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More on Moore: A Novel Strategy for Compensating the Human Sources of Patentable Cell-Line Inventions Based on Existing Law

Christopher Scott Pennisi*

In 1986, Clonetics Corporation introduced the first commercial product containing live human skin cells.¹ The “EpiPack” provides normal human epidermal cells, grown in the laboratory, in a unique growth medium, enabling researchers to quickly screen the reaction of human skin cells to “drugs for diseases such as cancer, chemicals like pesticides, a variety of cosmetics or even biological warfare agents.”² Such an invention allows pharmaceutical, cosmetic and medical researchers to test products without using animals or other, less accurate, biological models.³ The EpiPack was created from human skin samples purchased from doctors and patients following elective plastic surgery.⁴

INTRODUCTION

Cells are the basic structural unit of living animals and plants.⁵
Cells are self-regulating entities containing miniature organs

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¹ See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS, at 24 (1987) [hereinafter OTA REPORT], available at http://www.wws.princeton.edu/~ota/ns20/alpha_f.html (last visited Apr. 8, 2001); see also Rex Dalton, *Cloned Human Skin Cells Go On The Market*, SAN DIEGO UNION-TRIB., Feb. 15, 1987 at B1.

² See Dalton, *supra* note 1, at B1.

³ See *id.*

⁴ See OTA REPORT, *supra* note 1, at 24.

⁵ See *id.* at 5.

(organelles) surrounded by a living membrane filled with liquid (cytoplasm).⁶ Cells can be specialized or “differentiated” for a variety of functions, including the manufacture or digestion of compounds, photosynthesis, and antibody production, among others.⁷ Scientists and medical researchers often study the various functions of an organism by examining isolated cells.⁸ This is an essential technique for the development of biotechnology.⁹ Before they can be studied, however, cells must be removed from a body, isolated and cultured on a medium.¹⁰ These cell cultures are known as “cell-lines” because they come from, and give rise to, other cells along a similar hereditary lineage.¹¹ Due to the relative difficulty of developing and growing a cell-line in a laboratory from a human cell sample, the process is considered an art form.¹² Once developed, cell-lines can be used for diagnostic, therapeutic, research and commercial purposes or any combination thereof.¹³

Research uses for human tissue generally focus on expanding the depth of biological research through study of the characteristics and functions of organs, tissues, and cells.¹⁴ Commercial development stems from this scientific or basic research.¹⁵ Commercial usage of cell-lines focuses on developing products for further scientific research or medical treatment purposes.¹⁶ In product-oriented contexts, random specimens of human tissue can be used in one-time processes to create or test products and can then be discarded — as cells in an EpiPack are intended to be used.

⁶ See OTA REPORT, *supra* note 1, at 5; See MOLECULAR CELL BIOLOGY 5-9 (Harvey Lodish et al. eds., 3d ed. 1995).

⁷ See OTA REPORT, *supra* note 1, at 31 (noting that cells are specialized, or differentiated, to perform specific functions).

⁸ See OTA REPORT, *supra* note 1, at 5.

⁹ See *id.* at 5.

¹⁰ See *id.* at 5, 32.

¹¹ For example, epithelial cells can give rise to genetically similar epithelial cells. See MOLECULAR CELL BIOLOGY, *supra* note 6, at 196; see also OTA REPORT, *supra* note 1, at 3 (defining a “cell-line” as “a sample of cells, having undergone the process of adaptation to artificial laboratory cultivation, that is now capable of sustaining continuous, long-term growth in culture”).

¹² See OTA REPORT, *supra* note 1, at 5 (noting that establishing a successful human cell culture from a given sample of tissue varies in probability between .01 percent for some liver cells and 100 percent for skin cells).

¹³ Annie O. Wu, Note, *Surpassing the Material: The Human Rights Implications of Informed Consent in Bioprospecting Cells Derived From Indigenous People Groups*, 78 WASH. U. L.Q. 979, 986-87 (2000) (describing the utility of cell-lines).

¹⁴ See OTA REPORT, *supra* note 1, at 8.

¹⁵ See *id.* at 8.

¹⁶ See *id.*

Alternatively, tissue specimens with particular properties might be sought out and made part of long term research, investigating specific scientific questions or producing particular products, like cells used to create cell-lines. The potential for economic gain from commercialization of cell-lines, while sometimes great, is difficult to predict during the cell-lines' development.¹⁷ Without human biological samples, the biotechnology industry would have great difficulty producing and testing the drugs, devices, and other products that it develops in an effort to improve medical care and the general quality of human life.¹⁸ Despite its noble purpose, the biotechnology industry is motivated in part by profit.¹⁹ The expansion and diversification of the industry raises many ethical questions regarding ownership in human-derived tissue and cells used in the production of commercially successful cell-lines.²⁰ These questions were thrust into the legal limelight by the seminal California Supreme Court case of *Moore v. The Regents of the University of California*.²¹ The court, in a conservative opinion, refused to extend any ownership rights in a cell-line invention to its human source.²² Due in part to the moral backlash over the court's rejection of any such ownership rights, the question of property rights to profitable cells will undoubtedly be revisited by future courts.

This Note analyzes the law and policies surrounding the denial of property rights to the human sources of cell-line inventions as

¹⁷ As with all commercial products, for a cell-line to be profitable there must be a demand for the product. Demand for cell-lines is tied to the type of research the line facilitates. Because it is difficult to predict what the scientific community will focus on in terms of research, it is difficult to predict whether a cell-line will be "in demand," and thus profitable.

¹⁸ "Currently, researchers testing drugs or chemicals use hard-to-obtain cadaver skin, hairless animals and . . . humans. Each of these test modes has its own faults – even humans, whose bathing habits can distort results." Dalton, *supra* note 1. It is believed that lab-grown skin cells may be "a more exact, efficient and less costly method of testing drugs . . ." *Id.*

¹⁹ *See, e.g., id.* (For example, in the context of epidermal cell-lines there is "intense competition in the growing tissue-cloning field – where investors are staking millions of dollars on the technology of individual firms."); *see also Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 509 (Cal. Ct. App. 1988) (noting that "[i]t has been suggested by writers that biotechnology is no longer a purely research oriented field [and that] links . . . between academics and industry to profitize biological specimens are a subject of great concern").

²⁰ *See* OTA REPORT, *supra* note 1, at 3.

²¹ 793 P.2d 479 (Cal. 1990).

²² *See id.* at 480.

highlighted by *Moore v. The Regents of the University of California*.²³ It suggests a novel solution to the dilemma of human-source rights that would adequately recompense the source of a cell-line invention for his contribution. It argues that a right to compensation can be asserted under existing elements of patent law by applying the decades old shop right doctrine. It then argues that the most effective means of administering this relationship is to alter standard informed consent documents for medical procedures so that a patient does not release all interest in inventions resulting from his tissue merely by consenting to the procedure. By drawing on existing elements of patent and contract law, this solution requires no legislative effort and avoids many of the pitfalls of simply paying sources for tissue samples before the true value of their cells is known. Part I of the paper provides the factual background of the *Moore* case. Part II critiques the California Supreme Court's reasoning in refusing to allow Moore to recover against his physician and the University of California at Los Angeles ("UCLA") Medical Center. Part III discusses whether medical patients should retain rights in their potentially valuable excised tissue cell-line inventions. Finally, Part IV presents an efficient system for managing a patient's hypothetical right to share in the commercial exploitation of his tissue within the existing body of law.

I. IS IT ETHICAL TO COMMERCIALIZE PRODUCTS BASED ON HUMAN-DERIVED CELL SAMPLES INDEPENDENT OF CONSENT FROM THE SOURCE?

A. *Moore v. The Regents of The University of California*

John Moore first visited UCLA Medical Center (operated by the Regents of the University of California (the "Regents")) on October 5, 1976, shortly after he learned that he had hairy-cell leukemia, a rare type of cancer.²⁴ Moore was admitted to the

²³ *Id.*

²⁴ *Id.* at 481. See generally Arnold S. Freedman & Lee M. Nadler, *Malignancies Of Lymphoid Cells*, available at <http://www.harrisonsonline.com> (last visited April 27, 2000) (explaining that hairy cell leukemia is a rare type of cancer occurring predominantly in males over age 40 with expression of specific adhesion molecules involved in localizing cells to the spleen and marrow as well as massive splenomegaly,

hospital and had blood, bone marrow aspirate, and other bodily substances taken from him by attending physician Dr. David W. Golde, who confirmed Moore's diagnosis.²⁵ Golde was "aware that certain blood products and blood components were of great value in a number of commercial and scientific efforts and that access to a patient whose blood contained these substances would provide competitive, commercial, and scientific advantages."²⁶ Three days later, Golde recommended that Moore's spleen be removed, and informed Moore that he "had reason to fear for his life, and that the proposed splenectomy operation . . . was necessary to slow down the progress of his disease."²⁷ Prior to the splenectomy, Golde and Shirley G. Quan, a researcher employed by the Regents, made arrangements to obtain portions of Moore's spleen after it was removed, for research purposes unrelated to Moore's medical care.²⁸ Golde gave written instructions to this effect on October 18 and 19, 1976.²⁹ Moore's spleen was removed on October 20, although he was not informed of what subsequently happened to it.³⁰

Moore returned to UCLA Medical Center several times between November 1976 and September 1983 pursuant to Golde's "representations 'that such visits were necessary and required for [Moore's] health and well-being, and based upon the trust inherent in and by virtue of the physician-patient relationship . . .'"³¹ Moore traveled to UCLA Medical Center where Golde removed samples of Moore's blood, blood serum, skin, bone-marrow aspirate, and sperm.³² Moore was advised that "the procedures were to be performed only [at UCLA Medical Center] and only under Golde's direction."³³ Golde ultimately realized significant financial gain through his exclusive access to Moore's cells.³⁴

where the spleen extends greater than 8 cm below the lowest rib on the left side and/or weighs more than 1,000g).

