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When and Why Does What belong to Whom - A Proposed Model for the International Protection of Human Donors of Biological Material

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WHEN AND WHY DOES WHAT BELONG TO WHOM? A PROPOSED MODEL FOR THE INTERNATIONAL PROTECTION OF HUMAN DONORS OF BIOLOGICAL MATERIAL

I. INTRODUCTION

Human genetic information has become one of the most valuable and most exploited resources of the biotechnology era. New scientific discoveries are increasingly devised and built from the raw material of people themselves – their DNA. The question of who owns our genetic material, if genetic material can be owned, becomes paramount. Academics, scientists, legislators and legal scholars have been forced to consider a myriad of questions, including: What are the rights of those who either voluntarily or unknowingly contribute their genetic information to research? What control do people have over the use to which their genetic material is put? How much information must be disclosed to those who provide genetic samples such as tissue, organs, blood, urine or semen? What rights, if any, do those donors have to share in the profits made from their genetic material?

The debate over informed consent and benefit sharing is not new. Studies of indigenous or specialist populations, for example, have provided the raw material that has led to some of the most fundamental discoveries in genetics, and have raised questions concerning how much information research participants should receive and what type of compensation is appropriate. The two concepts are very much interrelated. Academics have argued that informed consent should include providing patients with a full understanding of the procedure to be undertaken; the risks involved (including those not directly related to the procedure, but associated with disclosing genetic information); the possible future uses of any material collected; and the prospective results and consequences of those uses, including potential commercial benefits. These academics feel such disclosure is essential to build trust,

1 For example, in the early 1990s, Myriad genetics was able to win the race to isolate the BRAC 1 gene because of their access to a specialist population, the Mormon population in Utah, who in addition to providing genetic material, had kept detailed genealogical records. The BRAC 1 gene is used to diagnose women who are predisposed to developing breast and ovarian cancer.

especially in the researcher to patient scenario where trust does not flow as easily as it does from patient to physician, and to encourage people to donate their tissues. Further, as the ramifications of our culture’s fixation on genetics continue to expand into unknown areas, the risks to those who donate their genetic information have increased. Such risks must not only be explained to patients, but also bolster the argument that patients should share in the benefits derived from the information contained in their tissues. Information found in tissue samples can be harmful. It can reveal health information which can be emotionally upsetting and can also have consequences for subjects’ family members; may result in a loss of privacy; and can negatively impact important areas of the subjects’ daily lives such as employment possibilities and insurance coverage options due to genetic discrimination.

II. GUIDE TO ANALYSIS

The issues of informed consent and benefit sharing have become even more prominent subsequent to a recent string of cases and developments in the United States. In Part One of this paper, three events that have addressed the question of informed consent and benefit sharing are analyzed, namely the cases Moore v. Regents of the University of California, Greenberg v. Miami Children’s Hospital Research Institute, Inc., and the PXE International situation. The failure of any of these developments to provide a clear answer as to how much information must be given regarding the donation of genetic material or to provide a satisfactory method to ensure the benefits of developments stemming from such donations are fairly and justly allocated is highlighted. Part One concludes by arguing that there is a need to move beyond attempts to solve these issues by framing problems within the legal protection methods currently available, and shows how the only way to address these issues is through drafting legislative change internationally.


3 See Savulescu, supra note 2; Gitter 2004 supra note 2; Oberdorfer, supra note 2; Marshall 2001, supra note 2; Ho, supra note 2.

4 Moore v. Regents of the University of California, 793 P. 2d 479, (Cal. 1990) [hereinafter Moore].


6 PXE International is a patient advocacy group for those affected by pseudoxanthoma elasticum (PXE). For more information, see http://www.pxe.org/.
Part Two looks briefly at two proposed models for legislative change - the Harrison Hybrid Donative/Liability Model and the Hybrid Property Rights/Liability Model - and discusses the pros and cons of each.

Part Three discusses the issue of allowing human genetic material to be considered property and proposes a new way of viewing genetic property to best facilitate an equitable solution to the benefit sharing dilemma.

Finally, Part Four proposes a novel international legislative solution, the Hybrid Individual/Community Property Rights Model. The solution is in part an amalgamation of the best features of earlier envisioned schemes and international conventions and declarations. This model incorporates the redefinition of genetic material as hybrid personal/communal property that was outlined in Part Three. This scheme best facilitates benefit sharing and does so within a system that addresses the major fears and concerns of both those for and opposed to benefit sharing. Further, the proposed method ensures that it is in the best interests of researchers that participants be fully informed.7

III. PART ONE: “THE BIG THREE: ATTEMPTS TO PUSH SQUARES THROUGH CIRCLES AND PASS THE BUCK.”

Part One begins by providing a brief synopsis of the three relevant cases and then discusses how, especially when considered in combination, the solutions provided in each are inadequate to ensure proper patient protection.8

A. Moore v. Regents of the University of California9

The 1990 decision by the California Supreme Court in Moore first articulated the proposition that research participants hold no property rights in their own tissue or commercial products developed from such tissue. Diagnosed

7 This paper sets aside the ethical debate surrounding the patenting of human gene sequences and works from the presumption that such sequences are and will continue to be patentable, despite some of the negative ramifications of gene patents on biomedical research and clinical medicine that have become evident. For further discussion of this issue please refer to M. Cho et al., Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services, 5 J. OF MOLECULAR DIAGNOSTICS 3 (2003); JF Merz et al., Diagnostic testing fails the test: the pitfalls of patents are illustrated by the case of hemochromatosis, 415 NATURE 577-579 (2002).

