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Balancing the Interests of Researchers and Donors in the Commercial Scientific Research Marketplace

In recent years, commercialization is becoming increasingly prevalent in the scientific research community.¹ In this Note, “commercialization” refers to a situation where researchers profit from their scientific research, which is often publicly funded.² For example, researchers may profit by selling products to the public developed from their results, such as pharmaceutical drugs.³ Additionally, researchers may profit by acquiring intellectual property rights as a result of their research, such as patents.⁴ While the government has taken affirmative actions to encourage the commercialization of science,⁵ there is significant opposition to this type of exploitation of research.⁶ Yet despite this growing opposition, many tissue donors are unaware of this on-going commercialization.⁷ If given a preference, these donors may prefer donating their tissues to researchers that would not use the research for profit. Indeed, in one study, almost one-third of participants indicated they would be against the patenting of products developed from

¹ See The Patent and Trademark Law Amendments (Baye-Dole) Act, 35 U.S.C. §§ 200-211 (2000); Michael J. Malinowski, *Technology Transfer in Biobanking: Credits, Debits, and Population Health Futures*, 33 J.L. MED. & ETHICS 54, 54-56 (2005) (describing the history of the commercialization of science); Eric G. Campbell, Greg Koski, & David Blumenthal, *The Triple Helix: University, Government and Industry Relationships in the Life Sciences* 10-12 (Working Policy Paper of the AEI-Brookings Joint Center on Regulatory Studies, 2004), available at <http://www.kauffman.org/research-and-policy/triple-helix.aspx>; see also *infra* Part I.

² See Ron A. Bouchard, *Balancing Public and Private Interests in the Commercialization of Publicly Funded Medical Research: Is There a Role for Compulsory Government Royalty Fees?*, 13 B.U. J. SCI. & TECH. L. 120, 126 (2007). Often researchers may profit from relationships with industry, such as “[r]esearch relationships,” “[c]onsulting relationships,” “[l]icensing relationships,” “[e]quity relationships,” “[t]raining relationships,” and “[g]ift relationships.” Campbell et al., *supra* note 1, at 5-6.

³ Bouchard, *supra* note 2, at 126. For example, publicly-funded research led to the development of the five pharmaceutical drugs with the highest sales in 1995. *Id.* at 143-44.

⁴ See, e.g., *id.* at 124. For example, in 2002, U.S. universities brought in about \$1 billion in licensing royalties from various patents resulting from research at the universities. *Id.*

⁵ See 35 U.S.C. §§ 200-211; 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

⁶ See, e.g., Ken Gatter, *Fixing Cracks: A Discourse Norm to Repair the Crumbling Regulatory Structure Supporting Clinical Research and Protecting Human Subjects*, 73 UMKC L. REV. 581, 619 (2005); Melody Petersen, *A Conversation with: Sheldon Krimsky; Uncoupling Campus and Company*, N.Y. TIMES, at F2 (Sept. 23, 2003); see also *infra* Part II.

⁷ See, e.g., *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003) (tissue donors expected research results would remain in the public domain).

research on their genetic material.⁸ Yet the current legal system is not adequately set up to ensure these donors' interests are protected.⁹

Many scholars have proposed methods to protect donors' interests.¹⁰ Some of the most frequent proposals include unjust enrichment causes of action, expanded property rights in the donors' tissues, and informed consent requirements.¹¹ However, most of these proposals address only the protection of donors' rights.¹² They fail to acknowledge the interest on the other side—that of the researchers in performing their research with as few burdens as possible.¹³ As there are two interests involved, an adequate solution will require a balancing of these two interests.

This Note argues that a mandatory disclosure requirement provides the best balance between donors' interests and researchers' interests. Part I describes the events contributing to the commercialization of science. These events include the passing of the Bayh-Dole Act¹⁴ and the expansion of patentable subject matter. Part II

⁸ Jon F. Merz & Pamela Sankar, *DNA Banking: An Empirical Study of a Proposed Consent Form*, in STORED TISSUE SAMPLES: ETHICAL, LEGAL, & PUBLIC POLICY IMPLICATIONS 198, 211 (Robert F. Weir ed., 1998). The study presented ninety-nine participants with a proposed informed consent form for providing blood and other tissues for storage in a DNA bank. *Id.* at 198, 203. Participants were then asked numerous questions, including, "Assuming you were to permit research to be performed with your blood, would you be offended if researchers patent inventions resulting from this research (which gives them the ability to prevent others from making, using, or selling those inventions)?" *Id.* at 224. Twenty-nine participants responded yes out of a total of ninety-one respondents. *Id.* at 211.

⁹ See *infra* Part III.

