property, it is still properly the subject of some other property right.¹¹³ The most commonly cited

109. CAL. HEALTH & SAFETY CODE § 7155.5(d) (West Supp. 1989). This section replaced CAL HEALTH & SAFETY CODE § 7155.6, repealed by 1988 Cal. Stat. ch. 1905, § 1, which paralleled section 1606 and provided that donated tissue was treated as a service.

110. Cf. CAL HEALTH & SAFETY CODE § 1606 (West 1988), which would appear to protect both the paid and unpaid donor of blood in California. See *infra* Section VI for a discussion of the limited circumstances under which the use of paid blood donors is allowed in California.

111. It is likely that the paid source of the tissue would be held to a negligence standard of liability. See Note, *supra* note 106, at 161.

112. *Yuba River Power Co. v. Nevada Irrigation Dist.*, 207 Cal. 521, 523, 279 P. 128, 129 (1929).

113. Martin & Lagod, *Biotechnology and the Commercial Use of Human Cells: Toward an Organic View of Life and Technology*, 5 SANTA CLARA COMPUTER & HIGH TECH. L.J. 211, 238-44 (1989); *Toward the Right of Commerciality*, *supra* note 90 at 260-64.

precedents for this type of treatment are the common law recognition of a quasi-property right in dead bodies and the right of publicity.

1. THE LAW OF DEAD BODIES

Under early English common law there was no property right in a dead body.¹¹⁴ The earliest laws controlling the disposition of a corpse were a reaction to infamous cases in England, where persons were murdered in order to sell the corpses to medical schools.¹¹⁵ Courts now recognize a limited right to control the disposition of the corpse for the purposes of burial and to recover damages for the mishandling of dead bodies.¹¹⁶ However, Dean Prosser states that this "dubious property right" possesses none of the attributes of traditional property.¹¹⁷ "It seems obvious that such property is something evolved out of thin air to meet the occasion, and that in reality the personal feelings of the survivors are being protected, under a fiction likely to deceive no one but the lawyer."¹¹⁸

Nonetheless, the Court of Appeals in *Moore* cited to California cases that found such a right in a dead body as support for the proposition that there is a property interest in the human body.¹¹⁹

The severe limitations on the so-called "quasi-property right" do not seem to support giving human tissue the full extent of rights granted tangible personal property. Nor does this right provide any precedent for allowing persons to be compensated for the use of their tissue.¹²⁰ However, the existence of a quasi-property right in dead bodies provides support for the underlying rationale of the Court of Appeals, which is that human beings have a right to control what becomes of their body.¹²¹

114. *Toward the Right of Commerciality*, *supra* note 90, at 225-26.

115. R. SCOTT, *THE BODY AS PROPERTY* 4-12 (1981).

116. *O'Donnell v. Slack*, 123 Cal. 285, 55 P. 906 (1899); *Enos v. Snyder*, 131 Cal. 68, 63 P. 170 (1900); *Cohen v. Groman Mortuary, Inc.*, 231 Cal. App. 2d 1, 41 Cal. Rptr. 481 (1963).

117. E.g., it can not be conveyed and has no pecuniary value. W. PROSSER AND W. KEETON, *supra* note 73, § 12, at 59.

118. *Id.*

119. *Moore v. The Regents of the Univ. of California*, 215 Cal. App. 3d 709, 724-26, 249 Cal. Rptr 494, 504-05 (1988), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990). The court noted that the limits placed on the disposition of a corpse "reflect significant public health concerns, rather than a legislative policy against a property interest in a living body. We see no inconsistency between the cases dealing with dead bodies and our conclusion." *Id.* at 726, 249 Cal. Rptr. at 505.

120. See *infra* Section VI.

121. See *supra* text accompanying notes 58-59.

2. THE RIGHT OF PRIVACY/PUBLICITY

The Restatement (Second) of Torts recognizes four separate actions under the general heading of the Right to Privacy: appropriation of name or likeness, unreasonable intrusion, public disclosure of private facts, and false light in the public eye.¹²²

Commentators have suggested that the appropriation of the name or likeness aspect of the right to privacy provides individuals with the right to recover damages for the unauthorized commercial use of their cells.¹²³ The tort of appropriation of the right to one's name or likeness has been more commonly called the right of publicity.¹²⁴ The effect of this right is:

to recognize or create an exclusive right in the individual plaintiff to a species of trade name, his own, and a kind of trade mark in his own likeness. It seems quite pointless to dispute whether such a right is to be classified as property; it is at least clearly proprietary in its nature. Once protected by the law, it is a right of value upon which the plaintiff can capitalize by selling licenses.¹²⁵

California has a statutory counterpart to the right of privacy/publicity which provides that "any person who knowingly uses another's name voice, signature, photograph, or likeness in any manner, on or in products, merchandise or goods ... without such person's prior consent ... shall be liable" to the injured party.¹²⁶

In *Lugosi v. Universal Pictures*,¹²⁷ the California Supreme Court expressly refused to decide whether the right of appropriation was a property right as defined in California Civil Code section 654.¹²⁸ The Court went on to hold that the right to recover for the misappropriation

122. RESTATEMENT (SECOND) OF TORTS §§ 652A-E (1977); see also Prosser, *Privacy*, 48 CAL. L. REV. 383, 384 (1963).

123. Martin & Lagod, *supra* note 113, at 232-44; *Toward the Right of Commerciality*, *supra* note 90, at 259.

124. *Zacchini v. Scripps-Howard Broadcasting Co.*, 433 U.S. 562, 564 (1976) (interpreting Ohio law).

125. W. PROSSER & W. KEETON, *supra* note 73, § 117, at 854 (footnotes omitted).

126. CAL. CIV. CODE § 3344(a) (West Supp. 1990). This statute provides, among other things, that the damages recoverable for its violation include the profits attributable to the unauthorized use, as well as attorney's fees. *Id.* "The statute applies only to use of a person's name, voice, signature, photograph or likeness and does not extend to the use of human tissue." *Id.*

127. 25 Cal. 3d 813, 603 P.2d 425, 160 Cal. Rptr. 323 (1979) (holding that the right to exploit one's name and likeness is personal and cannot be exercised by the decedent's heirs).