8 There are two basic ways in which the tissue used in biological research is obtained from living humans: (i) physicians remove tissue for therapeutic or diagnostic reasons and retain that tissue for future research purposes; or, (ii) medical researchers obtain tissue samples with the express intent of using the sample for research from individuals who are not patients but who wish to contribute to biomedical research; these people may be solicited and sought after by researchers working on a particular project or may come forward voluntarily. Tissue obtained for the research in Moore, supra note 4, was obtained in the first manner, and the tissue in Greenberg, supra note 5 was obtained in the latter manner.

9 Moore, supra note 4.
with hairy-cell leukemia, Mr. Moore sought treatment at the University of California at Los Angeles Medical Centre. After confirming the diagnosis, Dr. David Golde recommended the removal of Mr. Moore's spleen for therapeutic purposes, and a splenectomy was performed in October 1976. Dr. Golde noticed the unique tendency of Mr. Moore's spleen to overproduce certain proteins, called lymphokines, and without informing Mr. Moore, future studies were performed on his spleen. Ultimately, a lucrative cell line was derived from Mr. Moore's tissue. Over the seven years following his surgery, Mr. Moore traveled from Seattle to California several times, at his own inconvenience and expense, under the premise that blood and tissue samples were necessary for his own treatment. In reality, he was providing tissue to continue the promising research. When Mr. Moore later learned of the "Mo" patent developed from his tissue, he initiated a lawsuit alleging, among other things, conversion, lack of informed consent, and breach of fiduciary duty. The California Supreme Court held in a five to two decision that a patient had no personal property rights in his own excised organs and thus the law of conversion was not applicable. The majority further held that the plaintiff's rights were adequately protected under the theories of breach of fiduciary duty and lack of informed consent, deciding both of these claims in Mr. Moore's favor.10

B. Greenberg v. Miami Children's Hospital Research Institute, Inc.11

In 1987, Daniel and Debbie Greenberg, parents of two children diagnosed with a rare genetic disorder called Canavan disease, and more than 150 other families, collaborated with a researcher, Dr. Reuben Matalon, attempting to locate the Canavan gene. These parents provided a combination of personal data, biological material and financial support. In 1993, Dr. Matalon located the gene for the Canavan disease and developed a genetic test. His employer, the Miami Children's Hospital (MCH), obtained a patent on the gene in 1997 and began licensing the genetic test. A group of three families, angered by the fact that neither Dr. Matalon nor the hospital had disclosed their plan to patent the gene or test developed from the resources they had provided, filed suit along with three non-profit organizations. The six-count complaint asserted: lack of informed consent; breach of fiduciary duty; unjust enrichment; fraudulent concealment; conversion; and misappropriation of trade secrets. The plaintiffs sought an injunction restraining the defendant from enforcing its patent rights, damages in respect of the patent royalties, and the recovery

10 For further elaboration on the facts of Moore, supra note 4, See Gitter 2004, supra note 2; Ho, supra note 2; E. Chen, Who owns the property rights to your genetic material?, 13 U. BATT. INTELL. PROP. L.J. 1 (2004) [hereinafter Chen].
11 Greenberg, supra note 5.
of financial contributions made to benefit the research. On May 29, 2003, the District Court dismissed all of the plaintiffs’ claims, with the exception of the unjust enrichment count. This allegation was never litigated on its merits, however, because the parties reached a settlement in 2003.

C. PXE International

Another parent team, Sharon and Patrick Terry, who had two children affected by pseudoxanthoma elasticum (PXE), organized the patient-based group PXE International in 1996. PXE International maintains its own bank of family data and biological material and requires that interested researchers agree to share any resulting patent rights before accessing the material. In 2001, PXE International successfully negotiated for a share in the patent rights obtained by researchers who identified and filed a patent application for the gene associated with the disorder in exchange for its contributions to the research effort. In 2004, Sharon Terry accomplished another first when she was named as one of five inventors on the issued patent. Like the plaintiffs in Greenberg, PXE International sought to ensure broad and affordable availability of the test for its disease as well as any downstream developments. The difference was that PXE International negotiated directly with scientists prior to giving them research support and material in exchange for specific rights.

