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Moore v. Regents of the University of California Revisited[†]

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I. INTRODUCTION

¶1 The development of new effective techniques to produce medically and scientifically useful substances from the cells of patients has helped to create a climate in which the ownership of those substances is at issue. When Sandoz Pharmaceuticals Corporation (Sandoz) and Genetics Institute, Inc., together with a University of California at Los Angeles (UCLA) researcher, appeared to become interested in the commercialization of the biological products of an identifiable cell line, a suit resulted. In retrospect, the plaintiff's allegations of conversion and failure to provide ample facts for informed consent as described in *Moore v. Regents of the University of California*[1] were inevitable; the California Supreme Court's decision was not. Nevertheless, the *Moore* decision extended, in California, at least, the scope of those facts that must be divulged to the patient by the physician-researcher. In addition, *Moore* suggested that the research sponsor may share the responsibility for the candor of that disclosure and raised the possibility of the sale of diseased body parts to the highest bidder.

II. THE *MOORE* DECISIONS

A. *Facts*

¶2 In 1976, the plaintiff, John Moore, learned that he was suffering from hairy-cell leukemia. His physician referred him to Dr. David W. Golde at the UCLA Medical Center. Dr. Golde confirmed the diagnosis and advised the plaintiff to have his enlarged spleen removed to retard the progress of the disease. The plaintiff agreed to the operation and signed a consent form. Dr. Golde and his assistant, defendant Ms. Shirley Quan, arranged, prior to the operation, to obtain portions of the diseased spleen for use in their research.

¶3 After the operation, Dr. Golde and Ms. Quan received portions of the excised spleen. Over a period of time, they cultured cells taken from the spleen and were successful in establishing a cell line from the plaintiff's T Lymphocytes, important cells in the body's immune response. On March 20, 1984, Dr. Golde and Ms. Quan were awarded a patent entitled "Unique T Lymphocyte Line and Products Derived Therefrom" that, among other things, included claims on the cell line derived from the plaintiff's spleen.

¶4 The cell line produced substances called lymphokines, which were of considerable interest to the pharmaceutical industry. Accordingly, Sandoz and Genetics Institute began to support Dr. Golde's research. According to the complaint, the amount of this support was as high as $440,000 per year, and Dr. Golde received 75,000 shares of Genetics Institute's common stock.

¶5 In the meantime, the plaintiff, during the period 1976 to 1983, traveled from his home in Seattle to UCLA so that Dr. Golde could obtain additional samples of blood, blood serum, skin, bone

marrow aspirate, and sperm. The plaintiff alleged that Dr. Golde had advised the plaintiff that this procedure was necessary in monitoring the leukemia and that the procedure should be performed by Dr. Golde at UCLA.

B. *Case Progression*

1. *The Trial Court*[2]

¶6 Mr. Moore, the plaintiff, alleged that until some time in 1983, Dr. Golde concealed his research activity from the plaintiff. He also alleged that the defendants would profit from the projected three-billion-dollar market in therapeutic uses for lymphokines. The plaintiff's thirteen count complaint against the Regents of the University of California (the Regents), Dr. Golde, Ms. Quan, Sandoz, and Genetics Institute alleged, among other things, conversion, lack of informed consent, and breach of fiduciary duty. All defendants demurred. The trial court upheld the demurrer of each defendant as to the first cause of action, conversion. The trial court dismissed the remaining claims as well because each claim relied upon defective allegations in the first cause of action.

2. *The Court of Appeal*[3]

a. The Opinion

¶7 The Court of Appeal of California, Second Appellate District, Division Four, reversed in an impassioned opinion in which it found, in the face of statutory law, case law, and treatise authority to the contrary, that the plaintiff had a property right in the diseased spleen and that, on the face of the complaint, the Regents, Dr. Golde, and Ms. Quan had converted the spleen.