128. *Id.* at 818-19, 603 P.2d at 428, 160 Cal. Rptr. at 326.

of one's name or likeness was personal and that it must be asserted during one's lifetime.¹²⁹

In response to the holding in *Lugosi*, the California legislature enacted Civil Code Section 990, which extended the protection of Civil Code section 3344 to the likeness of a deceased person.¹³⁰ Civil Code section 990 expressly states that the rights it provides are "property rights."¹³¹ In *Midler v. Ford Motor Co.*,¹³² the Ninth Circuit cited to Civil Code section 990(b) as support for its statement that "[b]y analogy, the common law rights [in the use of one's likeness] are also property rights."¹³³

Although the express terms of Civil Code sections 3344 and 990 do not apply to the use of an individual's tissue, they do suggest that the right of publicity is indeed a kind of property right. Yet, the crucial question is not whether the right of publicity is a type of quasi-property right,¹³⁴ but whether the right of publicity is the appropriate vehicle for the protection of an individual's right to control the disposition of her body.

The right of publicity is different from the other three privacy-based rights, in that the other three rights are based on a "direct wrong of a personal character, resulting to an injury to the feelings."¹³⁵ One commentator has suggested that:

[T]he right of publicity is a species of the right of privacy, rather than an entirely separate interest.... Furthermore, when the right of publicity or the right of privacy is violated, the gravamen of the tort is the same: An individual's identity has been used without his or her consent for another's advantage. Hence, the only real difference ... seems to be whether one seeks to exploit or prevent the public use of his or her identity. In the former instance, the right is used offensively as a sword; in the latter instance, the right is used defensively as a shield.¹³⁶

129. *Id.* at 824, 603 P.2d at 431, 160 Cal. Rptr. at 329; see *supra* note 70 and accompanying text.

130. CAL. CIV. CODE § 990(a) (West Supp. 1990).

131. *Id.* § 990(b).

132. 849 F.2d 460 (9th Cir. 1988) (construing California law, the court held that, although Bette Midler had no cause of action under Civil Code § 3344 where the defendant used a singer whose voice sounded like Ms. Midler's, there was a cause of action at common law).

133. *Id.* at 463.

134. Under California law, even if the right to publicity is considered a type of property, it is not a type of tangible personal property that would properly be the subject of a cause of action for conversion. See *supra* notes 73-98 and accompanying text.

135. *Lugosi v. Universal Pictures*, 25 Cal. 3d 813, 833, 603 P.2d 425, 437, 160 Cal. Rptr. 323, 335 (1979) (Bird, C.J., dissenting) (quoting *Fairfield v. American Photography Equip. Co.*, 138 Cal. App. 2d 82, 291 P. 2d 194 (1955)).

136. *Martin & Lagod*, *supra* note 113, at 235.

However, as noted by the United States Supreme Court, the underlying rationales of the rights are very different. The Court has explained that the right of publicity does not involve the mere use of a person's attractiveness to enhance a product, it involves the "appropriation of the very activity by which the entertainer acquired his reputation in the first place."¹³⁷ The Supreme Court further stated that the protection of the right of publicity:

is more than a desire to compensate the performer for the time and effort invested in his act; the protection provides an economic incentive for him to ake the investment required to produce a performance of interest to the public. This same consideration underlies the patent and copyright laws long enforced by this Court.¹³⁸

Dissenting in *Lugosi*, Justice Bird also recognized that the right of publicity "intrudes on interests distinctly different than those protected by the right of privacy."¹³⁹ She went on to note that "the loss may well exceed the mere denial of compensation for the use of the individual's identity. The unauthorized use disrupts the individual's effort to control his public image, and may substantially alter that image."¹⁴⁰

As defined by both the California and the United States Supreme Court, the right to publicity is designed to protect a public figure's investment in his or her public persona, in order to encourage people to invest in developing that persona. In this way, the right of publicity is more than just an "offensive sword" that is used to protect an individual's privacy. It is a mechanism to reward an individual's efforts to create valuable rights in his or her persona. If this right were to be extended to protect the commercial use of human tissue, the courts would be implicitly stating that it is desirable for the individual to treat his or her body as a commercial product. This is fundamentally inconsistent with the way we currently treat other potentially valuable uses of the human body.¹⁴¹

Perhaps more importantly, the vast majority of individuals are not equipped to discover and develop any potential commercial value that might exist in their cells. Therefore, the rationale behind the right of publicity simply does not apply to the use of human tissues in biotech drugs. Furthermore, extending the right to such situations would

137. *Zacchini v. Scripps-Howard Broadcasting Co.*, 433 U.S. 562, 576 (1976).

138. *Id.*

139. *Lugosi*, 25 Cal.3d at 834, 603 P. 2d at 437, 160 Cal. Rptr. at 335 (Bird, C.J., dissenting).

140. *Id.* at 835, 603 P.2d at 438, 160 Cal. Rptr. at 336.

141. *See infra* Section VI. Even though we do allow some compensation for the use of human tissue in very limited circumstances, the general rule is not to allow compensation to be paid to tissue donors.

conflict with the public policy of rewarding the efforts of the inventors of these drugs.¹⁴²

Another fundamental problem with the right to publicity is that the right would not be violated until a successful commercial product is created. Due to the fact that most biotechnology research does not result in the development of a successful commercial product,¹⁴³ this right fails to protect the rights of the vast majority of persons whose tissues are used in biotechnology research to decide whether their cells will be commercialized.