D. Analysis

Conversion claims brought by patients cannot succeed unless human research participants are held to possess property rights in their tissue and, by extension, the commercial products developed from that tissue – a proposition courts have thus far been reluctant to accept. Despite the fact that the court in Greenberg was not bound by the precedent set in Moore, the judges cited Moore when they held that research participants have no property rights in their tissue. The court further stipulated that the families in Greenberg had

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12 Id. at 1177-78. These five claims were dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted.
13 For further elaboration on the facts of Greenberg, supra note 5, see Oberdorfer, supra note 2; Gitter 2004, supra note 2; Ho, supra note 2; and Marshall 2001, supra note 2.
even less of a proprietary claim than Mr. Moore as they had chosen to donate their tissue.16

In Moore, one of the ways the court justified its decision to deny patients’ property rights in their own tissue was by asserting that Mr. Moore’s rights were adequately protected under the common law claims of breach of fiduciary duty and lack of informed consent.17 There are many problems, however, associated with forcing patients to rely on causes of action such as lack of informed consent and breach of fiduciary duty. These were exemplified in Greenberg. First of all, the doctrines of informed consent and breach of fiduciary duty only protect those research participants involved in a physician to patient relationship with the researchers.18 The court in Greenberg dismissed the plaintiff’s claim of lack of informed consent by not only questioning whether researchers who lack a therapeutic relationship with the research participant even owe a duty, but also by finding that even if they did, the disclosure required would not extend to the researcher’s economic interests.19 This finding contradicts Moore whose precedent concerning property rights the Greenberg court followed. In Moore, the court held that economic interests should be disclosed. It further recognized a special duty on the part of a physician researcher to “disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect his medical judgment” when recommending procedures to patients.20

In terms of a fiduciary duty, the court in Greenberg held that “[t]here is no automatic fiduciary relationship that attaches when a researcher accepts medical donations.”21 The court was unconvinced that the perceived trust between researcher and patient — a relationship of trust and confidence without which research collaborations would fail — was sufficient. The court held that the plaintiffs must prove not only that they placed their trust in the defendants, but that the defendants accepted that trust.22 Typically, it is the researcher who collaborates with patient contributors but the researcher himself is bound by an employment contract that dictates his employer owns all patents that arise from his work. Thus, the ability of a patient to rely on a common law cause of action like breach of fiduciary duty is further aggravated because the patent owner in this scenario has no direct interaction with the

16 Greenberg, supra note 5 at 1074. Note that the discussion of who owns a person’s genetic material is continued in Part Three.
17 Moore, supra note 4, at 494, 497.
19 Greenberg, supra note 5, at 1070.
20 Moore, supra note 4, at 485.
21 Greenberg, supra note 5, at 1072.
22 Id.
affected patient population. Another problem with *Greenberg*, as noted by one commentator, is that researchers, aware of this litigation and the courts' interpretation, may now use even more rigid consent forms that protect researchers' rights completely and make it even harder for participants to gain control after the fact.\(^2\) This potential problem is exacerbated by the limited definition of informed consent outlined in *Greenberg*. Lastly, there is concern that even in cases involving physician-researchers who are found to owe a fiduciary duty to their patients, these researchers will remain unmotivated to disclose their financial interests to patients as damages available under the actions of lack of informed consent and breach of fiduciary duty are minimal.\(^2\)

The court in *Greenberg* did not dismiss the unjust enrichment claim leaving a potential avenue for research participants to help themselves regain some control and share in the benefits. Under unjust enrichment, the key to the claim is the impermissible benefit to the physician rather than the actualization of risk for the patient. However, a major problem remains. In the usual scenario, it is a third party biotech company, rather than the research participant's physician, who garners the majority of the profits from the study of that patient's tissue, meaning damages will prove to be quite limited and small. Additionally, patients in these cases are not always financially motivated. Instead, they are seeking to see the genetic test or other treatment developed from their tissue made accessible to all. According to one parent who lost a child to Canavan disease, the legal battle "'[was] not about the Canavan families wanting a piece of the pie'; it [was] about 'having a say in how their contributions are used.'"\(^2\)

It would appear that the contractual method used by PXE International is the ultimate solution. Regarding individuals, however, material transfer agreements will only prove useful to those participants with the legal foresight, education (as these agreements involve health law, patent law and contract law) and money to ensure their interests are fully protected. Further, without requiring that informed consent include an explanation of the commercial possibilities, many people will not even be aware that they had something to negotiate. Although the contractual approach may become more accessible to patients, it appears unlikely to be used very frequently as patients are generally too overcome with grief, fear or concern for themselves or a loved one to properly appreciate the situation or have no alternative to the proposed treatment.\(^2\) Additionally, even if groups like PXE International are available, people may not join these groups. Donors may lack knowledge of

\(^{23}\) Oberdorfer, *supra* note 2, at 393.
\(^{26}\) Ho, *supra* note 2, at 226.
the existence of these groups or may not have access to them; they may fear
the psychological impact of grouping with other sufferers; or they may be
concerned about genetic discrimination as a result of being associated with a
particular group. 27 Finally, Professor Rebecca Eisenberg has warned that the
presence of more parties at the bargaining table can result in longer negotia-
tions, unintentionally slowing up access to developments. 28

The dissent in Moore and the recent excitement over Sharon Terry being
named as an inventor on US patent 6,780,587 have raised the question of
whether making research participants joint inventors might solve the prob-
lem. In the US, joint inventors have extensive privileges and can freely grant
licenses, regardless of the desires of the other inventors. 29 Patients do not,
however, easily fit within the current definition of inventor in the US Patent
Act. 30 Attempts to have them considered as such have failed. 31 Richard
Collins, Director of the National Human Genome Research Institute, ex-
plained that Sharon Terry received her inventor status because of her direct
contribution to the scientific work - a point that was subjected to “careful
evaluation” by patent examiners. 32 Additionally, amendments are currently
being discussed which would change joint inventorship status from one of
equivalent rights for all named inventors to one where an inventor’s degree
of control is linked to the degree of inventorship contributed. The strong dis-
sent by Justice Newman in Ethicon, Inc. v. US Surgical Corp. 33 has accel-
ERATED these discussions. Even if the Patent Act were amended to allow patients
as contributors of raw material to be considered joint inventors, it is unlikely
such a contribution would be considered significant enough overall to pro-
vide them with a controlling share.

