The New Paradigm: Donor Ownership of Patent Rights Through Contract Law

By Lawrence Dick

I. Background

There is an axiom in Law that Law never moves faster than Science. In the case of Genetic law, this is a truism. There is a race to the Patent Office among researchers and universities to discover novel genetic diseases. The royalties from such discoveries have created a multi-billion dollar industry[1]. Yet, this race is missing a few participants, the Donors. Once the biological material is separated from the donor, ownership rights reside within the researcher and university. The research will typically find grants from the government or outside sources, while the university will act through the Technology Transfer Department ("Tech transfer department"). Many times, the patient is unaware his blood or tissue sample is being used in medical research[2]. That leaves a naive precatory donor dependent upon the decision of the Tech Transfer department and Researcher. According to United States Patent Statutes, only an inventor may file for a patent[3]. The inventor then assigns the patent right to an interested third party. The tech transfer department will typically require a partial assignment of rights go to the University. While the rule adopted in the leading case of Moore v. Regents of the University of California[4] grants free reign to the biotechnology industry to utilize genetic raw materials, the court's decision fails to adequately protect a patient-donor's interests and further fails to provide patients with any incentive to allow researcher to utilize their tissues[5].

This paper proposes a theoretical contract between the donor, researcher and university and look at the current methods of operation of Technology Transfer Departments at the university setting. In order to protect patient interests, the use of

contract law, instead of previously recommended informed consent principle, requiring the assignment of any patents should be used. The donor should possess partial patent rights in the discoveries to ensure proper distribution, production and availability of the discoveries for the general public while receiving a monetary interest. The current practice by Technology Transfer Offices does not grant these rights to donors. A technology transfer department controls the license agreements between the university and third parties. There are no laws to protect the donor's rights in the licensing agreements or after the tissue has been separated from the body.

a. Evolution of Ownership Dispute

Traditionally, a researcher may use a patient's tissues, cells, or other bodily material in the development of patentable "cell lines" or "products" which might have economic value[6]. In more recent times, patients are trying to challenge the status quo by seeking to recover a share of the profits thought the use of the patient's tissues, cells, and other bodily material[7].

A physician is under the obligation to disclose personal research or economic interests unrelated to the patient's health[8]. There exists four distinctly interested and potentially conflicting parties involved when discussing research: The raw-material donor, the researchers, the research institutions, and the public, who will benefit from the actions of the first three parties[9]. The interest of the biological donor concerns the curing or resolution of their condition or disease. Donors are often unconcerned with the medical research, unless the research results in a cure to their illness. The researcher and university are driven by economic incentives, the advancement of science, and reputation. Finally, the public remains the final beneficiary of the first three groups. The public desires for the general health and welfare of the population to rise, while recognizing the economic incentives and protections granted to the researcher and university. The remainder of this article will focus on formatting a working agreement between the patient-donor, researcher, and university.

b. Moore v. Regents of the University of California[10]

The first and most famous case examining property rights in bodily tissues is *Moore v. Regents of the University of California*. The 1990 *Moore* decision held that the removal of a person's cells and bodily tissues extinguishes a patient's property interest in his cell's and genetic material[11]. Moore sought treatment at the University of California at Los Angeles Medical Center (UCLA) for hairy-cell leukemia. Dr. Golde, the physician, recommended that Moore's spleen be removed so as to slow down the disease. Although Moore consented to the operation, he was unaware Dr. Golde arranged to retain parts of the spleen for research purposes. For seven years thereafter, Moore continued to return to UCLA for follow up donations of tissue, sperm, bone marrow and blood to Dr. Golde. Dr. Golde received a patent for what would be known as the MO cell line derived from Moore's donation[12]. Dr. Golde, the University of California, and Dr. Quan entered into a commercial contract and licensed agreements for which biotechnology companies paid them stocks, fringe benefits, and more than $400,000 for access to a potential market estimated at over 3 Billion dollars. In 1984, Moore sued Dr. Golde, Dr. Quan and the Regents of the University of California, claiming thirteen causes of action. The Supreme Court of California held that Moore had stated a valid cause of action for breach of doctor's disclosure obligations, but agreed with the trial court that Moore's conversion claim fails[13]. The Court held that the defendants failed to convert Moore's cells because

he abandoned them when the doctors removed them from his body[14]. The Court believed that to hold otherwise would restrict access to needed raw materials, both legally and as a practical matter[15]. The Moore majority sought the "appropriate balance" between avoiding judicially created disincentives to medical research and protecting patient autonomy.