The California Supreme Court gave a more basic reason for finding that the right of publicity cases were irrelevant to the issue of conversion. The court stated:

Not only are the wrongful publicity cases irrelevant to the issue of conversion, but the analogy to them seriously misconceives the nature of the genetic materials and research involved in this case. ... [T]he goal and result of the defendants' efforts has been to manufacture lymphokines. Lymphokines, unlike a name or a face, have the same molecular structure in every human being and the same important functions in every human being's immune system.¹⁴⁴

The courts' and commentators' focus on whether there is a property right in human tissue and, if so, what the nature of that right is, has obscured the underlying issues of the *Moore* case. Society's two important goals of protecting individual autonomy as well as furthering the ability of researchers to conduct potentially valuable research (both commercial and noncommercial) in a way that leaves them free from future claims of impropriety, will be better served by the imposition of a clear right that attaches at the time that the tissue is first removed.¹⁴⁵ Even though the use of human tissue does not fit into a recognized right of privacy cause of action, it is recognized that there is a zone of privacy protected by the Constitution. "It embraces not only the interests protected by the common law action..., but it also protects to a

142. See *supra* text accompanying notes 80-81.

143. See *supra* text accompanying note 23. In addition, the classic case of the right to publicity involves the use of a person's face or voice. This type of use involves relatively simple problems of proof that are resolved by showing the offending picture or recording. Similarly, in *Moore*, it is relatively easy to show that the "Mo cell-line" was created using only Mr. Moore's cells. See *supra* text accompanying note 46. This is in contrast to the problems of proof that would be encountered in the more common situation where the cells of more than one individual are used to create a single product. See *supra* note 33 and accompanying text.

144. *Moore v. The Regents of the Univ. of California*, 51 Cal. 3d 120, 138-39, 793 P.2d 479, 489-90, 271 Cal. Rptr. 146, 154-55 (1990).

145. The California Supreme Court recognized this fact when it held that Mr. Moore had a cause of action under informed consent law. *Id.* at 147, 793 P.2d at 497, 271 Cal. Rptr. at 164.

considerable extent the autonomy of the individual to make certain important decisions of a very personal nature."¹⁴⁶ It is this right to make important decisions of a personal nature that the Court of Appeals was trying to protect in the *Moore* case. In this way, it is an individual's interest in making such decisions that is analogous to the quasi-property right to control the disposition of a corpse.¹⁴⁷ The most effective way to protect this right for all patients and research subjects is to expand both the common law and statutory rules of informed consent.

V. INFORMED CONSENT

In the *Moore* case, the alleged injuries occurred during the course of a relationship that was both therapeutic and research-oriented in nature.¹⁴⁸ Therefore, the Supreme Court reasonably focused on examining whether the common law duty of informed consent imposes a duty of doctors to inform patients of possible research on, and commercial exploitation of, their tissue. The court held that:

[A] physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may effect his medical judgement.¹⁴⁹

In order to understand the Court's holding, this section will analyze the doctrine of informed consent. In addition, this section will examine the scope of the statutory and regulatory duty of informed consent as it is currently applied to medical researchers and suggest some changes that should be made in this area.

A. The Treating Researcher/Physician's Duty of Informed Consent

Originally, the failure to obtain consent for medical treatment was considered subject to a cause of action in battery for unconsented touching.¹⁵⁰ This cause of action was generally limited to situations where the treatment itself was performed without the patient's consent.¹⁵¹

146. W. PROSSER & W. KEETON, *supra* note 73, § 117, at 866.

147. Analogous to the right in a dead body, the right to control the disposition of one's bodily tissue does not necessarily include the right of alienation or of conveyance, however damages can be recovered for violation of this right. *See supra* note 116 and accompanying text.

148. *See supra* Section III B.

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

150. Schultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 224 (1985). For a description of the tort of battery, see W. PROSSER & W. KEETON, *supra* note 73, § 9, at 39-42. For an analysis of the doctrine of informed consent to medical

The advantage of a battery-type cause of action was that "the patient's wishes take priority over even the fully competent recommendation of a doctor, unless an exception applies."¹⁵² Professor Shultz, however, cites two primary reasons why the tort of battery has become disfavored by many courts in informed consent cases. First, in most cases of medical treatment, the patient did consent to some form of medical treatment.¹⁵³ Second, battery is an intentional tort and in most informed consent cases, doctors are not acting with antisocial intent; the issue instead is the failure of the physician to provide enough information about the risks of treatment, as well as the alternative medical treatments available.¹⁵⁴

[T]o hold that such uninformed consent was invalid, thereby subjecting doctors to actions for battery, threatened to yield unacceptably harsh results. Given the absolute nature of battery, the narrowness of its defenses, and the breadth of its remedies, doctors could end up paying significant damages after providing faultless medical treatment, simply because some minor informational aspect of the consent process was questioned.¹⁵⁵

Due to these difficulties, it became more common over time for the doctrine of informed consent to be treated as a subset of doctors' professional malpractice law, rather than as a type of battery.¹⁵⁶

The physician's traditional duty, under the professional malpractice standard, was to inform the patient of all risks that a physician would customarily disclose under the circumstances.¹⁵⁷ The adoption of this standard effectively substituted the doctor's judgement for the patient's.¹⁵⁸ Recognition of this fact led the California Supreme Court to hold in *Cobbs v. Grant* that "there is a duty of reasonable disclosure of the

treatment, see Schultz, *supra*; see also Studer, *The Doctrine of Informed Consent: Protecting the Patient's Right to Make Informed Health Care Decisions*, 48 MONT. L. REV. 85, 86-88 (1987).

151. Schultz, *supra* note 150, at 226. In the case of *Schloendorff v. Society of New York Hospital*, Justice Cardozo stated that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable for damages." 211 N.Y. 125, 127, 105 N.E. 92, 93 (1914), *overruled by* *Bing v. Thunig*, 2 N.Y. 2d 656, 163 N.Y.S. 3, 143 N.E.2d 3 (1957).

152. Schultz, *supra* note 150, at 224 (footnotes omitted).

153. *Id.* at 225.

154. *Id.*

155. *Id.*

156. *Id.* at 226; Studer, *supra* note 153, at 87-88; see also *Salgo v. Leland Stanford Jr. Univ. Board of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957).

