Miami Heat: Patent Law, Informed Consent, and Benefit-Sharing

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Abstract

This article considers whether the granting of patents in respect of biomedical genetic research should be conditional upon the informed consent of research participants. It focuses upon several case studies. In Moore v the Regents of the University Of California, a patient sued his physician for breach of fiduciary duty and lack of informed consent, because the doctor had obtained a patent on the patient’s cell line, without the patient’s authorisation. In Greenberg v Miami Children’s Hospital, the research participants, the Greenbergs, the National Tay Sachs and Allied Diseases Association, and Dor Yeshorim brought a legal action against the geneticist Reubon Matalon and the Miami Children’s Hospital over a patent obtained on a gene related to the Canavan disease and accompany genetic diagnostic test. PXE International entered into a joint venture with Charles Boyd and the University of Hawaii, and obtained a patent together for ‘meth-ods for diagnosing Pseudoxanthoma elasticum’. In light of such case studies, it is contended that there is a need to reform patent law, so as to recognise the bioethical principles of informed consent and benefit-sharing. The 2005 UNESCO Declaration on Bioethics and Human Rights provides a model for future case law and policy-making.

Introduction

Over the last decade, there has been a debate about whether patents in biomedical research should be granted in circumstances in which research participants have not provided informed consent or received any benefits.

In April 2000, the Human Genome Organisation Ethics Committee released the HUGO Statement on Benefit-sharing. The Committee recommended:

1) that all humanity share in, and have access to, the benefits of genetic research.
2) that benefits not be limited to those individuals who participated in such research.
3) that there be prior discussion with groups or communities on the issue of benefit-sharing
4) that even in the absence of profits, immediate health benefits as determined by community needs could be provided.
5) that at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation.

6) that profit-making entities dedicate a percentage (e.g. 1% - 3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.

The statement emphasized the need for prior informed consent: ‘Prior consultation with individuals and communities and their involvement in the research design is a preliminary basis for the future distribution of benefit and may be considered a benefit in itself.’ The declaration emphasized that the human genome should be viewed as part of the common heritage of humanity; it observed that there was a need for compensatory, procedural and distributional justice in the distribution of benefits within a community. The HUGO Statement on Benefit-Sharing stressed that genetic research should foster health for all human beings.

In an editorial in the leading journal Science, the chair of the Committee, Professor Bartha Knoppers (2000) from the University of Montreal, explained the intent behind the HUGO Statement on Benefit-Sharing. She argued that there were three justifications for the development of a statement on benefit-sharing in genetic research. First, Knoppers contended that human genome was common heritage: ‘In the interests of human solidarity, we owe each other a share in common goods, such as health’ (2000: 49) Second, Knoppers explained that the HUGO Statement on Benefit-Sharing had been inspired in part by international treaties dealing with the area of biodiversity and genetic resources in food and agriculture – such as the 1993 Rio Convention on Biological Diversity and the 2001 FAO International Treaty on Plant Genetic Resources for Food and Agriculture. She believed that the principles of informed consent and benefit-sharing should apply equally to the clinic, as well as the fields and the sea. Third, Knoppers argued that there was a need to redress inequalities of power and wealth between biotechnology companies, and research participants: ‘Considerations of justice require action to meet

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basic health care needs’ (2000: 49). She recognised that biotechnology companies could be hostile to the recommendation that profit-making entities dedicate a small percentage of their annual net profit to healthcare infrastructure and humanitarian efforts: ‘In setting this figure, we intend to provide a minimal moral guideline to encourage companies to become good global citizens’ (2000: 49).

This article considers whether the granting of patents in respect of biomedical genetic research should be made conditional upon the informed consent of research participants. Part 1 reviews the famous case of Moore v the Regents of the University of California, in which a patient objected to his physician obtaining a patent on his cell line and commercialising it, without his authorisation. The courts considered such claims in terms of informed consent, fiduciary duties, and the conversion of property. Part 2 considers the case of Greenberg v Miami Children’s Hospital, which concerned research participants suing a hospital for filing a patent for a genetic diagnostic test for Canavan disease. Part 3 considers the strategies of patient advocacy groups. Most notably, PXE International entered into an agreement with Charles Boyd and the University of Hawaii, and secured rights to a patent for ‘methods for diagnosing Pseudoxanthoma elasticum’. Part 4 maintains that there is a need for legislative reform to incorporate principles of bioethics into the framework of patent law. In particular, there is a need to recognise the doctrines of informed consent and benefit-sharing, especially in light of the 2005 UNESCO Declaration on Bioethics and Human Rights.

Seattle Blues: Moore v the Regents of the University of California

The case of Moore v the Regents of the University of California is a touchstone in discussions of patent law, informed consent, and benefit sharing.

A Seattle businessman, John Moore, was diagnosed as having hairy cell leukaemia and sought help from the physician, Dr David Golde, at the UCLA Medical Centre. John’s cancerous spleen was removed and Dr Golde and his laboratory cultured cells from the tumour. The treating physician realised that the combination of substances in Moore’s blood held great scientific and commercial prospects. The physician proceeded to aggressively withdraw samples of ‘blood, blood serum, skin, bone marrow aspirate, and sperm,’ as well as part of the Moore’s spleen, ultimately establishing an independent cell line. In August 1979, Golde established a cell line from Moore’s Tlymphocytes. On January 30, 1981, the Regents of the University of California applied for a patent on the cell line, listing Golde and a University of California employee, Quan, as inventors. US Patent No. 4,438,032 was issued on March 20, 1984, naming Golde and Quan as the inventors of the cell line and the Regents of the University of California as the assignee of the patent.

Moore felt that his integrity was violated, his body exploited, and his tissue turned into a product. He said:

“What the doctors had done, was to claim that my humanity, my genetic essence, was their invention and their property. They view me as a mine from which to extract biological material. I was harvested (Andrews, 1999: 191).”

The Seattle businessman brought a legal action against the Regents of the University of California. At first instance, the claims of Moore were rejected. The judge held that there was no recognized cause of action for the claim being made by the plaintiff, and the court did not intend to create a new cause of action.

In the Court of Appeal, Rothman AJ in his lead judgment observed that the patient had adequately stated a cause for conversion:

“Biological materials no longer pass freely to all scientists. As here, the rush to patent for exclusive use is rampant. The links being established between academics and industry to profitize biological specimens are a subject of great concern. If this science has become science for profit, then we fail to see any justification for excluding the patient from participation in those profits (1988: 509).”

The judge concluded: ‘A patient must have the ultimate power to control what becomes of his or her tissues’ (1988: 508). His Honour observed: ‘To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress’ (1988: 508).