²⁵ See *Moore*, 793 P.2d at 481.

²⁶ *Id.* at 481 (citation omitted in original).

²⁷ *Id.* (ellipsis in original) (citation omitted).

²⁸ See *id.*

²⁹ See *id.*

³⁰ See *Moore*, 793 P.2d at 481.

³¹ *Id.* (citation omitted).

³² See *id.*

³³ *Id.*

³⁴ See *id.*

Throughout the period of time that Moore was being treated by Golde, Golde conducted research on Moore's unique cells.³⁵ Although the commercial potential of cells is difficult to predict at the outset of research, "competing commercial firms in . . . relevant fields have . . . predict[ed] a potential market of approximately \$3.01 Billion Dollars by the year 1990 for [such cells]."³⁶ As a result, when Golde ultimately developed a cell-line from Moore's T-lymphocytes,³⁷ he and Quan applied for and were issued a patent for that line, with the Regents of the State of California named as its assignees.³⁸ Pursuant to the established policy, the Regents, Golde, and Quan were to share in any profits arising from the patent and, with the Regents' assistance, Golde negotiated contracts for commercial development of the cell-line and derivative products.³⁹ Under one such agreement, Golde became a consultant to Genetics Institute, acquired 75,000 shares of stock, and was to be paid \$330,000 over three years in exchange for exclusive access to the materials and research performed on the "Mo" cell-line and products derived from it.⁴⁰ Sandoz Pharmaceuticals⁴¹ was "added to the agreement," and compensation payable to Golde and the Regents was increased by \$110,000.⁴²

As a result of Golde's failure to disclose his preexisting research and economic interests in Moore's unique cells prior to performing any invasive procedures, Moore named Dr. Golde, Shirley Quan, the Regents, Genetics Institute, and Sandoz as defendants in a lawsuit stating thirteen causes of action.⁴³ The trial court,

³⁵ See *Moore*, 793 P.2d at 481.

³⁶ *Id.* at 482 (citation omitted in original).

³⁷ Golde initially named the cell-line "Mo" after Moore, but later renamed it to conceal the connection between patient and profit. See Charles E. Lipsey et al., *Protecting Trade Secrets In Biotechnology*, 224 PRACTICING L. INST. 807, 915 (1986).

³⁸ See *Moore*, 793 P.2d at 481-82.

³⁹ See *id.* at 482.

⁴⁰ See *id.*

⁴¹ In April, 1996, following a corporate merger with Ciba, Sandoz became part of Novartis Pharma. See *Strong Swiss Franc Mars Ciba/Sandoz Results Will Merge With Sandoz to Form Novartis in Move That Has Been Approved by Shareholders*, EUR. CHEMICAL NEWS, Apr. 29, 1996, at 19.

⁴² See *Moore*, 793 P.2d at 482 (citation omitted in original).

⁴³ The causes of action were 1) conversion; 2) lack of informed consent; 3) breach of fiduciary duty; 4) fraud and deceit; 5) unjust enrichment; 6) quasi-contract; 7) bad faith breach of the implied covenant of good faith and fair dealing; 8) intentional infliction of emotional distress; 9) negligent misrepresentation; 10) intentional interference with prospective advantageous economic relationships; 11) slander of title; 12) accounting;

however, considered only the first, conversion, and sustained a general demurrer on the remaining actions.⁴⁴ Moore claimed that he had a property interest in his own cells which extended beyond their removal from his body, and that the defendants' conduct constituted a substantial interference in his right of possession of those cells.⁴⁵ Moore further argued that, despite his execution of a general waiver of rights to his cells, he had never authorized the use of his cells for research and that Golde's usage constituted conversion.⁴⁶ Under California state law, conversion is a strict liability tort requiring proof that the property allegedly converted is personal property, and that the conversion itself resulted in damages.⁴⁷

The trial court sustained the defendant's demurrers to the conversion allegation on the grounds that Moore failed to specifically allege that he did not know that tissues removed during his treatment at UCLA might be used for research as well as for his personal medical treatment.⁴⁸ Although the Superior Court gave Moore leave to amend his original complaint, he appealed to the California Court of Appeals instead.⁴⁹ The Court of Appeals reversed the dismissals of the trial court and concluded that Moore's claim of a property interest in his own excised tissues did not lack basis in legal authority, public policy or scientific fact.⁵⁰ Further, the court found that Moore had sufficiently stated an action for conversion.⁵¹

and 13) declaratory relief. *See id.* at 482 n.4.

⁴⁴ *See id.* at 482-83.

⁴⁵ *See id.* at 487.

⁴⁶ *See* Maureen S. Dorney, *Moore v. The Regents of the University of California: Balancing the Need for Biotechnology Innovation Against the Right of Informed Consent*, 5 HIGH TECH. L.J. 333, 340 (1990) ("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.'").

⁴⁷ *See* *Poggi v. Scott*, 139 P. 815, 816 (Cal. 1914) ("The foundation for the action of conversion rests neither in the knowledge nor the intent of the defendant. It rests upon the unwarranted interference by defendant with the dominion over the property of the plaintiff from which injury to the latter results. Therefore neither good nor bad faith, neither care nor negligence, neither knowledge nor ignorance, are of the gist of the action.").

⁴⁸ *See Moore*, 249 Cal. Rptr. at 502.

⁴⁹ *See id.*

⁵⁰ *See id.* at 503-506.

⁵¹ *See id.* at 511.

The Supreme Court of California reversed the Court of Appeals, finding that Moore was not entitled to share in the profits from the cell-line, because it was legally and factually distinct from Moore's cells.⁵² With respect to the issue of informed consent, the California Supreme Court analyzed Moore's cause of action under three well established principles. These were, "[f]irst, 'a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment' . . . [s]econd, 'the patient's consent to treatment, to be effective, must be an informed consent' . . . [t]hird, in soliciting the patient's consent, a physician has a fiduciary duty to disclose all information material to the patient's decision."⁵³ Specifically, the court concluded that:

1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and 2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.⁵⁴

Not surprisingly, the court held that the sufficiency of such disclosures must be measured from the patient's perspective.⁵⁵

The California Supreme Court held that Moore's assertion that Golde concealed an economic interest in the postoperative procedures gave rise to a legitimate breach of fiduciary duty, regardless of the fact that the splenectomy had some therapeutic value.⁵⁶ Because the Regents, Quan, Genetics Institute and Sandoz were not physicians, much less Moore's physician, none of these defendants were held liable for breach of fiduciary duty as they had no responsibility for obtaining Moore's informed consent.⁵⁷ Although the court did find that Golde breached the principles of informed consent law by failing to inform Moore of his research

⁵² The court felt that because the cell-line is the product of an inventive effort, it was a entity distinct from Moore's original cells and that this therefore extinguished Moore's rights. *See Moore*, 793 P.2d at 492-493.

⁵³ *See id.* at 483 (citations omitted).

⁵⁴ *Id.*

⁵⁵ *See id.*

⁵⁶ *See Moore*, 793 P.2d at 485.

⁵⁷ *See id.* at 486.

interest,⁵⁸ it did not specifically discuss whether informed consent must address research performed on human tissue after it is excised from the body.⁵⁹ The court did not have to address this issue, because it could settle the underlying monetary dispute based on well-settled principles of informed consent rather than incorporating non-legal impressions of patients' rights into the common law.⁶⁰ By basing its decision on informed consent, the court was able to ground its reasoning in the more germane tort of performing unauthorized procedures on a patient rather than addressing the esoteric problem of who owns cell-lines.⁶¹ Informed consent law gives research subjects a right to determine whether research is performed on them, but not an interest in that research once they have consented to it.⁶² Because the research had not been consented to, the court did not look beyond the informed consent cause of action to the deeper question posed by Moore, namely, whether the human source of a cell-based invention should retain rights in the tissue co-opted by the inventors, including the right to profit from it.

II. WHO SHOULD DERIVE FINANCIAL BENEFIT FROM THE SALE OF PATENTED CELL-LINES?

Moore's conversion cause of action was rejected by the California Supreme Court because Moore failed to establish a property interest in his spleen after it was removed.⁶³ The court held *inter alia* that "[s]ince Moore clearly did not expect to retain possession of his cells following their removal, to sue for their conversion he must have retained an ownership interest in them.