157. W. PROSSER & W. KEETON, *supra* note 73, § 117, at 191.

158. *Cobbs v. Grant*, 8 Cal. 3d 229, 243-44, 502 P.2d 1, 10, 104 Cal. Rptr. 505, 514 (1972). The seminal case in this area is *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972). "Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose on themselves." *Id.* at 784.

available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each."¹⁵⁹ As way of guidance as to what constitutes reasonable disclosure, the court stated that:

In sum, the patient's right of self-decision is the measure of the physician's duty to reveal. That right can be effectively exercised only if the patient possesses adequate information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision. Thus the test for determining whether a potential peril must be divulged is its materiality to the patient's decision.¹⁶⁰

However, in *Cobbs*, the court also clearly established that the requisite causal connection between the plaintiff's injury and the failure to inform is only satisfied when it "is established that had revelation been made consent to treatment would not have been given."¹⁶¹ In other words, unless the patient would not have elected to have the treatment if full disclosure had been given, there is no cause of action for lack of informed consent. This would effectively prevent recovery in a case like *Moore*, unless the plaintiff can show she would have refused treatment if she had known of possible commercialization of her cells.¹⁶²

Yet, the doctrine of informed consent has been expanded in California to create a duty to inform that goes beyond mere disclosure of the risks of a given course of treatment. In *Truman v. Thomas*,¹⁶³ the California Supreme Court extended the duty of disclosure required under the patient-oriented standard of informed consent to include the duty to advise a patient who refuses to undergo a risk-free diagnostic test of all "material risks of which a reasonable person would want to be informed before deciding not to undergo the procedure."¹⁶⁴

More importantly, in *Jamison v. Lindsay*,¹⁶⁵ the plaintiff claimed that the failure to disclose that some of the tissue from her ovarian tumor was of a type that some pathologists considered to be malignant or pre-malignant was a breach of the duty of informed consent because she was entitled to know of the potential malignancy so that she could choose to

159. *Cobbs*, 8 Cal. 3d at 243, 502 P. 2d at 10, 104 Cal. Rptr. at 514.

160. *Id.* at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515 (citing *Canterbury*, 464 F.2d at 786).

161. *Id.* at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515.

162. Note that in his complaint Mr. Moore did allege that he would have sought treatment elsewhere if he had known of Dr. Golde's research. See Third Amended Complaint, *supra* note 38.

163. 27 Cal. 3d 285, 611 P.2d 902, 165 Cal. Rptr. 308 (1980).

164. *Id.* at 292, 611 P.2d at 906, 165 Cal. Rptr. at 312 (trial court erred in refusing to give jury instruction on the issue of negligence of a doctor who refused to warn of risks of not having a pap smear).

165. 108 Cal. App. 3d 223, 166 Cal. Rptr. 443 (1980).

seek further medical treatment.¹⁶⁶ Although the Court of Appeals denied recovery by rejecting the plaintiff's proposed jury instructions,¹⁶⁷ it opened the door to a broader definition of the duty of informed consent when it held that it would be proper to give a jury instruction that stated; "it is the duty of a physician or surgeon to disclose to the patient all relevant information to enable the patient to make an informed decision whether to seek additional treatment following surgery."¹⁶⁸ The holding in *Jamison* provides support for the proposition that there is an ongoing duty of disclosure that applies to information discovered by a physician after the consent to surgery has been validly obtained. It would be consistent with the reasoning of *Jamison* to impose upon a physician who is in an ongoing therapeutic relationship with a patient, the duty of informing the patient of the ongoing efforts to commercialize his cells.

The rationale behind the duty of informed consent is that the patient's right of self-decision (regarding whether or not to undergo medical treatment) compels the disclosure of all information regarding the treatment that is material to that patient's decision-making process.¹⁶⁹ If it is recognized that the decision to have a portion of one's body used for research, as well as in commercial products, is encompassed in an individual's right to privacy,¹⁷⁰ the failure of the physician to disclose such research causes a cognizable injury to the patient and should be sufficient to create a cause of action for lack of informed consent.

The Supreme Court correctly noted that:

[A] physician who treats a patient in whom he also has a research interest has potentially conflicting loyalties. ... The possibility that an interest extraneous to the patient's health has affected the physician's judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment.¹⁷¹

An alternative legal theory that could be used to protect a patient's right to control what research is performed on her body (or its parts), could be found in the an expansion of the tort of battery. Despite the more common use of a negligence-based cause of action in California, a cause of action for battery can still be maintained against a physician.

166. *Id.* at 229, 166 Cal. Rptr. at 446.

167. *Id.* at 230-31, 166 Cal. Rptr. at 446-47.

168. *Id.* at 230, 166 Cal. Rptr. at 447 (citation omitted).

169. *See supra* text accompanying note 160.

170. *See supra* text accompanying notes 145-146.

171. *Moore v. The Regents of the Univ. of California*, 51 Cal. 3d 120, 130, 793 P.2d 479, 484, 271 Cal. Rptr. 146, 151 (1990). The court went on to note that even though the "disclosure of research and economic interests may corrupt the patient's own judgment by distracting him from the requirements of his health," the patient has a basic right "to ... 'make the ultimate informed decision.'" *Id.* at 131, 793 P.2d at 484, 271 Cal. Rptr. at 151 (citing *Cobbs v. Grant*, 8 Cal. 3d 229, 243 (1972)).

Unfortunately, in *Cobbs v. Grant*,¹⁷² the California Supreme Court explicitly limited the battery cause of action to those cases where "a doctor performs an operation to which the patient has not consented."¹⁷³ This limitation on the tort of battery is derived from the theory that there must be an unconsented-to touching in order to maintain an action for battery.¹⁷⁴ Such a limitation would appear to bar the application of the doctrine in a case such as Mr. Moore's, where there was a valid consent to surgery.