George AJ dissented and refused to find the patient had a cause of action for conversion in respect of his blood samples, tissue, and spleen, because it could not be conceived of as property: ‘I find the foregoing assertions by the majority unpersuasive, as I do its reliance on case authority dealing with the harvesting of a beet crop, the right of a deceased motion picture actor during his lifetime to exploit his own name and likeness as Count Dracula, and the right of surviving family members to control the burial of a dead body’ (1988: 534).

The Supreme Court of California

The Supreme Court of California granted a review of this decision. For the majority, Panelli J held that Moore did not have a property right in his tissues, but only had a right to be informed about both the intent to develop a cell line and the potential com-
mmercial interests of the clinician researchers with whom he interacted. The judge held that the physician, Colde, stood in a fiduciary relationship with Moore and had a duty to obtain Moore’s informed consent to medical procedures.

For the majority, Panelli J held that the patient did not have cause of action for conversion: ‘Since 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’ (1990: 136-137). Panelli J emphasized that the subject matter of the Regents of the University of California’s patent - the patented cell line and the products derived from it - could not be Moore’s property 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 (1990: 141-142).”

Panelli J denies that the definition of ‘joint inventor’ should be expanded to include the human source of biological materials used in research: ‘Because exclusive power to effect change in the law of patents lies with Congress and the federal courts the dissent’s criticism of the law’s present state has no legitimate bearing on our disposition of this case’ (1990: 142).

In dissent, Mosk J denied the assertion of the majority that Moore had no cause of action for conversion under existing law is that ‘the subject matter of the Regents’ patent - [t]he patented cell line and the products derived from it - cannot be Moore’s property’ (1990: 137). His Honour challenged the majority’s explanation that the cell line is factually and legally distinct from the cells taken from Moore’s body:

“To be sure, the patent granted defendants the exclusive right to make, use, or sell the invention for a period of 17 years. But Moore does not assert any such right for himself. Rather, he seeks to show that he is entitled, in fairness and equity, to some share in the profits that defendants have made and will make from their commercial exploitation of the Mo cell line. I do not question that the cell line is primarily the product of defendants’ inventive effort. Yet likewise no one can question Moore’s crucial contribution to the invention - an invention named, ironically, after him: but for the cells of Moore’s body taken by defendants, there would have been no Mo cell line (1990: 168).”

The judge disagreed with the majority’s view that the patent cut off all Moore’s rights to share in the proceeds of the exploitation of the cell line derived from his own body tissue: ‘The majority cite no authority for this unfair result, and I cannot believe it is compelled by the general law of patents: a patent is not a license to defraud’ (1990: 168).

Mosk J wondered whether it would be appropriate to classify a research participant such as Moore as analogous to a ‘joint inventor’ for the purposes of patent law:

“I am aware that ‘patients and research subjects who contribute cells to research ill not be considered inventors.’ Nor is such a person strictly speaking a ‘joint inventor’ within the meaning of the term in federal law. But he does fall within the spirit of that law: ‘The joint invention provision guarantees that all who contribute in a substantial way to a product’s development benefit from the reward that the product brings.’ Thus, the protection of joint inventors encourages scientists to cooperate with each other and ensures that each contributor is rewarded fairly (1990: 168-169).”

The judge cites with approval the view of Mary Taylor Danforth that ‘a patient’s claim to share in the proceeds flowing from a patent would be analogous to that of an inventor whose collaboration was essential to the success of a resulting product’ (1988: 197). The judge concludes: ‘Under this reasoning, which I find persuasive, the law of patents would not be a bar to Moore’s assertion of an ownership interest in his cells and their products sufficient to warrant his sharing in the proceeds of their commercial exploitation’ (1990: 169). This dissenting judgment anticipates modern jurisprudence about research participants, informed consent, and benefit-sharing.

The Supreme Court of the United States declined to grant a writ of certiorari to appeal the matter.

Reception of the Decision

The decision of the Californian Supreme Court in Moore v Regents of the University of California certainly has captured the public imagination (Frow, 1997). However, the judgment has proved to be less influential as a precedent. Other state jurisdictions in Minnesota, Washington, Illinois, and Florida have been reluctant to embrace the verdict of the Californian Supreme Court in Moore v the University of California.

In D.A.B. v Brown, a Minnesota court considered a class action by patients against a physician who had prescribed synthetic growth hormone and received kickbacks from the manufacturer and distributor of the drug. Short J in the Court of Appeals was reluc-
tant to recognize a new tort based on breach of fiduciary duty to cover the wrong perpetrated by a physician who receives kickbacks for prescribing a manufacturer’s and distributor’s products. His Honour declined on this point to follow Moore v the University of California.

In Whiteside v Lukson, a Washington Court of Appeals declined to follow the judgment in Moore v the University of California in a medical malpractice action against a surgeon for negligence and lack of informed consent. Brown J noted: ‘Washington courts have not yet adopted the more expansive construction of the physician’s duty to disclose’ (1997: 112). His Honour concluded: ‘Following this traditional approach, we conclude that a surgeon’s lack of experience in performing a particular surgical procedure is not a material fact for purposes of finding liability predicated on failure to secure an informed consent’ (1997: 112).

In Neade v Portes, an Illinois court distinguished the judgment in Moore v the University of California. The judge held that the plaintiff’s reliance on Moore was misplaced. His Honour held that ‘a physician’s failure to disclose [health maintenance Organization] HMO incentive plans is significantly unlike the egregious nature of the alleged behavior at issue in Moore’ (2000: 449). Furthermore, unlike Moore, the plaintiff could learn of the physician’s research plans: ‘In Illinois, a patient can obtain information about the relationship and payment practices between her physician and her HMO by contacting the HMO’ (2000: 449).

In Miles Inc. v Scripps Clinic and Research Foundation, in the Southern Californian District Court, Rhoades J. considered a suit brought by Miles alleging that the Scripps Clinic and Research Foundation improperly converted Miles’ right to commercialize a cell line used to combat haemophilia. The judge applied the decision in Moore v the University of California and held that ‘no cause of action for conversion has been recognized under California law for the alleged conversion of a right to commercialize cell lines’ (1993: 1095). The judge ruled that the foundation, vice president, and consultant did not owe fiduciary duties to the plaintiff.

There has been criticism of the reasoning in the decision of the Californian Supreme Court in Moore v the University of California. Jon Merz notes: ‘This view fails to capture the myriad interests and motives of the different actors involved in the research enterprise, including academic scientists, public and private sponsors, commercial institutions, patient groups, and research subjects themselves’ (2002: 965). Furthermore, the judgment of Moore v the University of California has provided little protection for research participants, because of its weak precedential value.

Miami Heat: Greenberg v Miami Children’s Hospital

The recent United States District Court of Florida case of Greenberg v Miami Children’s Hospital has resulted in much debate as to whether the granting of patent rights in respect of genetic research should be conditional upon the informed consent of patients.