¶8 In reading the majority opinion, it is difficult to find any reference to the fact that the removal of the enormous, cancerous spleen and subsequent monitoring of the plaintiff's body fluids had any beneficial effect on him. In fact, the majority erroneously concluded that the record contained no recital at all of the diseased nature of the excised organ. Rather, the majority focused on the assertion that

> [t]he market potential of products from plaintiff's cell-line was predicted to be approximately three billion dollars by 1990. Hundreds of thousands of dollars have already been paid under these agreements to the developers.[4]

¶9 The Court of Appeal concluded categorically that the subsequent fluid removals were to serve research purposes apparently without regard to medical necessity or utility.[5] While stopping just short of invective, the decision is replete with references to Dr. Golde's and Ms. Quan's financial motivation in dealing with Mr. Moore, the plaintiff.

b. Public Reaction

¶10 The decision of the Court of Appeal opened to question rights of ownership of thousands of cell lines and left medical researchers and their counsel with the problem of writing informed consent documents which would avoid future difficulty. One University of California hospital included the following statement in its form, *Consent to Act as a Human Subject in a Medical Investigation*: "I or my child realize [sic] that any potential inventions or treatments that are the result of this study are the sole property of the University of California." One is tempted to ask how binding this is on "my child," at least. One may also ask what becomes of the University's actual inventions or treatments and what it did with the rest of its property, but that is to quibble. In any event, if the study has attracted commercial support at the time of disclosure or even afterwards, the blanket waiver may

not be enough to avoid claims against future research support payments or a claim of undue influence.

¶11 I was asked my opinion concerning what additional steps Pfizer should take in protecting our intellectual property in light of the Court of Appeal's decision. At that time, we were negotiating a major research collaboration with the University of California regarding the properties of potassium channels in T cells. We received no help from our counterparts at the University other than a copy of the aforementioned informed consent language. Consequently, it was left to me to help Pfizer decide how to go forward with the transaction. I suggested to both sides that we continue negotiations as if the decision had not been announced because the opinion seemed counter-intuitive to me. Moreover, it was too early to panic because the Supreme Court of California had not considered the matter. I also counseled our Central Research division that, given the expense and negative effect on productivity, an inventory of all cell lines in use at Pfizer was premature. Needless to say, we were concerned about the outcome in the Supreme Court of California.

3. *The Supreme Court*[6]

¶12 In reversing the Court of Appeal with respect to the conversion count, the Supreme Court of California provided some relief to the medical research community and its sponsors. The threat to the ownership of materials derived from patients' tissue abated. The court stated:

> There are three reasons why it is inappropriate to impose liability for conversion based upon the allegations of Moore's complaint. First, a fair balancing of the relevant policy considerations counsels against extending the tort. Second, problems in this area are better suited to legislative resolution. Third, the tort of conversion is not necessary to protect patients' rights. For these reasons, we conclude that the use of excised human cells in medical research does not amount to a conversion.[7]

¶13 In addition, the court found that the plaintiff had no rights in the patent. Because the court's analysis is correct with respect to the intellectual property at issue and sets forth the best reason for dismissing the entire complaint in the first instance, I quote from the opinion at length.

> Finally, the subject matter of the Regents' patent—the patented cell line and the products derived from it—cannot be Moore's property. This is because the patented cell line is both factually and legally distinct from the cells taken from Moore's body. Federal law permits the patenting of organisms that represent the product of "human ingenuity," but not naturally occurring organisms. Human cell lines are patentable because "[l]ong-term adaptation and growth of human tissues and cells in culture is difficult—often considered an art…," and the probability of success is low. It is this inventive effort that patent law rewards, not the discovery of naturally occurring raw materials. Thus, Moore's allegations that he owns the cell line and the products derived from it are inconsistent with the patent, which constitutes an authoritative determination that the cell line is the product of invention.[8]

¶14 The court could have stopped there, given that the plaintiff had no property interest in the excised spleen, that the patent represented the fruits of someone else's inventiveness, and that "problems in this area are better suited to legislative resolution."[9] Instead, the court's sense of outrage seemed to overwhelm its judicial restraint and intellect. Despite the fact that Mr. Moore, the plaintiff, had no cognizable interest in the spleen, the cell line, or the patent and that there is no allegation that Mr. Moore suffered a medical injury, the majority concluded that the complaint

properly alleged a cause of action for breach of fiduciary duty or lack of informed consent. In addition, the court gave the plaintiff leave to amend his complaint to perfect his allegations of secondary liability against Sandoz and Genetics Institute with respect to the same issues.