c. The Hagiwara Incident

The Hagiwara incident is another case where the patient received no rights, and the rights were granted to the researcher and institution[16]. The dispute revolved around researcher's rights versus raw-materials donor's rights. Although no clear judgment arose because the parties settled out of court, the incident provides the close situation to the topic of this paper. In 1982, Dr. Hagiwara brought his mother's tumor cells from Japan to the United States in an attempt to develop a cure for her[17]. Hagiwara and other researchers at the University of California at San Diego Medical Center (UCSD) believing that these cells possessed unusual cancer-fighting potential, began experimentation and eventually produced a cell line from them. Without notifying the technology transfer department at UCSD, Hagiwara brought some of the cells from the cell line back to Japan to attempt to treat his mother. At this time Hagiwara applied for a Japanese patent for the cell line's product. UCSD claimed ownership of the cell line as assignees of its employees' discoveries because Hagiwara was an employee of UCSD. Hagiwara claimed ownership because he provided the cells, conducted the research, and possessed familial ties to the cell line. The parties settled before completion of a full trial. UCSD became the owner of the patent rights of the United States Cell line while Hagiwara gained the rights of the Asian market.

d. Results in ownership dispute- Availability, Distribution, and Production

In order to protect patient interests, the use of contract law, instead of previously recommended informed consent principle, requiring the assignment of any patents, trademarks, or copyright should be used. The future of patents within the research university realm might forever be changed based on the developing paradigm created by PXE International[18]. The United States National Bioethics Advisory Commission and the Human Genome Organization are emphasizing that genetic researchers should share the benefits of their research with the subjects who make it possible[19].

Sharon Terry, president of PXE International, says that the group made the move [to contracting with researchers] because it wants to ensure that license for any resulting genetic tests will be inexpensive and widely available[20]. PXE International provided University of Hawaii with blood and tissue samples from patients with Pseudoxanthoma Elasticum (PXE). The organizations goal is to ensure free licensing but says that if the university insists on a fee, the organization will try to keep the costs low and split costs through all patent assignees. When Patrick and Sharon Terry started PXE International, they rapidly amassed a group of 2,000 members and raised more than $150,000[21]. PXE International then took matters into their own hands. In a 1-by3-by3 foot freezer is deposited blood and tissue samples of PXE. Before any researchers can take a sample, they must sign a contract saying that they will share with PXE international the ownership and profits of any research from the samples. In February 2000, University of Hawaii pathobiologist Charles Boyd located the PXE gene. He signed the agreement saying he would share the patent with PXE. On the patent for the PXE gene, Ms. Terry's name appears as partial owner.

Currently, in Chicago a similar battle is raging in the court system. A group of patients suffering from the Canavan disease donated tissue a researcher[22]. In 1993, the researcher isolated the gene. The Miami Children's hospital received the patent that claims all methods for detecting the gene for Canavan. The hospital has imposed a royalty for each test, and threatened legal action against disobedient testing laboratories. Four Canavan families say that they gave blood and tissues believing that the test would be available to all who want it. The group of donors did not formally enter into a contract with the University or researcher at the time the donation was made.

The four situations described above all show a need to control your rights as a donor through a contract requiring assignment of rights from any and all commercial values derived from the donation of biological material. The assignment will control the availability, production, and distribution of the product. In the Moore case, the physician and hospital achieved exclusive rights[23]. The Regents of California, Dr. Golde and Dr. Quan exclusively controlled the Mo-Cell line. The Court found that Moore's only legal injury was derived from a tort claim. Yet, if Moore initially established a contractual relationship with the researchers and himself, the Court would have the tort claim and a much stronger Contract claim. When the terms of a contract are clearly defined, a Court will consider the contents within the four corners of the contract. A Court will also enforce the contract to its terms since both parties entered into the agreement. Yet, a trier of fact must decide if there was a breach of a fiduciary duty. Clearly, from a judicial standpoint, Moore would have been far better off if he entered into a contract. Next, the Canavan case is within the terms of the hospital setting where a researcher and the hospital's technology transfer department retain the patent rights. Canavan is before the courts in Chicago treading the Moore waters. Finally, the PXE case is the new paradigm for future ownership donor-patient ownership rights. If the all the parties enter into a clearly defined contract before the biological material is transferred from the possession of the donor to the researcher, then the donor will have a stronger foothold on future control of the anticipated patent.