⁵⁸ See *id.* at 485 (finding that Moore adequately alleged that Golde had an "undisclosed research interest in Moore's cells at the time he sought Moore's consent to the splenectomy").

⁵⁹ See *id.* at 483-87.

⁶⁰ See *id.* at 483-97. The court found that Moore sufficiently alleged a cause of action for "breach of a fiduciary duty to disclose facts material to the patient's consent." *Id.* at 483. The court, however, declined to extend conversion liability to encompass Moore's situation, believing that "problems in this area are better suited to legislative resolution." *Id.* at 493.

⁶¹ See *Moore*, 793 P.2d at 483-97.

⁶² See Dorney, *supra* note 46, at 361 (commenting that while there are federal guidelines on informed consent, they were drafted to protect people from the dangers of physical and mental experimentation rather than commercial development of excised tissue).

⁶³ See *Moore*, 793 P.2d at 487-93.

But there are several reasons to doubt that he did retain any such interest.”⁶⁴ The court cited three fundamental reasons for rejecting Moore’s claim to a property interest in his spleen cells: 1) no court had previously found that a person had a common law property interest in their cells; 2) analogous statutory law in California limited patients’ control over their excised cells;⁶⁵ and 3) the patented Mo cell-line was factually and legally distinct from the original cells taken from Moore.⁶⁶ The court also concluded that, contrary to public policy, the existence of such a right would enact a significant barrier to efficient medical research.⁶⁷ The majority did not take a firm position on whether property interest in bodily organs could ever arise.⁶⁸

The California Supreme Court relied on the premise that rights not embodied within a statute do not exist and that therefore, Moore lacked a right under California law in excised human cells.⁶⁹ The court looked to the California Health and Safety Code for the source of any such right in tissue and identified § 7054.4, concerned primarily with disposal of human products used in research,⁷⁰ as the most relevant statute to the determination of property rights in excised cells.⁷¹ According to the court:

⁶⁴ See *id.* at 488-89.

⁶⁵ The court was referring to California Health and Safety Code § 7054.4, concerned primarily with disposal of human products used in research. See discussion *infra* pp. 756-58.

⁶⁶ See *Human Cells and Tissue for Sale (A Caveat) – Did you Advise Your Patient or Client of His Commercial Rights?*, 62 PA. B. ASS’N Q. 199, 201 (1991) (explaining that California statutes governing analogous subjects such as human tissue, corneal tissue and dead bodies demonstrated to the *Moore* court that the California legislature had chosen to regulate the disposition of these items by specialized statute and not through judicial expansion of tort law).

⁶⁷ See *Moore*, 793 P.2d at 487.

⁶⁸ See *id.* at 488-89. See also Judith B. Prowda, *Moore v. The Regents of the University of California: An Ethical Debate on Informed Consent and Property Rights in a Patient’s Cells*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 611, 617 (1995).

⁶⁹ See *Moore*, 793 P.2d at 491-92 (stating that the statute’s practical effect is to drastically limit a patient’s control over his excised cells, eliminating “so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to ‘property’ or ‘ownership’ for purposes of conversion law”).

⁷⁰ Cal. Health and Safety Code § 7054.4, *Human remains following conclusion of scientific use; disposal* (2000).

⁷¹ The court cited the following excerpt from the statute in support of its choice: “Notwithstanding any other provision of law, recognizable anatomical parts, human tissues, anatomical human remains, or infectious waste following conclusion of scientific use shall be disposed of by interment, incineration, or any other method determined by the state department [of health services] to protect the public health and safety.” See

[O]ne cannot escape the conclusion that the statute's practical effect is to limit, drastically, a patient's control over excised cells. By restricting how excised cells may be used and requiring their eventual destruction, the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to 'property' or 'ownership' for the purposes of conversion law.⁷²

Paradoxically, the court acknowledged that "the Legislature did not specifically intend this statute to resolve the question of whether a patient is entitled to compensation for the nonconsensual use of excised cells."⁷³ As a result, it is difficult to understand exactly how the court relied on this statute for anything other than what its plain language identifies as its purpose, the proper disposal of potentially infectious human tissue.⁷⁴ Furthermore, the court failed to explain why this statute extinguishes a source's rights in their tissue once it is separated from the body, yet supports the conclusion that an invention in these cells becomes the property of researchers without an explicit statutorily created right.⁷⁵ It is axiomatic that individuals own the cells currently growing within their bodies much as they own the whole body. Although a patient may consent to the removal of some of those cells for medical treatment, or even research purposes, it is intuitive that at some point any consent to such procedures lapses or expires, and that without the renewed consent by the source, the removed cells should be disposed of. California Health and Safety

Moore, 793 P.2d at 491 (alterations in original).

⁷² *Id.* at 491-92.

⁷³ *Id.* at 491.

⁷⁴ See Cal. Health and Safety Code § 7054.4, *Human remains following conclusion of scientific use; disposal* (2000).

⁷⁵ See *Moore*, 793 P.2d at 491-92. The court offers only a weak economic argument in support of this illogical conclusion. See *id.* at 495-96.

The theory of liability that Moore urges us to endorse threatens to destroy the economic incentive to conduct important medical research. If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery. Because liability for conversion is predicated on a continuing ownership interest, "companies are unlikely to invest heavily in developing, manufacturing, or marketing a product when uncertainty about clear title exists."

Id. (quoting OTA REPORT, *supra* note 1, at 27).

Code § 7054.4 merely codified this expectation.⁷⁶

The court mistakenly equated possession of tissue with retention of rights in the tissue, and thus its entire reasoning on the issue of property rights in cell-lines is suspect. Moreover, the court did not provide any reasoning to buttress its conclusion that Moore had no property interest in his tissue because the court confused the issue of ownership with the issue of determination.⁷⁷ Ultimately, however, the question not posed by the court is more relevant than the issues the court did address. The court did not address why there is no common law or statutory property right in one's own tissue independent of whether that tissue is in the actual possession of its former host. In requiring consent for research to be performed upon excised tissue, Health and Safety Code § 24175 implies that such a right exists,⁷⁸ yet the *Moore* court affirmatively declared that it does not.⁷⁹

⁷⁶ Cal. Health and Safety Code § 7054.4 (2000) (legislating the disposal of tissue at the conclusion of scientific use).

⁷⁷ See *Moore*, 793 P.2d at 488-97. The *Moore* court stated, in part, “[s]ince Moore clearly did not expect to retain possession of his cells following their removal, to sue for their conversion he must have retained an ownership interest in them.” See *id.* at 488-87. In so stating, the court completely ignored the possibility that Moore had, in granting limited consent for research purposes, retained the right to determine the use of his tissue, but not to demand that the tissues be returned. Thus, it confused his claim of right to determine the use of his tissue with his right to continued possession of it. This concept is analogous to a copyright, wherein the artist creating a work remains the creator regardless of who owns the rights to profit from the work. Although the artist cannot demand the return of his work from the owner of the performance right, it is axiomatic that he retains the ability to institute legal action against pirates who use his creation without permission.

⁷⁸ See Cal. Health and Safety Code § 24175, *Medical experiments; informed consent* (2000). The statute states, in part, that “[e]xcept as otherwise provided in this section, no person shall be subjected to any medical experiment unless the informed consent of such person is obtained.” See *id.* The California Supreme Court in *Moore* did acknowledge 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 affect his medical judgment.” *Moore*, 793 P.2d at 485. The *Moore* court, however, did not extend this idea of consent to the granting of property rights in excised cells, stating that this right to consent is a “limited right to control the use of excised cells” which may still exist despite the fact that California Health and Safety Code §7054.4 eliminates “so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to ‘property.’” See *id.* at 491-92.

⁷⁹ See *Moore*, 793 P.2d at 491-92 (stating that California Health and Safety Code §7054.4 eliminates “so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to ‘property’”); see also *id.* at 503 (dissent) (refuting the majority’s reliance on section 7054.4 in determining that no property right in excised body cells exists).

III. SHOULD PEOPLE HAVE PROPERTY RIGHTS IN THEIR DISCARDED TISSUE?

Until recently, blood drawn for medical testing was considered useless after the test was performed.⁸⁰ Today, however, we have reached an age in medicine where what was once waste is now a valuable commodity.⁸¹ Yet, the legal view of these once-discarded tissues and fluids has not changed to reflect their new value. As Moore's failed conversion cause of action demonstrates, we do not recognize rights in what is voluntarily removed from our bodies.⁸² This has created a paradoxical duality whereby researchers can claim patients' tissue as their own, base an invention around the tissue, commercialize it, then exclude the human source from any benefits realized. What is created is undoubtedly due in part to the contribution of the source, but the source cannot enforce any claim to part-ownership because he lacks a property interest in his excised cells or tissue.⁸³ If property rights in one's excised tissue were recognized, a patient would be empowered with the myriad causes of action available in property and tort for any injury to, taking of, or unauthorized use of their "property."⁸⁴ It would also enable the holder to grant rights of usage to others via sale, lease, license or any legal device used to transfer interests in real property in whole or in part to another person or entity, and thus demand compensation for a role in the production of a cell-line invention.⁸⁵ At present, however, the only property rights recognized in the human body are limited to personal use, sale of a few of its products, and transferability of cadavers following death.⁸⁶

⁸⁰ See Prowda, *supra* note 68, at 612.