It seems clear that the current stance whereby patent rights are vested
solely in the inventor and research participants have no rights is grossly un-
fair. People undertake both direct and indirect risks when donating genetic
material and should be rewarded for such. Unfortunately, courts have inter-
preted common law actions in such narrow and onerous ways as to render

27 L. Gostin, Genetic Discrimination: The Use of Genetically Based Diagnostic and Prog-
28 See M. Fleischer, Pitfalls of Pro Se Patenting, AM. LAW. 87, 87 (2001) (citing Professor
Eisenberg’s concerns that PXE International’s humanitarian demands might complicate and
delay the otherwise profit-driven drug development process).
29 Ho, supra note 2, at 207.
30 Id. at 208; See also 35 U.S.C. § 116 (2000) (defining the requirements for joint inventor-
ship. Case law has defined a joint inventor as one who contributes to the “conception of the
invention”); See Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998)
[hereinafter Ethicon].
31 Ho, supra note 2, at 220.
33 Ethicon, supra note 30, at 1468.
them virtually useless to patients seeking to enforce their rights. The contractual model has shown success, but only in limited circumstances and is not generally accessible. Nevertheless, it is important that a system devised to address the problems with informed consent and benefit sharing is flexible enough to allow groups like PXE International to function. These groups, in addition to providing a means to negotiate fair and equitable benefit sharing, are also crucially important as they encourage and support research into so-called “orphan” diseases. “Orphan” diseases are traditionally low priorities for research companies who prefer to devote their resources to projects with large commercial impact.34

E. The Need for Legislative Change

It appears obvious that legislative change is required to properly and fully address these issues, a proposition supported by the majority in Moore who stated: “[l]egislatures ... have the ability to gather empirical evidence, solicit the advice of experts, and hold hearings at which all interested parties present evidence and express their views”.35 This change needs to occur outside the patent system. In both the US and Canada, patent examiners have no discretion to consider moral or ethical issues when determining patentability.36 Further, the Canadian Biotechnology Advisory Committee (CBAC), in its report on the Patenting of Higher Life Forms, rejected the idea that an “ordre public” clause similar to s. 53(a) of the European Patent Convention should be incorporated into the Canadian Patent Act. The CBAC stated: “the status quo should be maintained; that is social and ethical considerations raised specifically by biotechnology should continue to be addressed primarily outside the Patent Act.”37 The Australian Law Reform Commission also agreed that such issues are best dealt with outside the patent system.38

A recent article in the Globe & Mail titled “Sex slaves for science?” illustrates why a system to ensure informed consent and benefit sharing with research participants that operates on an international level is desperately

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34 Ho, supra note 2, at 221.
35 Moore, supra note 4, at 496.
38 Australian Law Reform Commission, Genes and Ingenuity: Gene Patenting and Human Health. Report 99. Sydney: Australian Commonwealth, June 2004, s. 3.55 (stating however, the ALRC considers that issues of control and benefit sharing are better addressed outside the patent system...”).
needed. The article discussed a research participant in the Manitoba-Nairobi partnership, Salome Simon. Among the numerous Nairobi prostitutes studied, Ms. Simon is one of the few whose apparent immunity to HIV has been heralded by researchers as the key to defeating AIDS. The Manitoba-Nairobi research collaboration has received millions of dollars in funding and the researchers themselves have gained national and international notoriety and prestige. Meanwhile, Ms. Simon, who has been involved in the study for twenty-five years, remains an ill-paid prostitute in Majengo's industrial slums. As a participant, Ms. Simon does receive basic health care and counseling and should she catch HIV that develops into AIDS, she will receive free antiretroviral medication, however, other than shorter wait times for Ms. Simon, none of this is unique. While many are distressed by the clear imbalance, Walter Jaoko, head of microbiology at the University of Nairobi which is currently receiving a $3.8 million dollar Canadian grant to construct a lab to continue its collaboration with the University of Manitoba, views things differently, stating:

It's unfair to compare people's scientific progress with the life of women in Majengo ... We're a scientific group and not a charity. It's not a personal gain; it's an international gain. We're looking at innovative ways to develop a vaccine which will benefit globally. And you can't say any research group has done research and lifted up an entire community. It doesn't happen -- ever. A comprehensive international scheme that promotes progress while ensuring that research participants are fully informed and share in the benefits their contributions generate, as proposed in Part Four as part of the Hybrid Individual/Community Property Rights Model, may be able to change this.