The Canavan disease is a rare neurological birth disease, which primarily affects children from Ashkenazi Jewish families. The Chicago residents Daniel and Debbie Greenberg are the parents of two children who were afflicted with Canavan disease. Their first child, Jonathan, was born in 1981, and their second child, Amy, was born in 1983. Daniel Greenberg observed: ‘It was a tough haul trying to think of your child as a dying child and never being able to do the things that other children can do’ (Kolata, 2000).

The Greenbergs approached Dr Reuben Matalon for assistance in searching for the genes associated with this fatal disease, so that tests could be administered to carriers and allow for prenatal testing for the condition.

At the outset of the collaboration, the Greenbergs and the Chicago Chapter of the National Tay-Sachs and Allied Disease Association, Inc. located other Canavan families and convinced them to provide tissue, financial support, and aid in identifying the location of Canavan families internationally. The Greenbergs and the Association also created a confidential database and compilation - the Canavan registry – with epidemiological, medical and other information about the afflicted families.
In 1988, Reuben Matalon and his team determined that Canavan disease was caused by a deficiency of the enzyme aspartoacylase (ASPA) encoded by the gene ASPA (located at chromosomal locus 17p13). The scientist was able to develop a prenatal screening test. In 1993, Reuben Matalon and his research team was able to locate the gene for the Canavan disease, using blood and tissue samples, and familial pedigree information. After this key advancement, the Greenbergs and other families continued to provide Matalon with more tissue and blood in order to learn more about the disease and its precursor gene.

In 1994, Reuben Matalon and his employer, the Miami Children’s Hospital, applied for a patent on the gene related to the Canavan disease, and a genetic diagnostic test. In 1997, the United States Patent and Trademark Office granted US Patent no 5,679,635 to Matalon and the Hospital for an invention entitled ‘Aspartoacylase gene, protein, and methods of screening for mutations associated with canavan disease’. The Hospital and Matalon received exclusive rights to perform any activity related to the Canavan disease gene, including carrier and prenatal testing, gene therapy and other treatments for Canavan disease and research involving the gene and its mutations.

A year later, the Hospital sent letters to clinical laboratories engaged in Canavan testing, informing them of the patent and the hospital’s plans for commercialising the test. These letters indicated the defendants’ intent ‘to enforce vigorously [their] intellectual property rights relating to carrier and patient DNA tests for Canavan disease mutations’ (Gitter, 2004: 328). The Hospital planned to engage in a two-stage process of commercialisation of the genetic test. Initially, it planned to grant non-exclusive licences to a limited number of academic laboratories to perform a limited number of tests for a fixed $12.50 per test royalty. Long term, it hoped to provide an exclusive licence to a large commercial laboratory to provide testing for the remainder.

The research participants ran a newspaper advertisement in Miami criticising the hospital, and they asked it to dedicate the patent to the public (Gillis, 2000). The Hospital declined to do so. The law offices of Chicago-Kent College of Law filed a law suit against the Miami Children’s Hospital on behalf of three families, the National Tay Sachs and Allied Diseases Association, and Dor Yeshorim. The law offices filed a six-count complaint against the hospital and Matalan, asserting the following causes of action: lack of informed consent; breach of fiduciary duty; unjust enrichment; fraudulent concealment; conversion; and misappropriation of trade secrets. They sought an injunction restraining the defendants from enforcing their patent rights, damages in respect of the patent royalties, and the recovery of financial contributions made to benefit the research. The hospital and the physician moved to dismiss the action.

The plaintiffs Daniel Greenberg, Fern Kuper, and David Green were upset that they were not informed by Reuben Matalon and the Hospital that they intended to seek a patent on the research. Dan Greenberg said: ‘It was a common understanding that we were all doing this to benefit the public good’ (Gillis, 2000). Furthermore, the research participants were not told of the defendants’ intentions to commercialize the fruits of the research and to restrict access to Canavan disease testing. Dan Greenberg said: ‘We had no idea anyone was really proceeding along those lines’ (Gillis, 2000).

Professor Judith Tsipis, the vice-chairwoman of National Tay-Sachs and Allied Disease Association, Inc, observed: ‘This case is the ultimate nightmare of how a gene patent can be used against the very families who made possible the discovery of the gene’ (Ahuja, 2002).

Dor Yeshorim is an international, confidential genetic screening system used mainly by Orthodox Jews, which attempts to prevent the transmission of genetic disorders that have an increased frequency among members of the Ashkenazi Jewish community. Dor Yeshorim seeks to arrange marriages so that children will not be born with a devastating genetic disorder. The founder, Rabbi Joseph Ekstein, is an orthodox Ashkenazi Jew who lost four children to Tay-Sachs disease. He expressed his opposition to the patenting of genetic tests:

“Patenting can threaten the entire genetic prevention system. Yes, a small royalty should be paid to companies or individuals who make the discovery. However, patenting can destroy all the advantages made from a discovery, and prevent developments from benefiting mankind. Companies sometimes get greedy and charge way too much, which can prevent people from taking a test (George, 2004).”

Dor Yeshorim sought to convince Matalon and the Hospital that its testing for Canavan gene mutations should not be viewed as infringement of the ’635 patent. However, the Hospital was adamant that Dor Yeshorim would be considered infringing the patent if it tested genetically for Canavan disease. As a result, Rabbi Ekstein observed: ‘If Canavan testing won’t be available - which is how it looks if they enforce the patent - there’s no question Canavan children will be born’ (Peres, 1999).
The People's Medical Society, a non-profit organization, sought to intervene in the case because of its long-standing interest in ensuring informed consent to research that includes disclosure of economic interests. The Society submitted:

"[The] plaintiffs are vulnerable, grieving individuals who turned to Dr. Reuben Matalon and MCH out of trust and desperation for help in developing a carrier test and prenatal test from which they and similarly situated families could benefit."

The Society feared that ‘doctors and hospitals undertaking genetic research may view their patients and subjects as mere treasure troves’ (2003: 5). The Society concluded: ‘The harvesting of research subjects' blood and other tissue for patent purposes, without disclosure, will force people to be unwitting victims of doctors' and hospitals' commercial arrangements, in ways that ultimately impede research and health care' (2003: 5).

In response, the Miami Children's Hospital observed that it was entitled to a financial return from the discovery because ‘privately financed scientists, supported by Miami Children's Hospital, unlocked those secrets and as a result of this, mankind benefits’ (Gillis, 2000). The Hospital maintained that the public policy was also unavailing to the plaintiffs: ‘The spectre of a few contributors belatedly demanding veto power over how and with whom the results of medical research are shared, based on assumptions they silently made years ago, would bring important medical research to an abrupt halt’ (Miami Children's Hospital, 2002: 1).