⁸¹ See *id.* at 612 (noting that "as the field of biotechnology has expanded, human body components . . . have acquired real monetary value").

⁸² See Moore, 793 P.2d at 487-97.

⁸³ See, e.g., *id.* (denying Moore's cause of action in conversion and claim of a proprietary interest in each of the products created from his cells).

⁸⁴ For example: conversion, replevin, adverse possession, unjust enrichment, and misappropriation. See PROSSER AND KEETON ON TORTS §§ 15, 130 at 1020 (W. Page Keeton ed., 5th ed. 1984) (conversion, misappropriation); *Jim's Furniture Mart, Inc. v. Harris*, 356 N.E.2d 175, 176 (Ill. App. Ct. 1976) (replevin); ROGER A. CUNNINGHAM ET AL., THE LAW OF PROPERTY § 11.7, (1984) (adverse possession); *Tulalip Shores, Inc. v. Mortland*, 511 P.2d 1402, 1404 (Wash. Ct. App. 1973) (unjust enrichment).

⁸⁵ See, e.g., RAY ANDREWS BROWN, THE LAW OF PERSONAL PROPERTY 189-208 (3d ed. 1975).

⁸⁶ See Hannah Horsley, *Reconsidering Inalienability for Commercially Valuable*

Three justifications are proffered for the failure to acknowledge any further property rights in the human body: 1) selling the human body is rightly eschewed as an immoral infringement on the sanctity of personhood; 2) the marketing of the human body would lead to exploitation of the poor and ignorant; and 3) the individual products of the human body have no inherent value once the host is finished using them and thus cannot be exchanged for valuable consideration.⁸⁷ As further explored below, none of these three justifications has any substantial foundation in law or even logic, and thus fail to bolster the argument for limited property rights in the products of one's body. Given the failure of these traditional justifications, it follows that plaintiffs such as Moore might have legitimate recourse to claim compensation for their role in producing a profitable cell-line invention.

The most common argument against the recognition of property rights in anything less than the totality of one's body is that this would "result in the commodification of the person and violate notions of human dignity and personhood."⁸⁸ While this argument holds true when considering essential and unique parts of the human body, such as limbs, it is hard to support the notion that regenerating body products, such as blood, cells, or tumors, are part of anyone's personhood.⁸⁹ If these body products are not central to personhood, the removal and subsequent sale of such products cannot diminish human dignity so long as their sale or removal is not forced or required.⁹⁰

Unfortunately, the sale of scientifically or commercially valuable products of the human body is severely restricted under

Biological Materials, 29 HARV. J. ON LEGIS. 223, 230 (1992) ("A few [body parts] may be sold (e.g. blood, semen, hair), but the majority may only be given away (i.e. [organs and tissues and other scientifically and commercially valuable] biological materials).").

⁸⁷ See Horsley, *supra* note 86, at 239; Roy Hardiman, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 237 (1986); Prowda, *supra* note 68, at 612.

⁸⁸ Horsley, *supra* note 86, at 230 ("Personhood" is used to represent the notion that the metaphysical characteristics of the "person" and the physical body are so interrelated as to be one in the same. Thus, that respect for the inalienability of persons includes similar respect for the body.).

⁸⁹ See *id.* at 232. Indeed, the sale of blood was fully accepted by society prior to the spread of deadly and difficult-to-detect blood borne pathogens such as H.I.V.

⁹⁰ Perhaps the real loss of dignity lies in the idea that the sale of body products is a derivative form of prostitution. But this argument carries little weight in light of the goal of the exchange – the contribution to the expansion of scientific knowledge.

the National Organ Transplant Act (“N.O.T.A.”).⁹¹ The restrictions under N.O.T.A. are based on the “commodification” justification and an anxiety over the potential market consequences of permitting such sales.⁹² The N.O.T.A. precludes the sale of organs out of a fear that allowing such sale would give rise to a black market in organs that would coexist with any legal one.⁹³ But, as this ban applies equally to non-traditional “organs,” such as cells and other replenishing tissue, and traditional organs, N.O.T.A. is overbroad in that it fails to take into consideration the fact that some “organ” sales do not present any danger of sustaining black market trade.⁹⁴

Upon first impression, it might seem that the sale of body products, like the sale of whole bodily organs, would lead to coercion of the poor or ignorant into such sales by unscrupulous organ traders motivated only by profit.⁹⁵ Theoretically, the denial

⁹¹ See National Organ Transplant Act of 1984, Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified as amended in scattered sections of 42 U.S.C.). N.O.T.A. 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.” 42 U.S.C. § 274e(a) (1991). Although § 274e encompasses cells, blood and other bodily tissue, it does not explicitly restrict the sale of these materials, and has never been read to do so. See Helen R. Bergman, *Rationing Health Care: Social, Political and Legal Perspectives: Note and Comment: Case Comment: Moore v. Regents of the University of California*, 18 AM. J.L. & MED. 127, 143 (1992).

⁹² See Horsley, *supra* note 86, at 230. Congress identified the intent of such legislation prohibiting the buying and selling of human organs as “directed at preventing the for-profit marketing of kidneys and other organs.” S. Rep. No. 98-382 (1984), reprinted in 1984 U.S.C.C.A.N. 3975, 3978.

⁹³ See Horsley, *supra* note 86, at 230; S. Rep. No. 98-382 (1984), reprinted in 1984 U.S.C.C.A.N. 3975, 3978.

⁹⁴ So-called “black market organ sales” only concern vital organs that have immediate present value for re-transplantation purposes, such as livers, hearts and kidneys. In precluding their transfer for valuable consideration, the N.O.T.A. achieves the laudable legislative aim of avoiding a wealth of problems that might result from the emergence of a black market in transplantable organs. But, some “organs” under the N.O.T.A., such as blood, stem cells, or excised tumors, have no present value except as material for research. As raw material for research, these “organs” have only potential, intangible, and uncertain value, which renders their black market worth zero. Therefore, legal recognition of their sale by medical patients to researchers presents none of the risks that recognition of vital organ sales would.

⁹⁵ See, e.g., John A. Robertson, *Human Flourishing and Limits on Markets*, 95 MICH. L. REV. 2139, 2140 (1997) (noting that extending markets to body parts “threatens to exploit poor and vulnerable persons”); Gloria J. Banks, *Legal & Ethical Safeguards: Protection of Society’s Most Vulnerable Participants in a Commercialized Organ Transplantation System*, 21 AM. J.L. & MED. 45, 74-75 (1995) (noting that the World Health Assembly’s 1991 resolution regarding organ donation recognized “the possible abuse, coercion, and undue influence involved with live organ donors”).

of property rights and the bar on any sales of organs would prevent such situations by removing the profitability of exploitation. This view fails to take into account the fact that biological materials (other than discrete organs) with commercial value are rare, most often discovered because they are malignant enough to require their removal.⁹⁶ It also fails to acknowledge the fundamental difference between “before-the-fact incentive for acquiescence in organ removal” and after-the-fact “participat[ion] in profits derived from tissue already removed.”⁹⁷ In fact, it can be argued that the failure to sanction sales in some circumstances does not eliminate the possibility of unscrupulous conduct, but merely shifts it from organ brokers to researchers seeking to exploit body products for commercial profits.⁹⁸ Additionally, despite the N.O.T.A.’s all-encompassing ban on organ sales from source to buyer, commercialization of bodily tissue has already occurred to a large extent via third party transfers between for-profit biomedical entities and research laboratories.⁹⁹ Therefore, prohibiting individuals from selling their own body products serves only to “defeat the individual’s right to profit from the commercial value of his or her own tissue, but not to defeat the commercial interest of the involved physician, investigator, university, or biotechnology companies.”¹⁰⁰ Recognition of a patient’s right to market bodily material that is considered valuable by the medical research community would “ensure a fairer distribution of wealth between doctors and patients, comport with the legal protection of a patient’s autonomy, and preserve the trust the doctor-patient relationship that is threatened by the disparity in their rights to the

⁹⁶ See Horsley, *supra* note 86, at 237.

⁹⁷ See Hardiman, *supra* note 87, at 239 (noting that “after-the-fact participation is morally supportable”).

⁹⁸ The *Moore* case did not contain any indication of the monetary judgment Moore would have received as a result of Golde’s failure to disclose his own interests in Moore’s cells and thus his failure to obtain Moore’s fully informed consent to the splenectomy. Even without the court’s pronouncement of a monetary judgment, however, we can conclude that Moore likely would have been awarded far less than the defendants would earn from marketing the cell-line. Therefore, simple reasoning dictates that in any case where consent to research is denied, but the potential profit from commercialization of the subject’s body products might exceed the potential judgment resulting from a action for breach of informed consent, conducting the research in defiance of the subject’s wishes is economically justifiable.