40 Id. For example, Frank Plummer who started working on this project as a student in the early 1980s is now one of Canada's most famous scientists and is considered Canada's top expert on infectious diseases. He is the director of the Centre for Infectious Disease Prevention and Control, as well as the scientific director of the National Microbiology Laboratory in Winnipeg.
41 Id. The drugs are supplied by the U.S. President's Emergency Plan for AIDS Relief and are free to all Kenyans.
42 Id. For example, Professor Elizabeth Ngugi, who has worked intimately with the study participants for twenty years, notes that the women's contribution, "has given the world such a huge body of knowledge, but what has the world done to help them change? ... Quite clearly there is an imbalance."
43 Id.
IV. PART TWO: ALTERNATIVE MEASURES

A. The Harrison Hybrid Donative/Liability Model

In designing a model for the compensation of human research participants, Charlotte Harrison proposed two things. First, she recommended retaining the general rule of tissue donation, as long as that donation was given with the research participant’s consent. Second, she suggested implementation of an objective, non-market mechanism for compensating research participants after scientists have commercialized their research results. Under her model, appropriate compensation would be determined by an objective third party, and research participants would only receive remuneration when their tissue led to a product of commercial value. In cases where tissue donors cannot be tracked, or do not wish to receive compensation, the companies would be required to redirect the adjudicated sum to a charitable purpose. Biotech firms would no longer benefit from intentionally losing linking information or from dissuading research participants from claiming their share of the proceeds. Ms. Harrison noted some of the advantages of her proposed system, including that it would “enable the acquisition and study of tissue to go forward without the delays, commodifying tendencies and other disadvantages of up-front negotiations”; “would operate evenhandedly after the fact of use”; and “could be applied uniformly ... to the full range of tissues collected in hospitals anywhere in the world.”

There are also disadvantages with Ms. Harrison’s system. It does not allow groups such as PXE International to make private arrangements. These arrangements are important because in addition to enabling patients to share in the benefits of research, such groups are often the best hope for those looking to have research done on orphan diseases. The biggest flaw with the Harrison Hybrid Donative/Liability Model is that such a system only provides monetary compensation. There is no mechanism for addressing participants’ non-economic interests, such as the right to participate in licensing decisions. Such issues are often of the utmost importance to those afflicted by the disease, as demonstrated by the plaintiffs in Greenberg whose main concern was to ensure the availability of commercial products and tests developed from their tissue.

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45 Id. at 99-103.
B. The Hybrid Property Rights/Liability Model

In a recent article, Donna Gitter proposed that,

Congress implement a hybrid property rights/liability model that: (1) recognizes 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; and (2) permits individual research participants to maintain an action for conversion of their tissue in the event that: (a) they were not informed that researchers were using their tissue for commercial purposes; or (b) they did enter into an agreement regarding the use of the tissue that is voidable under the doctrines of fraud, duress, undue influence, or mutual mistake.46

Ms. Gitter felt that the promise of compensation would encourage research participation beyond reliance on altruism as the benefits would be shared.47 She noted that such a system ensures that those who undertake the risk associated with donation will be rewarded.48 Further, her method enables groups such as PXE International to continue to function.49

There are problems associated with this model as well. First of all, actions for conversion require money and legal knowledge to initiate. Furthermore, using such a method assumes participants will discover that their tissue has been put to an unauthorized use and upon such a discovery, be aware that they have the option to pursue legal recourse. There are undoubtedly numerous Mr. Moores out there who have never discovered their “Mo patent”. Additionally, it would be necessary to establish a system to help individuals who wish to bargain up front with their researchers. Most donors do not understand contract law nor do they have access to, or the money to hire, people who do understand it to represent their interests.

The fundamental problem with this method, however, is that it provides an avenue for a research participant to receive direct compensation.50 This raises two related concerns. The first is that people in desperate need of money will make unhealthy choices in the hope of much needed financial

46 Gitter 2004, supra note 2, at 338.
47 Id. at 341.
48 Id.
49 Id. at 321 (noting that “[t]hese groups help to identify and recruit research participants, formulate informed consent policies, engage in efforts to increase public awareness of their disease and funding for medical research, and even become so knowledgeable about their disease that they offer researchers significant medical insights.”).
50 This is also a concern with the Harrison model, but to a lesser degree, as it is a third party who determines the remuneration a participant will receive.
return. In a book written in 2001, Professors Andrews and Nelkin take this argument even further by suggesting that allowing remuneration for tissue donation could lead to scenarios such as a man being denied welfare because of the value of his kidney, or a woman’s eggs being harvested to pay her hospital bill. It was this fear that led to legislation in several jurisdictions prohibiting the sale of human organs for transplant. The reverse concern is that such a system will cause a decrease in altruistic behaviour and result in participants refusing to donate until they find the highest bidder.

This debate over the commercialization and commodification of the human body will be further developed in Part Three, and the Hybrid Individual/Community Property Rights Model proposed in Part Four of this paper addresses and provides a compromise to resolve these concerns.

V. PART THREE: “WHAT’S YOURS IS MINE AND WHAT’S MINE IS YOURS!”

A. Research Participants Deserve Benefits

Many argue that research participants do not deserve a share in the wealth because they did not employ any skill and ingenuity in creating the final commercial product; they simply provided the raw materials. Nevertheless, the valuable research could not have been carried on without those raw materials. Why are donors of human tissue less deserving of compensation than the suppliers of other similar materials like chemical reagents and scientific equipment? As Justice Mosk, in his aggressive dissent in Moore, explains,

[N]o 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 ...