However, at least one court has held that the tort of battery applied to a case where there was no unconsented-to touching. In *Mink v. The University of Chicago*,¹⁷⁵ the plaintiffs were given the drug diethylstilbestrol ("DES"), as part of their regular prenatal treatment, without their knowledge.¹⁷⁶ The court held that a negligence action could not be maintained because the plaintiffs did not allege any personal physical injury.¹⁷⁷ However, the court also held that the plaintiffs had stated a valid cause of action for battery.¹⁷⁸ The court noted that: "[P]roof of the technical violation of the integrity of the plaintiff's person by even an entirely harmless, but offensive, contact entitles him to a vindication of his right...."¹⁷⁹ In addition, the court adopted a more narrow definition of what would qualify as a valid consent to treatment by the patient. The court stated that "the scope of the plaintiff's consent is crucial to their ultimate recovery in a battery action. The defendant's privilege is limited at least to acts substantially similar to those to which the plaintiff consented."¹⁸⁰

Under the rationale of the *Mink* court, a patient such as Mr. Moore, whose tissue was used for research without his consent, would be entitled to seek "vindication" of the invasion of his privacy right, even though he did not suffer any physical injury. A valid consent to medical treatment would not also constitute consent to research or consent to the commercialization of the patient's tissues.

172. 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

173. *Cobbs*, 8 Cal. 3d at 240, 502 P.2d at 8, 104 Cal. Rptr. at 512. A requirement for the tort of battery is that there be an unconsented-to touching of the patient by the physician. See *supra* note 150 and accompanying text.

174. See *supra* note 151.

175. 460 F. Supp. 713 (N.D. Ill. 1978).

176. *Id.* at 715.

177. *Id.* at 722. The alleged injury was mental anxiety and emotional distress caused by the increased risk of cancer to the plaintiff's children. *Id.* at 716.

178. *Id.* at 722.

179. *Id.* at 718 (citing to W. PROSSER & W. KEETON, THE LAW OF TORTS, § 9, at 35 (4th ed. 1971)).

180. *Id.* at 718.

An expanded battery theory would protect the rights of patients whose tissues are used for research by a treating physician, whether or not that research yielded a commercially viable product. Furthermore, under this approach, the researcher/physician could obtain a consent in advance of the research that includes consent to possible commercialization, thereby avoiding any impracticality associated with a requirement that the physician obtain an additional consent when it is proven that a given tissue sample has commercial applications.¹⁸¹ However, under the rationale of the *Mink* court, consent to research should not implicitly include consent to the commercialization of one's tissue, unless the consent expressly provided for that possibility.

The fiduciary nature of the doctor-patient relationship¹⁸² provides further support for holding the treating physician liable for the failure to inform a patient that the doctor is performing research upon his or her tissue, research which may prove quite lucrative to the physician. The dual role of researcher and healer creates an inherent conflict of interest for the physician. The California Supreme Court recognized that a doctor's fiduciary duty imposes an obligation to disclose a conflict of interest, such as profiting from commercially valuable research on a patient.¹⁸³

Although it was an expansion of prior law to hold that informed consent law expressly required full disclosure of all research performed on a patient (or in tissue removed from that patient), doing so was in accord with the basic principles behind informed consent doctrine. The rationale behind the holdings in *Truman v. Thomas*¹⁸⁴ and *Jamison v. Lindsay*¹⁸⁵ provided the grounds for such an expansion of the scope of informed consent.

Alternatively, in the future, courts could follow the rationale of the *Mink* court¹⁸⁶ and hold that there is a cause of action for battery when the

181. It is true that, especially in the doctor-patient relationship, where the balance of power is extremely unequal, a written consent is always open to challenge on the ground that it was improperly obtained. However, this alone is not sufficient a reason to deny an important individual right.

182. RESTATEMENT (SECOND) OF AGENCY § 387 (1957); Shultz, *supra* note 150, at 259-63.

183. The California Supreme Court explained that that the term "fiduciary" did not mean that the physician was the patient's financial advisor. It "signifies only that a physician must disclose all facts material to the patient's decision because "certain professional interests may effect personal judgement." *Moore v. The Regents of Univ. of the California*, 51 Cal. 3d 120, 131 n.10, 793 P.2d 479, 485 n.10, 271 Cal. Rptr. 146, 152 n.10 (1990). This description of the physician's fiduciary duty is similar to the duty to disclose conflicts of interest that is imposed on attorneys.

184. 27 Cal. 3d 285, 611 P. 2d 902, 165 Cal. Rptr. 308 (1980).

185. 108 Cal. App. 3d 223, 166 Cal. Rptr. 443 (1980).

186. *See supra* text accompanying note 180.

scope of consent given to medical treatment did not specifically include consent to research and commercialization of one's cells.

B. Statutory and Regulatory Treatment of Informed Consent

The failure of the common law doctrine of informed consent to protect research subjects has meant that the primary protection from unauthorized research being performed upon a patient has been found in federal regulations and state statutes.

In *Moore*, the Supreme Court held that because the hospital, Ms. Quan (Golde's researcher) and the biotechnology companies were not physicians, they did not have a duty to obtain Moore's informed consent to medical procedures. The Court further stated that, in order to hold these defendants liable, Moore would have to prove that they were liable under some theory of secondary liability.¹⁸⁷

This means that when the researcher is not also the patient's treating physician, the *Moore* case does not impose any duty to inform the patient that her tissue is being used for potentially lucrative biotechnology research. In such a case, the tissue source must turn to existing state and federal guidelines for protection.

Unfortunately, these statutes and regulations, while affirming the broad principle that informed consent must be obtained for all research on human subjects, were drafted to protect people from the dangers of physical and mental experimentation on their bodies. Therefore, they do not necessarily require obtaining valid consent for the commercial development of excised tissue.