Reuben Matalon left Miami for a post at the University of Texas in Galveston. He has emphasized that he obtained no personal gain from the patent:

“My contract said every invention I make would be theirs, and that’s it. I am not in the inventing business. I am a research person. If they make money on me, I don’t care (Kolata, 2000).”

For his part, the scientist felt that he discharged a duty toward hospital administrators in informing them that he had developed a patentable invention.

US District Court for the District of Florida
In the U.S. District Court for the District of Florida in the Miami Division, Monero J described the matter in these regretful terms: ‘This case presents an unfortunate legal dilemma set against the backdrop of a historic breakthrough in the treatment of a previously intractable genetic disorder’ (2003: 1066) The judge dismissed the actions in respect of lack of informed consent; breach of fiduciary duty; fraudulent concealment; conversion; and misappropriation of trade secrets. His Honour held that only the action with respect to unjust enrichment could proceed.

First of all, Monero J considered whether the physician owed a duty to participants in research on Canavan disease to obtain the informed consent for the commercial use of materials. His Honour doubted whether the duty of informed consent in medical research could be extended to the disclosure of a researcher's economic interests. Monero J distinguished the present facts from the case of Moore v the University of California:

“Moore involved a physician breaching his duty when he asked his patient to return for follow-up tests after the removal of the patient’s spleen because he had research and economic interests. The doctors did not inform their patient that they were using his blood and tissue for medical research. The allegations in the Complaint are clearly distinguishable as Defendants here are solely medical researchers and there was no therapeutic relationship as in Moore (2003: 1070).”

At a policy level, Monero J was worried about the practical implications of retroactively imposing a duty of this nature. He contended that the imposition of such a duty was unworkable and would chill medical research as it would mandate that researchers constantly evaluate whether there was a need to make a disclosure. Monero J argued that ‘this extra duty would give rise to a type of dead-hand control that research subjects could hold because they would be able to dictate how medical research progresses’ (2003: 1071) He asserted that ‘these Plaintiffs are more accurately portrayed as donors rather than objects of human experimentation, and thus the voluntary nature of their submissions warrants different treatment’ (2003: 1071).

Such reasoning is unconvincing. It is spurious to suggest Moore was an unwitting donor and the participants in the Canavan case were willing donors. As Donna Gitter observes:

“By classifying the latter plaintiffs as willing donors, the court misses an important point: A research participant can be a voluntary donor for one purpose (that is, noncommercial research), but not for another (that is, commercial research) (2004: 335).”

The fears of Monero J seem unwarranted - especially given that researchers are usually required by institutions to report upon any potential commercialisation. The threat of donors vetoing research is overblown. Again, this threat seems quite spectral. The Greenbergs were not seeking to dictate the course of the research; rather, they were concerned about the nature of its commercialisation.

Second, Monero J denied that the doctor and the Hospital were in breach of a fiduciary duty to donors of human tissues and fluids under Florida law: ‘There is no automatic fiduciary relationship that attaches when a researcher accepts medical
donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given’ (2003: 1072). The judge’s reasons seem to be twofold. First of all, he doubted whether there was a fiduciary relationship between the researcher and the research participants. Second, he was unconvincing that the defendants had accepted the trust placed in them by the participants.

Such a denial of the existence of a fiduciary relationship between the researcher and the research participant is problematic. As Donna Gitter observes:

“The problem with the court’s approach, however, is that it departs from the accepted notion that physicians owe their patients a fiduciary duty. As a practical matter, research participants perceive their researchers as fiduciaries, even in the absence of a therapeutic relationship, and will tend to reposes trust in them. Indeed, without such a relationship of trust and confidence, the scientific collaboration could not proceed. If researchers are not required to honor this trust, the situation is ripe for exploitation of the research participants (2004: 335).”

There is a danger that such a legal precedent would leave research participants vulnerable to exploitation in scientific experiments and research.

Third, Monero J held that the claim of unjust enrichment could proceed. He observed that the ‘defendants’ attempt to seek refuge in the endorsement of the U.S. Patent system, which gives an inventor rights to prosecute patents and negotiate licenses for their intellectual property fails, as obtaining a patent does not preclude the defendants from being unjustly enriched’ (2003: 1072). Monero J held that ‘the facts paint a picture of a continuing research collaboration that involved Plaintiffs also investing time and significant resources in the race to isolate the Canavan gene’ (2003: 1073). He therefore rejected the motion by the Miami Children’s Hospital to dismiss the claim.

There are certainly precedents in which United States courts have ordered the recoupment of patent royalties because of unjust enrichment. For instance, in University of Colorado Foundation v American Cyanamid, a court made an order for disgorgement of patent royalties in an unjust enrichment context. Two doctors had developed an idea to reformulate a prenatal multivitamin and mineral supplement, and had sent a confidential manuscript to American Cyanamid Company’s Chief of Nutritional Science. Cyanamid copied parts of that manuscript to obtain U.S. Patent No. 4,431,634. The United States District Court for the District of Colorado held Cyanamid liable for fraudulent nondisclosure and unjust enrichment. In addition to compensatory damages, the district court awarded exemplary damages of $500,000 to each of the doctors. The Court of Appeals affirmed this judgment.

Fourth, Monero J rejected the argument that the Hospital had fraudulently concealed from the research participants that it would patent the Canavan gene mutation, and economically benefit from licensing the invention. His Honour held that the plaintiffs failed to satisfy the threshold requirements in respect of this offence: ‘Their bare contentment that the intent to patent was fraudulently concealed is not sufficient, because this intent was not accompanied by any time and place details’ (2003: 1073). The judge added: ‘Allegations of fraudulent concealment by silence must be accompanied by allegations of a special relationship that gives rise to a duty to speak’ (2003: 1073). Furthermore, he suggested that the facts were accessible to the plaintiffs: ‘A patent becomes public knowledge when issued and Plaintiffs could have undertaken due diligence to uncover the facts surrounding the patent application’ (2003: 1073) Finally, the judge concluded: ‘The Complaint does not allege any individualized denial of testing nor does it claim any other economic injury’ (2003: 1074).

Fifth, Monero J dismissed the argument that the Hospital and Matalon converted the names on the Canavan register and the genetic information by utilizing them for the hospitals’ ‘exclusive economic benefit’ (2003: 1074). The judge declined to find a property interest for the body tissue and genetic information voluntarily given to defendants. His Honour explored the significance of the precedent of Moore v Regents of the University of California:

“(The) Plaintiffs have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion. (2003: 1074).”

Monero J held that there was no conversion. In his view, the plaintiffs had made donations to research without any contemporaneous expectations of return of the body tissue and genetic samples, and thus conversion does not lie as a cause of action. Monerò J found that the statute imposing penalties when informed consent of persons being genetically analysed was not obtained was inapplicable.