⁹⁹ See Hardiman, *supra* note 87, at 241.

¹⁰⁰ Patricia A. Martin & Martin L. 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, 247-48 (1989).

profits of commercialization.”¹⁰¹

The right to sell scientifically and commercially valuable biological products would “re-establish the trust necessary to the interaction between physician and patient”¹⁰² as well as “allowing [the] patient to enter the market that already exists in her commercially valuable materials.”¹⁰³ Presently, debate over such sales focuses on three principal areas: 1) the equity of production and distribution; 2) the added costs of payments to sources and the transaction costs associated with that process; and 3) the value of altruism in the donation of human biological materials.¹⁰⁴ While there are meritorious arguments against allowing tissue sales,¹⁰⁵ they are outweighed by others in favor of compensating the source of a cell-line that proves to be commercially successful. The primary argument against paying sources of biological materials is that biological materials have no inherent value in their “preinvention” state.¹⁰⁶ It is further argued that even if these materials do have some value, it is outweighed by the harmful physical impact if retained within the body.¹⁰⁷ Finally, this line of reasoning concludes that because the human sources do not contribute to the inventive process that confers measurable commercial value on their tissue, they should be excluded from realized profits.¹⁰⁸ This line of reasoning is both unfair and short-sighted with respect to the practical realities of such sales.

When a replenishing tissue can no longer perform its prescribed function, it is valueless to its host organism from a biological perspective. Similarly, diseased tissue may have a sizable negative value to its host, necessitating its removal at the earliest possible opportunity.¹⁰⁹ Neither of these facts support the conclusion that

¹⁰¹ Horsley, *supra* note 86, at 235.

¹⁰² *Id.* at 238.

¹⁰³ *Id.* at 242.

¹⁰⁴ See OTA REPORT, *supra* note 1, at 12.

¹⁰⁵ Arguments against legalizing tissue sales include higher costs for the scientific community (both transaction and actual costs in obtaining raw materials) and a longer development time for potentially lifesaving drugs.

¹⁰⁶ See Thomas P. Dillon, Note, *Source Compensation for Tissues and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628, 641 (1989).

¹⁰⁷ See *id.*

¹⁰⁸ See *id.*

¹⁰⁹ For example, the spread of tumors, gangrene, and localized infection can be substantially retarded or even halted through expeditious surgery to identify and remove the affected tissue, organ, or area. See, e.g., F. Bozzetti et al., *Comparing Surgical*

replenishing human tissue has no inherent monetary value once it has fulfilled its biological function. Discovery of a new use for what was once considered waste has frequently conferred a new commercial life on that "waste."¹¹⁰ For example, the need for cell samples for the production of cell-lines arguably gives rise to a new use and value for otherwise functionless parts of the human body, like Moore's diseased spleen. The rarer the cell type, the higher the value, assuming the sample is successfully converted into a viable and commercially successful cell-line. Because particular donors, like Moore, are sought out and prized for the rarity of their cells, it is counterintuitive to assert that the cells are devoid of value prior to the efforts of a particular inventor. This rarity is an inherent value even if the host cannot capitalize it.¹¹¹

Another factor that affects excised tissue's worth is its source's valuation of the private information this tissue contains. Bodily tissues and substances are often inseparable from certain information about their source, including the existence of diseases and medical conditions,¹¹² genetic markers for predisposition to others,¹¹³ and the full text of an individual's chromosomes.¹¹⁴

Resection of Limited Hepatic Metastases From Colorectal Cancer to Non-Operative Treatment, EUR. J. SURG. ONCOL. (1993) available at www.lexis.com.

¹¹⁰ For example, crop wastes that would otherwise be discarded at the end of a harvest can be sold to refineries for use in the production of ethanol for gasohol, a high-octane, clean-burning fuel for internal combustion engines. See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, GASOHOL: A TECHNICAL MEMORANDUM, at 3, 11, 47 (1979), available at http://www.wws.princeton.edu/~ota/ns20/alpha_f.html (last visited Apr. 6, 2001).

¹¹¹ As the California Appellate Court pointed out in *Moore*, "[a] simple analogy illustrates the point: 'Crude oil may be ruining a farmer's corn crop. The farmer may even be willing to pay an oil refinery company to take it off his land. But, the farmer, who would be unable without the refinery's aid to turn the crude oil into a usable commodity, is still entitled to a share of the refinery's profits from his land's product.'" 249 Cal. Rptr. at 507 n.13 (citation omitted).

¹¹² For example, genetic screening for cystic fibrosis, risk for breast cancer, Alzheimer's disease, and many other genetic diseases is either currently available or under development. See Marilyn Chase, *Genetic Testing Needs Clear Plans For How to Handle Treatment*, WALL ST. J., Feb. 26, 1996, at B1.

¹¹³ For example, the presence of genetic markers for a propensity to develop cancer. See, e.g., Joseph Palca, *Keeping Genetic Information Under Wraps*, HASTINGS CENTER REP., Mar. 13, 1997, at 6 (explaining that it is possible to evaluate a person's risk for developing certain types of breast and ovarian cancer based on the presence of the BRCA1 gene).

¹¹⁴ Theoretically, possession of this information enables cloning via creation of a complete copy of an individual's DNA, inserting it into a fertilized egg, and growing it as a "test tube" baby. See Gina Kolata, *Scientist Reports First Cloning Ever of Adult Mammal*, N.Y. TIMES, Feb. 23, 1997, at A1.

“Publication” of this genetic information might be undesirable, especially if express consent for such information transfer had not been secured.¹¹⁵ Thus, when contemplating rights in excised tissues, the potential for privacy invasion must be considered and the disclosure of genetic information bargained for by the source.

Because bodily tissues have inherent value, it is fundamentally indefensible to assert that biotechnology, as a commercial industry, should be provided with its raw materials free of cost.¹¹⁶ Like any other property, biological materials should be transferable for valuable consideration, whether the consideration is in exchange for the tissue’s uniqueness or to compensate the source for his authorization of the publication of his private genetic information.

Administering such a system would interject significant transaction costs into the world of biological research if it were necessary to conduct a tissue “sale” every time a scientist wanted to undertake biological research.¹¹⁷ These costs would be justifiable only if there were some guarantee that the researcher would recoup his investment. As the *Moore* court pointed out, this could stifle the progress of biomedical research.¹¹⁸ Fortunately, there is a more efficient system for administering such payments, one that would not place such a high burden on the entirety of biomedical research, but would focus particularly on compensating the sources of commercially successful cell-lines.

¹¹⁵ See Natalie Anne Stepanuk, Comment, *Genetic Information And Third Party Access To Information: New Jersey’s Pioneering Legislation As A Model For Federal Privacy Protection Of Genetic Information*, 47 CATH. U.L. REV. 1105, 1117-23 (1998).

¹¹⁶ This is similar to the California Court of Appeal’s argument in *Moore*. The court notes that Biotechnology has become a science for profit, and “[b]iological materials no longer pass freely to all scientists.” Thus, the court “fail[s] to see any justification for excluding the patient from participation in those profits.” *Moore*, 249 Cal. Rptr. at 509. The California Supreme Court disagreed, but the point remains a pertinent one.

¹¹⁷ These transaction costs include the actual cost of paying the source as well as the costs, both of time and effort, involved in contracting with the source for every intended use of the bodily material.

¹¹⁸ See *Moore*, 793 P.2d at 495.

IV. IF THE SOURCE OF A CELL-LINE HAS A RIGHT TO SHARE IN THE PROCEEDS OF COMMERCIAL EXPLOITATION OF HIS TISSUE, IS THERE AN EFFICIENT SYSTEM FOR ENFORCING THAT RIGHT WITHIN THE EXISTING BODY OF LAW?

The California Supreme Court's rejection of the conversion cause of action was a conservative decision based in part on its unwillingness to make medical researchers strictly liable for any unauthorized taking of bodily tissue.¹¹⁹ In retrospect, the decision was an attempt to limit litigation over the profits of medical research. Even though the ruling effectively limited meritless claims, it had the unfortunate side effect of eliminating legitimate claims like Moore's.¹²⁰ It need not have been so drastic.

After determining that it did not want to extend tort law to Moore's somewhat unique situation, the California Supreme Court should have more thoroughly examined other bodies of law for potential solutions to Moore's alleged injury. Intellectual property law was established for the precise purpose of assigning rights in the intangible financial capital of novel discovery, as well as rewarding individual contributions to the development of those discoveries.¹²¹ By statute, patents have attributes of personal property (albeit for limited periods of time) and the rights they confer may be assigned by written instrument.¹²² As a result, patent law contains possible solutions to the problem of the equitable division of rights in potentially lucrative inventions. There are two such elements of established patent law that could provide a solution for this issue: the shop rights doctrine¹²³ and the preinvention contract.¹²⁴ Both could have been adapted to address

¹¹⁹ See *id.* at 495-96 (“[T]he theory of liability that Moore urges us to endorse threatens to destroy the economic incentive to conduct important medical research. If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery.”). Additionally, because liability for tortious conversion is predicated on a continuing ownership interest, “companies are unlikely to invest heavily in developing, manufacturing, or marketing a product when uncertainty about clear title exists.” See OTA REPORT, *supra* note 1, at 27.