The regulations which control the use of research subjects in federally funded research are contained in Parts 21 and 45 of the Code of Federal Regulations. These regulations provides that experiments on human subjects funded or conducted by the federal government can only be performed if the subject is first informed of all the potential risks and the benefits of the experimentation.¹⁸⁸

Unfortunately, it is not at all clear that these regulations automatically apply in a case like the *Moore* case. First, as with the common law doctrine of informed consent, the concept of risks and benefits is limited to those of a physical nature.¹⁸⁹ Second, these regulations may be modified, or waived altogether, when a research

187. *Moore*, 51 Cal. 3d at 133-34, 793 P.2d at 486, 271 Cal. Rptr. at 153-54. Examples are found in employee-employer or joint-venture relationships. *Id.* at 133-34 n.12, 793 P.2d at 486 n.12, 271 Cal. Rptr. at 153-54 n.12.

188. 45 C.F.R. §§ 46.101-46.103 (1989).

189. 12 C.F.R. § 50.25 (1990).

project involves minimal risk.¹⁹⁰ Minimal risk exists where the risks of harm encountered in the proposed research are not greater in magnitude than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.¹⁹¹ Under this standard, Mr. Moore did not encounter any additional physical risks beyond those that he was subjected to in the course of necessary surgery. In fact, the federal informed consent guidelines are generally not applied to cases where research is performed on tissue removed incident to necessary surgery. Therefore, Dr. Golde's actions did not necessarily violate federal guidelines.¹⁹²

In order to protect the right of individuals to determine whether their body tissue will be commercialized, it is necessary to revise the federal regulations to define the commercialization of tissue used in biotechnology research as a risk and/or benefit to the research subject. Furthermore, the definition of minimal risk must be revised to explicitly include biotechnology research that has potential commercial applications.¹⁹³ The right to be informed of what type of research is being performed on one's tissues should not depend only on whether the researcher happens to be the donor's treating physician.

In California, laws regulating human experimentation were enacted under the Protection of Human Subjects in Medical Experimentation Act.¹⁹⁴ The Act mirrors federal regulation and is designed to provide minimal protection when research is not covered by federal regulations. As with the federal regulations, the Act provides that, for consent to research to be valid, the subject must be given a written statement that includes, among other things: information on "the nature and the purpose of the experiment";¹⁹⁵ a description of the attendant risks and discomfort reasonably to be expected from the experiment;¹⁹⁶ information as to any potential benefits to the subject that is reasonably to be expected

190. 45 C.F.R. § 46.102 (1989).

191. *Id.* § 46.102(g).

192. *Cf. Martin & Lagod, supra* note 113, at 226-32.

193. For an in depth critique of the federal guidelines, which includes several additional excellent suggestions for revision, see Delgado & Leskovac, *Informed Consent In Human Experimentation: Bridging The Gap Between Ethical Thought And Current Practice*, 34 UCLA L. REV. 67 (1986). The authors list four important rationales that support a broader definition of informed consent in human experimentation: (1) the risks of experimentation cannot be ascertained in advance; (2) there is no reason to defer to medical expertise because it does not exist in experimental settings; (3) experimentation often provides no certain benefit to the subject and; (4) the researcher and the subject often have conflicting interests. *Id.* at 88-92. It is reason number 4 that is at the heart of the *Moore* case.

194. CAL. HEALTH & SAFETY CODE §§ 24170 - 24172 (West 1984).

195. *Id.* § 24172(a).

196. *Id.* § 24172(c).

from the experiment;¹⁹⁷ the opportunity to ask questions; and instructions that the patient can withdraw from the experiment at any time.¹⁹⁸ Unfortunately, these requirements have also been traditionally considered to apply only to physical risks and benefits. As with the federal regulations, the California Legislature should revise the Act to explicitly provide that a subject must be fully informed of any potential for the commercialization of her tissue.

VI. SHOULD INDIVIDUALS BE ALLOWED TO SELL THEIR TISSUE?

Until this point, this Comment has confined its analysis to the issue of whether individuals have a right to control what becomes of their excised tissue and how that right should properly be enforced. Although the California Supreme Court established in *Moore* that a physician must disclose any interests that he might have that will affect a patient health, the Court did not address the issue of whether or not a patient has the right to sell her own tissue.¹⁹⁹ This section will explore a possible legal framework within which to analyze this issue. In addition, this section will examine the current scheme for regulating the use of bodily products and organs for medical research and treatment.

In order to properly accommodate the competing public policy considerations of individual autonomy and of furthering the development of science that is of potential benefit to mankind, it is important to distinguish the right to control the disposition of one's tissue from the right to sell that tissue. The Court of Appeals recognized this dichotomy when it stated that "[w]e are not called upon to determine whether use of human tissue or body parts ought to be 'gift based' or subject to a 'free market.' That question of policy must be determined by the legislature."²⁰⁰

The policy issue of whether there should be a "free market" in human tissue used for biotech products and research is extremely complex. In order to achieve a satisfactory solution, the California legislature must first understand the complicated and contradictory nature of the existing federal and state regulations and statutes that already control various uses of human tissue and body parts. Second, the

197. *Id.* § 24172(d).

198. *Id.* § 24172(g) & (h).

199. *Moore v. The Regents of the Univ. of California*, 51 Cal. 3d 120, 133, 793 P.2d 479, 487, 271 Cal. Rptr. 146, 154 (1990).

200. *Moore v. The Regents of the Univ. of California*, 215 Cal. App. 3d 709, 724, 249 Cal. Rptr. 494, 504 (1988), *rev'd*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).

Legislature must reconcile the contradictions that currently exist in the regulation of the sale of human tissue.

In the long run, better results will be achieved with rules that are fashioned with a clear policy rationale to govern the scope of the permissible limits on the commodification of the human body. In subsection A, I attempt to provide a theoretical basis for such a policy. Then, in subsection B, I examine current federal and state controls on the sale of human tissue. Finally, subsection C suggests two possible alternative approaches to the regulation of the sale of tissue for biotechnology research.