¹⁰ See, e.g., Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV. 257, 268 (2004) (proposing property rights will protect donors' interests in their biological tissues); Debra L. Greenfield, *Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material*, 15 ANNALS HEALTH L. 213, 237 (2006) (suggesting unjust enrichment will provide a method of challenging some gene patents); Douglas Andrew Grimm, *Informed Consent for All! No Exceptions*, 37 N.M. L. REV. 39, 40 (2007) (arguing informed consent doctrine should be expanded to meet modern science's needs); Melanie Baird, Note, *When and Why Does What Belong to Whom? A Proposed Model for the International Protection of Human Donors of Biological Material*, 32 CAN.-U.S. L.J. 331, 347-48 (2006) (proposing a combination of the informed consent and benefit-sharing models).

¹¹ See, e.g., Gitter, *supra* note 10, at 268 (proposing property rights will protect donors' interests in their biological tissues); Greenfield, *supra* note 10, at 237 (proposing unjust enrichment will provide a method of challenging gene patents in certain circumstances); Grimm, *supra* note 10, at 40 (arguing informed consent doctrine should be expanded to meet modern science's needs). For an overview of other solutions proposed, see generally Joyce Boyle, *To Pay or Not to Pay, That Is the Question: Finding an Intermediary Solution Among the Moore Spectrum*, 7 MICH. ST. U. J. MED. & L. 55, 72-78 (2002).

¹² But see William Hanes, Note, *Rejection of the Need for Informed Consent in Prostate Tissue Sample Research*, 14 CARDOZO J.L. & GENDER 401, 424-26 (2008) (considering both researchers' and donors' interests and proposing a patchwork of causes of action in response to various concerns, but not directly requiring researchers to disclose financial interests).

¹³ This focus on donors' rights is likely due to the fact that the federal government has already taken a strong interest in furthering research. See, e.g., 35 U.S.C. §§ 200-211 (2000); 66 Fed. Reg. 1092, 1093-94 (Jan. 5, 2001); see also *infra* Part I. However, this does not justify going too far in the other extreme direction.

¹⁴ Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-27 (codified as amended at 35 U.S.C. §§ 200-211 (2000)).

addresses objections to the commercialization of science. Additionally, it describes *Greenberg v. Miami Children's Hospital Research Institute*,¹⁵ a case in which the donors' and researchers' interests conflicted. Part III analyzes the potential effects of the proposed solutions on both donors and researchers. Finally, Part IV proposes a legislative solution that balances both interests involved and is modeled on the informed consent process.

I. THE COMMERCIALIZATION OF SCIENCE

The changes in the scientific landscape in the past thirty years shed light on the difficulties the legal system faces in dealing with conflicts between donors of biological tissues to research and researchers. Prior to the 1980s, research universities and corporate entities rarely interacted with each other.¹⁶ However, in 1980, Congress passed the Bayh-Dole Act,¹⁷ which permitted organizations to keep the ownership rights of intellectual property developed through the use of public funds.¹⁸ At the same time, the scope of patentable subject matter expanded.¹⁹ These two factors led to a further commercialization of science by increasing the manners in which researchers could profit from their scientific results.²⁰ As will be discussed in Part II, this resulted in increasing tensions between donors and researchers.

A. *The Bayh-Dole Act and Technology Transfer*

Prior to the 1980s, the government owned the vast majority of patents resulting from federally funded research.²¹ Researchers and companies could obtain title to the patents in certain circumstances, but each funding agency had a different policy for when it would grant a request.²² Furthermore, the government freely granted licenses to multiple parties using non-exclusive licenses.²³ At the time, only 5% of federally owned patents were in use in the marketplace, or, in other

¹⁵ 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

¹⁶ See *infra* Part I.A.

¹⁷ Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-27 (codified as amended at 35 U.S.C. §§ 200-211 (2000)).

¹⁸ 35 U.S.C. §§ 200-211; see also *infra* Part I.A.

¹⁹ See *infra* Part I.B.

²⁰ See Bouchard, *supra* note 2, at 126; see also Campbell et al., *supra* note 1, at 4-6.

²¹ Council on Governmental Regulations, Office of Technology Transfer, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations* (Sept. 1999), <http://www.ucop.edu/ott/faculty/bayh.html> [hereinafter *Guide to Bayh-Dole*].

²² *Id.*; Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE, Sept. 19, 2005, available at http://money.cnn.com/magazines/fortune/fortune_archive/2005/09/19/8272884/index.htm.