II. Purpose of Paper- Resolution of Biological Patent Ownership from Medical Research at the University Setting

To this day Moore[24] continues to generate controversy regarding the rights and entitlements of raw materials donor. The purpose of this paper is to create a boilerplate contract to be used between a patient-donor, researcher, and university. Traditional Contract principles should be used to catch law up to the speed of science to ensuring patients retain an ownership right in all patents derived from the donation of their biological material. This legal solution of using contract law instead of tort law has the flexibility to cope with unforeseen technologies while clearly defining the roles and responsibilities of all parties. The use of Contract law creates an incentive for the donors to bargain with the researcher and universities beforehand, so as to increase the donor's, researcher's and university's certainty or rights by securing them at an early stage. Plus, if a donor knew he would receive patent rights and royalties, while seeking a cure for his illness, a patient will be more willing to give of his tissues, blood, or biological material.

Finally, by use of Contract law, parties do not need to wait for Federal or State legislation action. Contract law sets clearly defined roles and expectations.

The current state of the law and current practice of the technology transfer departments do not protect the donor. Few jurisdictions have encountered the issues inherent in the ownership of genetic materials and cell lines[25]. Courts resoled the problem by using the informed consent tort[26]. Courts should not anticipate Congress drafting a statute protecting patient's rights. Part of the problem results from science changing at a much faster rate than lawmakers can understand the social implications and draft appropriate statutes. Statutes simply take a longer amount time to enact into law than for parties to enter into an enforceable contract. The current practice of technology transfer departments is to retain sole ownership of the patent rights. Researchers have access to donated biological material unbeknown to the patient. Technology transfer departments will acquire rights in the patent by assignment from the researcher.

III. Purpose of Contract

a. Current Legal Remedy Through Informed Consent

When cases of donor's ownership rights arise, courts use informed consent as a legal remedy for the patient's injury. In Moore, the California Supreme Court considered whether a patient could recover in tort for the economic value of the patient's expropriated cells and for a physician's failure to reveal "preexisting research and economic interests in the cells" prior to performing certain medical procedures[27]. Reluctant to sanction a cause of action that might chill "socially important medical research, " the Court refused to recognize property rights in human tissue but allowed a cause of action for lack of informed consent or breach of fiduciary duty. In light of these complex policy issues, the majority declined to recognize Moore's cause of action for conversion, concluding that any expansion of law should be made by the legislature. Writing separately, Justice Broussard maintained that the relevant question was not whether a patient retains an ownership interest in removed body parts, but whether the patient has "the right, before a body part is removed, to choose among the permissible uses to which the part may be put after removal."[28]

Finally, Justice Mosk criticized the court's suggestion that the doctrine of informed consent adequately protects patients' interests'[29]. Noting that informed consent is a negligence doctrine, he reasoned that plaintiffs in cases such as Moore would have difficulty demonstrating a causal relationship between nondisclosure and injury. Justice Mosk further argued that even if such a claim were successful, it would "fail to protect patient's rights to share in the proceeds of the commercial exploitation of their tissues." The Court's formulation of the informed consent cause of action inadequately protects a patient's right to determine whether bodily tissues may be used for purposes unrelated to the patient's therapy or treatment. In conclusion, the informed consent doctrine should be construed to permit nonparticipation in research activities, regardless of the nature of the contribution to the medical research of the social utility of such research. Instead of following the tort path, the donor can travel the contract path.

b. Establish a legal cause of action other than informed consent

The contract would exist between the donor, researcher and the tech transfer department. A primary tenet of contract law is that two or more parties may voluntarily enter into a binding agreement where there is an offer, acceptance and consideration. In the paradigm model, the donor is offering to give up part of his physical self; blood, tissue, sperm, or biological materials. The researcher is accepting the offer. In return for the biological material, the researcher is giving partial rights via an assignment to the donor. The third party, the technology transfer department is jointly needed in the contract. The researcher has a preexisting agreement with the university that research performed within the controlling boundary will be assigned to the university. The university will lose part of its right within the terms of the contract. Typically, the technology transfer department will be responsible for patenting and possession of partial or all research done at the university. If patients were responsible for partial or all research done, then the technology transfer department would be eliminated, and a contract would exist between the researcher and donor.

If the donor enters into a contract before transfer of biological material, then the terms of the agreement clearly set that ownership rights retain with the donor, and in case a patentable material is discovered from the tissue donation, then the right is assigned to the donor, researcher, and university. The patient will not rely on proving a tort claim before a trier of fact. Instead, by entering into a contract, he assures himself of the terms and agreements before any biological material is donated.

c. Assignment of Rights via Contract

Patents have the attributes of personal property, and patents and patent applications may be assigned by written instrument. For the patient to receive secured rights from the donation of his biological material, a contract allows for the assignment of rights to the researcher, University (Tech Transfer Department), and the donor. An assignment of rights is when a party to an existing contract transfers to a third parson his rights under the contract[30]. An assignment is a present transfer of one's rights under a contract. Plus, under Patent law, all assignments of ownership needs to be recorded with the Patent and Trademark Office to ensure public notice is given to all future third party buyers.