Finally, Monero J struck out the claim for misappropriation of trade secrets. His Honour held: ‘The Canavan Registry was not misappropriated by MCH because there is no allegation that MCH knew or should have known that the Canavan Registry was a confidential trade secret guarded by Plaintiffs, and furthermore, that Matalon had acquired through improper means’ (2003: 1076). The judge observed that the ‘plaintiffs cannot donate information that they prepared for fighting a disease
and then retroactively claim that it was a protected secret' (2003: 1077).

Settlement

The decision of Monero J to dismiss all but one of the claims encouraged the parties to discuss a settlement. Kimarie Stratos, the general counsel of the hospital, observed: 'We are confident that when and if the remaining claim is addressed, it … will be dismissed'. The parties finally reached a settlement in the case in 2003 - before the matter could proceed any further in the courts. The settlement allows license-free use of the Canavan gene in research to cure Canavan disease. In addition, the Canavan Foundation, National Tay-Sachs & Allied Diseases Association, Daniel Greenberg, and David Green have agreed not to further challenge the Hospital's ownership of the Canavan gene patent. In addition, the Hospital will continue to be able to license and collect royalty fees for clinical testing for the Canavan gene mutation.

However, the decision of Monero J is unsatisfactory. Mary Anderlik and Mark Rothstein (2003) criticise the reasoning behind the decision:

"Throughout his opinion, Judge Moreno expressed concern about adopting legal principles that will not 'cripple' the ability of researchers to carry on their work. Although this is an important concern, the participation and support of families of affected individuals and their associations also should be a motivating consideration in developing legal rules applicable to research. If researchers are free to use samples, information, and funding from family members and then develop tests and therapies priced beyond the reach of many affected individuals, the willingness of consumers to support researchers will be greatly diminished."

Upset at what she perceived to be the injustice of the case, the Congresswoman Lynn Rivers introduced the Genomic Research and Diagnostic Accessibility Act 2002 (US) and the Genomic Science and Technology Innovation Act 2002 (US). Such legislation, though, did not win the support of Congress; and Rivers was defeated at the subsequent election.

However, some commentators displayed greater sympathy to the position of the defendants. David Resnik wonders whether Matalon and the Miami Children’s Hospital are deserving of such opprobrium: 'The defendants in the Canavan case do not appear to be as unethical as the defendants in the Moore case' (2003: 204). He stressed that Matalon and the Hospital did not deceive the research participants; and the profit motive was not a major factor in the decision to charge licensing fees for the test. Resnik acknowledged that the Hospital, like the defendants in Moore, failed to establish a plan to share benefits with the Canavan community. He notes, though: 'MHC might reply, however, that it has already compensated the community for its contribution by developing the test' (2004: 205).

Similarly, John Robertson (2003) wondered whether the Canavan case was indeed 'the poster child... of bad behaviour in this field.' He noted that the claims made about benefit sharing were based purely in equity and not in property or other rights: 'I'm still unclear about why it would have been the right thing to do once we get beyond the question of etiquette.'

The decision in Greenberg v Miami Children’s Hospital has been cited with approval in more recent decisions in the field of bioethics. In Suthers v Amgen, the United States District Court in New York considered an unusual action. In this matter, patients who participated in a research trial for experimental treatment for Parkinson's Disease brought a legal suit against a drug manufacturer, seeking to compel the manufacturer to resume treatment following the termination of a trial. Castel J found that the patients failed to demonstrate that they would succeed in an action for breach of contract, promissory estoppel or breach of fiduciary duties. His Honour refused to grant a preliminary injunction, holding that the plaintiffs had acknowledged in signed consent documents that Amgen had a right to terminate the research trials. Castel J held that the sponsor of medical research trial did not owe a fiduciary duty to participants in the trial. In support of his ruling, the judge cited the decision in Greenberg v Miami Children’s Hospital, in which the judge declined to find a fiduciary duty to disclose researchers' economic interests to, among others, research participants in the absence of an allegation of ‘acceptance of trust’ by defendants.

Hawaiian Dreams: PXE International

A number of patient groups have been trying to develop legal agreements to clarify the roles of researchers and tissue donors. Jon Merz and his collaborators comment upon the emerging collaborative research enterprise:

"Patient groups are becoming more active in the promotion and facilitation of preclinical and clinical research. Although patient groups have long played a key role through participation in research (e.g., by helping coordinate subject identification and recruitment and fund-raising to support research), a new type of relationship is emerging as groups become key players in the promotion of studies of the causal role of genetics in diseases. This developing role has occurred concurrently with two other significant changes in biomedical research: the creation and rapid evolution of technology transfer and the explosion in biotechnology science and investment. The concurrent
rise in research subjects’ roles and commercial interests raises new ethical and policy challenges (2002: 965).”

The researchers cite the example of PXE International as an exemplar of an activist patient group. This foundation has negotiated with researchers to whom they provided support and access to biomaterials for research, and retained authorship in papers and ownership rights in any patents through the use of material transfer agreements.

PXE International

In late 1994, Sharon and Patrick Terry learnt that their two young children, Elizabeth and Ian, suffered from the genetic condition, Pseudoxanthoma elasticum (PXE). PXE is a genetic disorder which is characterized by the calcification and fragmentation of elastic fibres in the skin, eyes, the cardiovascular system and gastrointestinal system.

When Sharon Terry learned that her two young children had inherited PXE, groups of researchers called to ask for tissue samples from her children to try to find the gene. She inquired as to why they did not get samples from other researchers and was told that scientists would not share the samples.

Sharon and Patrick Terry helped establish PXE International in 1995. This charitable organization seeks to initiate, fund and conduct research; provide support for affected individuals and their families; and to provide resources for clinicians. Sharon Terry (2003) recalls the impetus for founding the organization:

“We began by surveying the literature, interviewing the researchers that had written the articles in journal, peer review journal articles on PXE and investigated the issues with the consumer community through the genetic alliance. The challenges that we saw were a limited pool of willing participants, inadequate funding, competitive fragmented and unfocused research environment and conflicting medical advice.”

Sharon Terry commented that this prudential model was not prompted by the litigation in Greenberg v the Miami Children's Hospital: ‘We actually crafted all these agreements before the Canavan issue surfaced and we didn’t really know anything about their work’ (2003).