53 Those critical of compensating research participants argue further that an individual does not deserve to benefit simply because, by the luck of mother nature, their tissue possessed genetic information that turned out to be valuable. Harrison, supra note 44 at 79, counters the argument by stating, “In our present society ... people can freely exploit their natural beauty, talent or scientific genius, and can even be paid for material contributions to a blood or sperm bank for purposes other than research. Unless current conditions change, an argument based on equality cannot justify denying payment to contributors of tissue samples for research”. 
[F]or all their expertise, defendants do not claim they could have extracted the Mo cell line out of thin air.\(^{54}\)

Others argue that research participants deserve no compensation because in the end they will be the very people whom the research benefits. As bluntly stated by Fima Lifshitz, the Chief of Medical Staff at MCH during the Greenberg litigation, “[t]he issue should be quenched [sic] at once because these people are going to derive a great deal of benefit from this. They shouldn’t be complaining.”\(^{55}\) Nevertheless, this is not always the case. Again, the story of Salome Simon exemplifies this perfectly. As reporter Stephanie Nolan quite aptly pointed out, it will take more than free drugs or a vaccine to help Ms. Simon feel her contribution was recognized, as “[a]fter all, she’s immune to AIDS”.\(^{56}\)

B. Commodification Concerns

In Justice Arabian’s concurring judgment in Moore, he stated:

Plaintiff has asked us to recognize and enforce a right to sell one’s own body tissue for profit. He entreats us to regard the human vessel—the single most venerated and protected subject in any civilized society—as equal with the basest commercial commodity. He urges us to commingling the sacred with the profane. He asks much.\(^{57}\)

And yet, if human beings have no property rights in their own tissue, over what did PXE International bargain? Professor Gitter considered the question,

...of how a court would rule if the researchers were to bring a suit alleging that their contract with PXE International is void as against public policy on the grounds that research participants cannot possess property rights in their tissue pursuant to Moore. Certainly, it would be surprising if the court were to strike this agreement, which was the product of free and full negotiation among the parties.\(^{58}\)

After considering that the defendants stood to profit more than three billion dollars from their research on Mr. Moore’s tissue, the appellate court in

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\(^{54}\) Moore, supra note 4, at 511; as cited in Gitter 2004, supra note 2, at 295.


\(^{56}\) Sex Slaves, supra note 39.

\(^{57}\) Moore, supra note 4, at 497.

\(^{58}\) Gitter 2004, supra note 2, at 264.
Moore pointed out that finding Mr. Moore could not own his own tissue but the researchers could, was “fraught with irony”. The simple fact is that in many ways human tissue is already commodified. Blood and gametes are bought and sold. Additionally, consideration of recent case law “on the issue of an individual’s ownership interest in excised bodily tissue reveals an inconsistency between the status of non-reproductive tissue and reproductive tissue”, with courts acknowledging patient ownership rights in reproductive tissue, even when the tissue was donated. Further, one can argue that having property rights in one’s own tissue means people have more control over their body, and should be better able to protect and enhance their dignity, in contrast to Justice Arabian’s assertion. As Professor Mahoney aptly noted, arguments regarding the dangers of commercialization of human tissue fail to consider that “[p]roperty is a flexible concept, not an all-or-nothing one … the choice is not between a completely unrestricted exchange system on the one hand and a total absence of commercial activity in human tissue on the other.”

C. A Lesson in Sharing

Individuals often intuitively feel that they own their bodies, and by extension, their genetic information because it comes from the body. Yet, as Bartha Knoppers, Chair of the Human Genome Organization Ethics Committee points out, we share 99.9% of our genetic makeup with all other humans. She feels that the very nature of genetic information, as both individual and universal, mandates taking a mutualistic approach to its treatment. She argues that the precedents set in consideration of global resources such as air, water and space should also be applied to the human genome. These resources have been viewed as common and attempts have been made to ensure their equitable and peaceful availability to all and their protection in the interest of future generations. Proposals to protect genetic information must consider this communal aspect and seek to protect all stakeholders involved.

A recent case in Iceland reiterates this point. In Guomundsdottir v. Iceland, the Icelandic Supreme Court held that the daughter of a deceased man

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60 Gitter 2004, supra note 2, at commentary in footnote 80.
61 Chen, supra note 10, at 4.
63 B. Knoppers, the Human Genome Organization Ethics Committee (HUGO), Genetic Benefit Sharing, SCIENCE, Oct. 6, 2000, at 50 [hereinafter Knoppers 2000].
64 B. Knoppers, Genetic information and the family: are we our brother’s keeper? TRENDS in Biotechnology Feb. 2002, at 86 [hereinafter Knoppers 2002].
65 Knoppers 2000, supra note 63, at 50.
had standing to challenge the inclusion of his medical information in that country’s health database. A recent article on this case notes that although the Icelandic Supreme Court framed the plaintiff’s interest in terms of privacy, “granting property rights in shared genetic information may be a better way to accommodate the relational nature of genetic information and to safeguard the privacy interests of all parties.” The article gave five reasons to support this assertion: (i) property law, through its notion of joint tenancy, commonly recognizes the interests of multiple parties in the same piece of property; (ii) property law recognizes that joint interests are not always simultaneous interests - they may also accrue in the future; (iii) the language of property carries symbolic weight conducive to a strong protection of interests; (iv) property protection runs with the information and given the propensity of some genetic information sources such as hair, skin cells or even spleens to wander from the patient, protecting genetic information when the patient no longer possesses its source is important; and, (v) property law permits entitlement holders to negotiate third-party use of private property (easements, licenses), and in some cases even requires owners to permit such third-party use when doing so is in the public interest (compulsory licenses, eminent domain, fair use).

