Mo Cell Case Has Its First Court Hearing

The University of California argues that a patient whose tissues were the basis of a patent has no valid claim to a share of potential profits

In September, John Moore, a leukemia patient who has been treated successfully at the University of California, Los Angeles (UCLA), filed suit against the University of California on the grounds that two UCLA researchers took unfair advantage of him by using his cells as the basis of research that has led to a patent of undetermined financial value (*Science*, 28 September, p. 1458). The case of *John Moore* versus *The Regents of the University of California* was the subject of a hearing in federal court in Los Angeles on 29 October when the two sides squared off in a procedural argument over whether the case belongs in state or federal court, or, as UC attorneys argued, in no court at all.

The outcome of that hearing—a ruling that the dispute should be heard in California state court—has now set the stage for a case that may turn out to focus on the behavior and motives of the researchers who cared for Moore but somehow left him feeling cheated, even though they saved his life.

Attorneys for Moore, a Seattle seafood salesman, see the case as a potentially precedent-setting suit that will spell out previously undefined "rights" that a patient has (or ought to have) in any commercial products derived from research on his bodily cells or tissues. On the basis of research on cells from Moore's spleen, which was removed in 1976 as part of his successful therapy for hairy cell leukemia (a rare form of cancer), UCLA scientists David Golde and Shirley Quan developed a productive cell line that they called Mo (for Moore) and on which they filed a patent in 1981. The patent was granted in March of this year; not long thereafter, Moore decided to find a lawyer. The Mo cell line produces a number of biologically valuable substances, including immune interferon (type II), macrophage-activating factor, and T-cell growth factor.

Sanford M. Gage, one of Moore's attorneys from the Beverly Hills firm of Gage and Mazursky, has said that "the central issue in this case is the patient's right to a share of the profits earned by drug companies and biogenetic firms from products derived from his body." Even though Moore signed standard informed consent papers in which he turned over to the university rights to his spleen and, later, to blood drawn both for his treatment and for research, his attorneys now claim that his informed consent is invalid because it was not truly informed. Had he known that the research to which he consented might lead to some commercial product, he might have demanded compensation or a share of the profits if there are any. Thus, they claim, Moore was misled. It is, as far as attorneys for each side know, a novel claim.

The case, which is likely to be aired in the press before a trial date can be scheduled 3 or more years from now, has riled university officials and scientists who see it as little more than a legally unjustified case of exploitation. Golde, the physician who has been treating Moore, says he was "shocked" by the suit. "The patient wants money. His lawyers seem to want publicity," he says. Others at the university and elsewhere, who believe that research is dependent on scientists' ability to freely use tissues that are obtained legitimately as Moore's were, have called the case "outrageous" and a "threat to the sharing of tissue for research purposes for pathology labs."

> The novel case suggests need for universities to consider policy issues for the future.

In papers filed for the court hearing last month, attorney Allen B. Wagner, who is in the university's office of the general counsel in Berkeley, argued that Moore has no valid claim for several reasons.

First, said Wagner, even though Moore alleges that the researchers misappropriated his tissues and failed to obtain full informed consent, "the true 'heart of the complaint' is his claim to the issued patent." Moore, he argued, "has no right, title or interest in the patent, notwithstanding the fact that his diseased spleen tissue presented a circumstance that stimulated the intellectual curiosity and ingenuity" of researchers Golde and Quan. Citing an earlier, unrelated patent case as legal precedent, Wagner quoted the court as saying, " 'patents are not granted for the natural properties inherent in things existing in nature, although they may be granted for things an inventor does with those properties.' "

The patent, Wagner asserts, is plainly the property of the university and the researchers. Because Moore had nothing to do with the research that constitutes the "intangible" idea that led to the patent, he cannot be considered in any way the inventor and, therefore, has no claim.

Moore's attorneys deny that the patent is the heart of their client's claim, insisting instead that the legal issues are "conversion," which in civil law is the equivalent of theft in a criminal case, and informed consent. To these points, Wagner put forth rebuttals on behalf of the university. The fact that Moore signed a consent form relinquishing his spleen ought to eliminate any issue about misappropriation, Wagner stated in court papers, adding that if there were any doubt the three-year statute of limitation has expired in any case. "Moreover," Wagner stated, Moore "seemingly asserts no objection to [the researchers'] "scientific research and academic endeavors' involving his spleen tissue.' " In fact, Moore consented "under the belief that he could thereby potentially provide a benefit to humanity through such research." Said Wagner, " . . . that is precisely what has occurred. . . . "

As to informed consent, Wagner argued that Moore's contention is "misplaced." Informed consent doctrine, he told the court, exists to guarantee that a patient will know the risks and choices open to him regarding medical procedures, including experimental treatment. The history and policy behind informed consent "do not justify an extension of the rule" to a legal requirement that patients be told about potential commercial uses of donated tissues. Informed consent exists to "promote two values—one is patient well-being and the other is patient self-determination," not financial gain, he said.

One of the more complete sources of information on informed consent is the set of reports compiled by the former President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and its predecessor federal ethics bodies. Those groups dealt extensively with informed

consent as a basis for protecting patients but said nothing about the danger that the doctrine might be used as a basis for advancing unspecified monetary ambitions. The commission did deal with compensation for research subjects who suffer injury, but even there it concluded that an obligation to offer compensation is greatly mitigated by the fact that the patient knowingly consented to something that he knew presented some risk.