¶15 In coming to the first of those conclusions, the court relied principally on its own decision in *Cobbs v. Grant*;[10] however, the court created a new duty for physicians by misapplying that precedent. Looking at the court's citation to *Cobbs* was important to me in deciding what advice I should give to Pfizer and indirectly to the hospital investigational review boards that asked what action we had taken. Freely citing *Cobbs*, the court wrote:

> Our analysis begins with the three well-established principles. First, "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." Second, "the patient's consent to treatment, to be effective, must be an informed consent." Third, in soliciting the patient's consent, a physician has a fiduciary duty to disclose all information material to the patient's decision.
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> These principles lead to the following conclusions: (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.
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> To be sure, questions about the validity of a patient's consent to a procedure typically arise when the patient alleges that the physician failed to disclose medical risks, as in malpractice cases, and not when the patient alleges that the physician had a personal interest, as in this case. The concept of informed consent, however, is broad enough to encompass the latter. "The scope of the physician's communication to the patient . . . must be measured by the patient's need, and that need is whatever information is material to the decision."
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> A physician who adds his own research interests to this balance may be tempted to order a scientifically useful procedure or test that offers marginal, or no, benefits to the patient. 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. It is material to the patient's decision and, thus, a prerequisite to informed consent.
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> We acknowledge that there is a competing consideration. To require disclosure of research and economic interests may corrupt the patient's own judgment by distracting him from the requirements of his health. But California law does not grant physicians unlimited discretion to decide what to disclose. Instead, "it is the prerogative of the patient, not the physician, to determine for himself the direction in which he believed his interests lie." "Unlimited discretion in the physician is irreconcilable with the basic right of the patient to make the ultimate informed decision . . . ."
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> Accordingly, we hold 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.[11]

III. In the Wake of the *Moore* Decisions

¶16 What is the breadth of the phrase, "personal interests unrelated to the patient's health?" Must the physician divulge that she hopes to get outside funding for her work or that sometimes people in her position are awarded research grants? What if the physician truthfully denies that funding exists or is contemplated and she later obtains it? These circumstances are fraught with litigable possibilities.

¶17 In spite of this unexpected and uncertain result, the *National Law Journal* confirmed the University of California's premature declaration of victory:

> The 131-page ruling is a victory for the medical research community. Allen B. Wagner, deputy general counsel for the university, said that recognition of such a property right would have deterred life-saving research and "could have sounded the death knell to the university physician-scientists."[12]

A. *The Parties*

¶18 Mr. Moore, the plaintiff, has lived a substantial number of years longer than ordinarily predicted for someone afflicted with his deadly leukemia. Nevertheless, he still proclaims to the world that he is an injured party in all of this. The *Guardian* reported that

> John Moore says he has been "essence-raped". The genial Burl Ives lookalike is effectively the world's first patented man. Yet he was grateful enough in 1976 when, as an oil worker, he came off the Alaskan pipeline to seek treatment for hairy-cell leukaemia. His doctor at the University of California found that Moore's spleen had enlarged from about half a pound to more than 14 pounds. It was removed and Moore recovered.
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> . . . .
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> [Moore did not] know that the university had applied for - and been granted - a United States patent on its "invention". He became suspicious only in 1983, when his doctor pressed him to sign over all rights to cell lines taken from his spleen. He refused. Only later did Moore learn that the "Mo line" had been sold to a biotechnology company for $1.7 million. . . . He was stunned: "What the doctors had done," he told the Guardian this week, "was to claim that my humanity, my genetic essence, was their invention and their property. They viewed me as a mine from which to extract biological material. I was harvested."[13]