Finally, by entering into a contract before the transfer of biological material transfers, the donor can revert to tort law if the terms of the contract are construed to be ambiguous. The entering of the contract provides a double security so the researcher and university will follow the wishes and desires of the infected donors.

IV. Ownership through Patent

The Constitution grants Congress the power "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[31] A patent is the grant to an inventor by a government of a limited monopoly on an invention. A patent is also a collection of rights given to an inventor by a government in exchange for the publication by the inventor of a description of the invention that is detailed enough to allow one skilled in the art to reproduce the invention[32]. According the Patent Code, the inventor of a "process, machine, manufacture, or composition of matter" may obtain a patent provided that the invention is "useful", "novel", and "non-obvious," the subject matter is

patentable, and the patentee complies with certain procedural requirements[33]. A patent, once issued, grants the patent holder the right "to exclude others from making, using, or selling the invention throughout the United States" for a period of years[34]. The patent, however, does not grant the patent holder the right to exploit the invention itself, as such right may be blocked by another patent. Patents shall have the attributes of personal property. Ownership of a patent, as with any property, carries with it the right to exclusive enjoyment. Assignments of applications, patents and registrations will be recorded in the Patent and Trademark Office[35].

Whatever the ethical issues, as a practical matter the process of obtaining such commercial rights is anything but simple[36]. The complexity of the patent process around individual genes requires scientists first to isolate those genes- each one a set of instructions encoded in Deoxyribosenucleic Acid (DNA) that are crucial to life at a molecular level. The researchers must determine what each gene actually does. Once that information is attained, Tech transfer departments file patents on the gene itself, any protein it produces and other technologies that could be crucial in finding or designing new drugs. Failure to do all that correctly could allow a competitor to exploit a loophole in what is supposed to be an exclusive commercial advantage.

Even then, there is no guarantee that universities will receive even a fraction of the patents they seek[37]. In addition to the risk that the U.S.P.T.O might find their claims deficient, universities often have to fend off competing claims to the same genes filed by their rivals.

a. Partial owner

The goal of the patent system in the biotechnology sector is to encourage competition in the development of innovative medical tests and treatment[38]. There is no necessary legal relationship between inventor and patent holder for any given invention. Although the inventor is the presumptive owner of property rights to patents issued for his invention, these rights are transferable by assignment. In fact, patents granted to inventors who have assigned their interest may be issued directly to the assignee, which may be any legal entity, including a corporation. A patent owner can assign partial ownership rights to his patent through a written document. This paper presents such a document. As partial owner, the donor will be accorded all the rights granted to the whole owner, as long as no exceptions are included within the assignment contract[39].

b. Allow for control for distribution, production, and sale of product

One of the biggest concerns for a donor is the control of distribution, production and sale of the invention. The invention might consist of a test for the genetic trait or the cure for the illness. These three rights of possession benefit the victims of the disease and promote the general health of society. As an assignee, the donor is in equal control of the distribution along with the other listed assignees. This right is granted in the assignment rights defined under the United States Code[40]. The assignees will potentially sell license agreements to third party manufacturers. These license agreements will be revocable, temporary, and set limits. If the donor or research is not satisfied with the advancement of science or use of the invention, they may request a hearing before the American Arbitration Association (AAA). If the AAA feels as though the distribution of the product under the license is not within a reasonable distribution of the product, sublicenses will be issued to fulfill the reasonable expectations the donors and researchers

had. Even though this shifts ownership control of the patent from the Tech transfer office to the researcher and donor, the donor has the majority of the bargaining power.

Currently, for common diseases, a researcher has access to multiple tissue sample banks where tissues samples are stored without restrictions. For common diseases, it will be difficult for a patient to receive patent rights under a contract theory. The contract bargains for specific performances. The contract specifically protects donors of uncommon genetic diseases. But for the donation of biological material from the donor, the researcher and university will not be able to conduct research. The uncommon disease carrier is at a better bargaining power than a carrier of a common disease.