¹²⁰ The most significant marker of the legitimacy of Moore's claim is that the Mo cell-line was a commercially successful product derived wholly from Moore's cells. See *Moore*, 793 P.2d 479.

¹²¹ See generally Frank H. Easterbrook, *Intellectual Property Is Still Property*, 13 HARV. J.L. & PUB. POL'Y 108, 112-13 (1990).

¹²² See 35 U.S.C.S. § 261 (2000).

¹²³ See *infra* pp. 767-73.

¹²⁴ See *infra* pp. 773-77.

the taking Moore attempted to articulate in his complaint, while avoiding the potential problem of high transaction costs stifling the progress of medical research.

A. *The Shop Right Doctrine*

Under the traditional shop right doctrine, when an employee makes and reduces to practice an invention on his employer's time, using his employer's resources, he implicitly grants the employer a limited, non-exclusive, royalty-free license to use ("practice"), make and sell that invention.¹²⁵ This license continues for the entire duration of the patent, regardless of whether the inventor remains an employee.¹²⁶ This right passes automatically, and may be transferred only if there is a complete succession of the entire business (including good will) of the shop right holder.¹²⁷ The employee, as the patentee, retains all other aspects of the patent's traditional right to exclude, including ownership, licensing and right to sue for infringement.¹²⁸ The mere existence of an employment relationship does not suffice to create a shop right in an employer.¹²⁹ The nature of the invention, the amount of employer resource contribution, and the nature of the employment all factor into a court's determination of a shop right.¹³⁰

There are three classes of employee inventions based upon the subject matter of the invention and the resources the employer has contributed. They are:

1. Employer-Specified Inventions — those made at the employer's request and expense;
2. General Inventions — those made partly or wholly at the employer's expense, but not specified by the employer;

¹²⁵ See C.T. Dreschsler, *Annotation, Application and Effect of "Shop Right Rule" or License Giving Employer Limited Rights in Employees' Inventions and Discoveries*, 61 A.L.R.2D 356, § 4 (1958).

¹²⁶ See Dreschsler, *supra* note 125, § 37; *Hobbs v. United States*, 376 F.2d 488, 494 (5th Cir. 1967).

¹²⁷ See Dreschsler, *supra* note 125, § 36.

¹²⁸ See Sandip H. Patel, Note, *Graduate Students' Ownership and Attribution Rights in Intellectual Property*, 71 IND. L.J. 481, 493 (1996).

¹²⁹ See Dreschsler, *supra* note 125, § 5.

¹³⁰ See Evelyn D. Pisegna-Cook, *Ownership Rights of Employee Inventions: The Role of Preinvention Assignment Agreements and State Statutes*, 2 U. BALT. INTELL. PROP. L.J. 163, 169-70 (1994).

3. Private Inventions — those made on the employee's own time, without the contribution of employer resources or other employees during working hours, unless it was specified by the employer.¹³¹

At common law, the employer is entitled to ownership of employer-specified inventions regardless of a lack of preexisting contract to this effect.¹³² He is entitled to a shop right in general inventions, the extent of the right turning on the degree of the employer's contribution in terms of labor and capital.¹³³ As to private inventions, absent an agreement to the contrary, the employer is not entitled to any ownership.¹³⁴

If the doctor-patient relationship is viewed as a limited employer-employee relationship (with the doctor in the role of employee), then the shop right doctrine enables the patient to financially benefit from patents based on his tissue. In a *Moore*-like fact pattern, where a physician obtains a patent based on resources harvested from the patient,¹³⁵ his employer, that patient should earn an enforceable shop right to use, make or sell the invention. The shop right would vest based on the category of general inventions because the invention arose out of the employer-employee relationship.¹³⁶ In order to maintain equity, the extent of the right should be limited by the degree of inventive effort required to transform the patient's tissue into the patented invention, balanced against the rarity of the cells.¹³⁷ In extreme cases, this could result in the patient having a very small or very large stake in the patent. Generally, the resulting shop right would be a fairly limited one because it is highly unlikely that a physician invents a cell-line entirely on time paid for by the patient. Nor is it likely that the physician would make use of any of the patient's resources other than his tissue. This is balanced against the fact that cell-lines (like *Moore*'s) are created almost exclusively out of cells from the patient-employer. This model has two

¹³¹ See *id.* at 166-68; see also *United States v. Dubilier Condenser Corp.*, 289 U.S. 178 (1933).

¹³² See Drechsler, *supra* note 125, § 39.

¹³³ See *id.*

¹³⁴ See *id.*

¹³⁵ See *Moore*, 793 P.2d at 481-81.

¹³⁶ See Pisegna-Cook, *supra* note 129, at 166 (defining General Inventions as "those made partly or wholly at the employer's expense, but not specified by the employer").

¹³⁷ See *id.*, at 169-70.

shortcomings. First, no analog to usage of an employer's tools or his physical plant exists in this hypothetical doctor-patient paradigm. Second, the patient will not bear any of the financial risks of the inventive process.

The nature of the doctor-patient relationship will likely undercut the scope of patient shop rights in cell-line inventions, but in today's growing biotechnology market even a limited shop right in a patented cell-line is a potentially lucrative intellectual property holding.¹³⁸ Regardless of its extent, however, the practical operation of such a right raises the question of what the average medical patient would do with a shop right in an invention which would have limited application outside the world of medicine. Although any shop right in a patient-derived medical invention would allow the patient-source to make and use the invention, these rights are meaningless if the patient lacks bio-engineering skills or experience.¹³⁹ It would be an absurdity to allow the creation of a right on which a holder is unable to capitalize. While the right to a cell-line invention is a powerful option for even the most unsophisticated holder of that right, the fact that these rights will be held by unsophisticated holders is also the fatal flaw of this solution.

Traditionally, shop rights allow employers to sell inventions made by employees on company time or with company resources only when the invention is related to the employer's business.¹⁴⁰

¹³⁸ In *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978) the court established that reasonable royalties for patent infringement are determined by the facts of each individual case. *Id.* at 1159. Although patent infringement is not directly analogous to the issue in *Moore*, it provides a useful guideline. Thus, at least from the perspective of the *Moore* case, even a nominal three percent of Golde's compensation from the sale of the resulting cell-line would have netted Moore \$13,200 and 2250 shares of stock in Genetics Institute. *See id.* at 1159; *Fromson v. Citiplate, Inc.*, 699 F. Supp. 398 (E.D.N.Y. 1988) (finding reasonable royalties of 3.1 to 7.5 percent); *Water Techs. Corp. v. Calco Ltd.*, 714 F. Supp. 899 (N.D. Ill. 1989) (finding reasonable royalties of 20 percent).

¹³⁹ *See, e.g.*, Charles J. Hanley, *A Case of Good Research or 'Genetic Colonialism'?; Medicine: A Papua New Guinea Tribesman Came Out of the Bush Seeking Help for Ill Children. When His Blood Was Found to Contain Clues to Leukemia, the U.S. Patented It, Generating Ethical Questions*, L.A. TIMES, Apr. 21, 1996, at A1 (reporting on a cell-line developed by NIH researchers from the blood of an indigenous Papua New Guinean. The researchers subsequently obtained a U.S. patent for the cell-line. The tribesman whose blood was used to create the invention is not listed as a beneficiary of the patent, nor was he aware of the use of his blood, the creation of the cell-line or the grant of the patent.)

¹⁴⁰ *See Drechsler, supra* note 125, § 39. ("All the authorities agree that the scope of a

With cell-line inventions, there is a unique employment relationship, and the traditional determination of the employer's "business" cannot be applied. This poses a unique difficulty for applying the shop right doctrine to the doctor-patient relationship. The patient-employer's "business," his purpose in hiring the physician, is "getting well" or staying that way. The subsequent invention by the employee physician will have little, if any, impact on this business interest. It would be tenuous for a court to hold that every patient has a business interest in exploiting his own body's potential. It would be more tenuous still to say that patients with no knowledge of their cells' potential, and no demonstrable intention to investigate, nonetheless deserve to be compensated for the resulting inventions.

Most people with potentially patentable cells do not have careers in biological-engineering or biotechnology. Thus, unless courts recognize that a desire to profit from one's bodily tissues is a business interest, few future Moores will succeed in holding their doctor accountable for profit sharing. Even if the patient-source was professionally involved in biotechnology, there remains the hurdle of finding a nexus between the patient's hiring of the doctor and the actual inventive process.¹⁴¹ Other than the unlikely situation where a patient hires a physician for the primary purpose of capitalizing on preinventions lurking within his body, it is improbable that a court would find such an invention to be related to the business interests of this employer-employee relationship. Nonetheless, as discussed below, there is a significant public policy rationale for courts to hold that any invention created from human source material is sufficiently related to the business interests of that source and gives rise to a shop right in the resulting invention.