PXE International established the PXE International Blood and Tissue Bank, and raised money to support studies through use of these resources. Sharon Terry (2003) explained: ‘Our solution was to use a commodity to create a community to leverage funding and to coordinate the research that we needed done.’ She observed that the ownership of the registry and the repository helped create an environment for ethical research: ‘The bank itself recruits individuals in an atmosphere of trust and support with ongoing educational information for them, engages in culturally sensitive comprehensive informed decision making process, encodes identifiers and a centralized data base maintained by us.’ PXE International negotiated with researchers to whom they provided support and access to biomaterials for research, and through use of Material Transfer Agreements, retained authorship in any papers and ownership rights in any patents, to ensure broad and affordable availability of the test and to retain influence over downstream developments. Five research teams studied the organization’s collection of DNA. All signed a contract giving PXE International co-ownership of any patent that ensues from study of their tissues. Sharon Terry noted that no one had objected to such conditions: ‘People are concerned that they not look bad in this climate, with all the Canavan publicity’ (Fleischer, 2001).

Collaboration with the University of Hawaii

In February 2000, pathologist Charles Boyd of the University of Hawaii isolated the crucial gene relating to PXE (Le Saux, 2000). He had worked in collaboration with PXE International for six years. Boyd was willing to list Sharon Terry as a joint inventor when a patent was filed. He believed that she was the catalyst for the successful hunt for the gene - through her assembly of the patients’ medical information, maintenance of confidentiality, and the recruitment of scientists.

In 2000, there was a discussion between the University of Hawaii and PXE International over the patent. Todd Dickerson, the former head of the U.S. Patent and Trademark Office, observed: ‘It would be very unusual for the university to agree, we’ll give you a patent if you give us the starting material’ (Fleischer, 2001).

The University of Hawaii was reluctant to give up control over licensing, even though the PXE group’s focus is on broad access. Sharon Terry recalls:

“They wanted to recoup the cost of filing the patent and to get some licensing fees. We told them that we would take care of all those costs, using the $150,000 PXE International budget and the pro bono services of Testa Hurwitz (Fleischer, 2001).”

PXE International offered to share the royalties equally if Hawaii would allow them to decide on licensing deals. A good licensing deal for PXE International would yield lower medication costs for PXE patients. A good licensing deal for Hawaii would add to its coffers. PXE’s designation under food and drug law as a so-called orphan disease, with little prospect of blockbuster revenues, weak-
ened the university’s incentive to hold a tight grip on the patient group’s request to make the licensing decisions, accepting 50 percent of the royalties from any diagnostic test or marketable product.

In 2004, the US Patent and Trade Mark Office granted US Patent No. 6,780,587 for ‘methods for diagnosing Pseudoxanthoma elasticum’. The abstract of the patent application observed:

“Methods and compositions are provided for diagnosing and treating Pseudoxanthoma elasticum (PXE) patients and PXE carriers. Methods and compositions are based on the discovery that PXE mutations are located in the MRP6 (ABCC6) gene.”

The inventors named included Charles Boyd, Katalan Csizsar, Oliver LeSaux, Zsolt, from the Laboratory of Matrix Pathobiology at the University of Hawaii, and Sharon Terry, the executive director of PXE International. The four co-inventors from Hawaii assigned their rights to the University of Hawaii and it in turn has given its rights to PXE International. Co-inventor Terry has also assigned her rights to the foundation. PXE International out-licensed the diagnostic rights on a co-exclusive basis to a public biotechnology company, Transgenomic and is moving toward another first, bringing an FDA-approved diagnostic kit for a rare disease to market (PXE International, 2002).

There was much excitement at the novelty of a member of a patient advocacy group being one of the named co-inventors of the patent. A press release trumpeted: ‘U.S. Patent Office Issues First Gene Patent to Patient Advocacy Group; Co-Inventors Include Non-scientist ‘Mom’’ (PXE International, 2004). Sharon Terry (2003) reflected that her status as a co-inventor was the product of her research contribution, rather than any negotiation:

“Contrary to published accounts and I realized in preparing for this paper that there’s quite a number of them, including some places on the web as well as in printed peer review journals, we did not negotiate for inventorship that’s impossible. US Patent Law does not allow for negotiating. Inventorship has a different test and we met that test by participating materially in the research. Contributions of samples we don’t believe, does not entitle anybody to inventorship. That again is not permissible by law.”

It was emphasized that the Terrys were engaged in genetic research on a very basic level – building a blood and tissue repository, a patient registry, and working with a consortium of 19 laboratories. Dr. Boyd actively encouraged Sharon’s participation in the gene hunt and she was a member of his five-person team that ultimately discovered the gene. There have been doubts as to whether a patient or a patient advocate could claim joint inventorship to a patentable invention in most circumstances (Ho, 2004).

Francis Collins, director of the National Human Genome Research Institute said, ‘I think it’s a wonderful example of how parents and lay organizations can play a catalytic role in research on rare diseases’ (PXE, 2004). He added: ‘By establishing this unique collaboration, Sharon and Pat Terry are once again showing how creative and dedicated consumer groups can empower research on rare diseases and speed the process of identifying causes and cures of genetic disorders.’

Dr Boyd commented that he had no desire to license the product himself:

“If I really want to make money on PXE, I would have to get out of the lab. That is a fantasy. [Principal Investigators] don’t have the communications skills. It’s an entirely different set of skills that allows one to reach out with passion and sensitivity (Fleischer, 2000).”

Boyd agreed with Terry’s morally driven, but practical, view that the laws of this market left patients no choice but to seek control of the intellectual property: ‘This was a way to ensure that that the test isn’t going to cost an arm and a leg’ (Fleischer, 2001).

Sharon Terry observed: ‘We are stewards of this gene, we are responsible for using it to develop diagnostics and therapeutics that are accessible and affordable’ (PXE, 2004). Sharon Terry (2003) discusses the benefits arising from holding ownership of the patent:

“We are co-holders of the patent… We take the lead on any negotiations with regard to licenses. We see ourselves as stewards for the people for whom we need to move this process along and we see that in a pretty broad way not just the individuals with the disease that, that our children have and the twenty-five hundred people registered with us have but for all the people who might be impacted by disease research in the future... We need access to the table so we can influence the direction, focus the research, leverage pathway and do all sorts of licensing arrangements.”

Terry promises that the group will not seek to tenaciously generate profits, like a pharmaceutical company: ‘We’re more interested in the search for treatments and patient support and research’ (Fleischer, 2001). She noted that their group will resist patent profiteering: ‘We always say, we don’t just represent people with PXE, we represent anybody who has anything’ (Fleischer, 2001).

PXE International has entered into a range of licensing arrangements - spanning exclusive licences, co-exclusive licences and non-exclusive licences - with nineteen laboratories and eight companies. Sharon Terry (2003) comments that the guiding principle in such arrangements is the need
to facilitate access to genetic tests: ‘Licensing ensures access, keeps the diagnostics affordable and facilitates treatment development.’ She acknowledged the expenses involved in such research and development: ‘In fact working on the diagnostic that we’re producing for PXE I know that it’s already cost us hundreds of thousands of dollars and only hundreds of people will take this test.’ Terry noted: ‘We’re going to subsidize the test so that patients don’t have to spend that kind of money.’ She observed: ‘The benefits for consumers are integrated or integral, ethical, legal and social protections.’