V. Practical Barriers

a. Ownership by Tech Transfer office

The current practice of ownership between the donor, researcher and tech transfer office eliminates the donor's ownership rights once the fluid, bodily material separates from the donor[41]. The only form of remedy available for the donor is through a tort action of informed consent[42]. Yet, creating a binding contract between the three parties will shift the power of ownership. Clearly each party has incentives to have the research done. The patient is a carrier of the illness. His incentive is for an immediate cure for himself, any further family carriers of the trait, the public, and future generation of carriers. The researcher's interests are threefold: 1. Economic, 2. Promotion and Advancement of Science, and 3. Reputation. The first incentive is economic. A researcher will receive partial patent ownership. As inventor of the patentable material, the researcher will be the initial owner, and then assign part of his rights to the Tech Transfer office, and part to the donor. Second, for the promotion and advancement of science, a research will work diligently for a cure. Science is making rapid improvements. Each scientist wants to contribute to the advancement of science. Finally, there is a reputation incentive for a researcher. Public notoriety and recognition of novel research is invaluable to a researcher. Through publication of articles, a researcher will attain tenure, gain more credibility with commercial entities, and receive greater federal funding. The last party to benefit from the research is the Tech Transfer Department in two ways, through economics and reputation. First, the researcher will assign part of the rights to a patent to the Tech Transfer department, and thereafter to the university. The royalties from patents can create a multi-billion dollar invention. Second, each institution desires to promote the general welfare of the academic reputation of the school. Reputation among universities is a driving recruiting force for research institutions.

These interests are interrelated and opposing. For the donor to get a cure, he is dependent upon the researcher's knowledge and skills as a scientist. The researcher is just as dependent as receiving a donation of biological material to conduct research on. Finally, the Tech Transfer department brings the two groups together under one roof. Plus the university will supply the housing framework for the research to be conducted. Included in the framework includes the necessary facilities, laboratories, and employees. Finally, the university will be responsible for the disposal and maintenance of all waste materials along with ensuring public safety from any potential biological hazardous material.

Currently there is imbalance of power between the donor, researcher and university. The researcher and Tech Transfer department possess all property rights once the biological material is extracted from the patient. Yet, these two parties are dependent upon the donation of biological material from the donor. Therefore, it is the contention of the contract to shift the power of ownership from the Tech Transfer department and researcher to the donor. It is necessary for a shift in the balance of power to increase bargaining power of the originator of the biological material, the donor. The contract presented shifts the assignment of rights from the researcher and tech transfer department to include the donor as a third part own of the patent rights. This will ensure that three rights defined under patent law not only stay with the researcher and Tech Transfer department, but also extended to the donor. A potential problem to this will be if one of the three parties does not agree, then the other two parties lose. Yet, using the example set out by the PXE disease this can be averted[43]. The carriers of the disease required the researchers enter into a contract before any samples were delivered to the researcher. It would be assumed that the university would be frustrated by the loss of revenue, but University of Hawaii instead cooperated with the PXE Corporation to find a cure[44]. By working together University of Hawaii, PXE corporation and the research team efficiently found the cure for PXE. The patent rights were divided between the three groups, and the fourth group, the public, directly benefited by having access to a cheap, available test for the genetic disease PXE.

b. Does the university own the research? Does the patient? Can a physician negotiate this contract?

Each group wants to control a part of the intellectual property right derived from the invention. The contract expressly divides the ownership into percentages. Those percentages will be decided between the three parties. The percentages will not be used to decide the amount of rights[45]. The rights are divided equally between the three parties to divide the royalties derived from the patent. The contract expressly lays out a plan where the university will decide who will be permitted a license to the patent, while the donor and researcher have the reserved right to appeal to the AAA. The variation between the amounts of assignment rights to the patent allows the parties to quantify the amount of royalties given to each party after the patent is issued.

Giving exclusive rights to the donor might discourage the technology transfer department from entering into an agreement. The current system gives complete rights to the university and researcher. This shift is gradual enough for the technology transfer department to enter into without shifting the rights too far away from the university setting. Finally, as a public policy, the right to assign is better to remain at the technology transfer department. The technology transfer department has established a practice of selling licenses, are centralized unlike a group of donor owners, and the monetary and human resources to research the best commercial entity to license the patent.

Universities have long claimed that the exclusive rights to the patent are justified from the billions of dollars they are pouring into research.[46] Yet, this raises questions of wisdom, morality, and economic efficiency to allow a university to lock up the commercial rights to a patent. If a university controls the patent for twenty years, then this can allow the exclusion of material from the science community. It is within the right of the patent holder to withhold the biological material from other researcher

laboratories. Plus, the university possesses a monopoly over the market. Patients stricken with the illness are at the mercy of the university. This way, the university can control the price of the patent or even more extreme, not offer the invention to the general public. This is contrary to all principles of patent law. The contract creates an avenue of joint ownership where society as a whole is made into a better place for an affordable invention that is accessible to society as a whole. Wisdom would dictate that ownership should extend to the donor, researcher and university.