Since publication of the *Moore* case, there has been public outcry over the potential exploitation of patients' tissue without proper compensation, or acknowledgment of the source of that tissue.¹⁴² Rational people now fear that blood taken for one reason

shop right or similar privilege in favor of the employer must be determined from such factors as the nature of the employer's business, the character of the invention involved, the circumstances under which it was created, and the relation, conduct, and intention of the parties.").

¹⁴¹ Presumably the patient "hires" a doctor to be treated for a medical problem and not to capitalize on potentially lucrative preinventions in his blood.

¹⁴² See generally Karen Wright, *The Body Bazaar; The Market in Human Organs Is*

can be used for unauthorized research and transformed into patentable products about which they will not be informed.¹⁴³ This fear represents a fundamental distrust of the medical community, which can be broken down into two parts. First, people fear that doctors are increasingly likely to use their patients as living experiments, and thus any inventions that may spring from such experimentation are morally and ethically objectionable.¹⁴⁴

Growing, DISCOVER, Oct. 1998, at 114.

¹⁴³ See Talk of the Nation/Science Friday: *Professor Lori Andrews, Professor David Cox and Chuck Ludlam Discuss the Current Situation Involving the Patenting of Genetic Materials and Sequences* (NPR radio broadcast, Oct. 29, 1999) (Transcript on file with author and available at www.lexis.com).

Prof. ANDREWS: And right now there are other fallouts. I mean, the Amgen patent on a gene is worth \$ 1.5 billion a year. And so that means that we're turning patients into potential treasure troves. I mean, John Moore, for example, a patient in California, was a target of his physician who, without his knowledge or consent, purportedly took out his cell-line and patented it. We're seeing that all over. I mean, for example, the breast cancer mutation that everybody knows about affecting Ashkenazi Jewish women. That was done on blood samples that they gave for other reasons without their knowledge or consent. And now information has been developed about Ashkenazi Jewish women that might be used to discriminate against them in insurance, and so forth.

Mr. LUDLAM: Well, actually, we've . . .

Prof. ANDREWS: And so we're not asking consent of patients in many situations because the money is just so big and attractive. They are. . .

Mr. LUDLAM: We've worked very hard on the discrimination issue. In fact, in the Health Insurance Portability Act in '95, our industry strongly supported a provision barring discrimination in group health insurance based on genetic information.

Prof. ANDREWS: But your group also. . .

Mr. LUDLAM: And we had a good deal to do with enacting—that's current law. Most people don't know.

Prof. ANDREWS: Mm-hmm.

Mr. LUDLAM: We're now working on medical confidentiality to deal with confidentiality of genetic information.

Prof. ANDREWS: Yeah, but your. . .

Mr. LUDLAM: We're very strong believers that you need to prevent abuse of this information.

Prof. ANDREWS: Sure. Yeah, but your industry also has pushed through in state legislatures that did have laws protecting people's right to consent to DNA testing exceptions that allow researchers, such as your companies, to have access to people's blood samples without their knowledge or consent.

Id.

¹⁴⁴ See, e.g., Kevin O'Sullivan, *Dolly's Maker Advises on Research Use*, IRISH TIMES, Mar. 16, 1998, at A8 (quoting Irish Green Party politician as saying that biotechnology was a "genetic assault on society" with patients exploited by pharmaceutical industry

Second, people have a general perception that medical patients are being unduly exploited without their input or consent in the name of technological progress.¹⁴⁵ Failure to address these issues will have widespread consequences, including undermining the public's confidence in the patent system and fostering the notion that government is unwilling to address the ethical concerns of its constituents, and is instead pandering to large biological research concerns.

To address these fears most completely, the medical community must be required to obtain consent for all uses of human-derived biological material. Yet, this would be nearly impossible given the sheer amount of biological material that would have to be tracked and the prohibitive expense of finding the source to obtain consent.¹⁴⁶ Derived from definite and readily identifiable sources, human cell-lines offer a more efficient method of balancing the individual's desire to control the use of his donated cells with the preservation of scientific freedom to research. This would link the financial success of the cell-line to the consent of the individual. This may be accomplished without legislative effort by eliminating the traditionally required nexus between an employee's invention and an employer's business. Unless the business nexus requirement is eliminated, it is unlikely that a court will order equitable division of patent rights between a physician-inventor and his patient-employer by operation of the common law shop right doctrine alone.¹⁴⁷ Some judges might be reluctant to

saying 'no patents, no cure.' Ireland was allowing companies to 'bio-prospect on patients for profit' . . . by facilitating secretive attempts to extract gene sequences.'").

¹⁴⁵ See, e.g., Elizabeth Pennisi, *NRC OKs Long-Delayed Survey of Human Genome Diversity*, SCIENCE, Oct. 24, 1997, at 568 (noting the fear that "indigenous populations would be exploited because researchers might try to patent their DNA for use in medical tests or other products without sharing the profits with the original donors"); Nicholas Hildyard & Sarah Sexton, *No Patents on Life*, F. FOR APPLIED RES. & PUB. POL'Y, Mar. 22, 2000, at 69.

¹⁴⁶ To put this in perspective, Ameripath, which performs pathology services for only 170 hospitals, analyzes nearly 3 million tissue biopsies every year. Under an agreement with DNA Sciences, a company that recruits people to donate their DNA to help find genes that cause disease, Ameripath will provide them with several hundred thousand of its accumulated samples. See Andrew Pollack, *DNA Sought Online: Web Site Recruits Donors to Contribute to 'Gene Trust,' Assist Disease Research*, DALLAS MORNING NEWS, Aug. 1, 2000, at 5D.

¹⁴⁷ See *Dubilier Condenser*, 289 U.S. at 187 ("One employed to make an invention, who succeeds, during his term of service, in accomplishing that task, is bound to assign to his employer any patent obtained. . . . On the other hand, if the employment be general, albeit it cover a field of labor and effort in the performance of which he obtained a patent,

recognize this concept because the public interest is presently rarefied due to the small number of *Moore*-like cases.¹⁴⁸ Therefore, in order to ensure that cell-line patents transmit shop rights to the source of the cells, it would be prudent to find a solution to the nexus problem outside of the judicial arena. One promising possibility is contracting for limited rights in any inventions resulting from tissue harvesting procedures in the preinvention stage. Preinvention contracts, private agreements to disregard some aspects of the common law shop right doctrine, can overcome any difficulties inherent in the doctrine.¹⁴⁹

B. Preinvention Contracts

A second long-established method of determining rights vesting in as-of-yet created inventions is by preinvention contract.¹⁵⁰ This instrument can obligate the employee to assign to the employer all interests in future patentable inventions conceived during the employment relationship as a condition of that employment.¹⁵¹ The scope of such agreements varies, but even the liberal require assignment of inventions made by the employee relating to the employer's business or research interests during the employment relationship.¹⁵² Although the employee is named as inventor on

the contract is not so broadly construed as to require an assignment of the patent.”).

¹⁴⁸ Regarding property rights in cell-lines, only a few cases have been filed. *See, e.g., Moore*, 793 P.2d at 479; *Miles, Inc. v. Scripps Clinic and Research Found.*, 810 F. Supp. 1091 (S.D. Cal. 1993); *United States v. Arora*, 860 F. Supp. 1091 (D. Maryland 1994). One other similar case was filed but settled out of court. In that case researchers patented a hybridoma that produced an anti-tumor antibody using cancer cells of the mother of a post-doctoral student, Dr. Heideaki Hagiwara. *See OTA REPORT, supra* note 1, at 26.

¹⁴⁹ For a discussion of preinvention contracts generally, see Steven Cherenky, *A Penny for Their Thoughts: Employee-Inventors, Preinvention Assignment Agreements, Property, and Personhood*, 81 CAL. L. REV. 595 (1993).

¹⁵⁰ *See generally id.*

¹⁵¹ *See Cherenky, supra* note 149, at 617-18.

¹⁵² *See id.* at 618 n.104.

Typical preinvention assignment agreements provide: The undersigned agrees that he will disclose to the Company all inventions, improvements, software, processes, ideas, and innovations (hereinafter referred to, for convenience only, as “Discoveries”), made or conceived by him, whether or not patentable or copyrightable, either solely or in concert with others, and whether or not made or conceived during working hours, during the period of his employment, which (a) relate to the existing or contemplated business or research activities of the Company; (b) result from the use of the Company's proprietary information, facilities, or resources;

any patent applications, the employer is named as the assignee, or legal owner of all relevant aspects of the patent by operation of the agreement.¹⁵³ This includes the right to exclude others (including, in some cases, the employee himself) from making, using, or selling the invention throughout the United States for a period of twenty years.¹⁵⁴ Parties who bargain for “preinvention” rights cannot be certain of the value or even the exact subject matter of their bargain at the time of contract,¹⁵⁵ yet virtually all technical employees work under such contracts.¹⁵⁶ Preinvention agreements, although adhesion contracts, are upheld by virtually all courts on the basis of freedom of contract.¹⁵⁷ In applying this existing body of case law to modern cell-line invention cases, the questions that must be answered are: 1) what kind of employee-employer relationship must exist in order to have a preinvention agreement upheld; 2) what is the duration of a doctor-patient employment relationship, and is it sufficient to keep a preinvention agreement in force for the length of time necessary to bring a cell-line invention to fruition; 3) what consideration must a doctor receive to make such an agreement binding; and 4) can a patient contract for a partial transfer of rights where they provide no contribution other than the source biological material?