²³ *Guide to Bayh-Dole*, *supra* note 21. A non-exclusive license permits the licensor to grant the same rights to multiple parties, whereas an exclusive license prohibits the licensor from granting the relevant rights to any additional parties. BLACK'S LAW DICTIONARY 938-39 (8th ed. 2004) (entry for "license").

words, were commercially available.²⁴ Congress concluded the public would benefit economically from a change in policy,²⁵ largely because they were concerned about the lack of commercial use of technological research.²⁶ Congress believed that in order to encourage researchers and companies to take the additional risks involved in getting products into the marketplace, title to the patents and the ability to grant exclusive licenses was necessary.²⁷

As a result of these concerns, Congress passed the Bayh-Dole Act.²⁸ The new policy, which became effective in 1981, left ownership of patents resulting from federally funded research in the hands of the research organization.²⁹ Therefore, the research organization could control the issuance of licenses and receive profits from licenses.³⁰ Furthermore, the organization could issue exclusive licenses in certain circumstances.³¹ In other words, the organization could grant a certain right, such as use of a patented product, to a single entity.³²

Despite Congress's conclusion that this new policy would be beneficial in advancing scientific research, academic institutions in particular remained skeptical into the 1990s.³³ Many institutions were concerned that increased commercialization would threaten the cultural characteristics of academic institutions such as unbiased research,

²⁴ Wendy H. Schacht, *Patent Ownership and Federal Research and Development (R&D): A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, in PATENTS: ISSUES AND LEGAL DEVELOPMENTS 61, 64-65 (John V. Martin ed., 2002).

²⁵ See Guide to Bayh-Dole, *supra* note 21; see also Department of Health and Human Services, National Institutes of Health, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected (July 2001), <http://www.nih.gov/news/070101wyden.htm> [hereinafter NIH Response] (stating the Bayh-Dole Act was passed "in response to concerns about U.S. competitiveness in the global economy"). Congress stated:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

35 U.S.C. § 200 (2000).

²⁶ Schacht, *supra* note 24, at 64; see also 35 U.S.C. § 200.

²⁷ Schacht, *supra* note 24, at 64-65.

²⁸ 35 U.S.C. §§ 200-211.

²⁹ *Id.*; see also Guide to Bayh-Dole, *supra* note 21.

³⁰ 35 U.S.C. §§ 200-211; see also Guide to Bayh-Dole, *supra* note 21.

³¹ 35 U.S.C. §§ 200-211; see also Guide to Bayh-Dole, *supra* note 21.

³² BLACK'S LAW DICTIONARY 938 (8th ed. 2004) (entry for "license") (an exclusive license "gives the licensee the sole right to perform the licensed act . . . , and that prohibits the licensor . . . from granting the right to anyone else").

³³ Malinowski, *supra* note 1, at 54.

collegiality, and a regard for academic responsibilities such as teaching.³⁴ However, many universities have since overcome these concerns and have begun amassing large numbers of patents.³⁵ Technology transfer, which is the process by which research results are transferred for sale in the public marketplace,³⁶ is now an everyday part of research at universities. For example, one survey of university-owned patents reported that about 70% of the patents had been licensed at least one time.³⁷ Some universities have gone even further and are engaging in research collaborations with industry, such as the plant and microbial research deal between the University of California, Berkeley and the pharmaceutical company Novartis.³⁸ Overall, the Bayh-Dole Act is viewed by many as succeeding in its goal of increasing the amount of research available in the marketplace.³⁹ As a result, it clearly has played a key role in the commercialization of science.

B. *The Expansion of Patentable Subject Matter*

In addition to changes in the ownership structure of intellectual property rights arising out of scientific research, the scope of patentable subject matter has also grown. In 1952, Congress amended the patent law to include “new and useful process[es].”⁴⁰ These amendments expanded patentable subject matter to include many diagnostic and treatment procedures that were not previously patentable, such as specific methods for cataract surgery.⁴¹

³⁴ *Id.* at 54-55. Interestingly, similar concerns exist today. *See infra* Part II.A; *see also* Campbell et al., *supra* note 1, at 13-17.

³⁵ Andrew Delbanco, *Academic Business*, N.Y. TIMES, Sept. 30, 2007, § 6 (Magazine), at 25. For example, in 2006 the University of California received 410 patents and M.I.T. received 139 patents. *Id.*; *see also* Malinowski, *supra* note 1, at 54. However, the NIH has observed that “most university technology transfer programs have very few, if any, products in the market” and “operate their technology transfer programs at a loss.” NIH Response, *supra* note 25.

³⁶ Guide to Bayh-Dole, *supra* note 21 (Technology transfer is “the transfer of research results from universities to the commercial marketplace for the public benefit.”).

³⁷ NAT’L RESEARCH COUNCIL OF THE NAT’L ACADS., REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH 117 (Stephan A. Merrill & Anne-Marie Mazza, eds., 2006) [hereinafter NATIONAL RESEARCH COUNCIL].

³⁸ Andrew Lawler, *Last of the Big-Time Spenders?*, 299 SCIENCE 330, 330 (2003).