The Genetic Alliance

Sharon Terry has since become the president and chief executive officer of the peak body, Genetic Alliance. This coalition is comprised of more than 600 advocacy, research and healthcare organizations that represent individuals with genetic conditions and their interests. Sharon Terry (2003) has sought to encourage members of the Genetic Alliance to emulate the success of PXE International, and develop a new paradigm for dynamic partnerships with research groups and companies.

The Alpha 1-Foundation has developed policies to protect the interests of the Alpha-1 community in new discoveries resulting from collaborative and sponsored research, while directly promoting research for treatments and a cure. Cure Autism Now, the Juvenile Diabetes Research Foundation International, and other groups have pooled members’ specimens. A number of patient advocacy groups have sought to allow access to biorepositories subject to conditions about intellectual property. After enumerating the strengths of the model presented by PXE International, Donna Gitter (2004: 315) argues that there are drawbacks to the contractual property rights approach adopted by patient advocacy groups, such as PXE International. First, she notes that not all patients will be affiliated with a patient advocacy group (2004: 322). Some individuals may prefer not to participate in such groups. Others will not have easy access to such a group. Second, she questions whether patient advocacy groups always advance scientific research (2004: 323). She worries that the presence of more parties at the bargaining table hinders the ability of pharmaceutical firms to negotiate the licensing agreements necessary to pursue planned drug development initiatives. Third, Gitter raises concerns that the group might exercise control over the discoveries in such a way as to maximize the group’s profits, while simultaneously limiting access to people afflicted by other diseases (2004: 324). Finally, she notes that the group rights approach is insufficient to protect the rights of research participants who did not negotiate with their researchers, such as those involved in the Greenberg litigation. As a result, Gitter concludes: ‘It is essential that the United States Congress recognize the right of each individual research participant to claim a property interest in his tissue’ (2004: 322).

Lori Andrews comments that there are limitations to the approach of claiming a property interest in a patent - such as the claim by Sharon Terry to be a joint inventor. She observes: ‘Allowing those from whom genes are taken to have a property interest in the patent is not a comprehensive solution to the problems created by gene patents’ (2002: 105). Andrews noted: ‘It will be an extremely rare case where researchers will actually need to negotiate with the people who have a gene mutation associated with a particular disease or their family members’ (2002: 105). She comments that, in most cases, researchers will not have to collect DNA from people in the first place, because samples will already exist in laboratories, research centres, and DNA banks.

The Paris Declaration: The 2005 UNESCO Universal Declaration on Bioethics and Human Rights

In light of such disputes, there has been a push for stronger protection of informed consent and benefit-sharing in biomedical research. There has been an intense debate amongst a range of stakeholders, including research participants, donors, scientists, researchers, biotechnology companies, and pharmaceutical drug manufacturers. Dianne Nicol weighs the competing interests of the various stakeholders:

“There can be little doubt that sound research and business practice requires that patent applications are lodged for all bona fide patentable inventions so that commercial funds will be invested in the long and arduous road from research to marketing of new healthcare products. At the same time, the high level of participation in research needs to be encouraged and basic non-commercial research needs to be supported. The difficulty will be in achieving all of these ends in an appropriate manner that balances the interests of the researcher, the investor, the donor and society as a whole (2004: 159).”

The policy debate over informed consent and benefit-sharing in biomedical research has taken place at a number of levels. At a local level, there has been much discussion about incorporating the principles of informed consent and benefit-sharing into ethical guidelines and research funding codes.
of practice. At a national level, a number of advocacy groups have lobbied for the recognition of the principles of bioethics within the confines of patent law. At an international law, there have been a number of important declarations, which have provided acknowledgment of informed consent and benefit-sharing - most notably the 2005 UNESCO Universal Declaration on Bioethics and Human Rights.

Ethical Review of Medical Research

Patient advocacy groups have sought to protect the principles of informed consent and benefit sharing through the system of ethical review of medical research, and contractual arrangements between researchers and research participants. Such groups have also relied upon legal actions for breach of fiduciary duties and unjust enrichment against researchers and their commercial partners.

Some commentators prefer such local arrangements to legislative changes. David Resnik reflected: ‘Even though the human genome is not literally our common heritage, it is still a very important common resource, and we have moral duties of stewardship and justice vis-à-vis the human genome’ (2003: 208). He observed: ‘Local benefit-sharing obligations require researchers to provide financial compensation to participants only in rare instances where researchers and companies stand to profit a great deal from the tissues collected from a single person or small group of people’ (2003: 208).

Some commentators have recommend law reform to better protect research participants in biomedical research. In a recent article, Donna Gitter proposed that the US Congress should enact legislation permitting and regulating the sale of human tissue used for research purposes: ‘Uniform national legislation is essential because scientists typically obtain the tissue upon which they experiment from research participants, tissue banks, and repositories throughout the United States, and from other nations as well’ (2004: 268). Such a scheme would recognize that individuals possess property rights in their tissue and therefore have the right to exchange it for valuable consideration, or to waive such rights if they prefer to make a gratuitous donation. Under such a regime, individual research participants could bring an action for conversion of their tissue in the event that they were not informed that researchers were using their tissue for commercial purposes.

A few law reformers have called for more radical changes. Lori Andrews (2005) argued that: ‘More radical policies might be needed - such as allowing health care providers and researchers to use the genetic sequences discovered in the people’s tissue in biobanks without having to pay a royalty in order to protect access to health care and to encourage research.’ She maintained that a true framework for informed consent and benefit sharing would require a restructuring of the biomedical research system, technology transfer laws, and intellectual property laws.

Patent Law, Informed Consent and Benefit-Sharing

A number of academics and bioethicists have argued that informed consent and benefit-sharing should be addressed by the patent system through introducing additional requirements for the grant of patents.

Jon Merz, Mildred Cho, David Magnus, and Arthur Caplan submit: ‘We believe there has been a market failure with respect to the value added to the research enterprise by patient and subject groups, and ways should be found to recognize and reward their contributions’ (2002: 967). Robert Cook-Deegan agreed that there is a need for law reform: ‘We have a system where the research participants are treated as pure altruists, but everyone else is treated as a pure capitalist’ (Kolata, 2000).

Similarly, Richard Gold and Timothy Caulfield (2002) argue that the patent system can indeed address ethical concerns in biotechnology: ‘The patent system provides a useful mechanism by which to address ethical and social concerns in biotechnology, not because patents are necessarily the cause of concern, but because the system for granting them provides a practical way to regulate compliance with ethical and social values’.