Given the fact that genetic information is a global resource shared by all humans, many commentators support the creation of a world wide gene trust. This is not easily accomplished. As explained by Professor Gitter, “the creation of a nonprofit, nongovernmental organization to control valuable tissue is unlikely, as private ownership of human DNA sequences is already firmly entrenched in both the US and throughout Western Europe.” In order to provide an adequate protection scheme for both the individual and the community, a compromise is necessary. Property rights in tangible objects, such as organs, should remain with the individual and it is the individual who should have the opportunity, after receiving full disclosure, to decide whether to donate his/her tissue to the research project at hand. Once the information is given and the intangible property extracted — namely genetic information — the property rights in that information belong to the community, and the benefits of research must be shared with that community. Part Four will address how a community is defined.

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68 Id. at 815-17.
VI. PART FOUR: PUTTING IT ALL TOGETHER...

A. The Individual/Community Property Rights Model

In order to address the concerns regarding informed consent and benefit sharing, a new international regime is necessary. Specifically, an international agreement is required under which each country would enact legislation to become compliant with the following five principles:

1. Informed consent is obtained from all who donate tissue, including those patients undergoing medical procedures after which their tissue may be retained and put to use in the future. This information must be given to all research participants, regardless of whether they are in a therapeutic relationship with the researcher, and must include full disclosure of the goal(s) of the research, including any potential commercialization. In the case of group study, individual consent from each and every research participant is required.

2. Each individual may independently decide whether or not to donate their tangible property, their tissue, to research.

3. Donated tissue is viewed as community property and a percentage of any profits made from the commercialization of this shared property must be allocated. This percentage will be taken from net profits above research and development costs. This percentage can be set by each country but must not be lower than 2%.

4. Each country will establish an administrative agency, an arbitration panel, a tribunal, or a similar objective, non-profit body. The purpose of this body will be to select projects and organizations that best represent the community of interest of tissue donors. Allocated profits will be shared between those selected. Donor submissions concerning where the money should be invested will be considered. In situations where a test, treatment, or medication is developed as a result, the agency may choose to grant individuals

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who donated genetic material to the project free, unfettered access to the end product. Allocation of the community share may be given or divided between, but is not limited to, the forms outlined in Article 15.1 of the UNESCO *Universal Declaration on Bioethics and Human Rights.*

5. The same non-profit agency described in (4) shall have the authority to grant compulsory licenses when they feel it is necessary to do so to maintain balance. Allowing for commercial gain and providing researchers with continuing incentive to innovate must be weighed against ensuring affordable access to the innovations resulting from the gratuitous donation of human tissue.

**B. The Rationale Behind the Model**

As this paper has shown, current policy regarding research participants' rights in their tissue is unclear, inconsistent, and largely unfair. Charlotte Harrison described the situation as follows:

The current state of affairs presents some of the least attractive features of a new and uncivilized frontier. Information is poorly distributed, if not concealed, and the failure to develop a social policy for the many is mitigated only by the self-help of the few - in particular, those few who are fittest for bargaining or litigation. When problems emerge in an activity so central to biomedical research, there is a public interest in promoting transparency and developing a rationally articulated policy for social, economic and professional responsibility.

Legislative changes must occur on an international scale to be effective as scientists typically obtain the tissue upon which they experiment from research participants, tissue banks, and repositories across the globe. In addition, implementing international legislation will not only help individual research participants, but also help protect specialist and indigenous popula-

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71 UNESCO 2005, *supra* note 70, at Article 15.1 (stating that "in giving effect to this principle, benefits may take any of the following forms: special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research; 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; capacity-building facilities for research purposes; and other forms of benefit consistent with the principles set out in this Declaration.").

72 Harrison, *supra* note 44, at 81.

Due to the cultural, social, and educational differences between research participants, informed consent must be provided to each and every research participant. Further, it is important that people retain control over their own body and determine the uses of their body tissue. As Professor Savulescu said, “morality should not be enforced. The best way to enhance the bank of tissues available for research is through education and encouraging people to donate their redundant tissues to research, not by requiring it or taking them without their knowledge”. Since research participants under this model will not directly benefit financially, leaving the choice to donate or not up to each individual will further force researchers to fully explain their work in an effort to demonstrate the value of donations to research and their global benefit. Because individuals will not gain monetarily from their tissue, fears that people will either be forced to sell their tissue to meet financial obligations or, alternatively, hold back valuable tissue until their price is met, are eliminated. In addition, because donation will remain an altruistic act, it will not compete with other life saving endeavours, such as organ donation, which many feared would decrease if people were essentially allowed to sell their organs.

Economically, inventors and companies are not punished by this system and actually benefit in some ways. Normally, a scientific research project requires payment for raw materials in advance. Under this proposed method, payment for raw materials – genetic information - is delayed until the culmination of the project. Further, remuneration is only owed if the research produces a successful commercial product, and even then, is only owed on profits above and beyond research and development costs. This system may even encourage companies to take risks on less certain research given initial costs are reduced.