A. Doctrinal Treatments of the Commodification of Personhood²⁰¹

Theorists have strongly disagreed on the degree of commodification²⁰² of the human body that is tolerable in a society that seeks to protect individual autonomy. At one extreme is the position of universal commodification.²⁰³ Proponents of this view suggest that all things can be conceived of as commodities, and that individual freedom is equated with unrestricted choice as to what goods to trade in.²⁰⁴ At the other extreme is Marxist theory, which suggests that "the market ought not to exist and that social interactions involving production and consumption should be reconceived in a non-market way."²⁰⁵

Professor Radin contends that the vision associated with traditional liberal values in western society is called pluralism.²⁰⁶ Under the pluralist view, there is a realm of alienable property rights and inalienable political or individual rights.²⁰⁷ However, competing with that view is the notion of "negative liberty," that is the right to be let alone, as long as one does not hurt anyone else.²⁰⁸ The inevitable result of negative liberty is that restraints on alienation are thought to be paternalistic. It follows that this

201. The discussion in this section is based on the analytical framework developed by Professor Margaret Radin in *Market Inalienability*, 100 HARV. L. REV. 1849 (1987).

202. In a narrow sense, the term "commodification" means the actual buying and selling of human tissue and body parts. In its broader sense, the term also refers to "the practice of thinking about interactions as if they were sale transactions." *Id.* at 1859.

203. *Id.* at 1859.

204. *Id.* at 1860-61. Posner, a major proponent of this system, suggests all things scarce should be subject to property rights and thus saleable. R. POSNER, *ECONOMIC ANALYSIS OF LAW* 29-33 (3rd ed. 1986). Posner has also advocated the creation of a market for the selling of babies. *Id.* at 139.

205. Radin, *supra* note 201, at 1870.

206. *Id.* at 1887.

207. In other words, certain personal rights are so central to our idea of personhood, that they may not be sold (commodified) without diminishing individual autonomy. *Id.* at 1888-98.

208. *Id.* at 1888.

concept of negative liberty comes into direct conflict with the principle that full human freedom requires that some individual rights not be commodified.²⁰⁹

Professor Radin suggests that a proper reconciliation of the competing principles of negative liberty and the protection of individual rights is achieved by allowing the individuals to make gifts of aspects of the self that are central to personhood, and by not allowing the sale of such intimate aspects of the self.²¹⁰ Professor Radin uses prostitution, surrogacy and baby selling as examples involving commodification of the person.²¹¹

However, Professor Radin also proposes an important limiting principle to the noncommodification of personhood. She suggests that when a given aspect of personhood is already commodified, prohibiting persons from selling that aspect of their personhood places them in a double bind of powerlessness, thereby reducing the individual's power of autonomy.²¹²

In such a case, Professor Radin suggests that the individuals should be allowed to sell that aspect of the person, but that the market should be regulated to reduce the negative effects to aspects of personhood.²¹³

B. Existing Regulation of the Sale of Human Tissue and Body Parts

As was discussed above, the tissue used in biotech research comes from blood and other replenishing body fluids, from tissue and organs removed incident to surgery and from cadavers.²¹⁴ Although they were not drafted with biotechnology research in mind, there are various regulations which apply to the sale of each of these sources of tissue.

209. *Id.* at 1903.

210. *Id.* at 1907-14. Professor Radin notes that the goal of a rule of noncommodification of personhood is to ensure free choice. It is crucial to note that, as Professor Radin points out, "to the extent that [a rule of noncommodification] equates poverty with coercion, the prophylactic argument requires a corollary in welfare rights." *Id.* at 1911. While I strongly agree with this argument, I also believe that noncommodification of intimate aspects of personhood is a principle that serves to protect the individual dignity of all persons.

211. *Id.* at 1911.

212. *Id.* at 1912-17.

213. For example, she suggests that a woman be allowed to engage in prostitution because sex is already so commodified in society. However, to reduce the negative effect on a woman's personhood, pimping should be prohibited. *Id.* at 1921-25. Professor Radin goes on to conclude that both baby selling and surrogacy are not sufficiently commodified to warrant allowing woman to be compensated. *Id.* at 1925-36.

214. OWNERSHIP OF HUMAN TISSUE AND CELLS, *supra* note 8, at 51; *see supra* notes 20-22 and accompanying text.

The sale of blood and other replenishing bodily fluids is not prohibited under existing state or federal law.²¹⁵ California law was amended in 1986 to make it unlawful to use blood from a compensated individual for a transfusion, unless no suitable blood is available from a donor.²¹⁶ However, this appears to be more a reaction to the spread of the AIDS virus than a policy against the sale of blood. In fact, income from the sale of blood remains exempt from California income tax.²¹⁷ It is currently legal, in California, for an individual to sell his blood to researchers for use in biotechnology research.

Federal law makes it "unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."²¹⁸ The definition of human organ is quite broad and includes replenishing tissue, such as skin and bone marrow.²¹⁹ The statute was amended in 1988 to include fetal tissue in the definition of the term human tissue.²²⁰ The definition of what constitutes a human organ under federal law seems to contemplate the prohibition of sale of most types of organs and tissue. Furthermore, the definition of a human organ seems to be broad enough to include most types of human tissue and organs that are used in biotechnology research. However, 42 U.S.C. § 274e only applies to the use of human organs for transplantation. Therefore, technically, there is no current federal prohibition on the sale of human tissue and organs for biotechnology research.

California has adopted the Uniform Anatomical Gift Act ("UAGA") to regulate the use of human tissue in transplantation.²²¹ The drafters of the UAGA were simply not concerned with the issue of whether organs may be sold. The purpose of the Act was to increase the supply of organs donated after death by making it easier for a person to consent to donation.²²² The only prohibition in California on the sale of human organs that is contained in California's UAGA is that "a person may not knowingly, for valuable consideration, purchase or sell a part for

215. OWNERSHIP OF HUMAN TISSUE AND CELLS, *supra* note 8, at 76; *see supra* notes 20-22 and accompanying text.

216. CAL. HEALTH & SAFETY CODE § 1626 (West Supp. 1989).

217. CAL. REV. & TAX. CODE § 33 (West 1987).

218. 42 U.S.C. § 274e(a) (West Supp. 1990).