¶19 Dr. David Golde is still one of the leading cancer physician-researchers in the United States. He is the mentor of several generations of other such physicians and researchers. I had always wondered what he made of his part in the suit. Consequently, I invited him to Pfizer Central Research last year to talk about the case. Dr. Golde told us that the case left him bemused and frustrated. He was bemused because, given the length of time Mr. Moore's leukemia had been in remission when the

lawsuit was brought, it was fair to say that Dr. Golde's treatment had cured him. In fact, Mr. Moore is still active today. This is exceptional for someone with his illness. Dr. Golde also said that he monitored Mr. Moore's health subsequent to the removal of his spleen both to determine if there was a recurrence and whether Dr. Golde could confirm his belief that a virus had caused Mr. Moore's leukemia. Although Dr. Golde did not establish a causal link between what became known as the HTLV-2 virus and the disease, he and Ms. Quan isolated this virus for the first time.

¶20 Dr. Golde thought Mr. Moore and the University were happy with all this until Mr. Moore brought his lawsuit and the University apparently decided that the future of America's biomedical research was at stake and that it could not be certain that its position and Dr. Golde's were congruent. As a result, Dr. Golde retained his own lawyer and was never reimbursed fully for his legal expenses. Dr. Golde was also frustrated because he never got to tell his side of the story—at least, not publicly. He told us that he was an excellent deponent, earning high praise from his lawyer because Dr. Golde understood that it was not the purpose of his testimony to make his own case. He became, as a result, quite adept at answering the question posed and not volunteering anything further. Nevertheless, he never got to tell what he viewed as a medical and scientific success story.

¶21 Parenthetically, biological substances related to those produced by the cell line at issue in *Moore* did not become part of the medical therapeutic products market. Except for their research support, Dr. Golde, Ms. Quan, and the Regents did not benefit financially by virtue of the patent they filed.

B. *Commentators*

¶22 The law review commentators hastened to add their analyses and suggestions to the Supreme Court of California's property analysis. Indeed, the discussion in the legal and scientific literature and the popular media has proliferated with the airing of news of the cloning of animals and near-completion of the identification of the human genome. Much of this is fascinating; there is no doubt that a number of very serious legal and ethical issues under the general heading of "the right to privacy" are open to public and legislative debate.

¶23 It is unclear where this debate is going to end; it is far from clear what intellectual property rights will evolve from this new knowledge and who will own them. On the other hand, it is disappointing that there is little if any informed discussion about the possibility that Mr. Moore, a cancer patient, arriving at a prestigious teaching hospital to see a great man, had an ethical duty to others. As the inheritor of Dr. Golde's knowledge and skill derived from the treatment of those who preceded him to Dr. Golde's office, did Mr. Moore have a duty to those patients who came after him? Is it relevant at all to that analysis whether Dr. Golde is remunerated for his research or results? May Dr. Golde refuse to take a case when he feels that his ability to pass on the knowledge gained in treating patients is inordinately restrained?

C. *A Practitioner*

¶24 When *Moore* was decided, I had little time to consider the relevant issues in the abstract because I had to give immediate advice. I was asked by Pfizer's officials what changes we needed to make in our informed consent form in use throughout the world in order to comply with the *Moore* decision. Also, a number of hospitals throughout the country asked Pfizer's clinical representatives the same questions informally. I read both *Moore* decisions, the *Cobbs* decision, and the leading informed consent cases in about a dozen states other than California, as well as a number of state statutes dealing with the disposal of corpses and surgically excised body parts. I read any number of informed consent forms—Pfizer's and others—from all over the world. My advice: make no changes.

¶25 I came to this conclusion for a number of reasons. First, all the consent forms I reviewed were quite complete. If they erred at all it was on the side of inclusion: there was much more explanation

than the average adult could hope to absorb. Also, every form I read stated that questions had already been encouraged and that a physician's name and phone number were included for the express purpose of answering additional questions. I found this persuasive.