Viewing intangible property, genetic information, as communal property is essential to the effectiveness of this method. This model ensures that

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74 Ideally, whether negotiated under the World Trade Organization or the World Heath Organization, this agreement would be similar to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in that it should have a dispute resolution mechanism built in to help prevent it from becoming nothing more than soft law, which many fear will be the ultimate demise of the UNESCO *Universal Declaration on Bioethics and Human Rights*, as noted by Professor Matthew Rimmer, Senior Lecturer at The Australian National University. See Class Lecture: Diagnostic Patents: Part 1; Miami Heat – Patent Law, Informed Consent, and Benefit-Sharing, January 11, 2006, presented at The University of Western Ontario.

75 Savulescu, supra note 2, at 651. Julian Savulescu wrote the “against” section in which he advocated for informed consent.

76 Gitter 2004, supra note 2, at 313.

77 Additionally, from a practical standpoint, considering property in genetic material as community property saves time, money and effort. Determining the amount of compensation each research participant’s contribution to a project warrants is very difficult and constitutes
even if the original individuals who donated genetic material cannot be tracked down or have died, the community will still benefit. Therefore, large biotech and life science companies no longer gain an advantage by "misplacing" donor lists, because benefits are not paid directly back to donors. Further, because the community property interest flows with the genetic information, benefits still must be shared no matter how far removed the final commercial product has become from the original interaction between the researcher and patient. This overcomes the problem with attempting to bring unjust enrichment claims. These claims are hard to make out against a company that never interacted directly with the patient contributors.

Having an objective, independent, non-profit agency decide where the money from benefit sharing should be allocated retains the main advantages of groups like PXE International, while ensuring that all research participants benefit from their contributions. For example, in dividing up the money, part of the profits would be allocated back to the disease organizations that helped initiate the research to cover their costs. These costs include soliciting researchers to take on the study of orphan diseases, and setting up the data banks and genetic repositories. Sharing benefits with a community approach, adjudicated through an independent third party, would ensure that the research result are made available to all, including those studying other interrelated diseases. Currently, people afflicted by such diseases often lose out when the contractual model is employed. In an effort to self-protect or even to maximize profits, powerful groups like PXE International often stipulate in material transfer agreements that discoveries can only be used to study the specific genetic disorder of the donating group unless permission is granted, thereby limiting access of people suffering from other interrelated diseases.

The purpose of these impartial agencies would be to consider the research populations involved and come up with an equitable means of rewarding all contributors, drawing inspiration from the broad guidelines listed in Article

an onerous task because rarely is the tissue provided by one or a small number of specific individuals the key to a discovery; Mr. Moore was a rare exception. Rather, commercially useful and rare research results are typically put together using samples provided by a great number of individuals over a long period of time. See United States Congress, Office of Technology Assessment. *New Developments in Biotechnology: Ownership of Human Tissues and Cells*, Special Report 24 (1987), OTA-BA-337, at 55.

78 Gitter 2004, *supra* note 2, at 323; "For example, there is evidence that the gene associated with PXE might also relate to hypertension and cardiovascular disease research. As president of PXE International, Ms. Terry has asserted that her group will resist bettering their own fortunes at the expense of other disease sufferers, stating that although "[i]t's been suggested that we could make a killing because who cares if we're making the costs of cardiovascular treatment huge," PXE International does not "just represent people with PXE, we represent anybody who has anything." As a practical matter, of course, she acknowledges that the group would insist upon licensing deals that would maximize the access of PXE patients to a future diagnostic test or treatment."
15.1 of the *UNESCO 2005*. For example, if the Manitoba-Nairobi partnership was to devise a treatment or cure for AIDS, the agency could choose to divide the community share of the benefits towards several ends. The agency could subsidize the cost of the drugs or vaccine for those unable to afford the needed medicine, and support community programs designed to help women like Salome Simon, whose immunity to AIDS led to the discovery, escape a life of prostitution and poverty. Finally, continuing with this example, the proposed model allows the agency to grant compulsory licences in the event the Manitoba-Nairobi partnership decided to unfairly overcharge for the medication developed.

**VII. CONCLUSION**

As Bartha Knoppers predicted in 2000, "[c]reating specific mechanisms for benefit sharing may well prove difficult, especially in the cases of large groups and multifactorial diseases. Further, profits may accrue many years after the initial research and to a different entity." The proposed Hybrid Individual/Community Property Rights Model accommodates all of these concerns. In addition, the model circumvents the main drawback of earlier proposals in that it allows individuals to assert control over their own body and allows benefits to be shared without engaging the risks associated with financially compensating the individual research participants themselves for their contributions. International agreement upon, and global enactment of, legislation implementing this model would make it possible "to advance biotechnological innovation, enhance the public accountability of researchers, and foster citizen involvement in pressing public health decisions, all while ensuring honorable and equitable treatment of research participants".

*Melanie Baird*

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79 UNESCO 2005, supra note 70.
80 Knoppers 2000, supra note 63, at 50.
81 Gitter 2004, supra note 2, at 345. Professor Gitter concluded these are essential features of a solution to the informed consent and benefit sharing dilemma.

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