The 29 October court hearing that marked round one in this dispute was dealt with by the judge on purely procedural grounds but points nonetheless to the direction the case may take. The judge denied the university's contention that the case be considered almost exclusively a patent dispute that should be adjudicated in federal court. Instead, he ruled that Moore's allegations of misappropriation and lack of informed consent should be dealt with on their merits in California state court.

It is because the state court calendars are so full that a trial is estimated to be 3-to-5 years away. However, Jonathan T. Zackey, another of Moore's attorneys, told *Science* that he thinks a lot will happen in this case before then. It is clear that Moore's lawyers plan to vigorously pursue their point that Moore was not given information he deserved in order to make an informed consent. It is also apparent that they will try to demonstrate during the process of legal "discovery" that Moore's physician, David Golde, and other researchers withheld information deliberately and, perhaps, conducted experiments with some commercial goal in mind.

Although the patent for the Mo cell line clearly states that the cells were derived from Moore's spleen, his attorneys hope to show that blood drawn from their client on several occasions in the years he was under treatment after the splenectomy contributed significantly to the research that lead to the patented cell line. From 1976 through 1983, Moore flew to UCLA for checkups during which, both sides agree, large quantities of blood were drawn. According to Zackey, on at least one occasion Moore signed a consent form giving the university rights to all cell lines but on at least one other he refused to do so. "We plan to pursue this," he said, "to find out just what was going on."

According to university officials, all that was going on was that a research patient who had been cured was undergoing careful follow-up, most of it paid for by UCLA or grants from the National Cancer Institute.

Although the Moore case is in the hands of the court, it raises a thorny issue whose consideration rests not with the court but with academic officials and scholars. It is simply this: In this new era of the commercialization of biological science, in which people have grand (and very exaggerated) visions of making money, should persons who donate tissues to research be given some contractual right to share in any profits that may one day ensue? To date, there appears to have been little, if any, serious discussion of the issue—only indications that people are beginning to think about it.

As a practical matter, if universities were to rewrite informed consent papers so that, as a matter of policy, patients or research volunteers were granted some right to a share of profits, an enormous record-keeping apparatus would have to be established, along with guidelines about percentages, and whether one's right extended for a limited time or in perpetuity. The question of heirs' rights would also have to be established. According to the chairman of one major pathology department, the potential complexity is horrifying to contemplate: first, because it is common for tissues to be distributed not only within the university but also to researchers at other institutions who have a special need for certain types of tissues or cells and, second, because it could be years between the time someone begins working with a cell and the time a product results. And, of course, in most cases, nothing of commercial value results at all.

An additional objection is more philosophical in nature and speaks to the change in attitude and physician-patient relations that could follow from a decision to encourage patients to think that as a consequence of their illness, they may hit the jackpot. On the other hand, some investigators reason that if the university and some researchers may reap substantial rewards in a handful of cases, there is no reason the patient should not share in it.

The subject now has clearly been raised. The best bet is that if changes are to be wrought, they will have to come from university or other policy-makers rather than the courts. One way or the other, it might be well for institutions to think about whether to rewrite informed consent documents to clarify the issue. At the University of California, the heads of the system's many institutional review or ethics boards meet jointly with university officials once a year. Said one, "If this isn't on the agenda for the next meeting, I'll put it there."

—BARBARA J. CULLITON

Fear of Nuclear Power: A Phobia?

The Washington *Post* recently triggered a flood of publicity over a research project by a Washington psychiatrist, designed to help the Department of Energy counter the public's "irrational fear" about nuclear power.

Robert L. DuPont, a former director of the National Institute on Drug Abuse, last year got $85,000 from the DOE for a study that has been ridiculed as an attempt to demonstrate that opponents of nuclear power are mentally ill.

DuPont portrays his project not as a study of opposition, but of fear, some of which is based on denial of reality and thus unhealthy. "Nobody's ever studied fear of nuclear power," he contends. It's "an important research question." For $85,000, "this has got to be one of the best buys the government ever made."

DuPont's project has entailed picking 170 adults and teenagers from the Washington area and giving them questionnaires probing their knowledge about and attitudes toward nuclear power (example: "can it explode like an atom bomb?"). Two-thirds of the group then read an "antifear" booklet on the subject prepared by DuPont. The rest read an unrelated booklet. The whole group was then given the questionnaire again.

Results have not yet been analyzed. But the purpose of the exercise is to find out whether positive information has an effect on reducing the fear. DuPont also wants to see if there is a pattern in the types of people who are afraid, and the types of fear they have—such as fear of a normally operating plant, of an explosion, of sabotage, or of cancer.

DuPont assumes two of the main bases for fear are the feeling of lack of personal control (unlike more hazardous but less feared phenomena such as drug-taking and car-driving) and lack of information. Better information could address these problems. But, he says, among those whose fear is irrational or phobia-like, the information will have no effect. This appears to contradict a DOE statement describing the hypothesis of the study as being "once people understand the principles governing the development