¶26 When I read the *Moore* opinions, I found more heat than light. The majority opinion in the Court of Appeal and all the opinions in the Supreme Court of California seemed to take the plaintiff's allegations as proved on the merits rather than assumed as a procedural matter. Indeed, the allegation that there was a three-billion-dollar market for Moore cell lines that generated lymphokines could only be a speculation, because, at best, it described future events. It was difficult to see the relevance of the allegation. There is no allegation that the medical treatment would have been different if there were a smaller market or no market. The Supreme Court of California, while admirably reluctant to extend the plaintiff's interest in his excised spleen into an interest in the defendants' intellectual property, nonetheless seemed to go to extraordinary lengths to extend the rationale in *Cobbs* to provide relief of some kind for the plaintiff. The reference to that plaintiff's rights in the majority opinion in the Supreme Court of California struck a jarring note.

¶27 In fact, dissenting in the Court of Appeal, Judge George, now the Chief Justice of the Supreme Court of California, wrote the single lawyerly, carefully crafted opinion in either court. Citing the California Health and Safety Code,[14] he wrote:

> Aside from the alleged economic interest in their use asserted by plaintiff, a patient who consents to surgical removal of his bodily substances has no reasonable expectation as to their subsequent use other than an understanding that the licensed medical personnel involved in the removal and use of these substances will comply with applicable medical standards and legal constraints, such as the mandate that substances removed from his body "*following conclusion of scientific use* . . . be disposed of by interment, incineration, or any other method determined by the state department to protect the public health and safety."[15]

¶28 I believed that his opinion was the correct analysis and more likely to be followed outside California than the majority opinion in the supreme court. My reading appears to be reinforced by the Patient's Bill of Rights Statute alluded to by Judge George as well as a number of state and federal statutes which encouraged use of body parts in healing and research, yet prevented their commercialization and protected patient privacy. The best line of defense in a *Moore*-like suit would be an attack on the broad, ill-defined fiduciary duty described by the majority.

IV. Ripple Effects Following the *Moore* Decisions

¶29 The focus of the debate has shifted to the identification, collection, and use of genetic information. There are a number of issues affecting intellectual property rights in deoxyribonucleic acid (DNA), for example. Should it be patentable? Should genes be patentable? What scientific uses should fall outside the scope of such patents? While I have been involved in these debates, I will limit this discussion to the effect the *Moore* case had on my considerations of the informed consent issues surrounding Pfizer's collection and information practices with respect to patient DNA obtained in clinical trials for use in studies unrelated to those specific trials.

¶30 Once again, I reviewed the *Moore* case, a number of state statutes regarding patients' bills of rights, and a number of articles sounding the alarm about the possibility of the misuse of genetic information by insurance companies. Again, I found Judge George's dissenting opinion instructive. It was readily apparent that a patient consenting to taking an experimental drug as part of a clinical trial had no "reasonable expectation" that part of the blood sample taken in compiling a medical

history was to be genotyped and stored for use in biomedical research having little or no relationship to the drug trial. Indeed, the DNA libraries compiled from these samples may be put to uses not contemplated or possible of contemplation now. Furthermore, the compilation, storage, and handling of thousands of DNA samples creates daunting privacy and security issues.

¶31 My advice to my clients was that there would have to be a new informed consent procedure directed specifically to the gathering of DNA material obtained for purposes other than the clinical trial that brought the patient to the hospital or the clinic in the first place. The consent had to be completely voluntary; the patient could not be disqualified from the clinical trial solely for the reason that she refused to consent to the DNA sampling. The DNA information had to be maintained apart from any personal identifying information consistent with not making gibberish out of the library. In other words, to make the samples useful it was necessary to "run them" against demographic information and medical parameters. This aside, once filed, the DNA could not be re-matched with its donor. Finally, the informed consent document was to be written in a way that made it understandable to a patient with a very limited education.