A too expansive right granted to the donor might cause adverse effects. For example, patients might abuse their power to restrict use of their tissues in other fields of research or to exclude as potential beneficiaries members of particular minority groups. Such situations could be avoided, however, by requiring that the exercise of the patient's rights be based on patients similarly situated rather than as an attempt to control the course of research.

VI. Proposed Contract

a. Introduction to Contract

The next section proposes a sample contract between a donor, researcher and research institution. Individuals can enter into a contract agreement with the university, which can involve sharing in patent rights and any revenues whereby the researcher acts in the role of an employee for the university. Or, the individual can retain the services of the researcher as a "consultant" and pay the university via a "gift" or research grant while attempting to retain ALL rights to discovery with the company. However, there are all possible variations on these themes via contracts, gifts, and grants. This paper will focus exclusively on the contractual relationship between the patient, researcher and "tech transfer" office of a university research facility. The contract will be divided into four basic parts. First, general provisions such as description of the donated biological material and location of medical extraction of biological material. Second, provisions stating the obligations of the donor, e.g. the specification of the donation that will be given, time of delivery. Third, provisions stating the obligations of the researcher, the patent, and assignment of patent rights.. Finally, provisions relating to the remedies of the parties in case of breach of contract[47].

b. Sample Contract

Contract for the Ownership Rights to Discoveries from Donation of Biological Material.

This agreement by and between the University of X Research Foundation having its principal Technology Transfer Center (hereafter "Tech Transfer Department") located at Y, and (Insert name of donor) (hereafter "Donor"), and (Insert name of Researcher) (hereafter "Researcher").

i. Description—Donation of biological material. Donor shall transfer ownership and deliver possession to researcher, and researcher shall accept the following materials: _____ used for the sole purpose of finding a cure or diagnostic test for _____.

ii. Mission: The researcher, as an employee of the university shall diligently conduct research on the donated biological material to discover and find a cure for said disease. All funded research studies at the University that leads to discoveries claimed in any future patents has rights to the Intellectual Property.

iii. Time of Delivery—Researcher shall have the right to specify the date of donation, but in no event shall the date specified be before _____20_, on or after _____20_.

iv. Delivery of additional material—Researcher shall have the right to demand all of the biological material at one time during the period stated in Paragraph 2, or in portions from time to time. The researcher must have approval from a licensed physician after a physical examination of donor in ensure the safety and health of the donor. Any material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE DONOR MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIATARY RIGHTS. Unless prohibited by law, researcher assumes all liability for the damages which may arise from the use, storage, handling, or disposal of Biological material except that, to the extent permitted by law, donor shall be liable to the researcher when the damage is caused by the gross negligence or willful misconduct of the donor.

v. Location of Donation—The biological material shall be extracted at a hospital or medical center conforming to standard medical procedures associated with the University, or third location agreed upon by said donor, registered physician and researcher. If the location shall be at the University, then the University shall supply the medical resources and instruments necessary for the removal of any biological material from the donor. Plus, the University shall be liable for any and all foreseeable injuries that occur in the course of removal of biological material from the donor.

vi. Identification of biological material—Once removed from the domain of the donor, the researcher shall conduct research in a professional standard and manor on the _____ of the donor. To ensure the health and safety of the donor, a medially qualified, board certified physician practicing in the medical field with good standing shall be present and supervise the removal of any tissue or organs from the donor. Removal of blood or fluids can be conducted under the control of a qualified medical staff.

vii. Authority of researcher—Once the biological material is out of possession from the donor, possession will be transferred to the researcher. The researcher has the expressed authority to conduct all necessary and essential

research for the express goal of discovering a cure, detecting the biological pathway causing the disease, or creating a test to detect the disease. The researcher may use in research involving University materials only in programs in compliance with all applicable statutes, regulations and guidelines for research of type.

viii. Transfer of Property— The researcher shall not transfer, sell, lend, reproduce for sale, or share with other researchers, research institutions, government institutions, private institutions or public institutions without the express consent of the donor any biological material donated by said donor. If the material is transferred, the right to patent ownership shall carry along with possession of material. Any discoveries, inventions, or patentable material derived from said donation shall be included in the transfer rights.

ix. Modifications—This agreement can be modified or rescinded only by a writing signed by said donor, said researcher and tech transfer department of said University.

x. Delegation of Performance— The Tech Transfer department of said University and researcher must delegate its performance under this contract only if the donor approves the party to whom delegation is made in writing. When approval is given, it shall not operate to release the delegating party from liability for the performance of its obligations under this contract.