Essentially, any clause in a contract for invention assignment is enforceable regardless of the nature or duration of the employment relationship, as long as it was not agreed to under duress and is not unconscionable.¹⁵⁸ Because preinvention contracts are enforceable

or (c) arise out of or result from work performed for the Company. [The undersigned acknowledges that he is employed to engage in research, design, and development.] The undersigned further agrees to keep full and complete records concerning the development of discoveries as above defined and to tender such records to the company upon request.)

Id.

¹⁵³ See 1 CHISUM ON PATENTS §§ 22.01, 22.02 (noting that the inventor is the presumptive owner of the property rights in a patentable invention, but that he can transfer ownership interest by written assignment. Even if ownership rights are assigned, patent law requires the inventor to be named in the application for a patent.)

¹⁵⁴ See 35 U.S.C. § 271(a) (2000).

¹⁵⁵ See Cherensky, *supra* note 149, at 598.

¹⁵⁶ See *id.* at 599.

¹⁵⁷ Signing a preinvention assignment agreement is an express condition of employment, yet an enforceable one, barring any finding of overreaching on the part of the employer. See Cherensky, *supra* note 149, at 600.

¹⁵⁸ 35 U.S.C. § 261 provides that patents are assignable by law. The enforceability of the resulting “contract of assignment” is then analyzed under general contract principles.

so long as they are not unconscionable, it is unlikely that a court will make an extended inquiry into the depth of the employment relationship.¹⁵⁹ Thus, in situations where a preinvention contract assigns limited rights in a patent to a patient, the courts do not need to determine the degree to which a doctor-patient relationship may be equated to a traditional employer-employee relationship. As to the issue of consideration, the simplest way of disposing of this issue is to tie the shop right either to the consent to research or to the physical transfer of cells from the source to the doctor.

Introducing a new contractual step in obtaining consent to research would, to some degree, increase the cost of medical care. More significantly, however, it would raise the informed consent burden of physician-researchers. Physicians would be forced to take on the role of informing a patient about the potential value of his cells or tissues as well as the pros and cons of having them removed for health reasons. While this appears to be a difficult issue to resolve in a doctor's office, the benefit of the preinvention contract approach is that, much like the second medical opinion, a patient has the ability to obtain a secondary legal opinion prior to consenting to the proposed research. No extended legal discussion need be conducted between the physician and the patient, so long as the physician recommends that the patient seek the advice of competent counsel. The issue of informed consent will therefore continue to focus primarily on the decision-making process surrounding the health reasons a patient should or should not have tissue removed. Assuming the two parties can come to an understanding as to how the potential profit rights should be distributed, they are free to codify this agreement in a contract with whatever provisions may be necessary under the particular circumstances. By separating the medical/research discussion from the legal one, the preinvention approach can be adapted to fit virtually any medical circumstances in which a doctor wants to conduct research on a patient. This separation interposes a new step in the informed consent process.

It is unlikely there will be a situation wherein the entire informed consent and preinvention contractual process must be completed at the time of the initial visit to the doctor, even if the need for treatment is urgent. The hypothetical emergency patient can

See, e.g., Hockerson-Halberstadt, Inc. v. Nike, Inc., 779 F. Supp. 49, 51 (E.D. La. 1991).

¹⁵⁹ *See* Cherensky, *supra* note 149, at 619-623.

simply deny consent for research until such time as he has contracted to protect his right to benefit from that research, while still consenting to treatment for his emergency condition.¹⁶⁰ Thus, no patient can be unduly pressured into accepting a less-than-equitable deal. Alternatively, the patient might grant the doctor provisional consent to store the cells without actually beginning research, or consent to research with a prohibition on commercializing any results until negotiations have been completed to the patient's satisfaction. With conditional consent, it may be necessary for the court or legislature to intervene to assure that the commercialization of the research does not proceed without the patient's express consent. This would only require a court or legislature to make minor changes to expand the existing informed consent laws of many states.

This preinvention contract system, combined with a small expansion of informed consent law, would minimize transaction costs. The initial transaction costs would be incurred in the expansion of the informed consent procedures. These procedures would be expanded to include a patient's ability to refuse consent to commercialization of their tissue, the recommendation that patients seek the advice of a lawyer prior to consenting to such commercialization, and the process of familiarizing patients with the effect of these new choices. Once these transaction costs are overcome, the only remaining cost would be an explanation of the various options that the patient could choose. These options are temporary storage pending later consent to research, research but no commercialization, or research and commercialization.

The shop right and preinvention contract address the most prevalent difficulty with cell-line patents: that by ignoring the source of the tissue, they fail to recognize that inventorship can have both a passive and an active component. In other words, by cutting the source of the original tissue out of the patent-proper, current cell-line ownership arguments fail to acknowledge that

¹⁶⁰ There is the possibility that a physician might want to publish his treatment of the patient's particular medical problem under the rubric of "medical research." My proposition, however, is accurate with respect to cell-line inventions. At the time of emergency treatment, there is no need to rush a patient into consenting to allow a sample of his tissue being taken for the purposes of producing a cell-line. This is because the types of cells he has at the time of treatment are the same as those he will have much later.

there would be no invention and thus, no patent, without the source's contribution. The benefit of a patent law approach to the allocation of profits between the patent owner and the source of the bodily materials is that it does not necessarily require any legislative action. It does, however, require a paradigm shift in the doctor-patient relationship from paternalism to something approaching parity. Working within the context of preinvention contract litigation, courts will be able to overcome resistance to this new paradigm by ratifying these restructured doctor-patient relationships.

CONCLUSION

The *Moore* decision raised many novel questions regarding the rights of medical research subjects in the world of biotechnology. Although the California Supreme Court was willing to expand the law of informed consent, it did not resolve the issue of individual rights in inventions based on a patient's discarded tissue.¹⁶¹ The failure to acknowledge such rights has contributed to public outcry over the ethical issues and financial inequities resulting from the assignment of intellectual property rights in living inventions.¹⁶² Although the consent requirement gives the modern medical patient some degree of control over the fate of his own bodily tissue, this only protects his right to personal autonomy.¹⁶³ In a market-driven biological research paradigm, the research participants should be afforded the freedom to control, and profit from, the rights in their cells, which are essentially miniature representations of their whole being. By refusing to grant such rights, the *Moore* court undervalued the contributions of research participants to the inventive process. In doing so, the court was thereby guilty of that which it accused Moore: stifling medical research by destroying the incentives for some of its participants. Yet, while the immediate recognition of property rights in all excised tissue would provide a solution to the problem articulated by *Moore*, it would ultimately increase the costs for biological research and medical care by expanding the administrative and actual costs of compensating tissue donors. Nevertheless, this

¹⁶¹ See generally *Moore*, 793 P.2d at 479.

¹⁶² See *supra* notes 144-145 and accompanying text.

¹⁶³ See *supra* note 77 and accompanying text.

should not preclude the extension of any rights to research subjects.

The patent system provides not only powerful incentives to invent, but well-developed solutions to allocate the financial rewards that the patented inventions generate.¹⁶⁴ By ratifying the use of shop rights and preinvention contracts by research subjects, courts can grant human sources compensation in proportion to their contribution to an invention. This can be done with only minor alterations in the current administration of medical treatment. Recognizing these limited property rights would protect individuals' commercial interest in their bodies when the scientific community is profiting from the use of the individuals' bodily materials. The disadvantages of this system are few, because the patent-based solution for apportioning profits from a cell-line protects the ability of academic and other not-for-profit research institutions to continue their work without fear of litigation.

If future courts do not resolve the ownership and right-to-profit issues, it is likely that public outcry over the inequities of the present system will result in a call for legislative action. Yet, legislative action is avoidable. While Moore broke new ground by raising his dispute in the biotechnology arena, he essentially only articulated new subjects for an old debate: the proper division of rights in intellectual property. The large body of common law in the various fields of intellectual property suggests that courts are experienced in arbitrating such disputes within existing statutes. Therefore, in order to protect the diverse interests of medical researchers and their subjects most effectively, it is the courts that should resolve the debate over property rights in human cells by adapting the shop right doctrine and preinvention contracts to balance the equities involved in this novel iteration of a classic debate.

¹⁶⁴ The shop right and preinvention contract are two examples of this.