¶32 It took three years to put this program in place. Perhaps the easiest part was the acceptance of my suggestion that the consent form should consist of two discrete sections. The first section allowed the patient to consent to participation in the drug study. The second section permitted the patient to decline to participate in the DNA program for any reason without prejudice to participation in the clinical trial itself. I will spare you the excruciating detail of the year-long drafting exercise on part two. Suffice it to say, in the end, we were satisfied that patients had the best opportunity to determine that participation was voluntary, that the file was anonymous, and that there was no financial benefit to them.

¶33 The balance of the three-year period was spent assuring ourselves that once the DNA samples had been separated from all alphanumeric identifiers, the file was anonymous. While I cannot say to you that the file is anonymous under all conceivable circumstances given the need to preserve its scientific utility, we believe we have taken all reasonable steps to preserve confidentiality. Someone with extraordinary knowledge of the workings of a computer and access to the file might, with a great deal of difficulty, trace a DNA sample back to its donor. Even then, one could not be sure of the donor's identity.

¶34 This informed consent document, storage, and retrieval system required only modest changes in light of a recent European Parliament directive.[16] These changes generally were directed to appropriate notification for removal of information form the European Union. Our program also complies with the provisions of the proposed regulations under the U.S. Health Insurance and Portability and Accountability Act of 1996.[17] We are particularly pleased that our study of the existing sources and our consideration of patient privacy rights put Pfizer in compliance prior to the promulgation of the directive and enactment of the statutes.

V. Conclusion

¶35 There are other issues that we cannot reach within the scope of this talk. Certainly, additional unforeseeable issues will arise as the knowledge of the genome and the ability of the use of the information engendered advance. The *Moore* case is unlikely to be a useful tool in dealing with any of this. It is an anomalous case, a case that produces more rhetoric than guidance. With respect to intellectual property rights in ownership of the body's substances, it provoked seemingly little legislative consideration and less action. The opinions in *Moore* will, however, remain important as early suggestions of what was to follow. The case should continue to be read on that basis.

¶36 Finally, Judge George's dissent will always remain valuable for its clarity and its reliance on time-tested rules of adjudication for cases of first impression. Judge George also reminds us of the

line which must remain, particularly in times of intellectual and emotional stress, between the courts and the legislature.

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† Edited transcript of remarks delivered to the Yale Law and Technology Society on February 1, 2000.

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1 793 P.2d 479 (Cal. 1990).

2 For a discussion of the trial court's decision, see *Moore v. Regents of Univ. of Cal.*, 249 Cal. Rptr. 494, 501-02 (Cal. Ct. App. 1988).

3 Moore v. Regents of Univ. of Cal., 249 Cal. Rptr. 494 (Cal. Ct. App. 1988).

4 *Id.* at 498.

5 *See id. at* 500.

6 Moore v. Regents of Univ. of Cal., 793 P.2d 479 (Cal. 1990).

7 *Id.* at 493.

8 *Id.* at 492-93 (footnotes and citations omitted).

9 *Id.* at 493.

10 502 P.2d 1 (Cal. 1972).

11 Moore, 793 P.2d at 482-85 (quoting Cobbs v. Grant, 502 P.2d 1, 9-12 (Cal. 1972)) (footnotes and citations omitted).

12 *Moore v. University of California Regents*, 6 NAT. L. J. (1990).

13 John Vidal & John Carvel, *Lambs to the Gene Market*, GUARDIAN, Nov. 12, 1994, at 25.

14 CAL. HEALTH & SAFETY CODE § 7054.4 (West 2000).

15 Moore, 249 Cal. Rptr. at 535 (Cal. Ct. App. 1988) (George, J., dissenting) (quoting CAL. HEALTH & SAFETY CODE § 7054.4 (emphasis added in opinion)).

16 Council Directive 95/46, 1995 O.J. (L 281).

17 Pub. L. No. 104-191, 110 Stat. 2087-2088 (1996).