Dianne Nicol suggests that there are a number of limitations inherent in importing notions of medical bioethics into the regime of patent law:

“One obvious problem is that disclosure of evidence of source consent to patenting is likely to have privacy implications if it requires that the source's personal information is disclosed to the public. It may also be difficult to put in place an appropriate mechanism to equitably distribute the benefits of commercialisation. This problem is accentuated by the fact that there is often a long time lag between the research phase and the marketing phase and many products never make it to the market (2004: 163).”

The critic predicts that there will be strong resistance from industry to any such measure: ‘One difficulty with a model of benefit sharing that distributes benefits to the afflicted community is that this community is also the market for the commercial product’ (2004: 164).

Indeed, patent loyalists - such as lawyers, patent attorneys, patent examiners, and biotechnology companies - have argued that the patent system is an inappropriate mechanism to address issues of
benefit sharing and control. Such defenders of the status quo maintain that patent law is primarily an economic tool designed to promote research and development (Sherman, 2003). The patent loyalists contend that the regulatory scheme is ill-adapted to deal with ethical and moral concerns. Some experts have warned that the rhetoric of benefit-sharing would encourage research subjects to demand financial rewards for participating in genetic research. For instance, Rebecca Eisenberg observed: ‘I hate to create incentives that would lead people to get greedy - I am worried that there are just too many mouths at the feeding troughs of pharmaceutical products’ (Kolata, 2000).

Such opposition may explain the lack of significant legislative reform by policy-makers and legislators. Inspired in part by the litigation over the Canavan disease, US Congresswoman Lynn Rivers sought to introduce reforms to deal with gene patents. However, this proposal was not supported by the US Congress; and Rivers was defeated at the congressional elections. In its report on gene patenting and human health, the Australian Law Reform Commission recognised that ‘individuals and organisations who participate in genetic research may consider they have an ethical right to control or own the results of that research, or share in the benefits of that research in some way’ (ALRC, 2004: 74). Nonetheless, it weakly concluded that ‘issues of control and benefit sharing are better addressed outside the patent system’ (ALRC, 2004: 74).

In 2003, the Canadian Biotechnology Advisory Committee recommended that the federal government develop policies and practices that encourage the sharing of the benefits of research involving genetic material. Despite such urging, there has been no progress within the Canadian Parliament on this issue. The 1998 European Union Biotechnology Directive provides that ‘if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.’ There has been some debate as to whether this requirement should be dealt with internally in patent law or cured by supplementary laws in other regulatory frameworks (van Overwalle, 2001).

UNESCO Universal Declaration on Bioethics and Human Rights.

There have been a number of international declarations and statements about the importance of informed consent and benefit-sharing in the context of biomedical research. Such international instruments have given a renewed impetus to the push for legislative reform in respect of informed consent and benefit-sharing.

The 1997 UNESCO Universal Declaration on the Human Genome and Human Rights provided: ‘Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard to the dignity and human rights of each individual.’

The 2003 UNESCO International Declaration on Human Genetic Data addressed the issue of benefit-sharing in the context of human genetic data. Article 19 emphasized that ‘benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community.’ These benefits would include ‘access to medical care, provision of new diagnostics, facilities for new treatments or drugs stemming from the research,’ and ‘support for health services.’

The 2005 UNESCO Universal Declaration on Bioethics and Human Rights. The Declaration places particular emphasis upon informed consent and benefit-sharing in the context of biomedical research.

Article 6 (1) provides that ‘Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.’ Moreover, it notes: ‘The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.’ Similarly, Article 6 (2) emphasizes: ‘Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned.’ Article 6 (3) observes: ‘In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought.’

Article 15 (1) provides that ‘benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.’ The Declaration observes that benefits may include special assistance to research participants; access to quality health care; provision of new diagnostic and therapeutic modalities or products stemming from research; support for health services; access to scientific and technological knowledge; and capacity-building facilities for research purposes. However, the Declaration
also warns that ‘benefits should not constitute improper inducements to participate in research.’

Article 22 provides: ‘States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law.’ Moreover, it suggests that such measures should be supported by action in the spheres of education, training and public information.

The bold intent and broad scope of the 2005 UNESCO Universal Declaration on Bioethics and Human Rights has sparked much debate. Hopefully, the Paris Declaration will encourage and spur on national governments to take legislative action to safeguard the rights of research participants, particularly with regards to informed consent and benefit-sharing. As one commentator observed, the Declaration will become influential in both policymaking and case law: ‘Although the UDBHR technically has no legal authority, it is not unusual for such statements to become incorporated in national legislation and court rulings’ (Wolinsky, 2006).

Conclusion

There has been a concerted push by patients, research subjects, and family members to have a greater say in whether or not their genes are patented and what uses are made of the patented genes.

The legal system, though, has provided scant recognition for such concerns. In the first instance, John Moore was successful in bringing claims for lack of informed consent and breach of fiduciary duties against his physician. However, he was unsuccessful in his attempt to claim broader rights in property or patent law. Furthermore, the case of Moore v the Regents of the University of California is of only a limited precedential value. Indeed, many other US states have distinguished the precedent. In the second key case, the Greenbergs and patient advocacy groups brought legal action against the Miami Children’s Hospital over a patent sought in respect of genes related to the Canavan Disease. The district court ruled that only the unjust enrichment action could proceed; the action was subsequently settled. In the third instance, PXE International relied upon Material Transfer Agreements and joint ownership of patents to obtain control over research, and guarantee the principles of informed consent and benefit sharing. However, it may be difficult for other members of the Genetic Alliance to emulate the success of PXE International.

There is a need to fashion a legislative solution to protect the ethical interests of research participants. Contract law provides no remedies in respect of third parties. Members of patient groups will only be recognised as joint inventors of patented inventions in exceptional circumstances. There is a need for wholesale legislative reform to protect the entitlement of research participants to informed consent and benefit sharing in biomedical research. As Lori Andrews comments:

“Whatever policies we develop, we cannot lose sight of the fact that the bio in biotechnology - the genes in the gene patents - come from people. And the scientific enterprise must have the trust of those people in order to get them to give up their tissue for research into diagnostics and cures. The raw material in the biotech industry is not widgets. It is pieces of my body, and your body, and all of our bodies. The policies that are developed should assure that society harnessed the benefits of biobanks for all of us (2005: 28).”

Ethical considerations are and should be relevant in assessing applications for gene patents. It is inappropriate for a Patent Office to grant an exclusive monopoly of commercial rights to a researcher or a company in circumstances in which the parties have engaged in unethical practices. Arguably, the grant of a patent should be made conditional upon patent applicants providing evidence that the genetic material has been obtained with informed consent, and proof of a fair and equitable benefit sharing agreement had been negotiated with the people or community concerned.

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