xi. Assignment of Patent Ownership— The Tech Transfer department of said University and researcher must assign patent rights from any and all inventions derived from the donation of biological specimen from the donor. The assignment to the donator shall constitute ownership of any filed patents before the Patent and Trademark Office and ownership to be divided among the Tech Transfer Office and researcher of the patent rights, as defined under 35 U.S.C. §101. The assignment shall be recorded in the Patent and Trademark Office according to 37 C.F.R. §1.12 for any and all patentable discoveries derived from the donor's biological sample as defined under 35 U.S.C. §101. If the discovery is anticipated or unanticipated from the donation, the patent shall be assigned partially to the donor.

xii. Filing with Patent and Trademark Office—The assignment relating to all inventions derived from said donation shall be filed in due time with the Patent and Trademark Office. The assignment must follow the M.P.E.P. §302 rule for Recording of Assignment Documents.

xiii. Rights of Ownership— As collective owners of the patent, the Tech Transfer Department, researcher and donor shall be granted all rights and privileges granted under 35 U.S.C. § 261. The researcher may make patentable discoveries, which may eventually be the basis of commercial products, that benefit public health. The Researcher agrees to use the Biological Material only

in compliance with all applicable statutes, regulations and guidelines relating to their handling, use or disposal.

xiv. Preexisting and Subsequent Research—The donor shall receive ownership rights and assignment on all patents from discoveries derived from his cells. This clause shall apply to preexisting and subsequent research conducted by the researcher, the university, or any third party the researcher or university transfer the biological material.

xv. Trade Secrets—If any discoveries are made with the said donation of biological materials, it shall not remain a trade secret. The researcher and Tech Transfer Office must file for patent rights and protection in a reasonable amount of time without due delay or abandonment of the discovery.

xvi. Control of Production, Distribution, and Sale of the Invention—The joint owners of the patent will have right to decide how the invention will be controlled, distributed, and sold. The Tech Transfer department will license the invention to ensure reasonable production, sales, and distribution of the invention to an entity approved by both the researcher and donor. If the researcher or donor is reasonably unsatisfied with the distribution, production or sale of the invention, they can petition to the American Arbitration Association. The American Arbitration Association will decide if additional licenses should be granted. This will be based on the reasonable expectation of the donor and researcher.

xvii. License—The tech transfer office shall grant a limited, revocable, commercial or research license to third parties. Any grant of license to a third party for commercial or research license shall be a separate written agreement with the tech transfer department, researcher and donor.

xviii. Applicable Law, Exclusive Jurisdiction, Venue and Removal—All disputes arising under, in connection with, or incidental to this contract shall be litigated, if at all, in and before the _____Court, located in _____ _____County, State of _____, United States of America.

xix. Breach—If any party shall breach their obligations as defined under this contract, the breaching party shall pay the damaged party reasonable costs. These costs will be decided upon either jointly or through the said court system mentioned in paragraph 14. The researcher, university or possessor of any subsequent biological material, upon breach of contract, agree to return all donated, derived material thereof, or destroy upon a material breach of the terms of this agreement.

xx. Nothing contained herein shall be considered to be the exclusive grant of a commercial license or patent right under the United States Code to the tech transfer department, researcher, or third party.

The Donor, Researcher, and Technology Transfer Department Representative of the University must sign all copies of this Agreement. One signed copy will remain with the Donor, one with the Researcher and a third copy with the Technology Transfer Department. The Donor, Researcher, and third party will then arrange for the extraction of the Biological Material to be prepared to transfer for research.

VII. Conclusion

In order to protect patient interests, the use of contract law, instead of previously recommended informed consent principle, requiring the assignment of any patents should be used. The contract attempts to find an appropriate balance between the donor, researcher and university. The contract is divided into four sections. The first section describes the biological material to be transferred from the patient to the university. Second, the contract describes the clauses pertaining to the responsibilities of the patient. Third, the contract describes the clauses pertaining to the responsibilities of the researcher. Finally the contract describes remedies offered to the patient in case of breach of contract. The potential contract offers the patient patent rights not offered before, while the researcher and university retain partial patent rights. The contract also limits the patient's rights by permitting the university to license the product. The license can be revoked only by appeal. This should limit the potential abuse by the patient to restrict the research and attempt to slow the progress of science. In conclusion, the Moore Court made an interesting observation[48]. The Uniform Anatomical Gift Act gives patients control over what is done with their bodies after they die, so it seems logical that they should similar control before they die. On a practical note, the court wrote, "If this science has become science for profit, then we fail to see any justification for excluding the patient from participation in those profits. Are researchers engaged in socially useful activities, and might be against a donor's wish."[49] The current state of the law does not protect the donor. Nor does the law give the donor any patent or ownership rights. A clear and convincing way to show the intent of the inventor is through the principles of CONTRACT LAW.