219. "The term 'human organ' means the human, (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin or any subpart thereof or any other human organ (or any subpart thereof, including that derived from a fetus) as specified by the Secretary of Health and Human Services or by regulation." *Id.* § 274e(c).

220. *Id.*

221. CAL. HEALTH & SAFETY CODE §§ 7150-7155 (West Supp. 1990).

222. OWNERSHIP OF HUMAN TISSUE AND CELLS, *supra* note 28, at 75.

transplantation, [or] therapy... if removal of the part is intended to occur after the death of the decedent."²²³

In fact, it appears that California law allows an individual to sell his or her own organs or tissue if the removal will not occur after the individual's death.²²⁴ This result is contained in California Penal Code, section 367f,²²⁵ which makes it unlawful to "acquire, receive, sell, promote the transfer of ... any human organ for the purposes of transplantation, for valuable consideration."²²⁶ However, section 367f does not apply to the person from whom the organ is removed, nor to the person who receives the transplant.²²⁷ The net effect, under California and federal law, is to allow an individual to sell his or her nonvital organs or other tissues, for the purposes of human transplantation, as long as interstate commerce is not affected, no profit is received by any third party broker, and the organs will not be removed after the source's death.²²⁸

C. Commodification of the Individual for Biotechnology Research

The sale of human organs and tissue involves aspects of the self that are central to personhood.²²⁹ Federal law reflects this fact when it prohibits the sale of human organs and tissue for transplantation, but allows people to choose whether to donate organs for this purpose.²³⁰ This would suggest that, under Professor Radin's analysis, human organs should be market-inalienable for the purpose of use in biotechnology research.²³¹

However, the fact that researchers and physicians can currently reap great profits from products developed from human tissue already results in a partial commodification of the human body. The fact that blood can clearly be sold for the purposes of biotechnology research,²³²

223. CAL. HEALTH & SAFETY CODE § 7155(a) (West Supp. 1988).

224. Note that this argument assumes that such a sale does not affect interstate commerce. Also, if a court were to hold that 42 U.S.C. § 274e preempts state law, this argument would no longer be valid. However, to date, there has been no such holding.

225. CAL. PENAL CODE § 367f (West 1988).

226. *Id.* § 367f(a).

227. *Id.* § 367f(e).

228. This result is not surprising in light of the underlying purposes of the UAGA.

229. *See supra* notes 202-213 and accompanying text.

230. *See supra* notes 218-220 and accompanying text. The California statute prohibiting the removal of organs after death also reflects this fact. *See supra* notes 221-228 and accompanying text.

231. Note that it does not follow from this conclusion that human beings do not have the right to control the use of their tissue. In a gift based system, the right to alienate tissue remains, but this right does not include the right to receive compensation.

232. *See supra* text accompanying notes 215-217.

along with the fact that the sale of human body parts by an individual is permitted under certain circumstances in California, lends further support to the proposition that the sale of human body parts is an area in which there is incomplete commodification.²³³ This incomplete commodification presents a serious risk that patients and research subjects will be placed in exactly the type of "double-bind of powerlessness" that is described by Professor Radin.²³⁴ This double-bind is especially acute for seriously ill patients because they are often in need of money, and also because their lives are often completely dependent on their physician's judgement.

There are two potential solutions to this problem. The first is to try to equalize the balance of power between the physician/researcher and the patient by allowing the patient to sell his or her tissue. The problem with this approach is that when there is such a disparity of power between the patient and the physician, the patient may not feel free to forcefully assert his or her right to compensation. In addition, merely paying some compensation to the patient may not be sufficient to adequately resolve any conflict of interest that the physician may have between his own research and the treatment needs of the patient.²³⁵

The Supreme Court correctly noted, however, that "progress in medicine often depends upon physicians, such as those practicing at the university hospital where Moore received treatment, who conduct research while caring for their patients."²³⁶ Given that prohibiting a physician from profiting from research done on their patients could have a devastating effect on the development of new advances in medicine, the second approach, and the approach that will be the most effective in protecting individual autonomy, is to amend federal and state law to clearly require a researcher to inform a patient of potential commercial uses of his or her research. Furthermore, research subjects should be allowed to profit from the use of their tissue.

VII. CONCLUSION

The *Moore* case raised several important questions concerning the effect advances in biotechnology will have on an individual's right to control the disposition of his body. As is the case with other advances in technology, it is important for the courts and legislature to insure that

233. See *supra* text accompanying note 202.

234. See *supra* text accompanying note 212.

235. For a suggestion that the federal regulations be amended to provide that a physician receiving federal funds should not be allowed to profit from the research so funded, see Delgado & Leskovic, *supra* note 193, at 126.

236. *Moore v. The Regents of the Univ. of California*, 51 Cal. 3d 120, 130, 793 P.2d 479, 484, 271 Cal. Rptr. 146, 151 (1990).

individual autonomy will not be diminished by new scientific discoveries. However, it is also important for society to encourage innovation that will be of benefit to all people.

The California Supreme Court took an important first step in accommodating this balance when it held in *Moore* that the law of informed consent to medical treatment requires a physician to disclose all research interests. In order to protect all research subjects, the federal and state laws regulating informed consent to research must be amended to provide that individuals be told of potential commercial applications of research performed on their tissues. Furthermore, individuals must have the right to refuse to consent to such research, if they so desire.

Finally, it must be remembered that the right to control is distinct from the right to profit. The goal of individual autonomy will best be served by prohibiting individuals from selling their tissue. However, given that our current system of medical research and advancement depends on research done by researchers who expect to profit from successful results, it is not just to prohibit the tissue donor from receiving compensation while the researcher profits. Therefore, those who provide tissue to be used in biotechnology research should have the right to receive compensation for its use. Otherwise, as the general public grows to perceive that they are being mined for profit by their treating physician and other researchers, the integrity of the doctor-patient relationship will be irreparably damaged and more and more people may refuse to provide biological materials needed for research.