Footnotes

[1] Sally Lehrman, "Foundations Funding Biomedical Bodies, 'Should Shfrt Focus,'" *Nature* 338 (1996), 112
[2] 22 Am. J. L. and Med 109
[3] 37 C.F.R. §1.12. In the European and Asian Patent System, the owner may file for patent protection.
[4] 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990)
[5] See *id*. at 125, 793 P.2d at 480 , 271 Cal. Rptr. at 147
[6] 104 Harv. L Rev. 808 (1991)
[7] 104 Harv. L Rev. at 810
[8] 22 Am. J. L. and Med. 109
[9] 22 Am. J. L. and Med. 109, 111
[10] See *id*. at 135, 793 P.2d at 488, 271 Cal. Rptr. at 155
[11] See *id*. at 125-36, 793 P.2d at 481, 271 Cal. Rptr. at 148
[12] See *id*. at 125-36, 793 P.2d at 481, 271 Cal. Rptr. at 148
[13] See *id*. at 129, 793 P.2d at 483, 271 Cal. Rptr. at 150
[14] See *id*. at 127-28, 793 P.2d at 482, 271 Cal. Rptr. at 149
[15] See *id*. at 136, 793 P.2d at 488, 271 Cal. Rptr. at 155
[16] OTA Report, OTA-BA-337 24, 26 (1987); Rorie Sherman, The Selling of Body Parts, Nat'l L.J., Dec. 7, 1981, at 1; Majorie Sun, Scientists Settle Cell Line Dispute: But Question of Claiming Ownership Based on Faily Ties to Cell Donor is Sidestepped, 220 Science 393 (1983)
[17] Sun, Supra Note 16, at 393 (noting the case is settled out of court).
[18] Matt Fleishcer, The National Law Journal "Seeking Rights to Crucial Gene" June 25 (2001)
[19] Paul Smaglik, Tissue Donors Use Their Influence in Deal Over Gene Patent Terms, 407 Science 821 (2000)
[20] Matt Fleishcer, The National Law Journal "Seeking Rights to Crucial Gene" June 25 (2001)
[21] Paul Smaglik, Tissue Donors Use Their Influence in Deal Over Gene Patent Terms, 407 Science 821 (2000)
[22] Matt Fleishcer, The National Law Journal "Seeking Rights to Crucial Gene" June 25 (2001)
[23] 37 U.S.C. §1.12 (2001)
[24] 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990)
[25] 22 Am. J. L. and Med. 109, 112
[26] See Note 4
[27] See *id*. at 125, 793 P.2d at 488, 271 Cal. Rptr. at 155
[28] See *id*. at 122, 793 P.2d at 481, 271 Cal. Rptr. at 148
[29] See *id*. at 122, 793 P.2d at 481, 271 Cal. Rptr. at 148
[30] Black's Law Dictionary
[31] U.S. Const. art. I, section 8, cl. 8.
[32] 35 U.S.C. §271 (2001)
[33] 35 U.S.C. §101 (2001)
[34] 35 U.S.C. §101
[35] Chapter 35 of the United States Code
[36] David P. Hamilton, Biotech Firms are Scrambling to Win Exclusive Rights to Newly Discovered Genes" The Wall Street Journal, 15 Oct. 2001, R8
[37] *id*.
[38] *id*.
[39] Chapter 35 of the United States Code
[40] Chapter 35 of the United States Code
[41] 22 Am. J.L. and Med. At 115
[42] See *id*. at 158-59, 793 P.2d at 504-05, 271 Cal. Rptr. at 169
[43] Paul Smaglik, Tissue Donors Use Their Influence in Deal Over Gene Patent Terms, 407 Science 821 (2000)
[44] id.
[45] Rights are equal to all parties assigned to a patent. Unless otherwise expressly stated in a contract, all parties possess the rights granted to a patent.

[46] David P. Hamilton, Biotech Firms are Scrambling to Win Exclusive Rights to Newly Discovered Genes" The Wall Street Journal, 15 Oct. 2001, R8.
[47] See UCC-2 Sales Forms and Procedures, p. 21.00
[48] See *id*. at 161-63, 793 P.2d at 505-07, 271 Cal. Rptr. at 170-72
[49] See *id*. at 161-63, 793 P.2d at 505-07, 271 Cal. Rptr. at 170-72