³⁹ *See* U.S. GOV’T ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 2 (1998), available at http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/15/9a/9c.pdf (“[University officials] said the act was having a positive impact and was working as the Congress intended.”); Guide to Bayh-Dole, *supra* note 21 (explaining that the Bayh-Dole Act has “fostered the commercialization of many new technological advances that impact the lives of millions of people across the nation”).

⁴⁰ 35 U.S.C. §101 (2000) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent”); *see also* COLL. OF AM. PATHOLOGISTS, STATEMENT TO THE SECRETARY’S ADVISORY COMMITTEE ON GENETICS, HEALTH AND SOCIETY (SACGHS) 6 (2006), available at http://www.cap.org/apps/docs/statline/pdf/sacghs_comments.pdf [hereinafter AM. PATHOLOGISTS STATEMENT].

⁴¹ AM. PATHOLOGISTS STATEMENT, *supra* note 40, at 6.

The courts have broadly construed these amendments. In a case in 1980, *Diamond v. Chakrabarty*,⁴² the Supreme Court held that “a live, human-made micro-organism is patentable subject matter.”⁴³ The Court stressed that Congress’s intent in passing the amendments was to “include anything under the sun that is made by man.”⁴⁴ Although “laws of nature, physical phenomena, and abstract ideas” remained not patentable subject matter,⁴⁵ the *Chakrabarty* decision is referenced as support for an expanding array of biotechnology patents, including patents on hybrid corn seeds and plants.⁴⁶

Chakrabarty is also referenced as support for patents on full or partial genes.⁴⁷ In 1992, the National Institutes of Health filed applications for patents on 2300 partial genes.⁴⁸ At the time, many members of the scientific and legal community were surprised that these patents were granted.⁴⁹ However, by 2001, the patent office had firmly adopted the position that genes are patentable subject matter.⁵⁰ The patent office consistently rejected the argument that genes were not patentable because they were products of nature.⁵¹ According to the patent office, the patent is for “the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other

⁴² 447 U.S. 303 (1980).

⁴³ *Id.* at 305. In *Chakrabarty*, the patentee had genetically engineered a bacterium that could break down crude oil, a property that was not possessed by any known naturally-occurring bacteria. *Id.* The Patent Office rejected the patent application because “as living things they are not patentable subject matter.” *Id.* at 306. The Supreme Court rejected this argument, stressing the difference between the patentee’s non-naturally occurring organism and “a hitherto unknown natural phenomenon,” which the court stated would not be patentable. *Id.* at 309. This decision has been met with some criticism. See, e.g., Mark O. Hatfield, *From Microbe to Man*, 1 ANIMAL L. 5, 6 (1995) (“In each session of Congress since 1987, I have introduced legislation to place a moratorium on allowing the Patent and Trademark Office to issue patents on living organisms.”).

⁴⁴ *Chakrabarty*, 447 U.S. at 309 (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

⁴⁵ *Id.*

⁴⁶ E.g., *J. E. M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 127, 129-31 (2001).

⁴⁷ See Michele Westhoff, *Gene Patents: Ethical Dilemmas and Possible Solutions*, HEALTH LAW., April 2008, at 1, 7; see, e.g., Christopher Jackson, *Learning from the Mistakes of the Past: Disclosure of Financial Conflicts of Interest and Genetic Research*, 11 RICH J.L. & TECH. 1, ¶¶ 38-45 (2004), available at <http://law.richmond.edu/jolt/v11i1/article4.pdf>. But see Lori Andrews et al., *When Patents Threaten Science*, 314 SCIENCE 1395, 1396 (2006) (stating *Chakrabarty* is “[o]ften mischaracterized as opening the door for patents claiming isolated and purified versions of naturally occurring products, including human genetic material . . .”); Westhoff, *supra*, at 7 (“Upon close examination, it seems that the [*Chakrabarty*] opinion’s own language forecloses the possibility that genes are patentable subject matter.”).

⁴⁸ Hatfield, *supra* note 43, at 6.

⁴⁹ *Id.*

⁵⁰ In 2001, the patent office issued regulations requiring applicants for gene patents to show a use that is substantial. *U.S. Issues Stiffer Regulations on Frivolous Patenting of Genes*, N.Y. TIMES, Jan. 6, 2001, at C3. Those regulations were viewed as firmly establishing the ability to patent genes or even portions of genes. *Id.*; see also 66 Fed. Reg. 1092, 1092-93 (Jan. 5, 2001). In fact, as early as 1998, this was the patent office’s position. See e.g., John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689, 689 (1998).

⁵¹ See, e.g., 66 Fed. Reg. at 1093.

molecules naturally associated with it.”⁵² Therefore, genes can be patented if the inventor meets the general requirements of a patent.⁵³

The expansion of the subject matter of patents has also increased the number and types of patents that may result from scientific research. For example, patents are now available for diagnostic and treatment processes such as specific methods for cataract surgery,⁵⁴ human-engineered organisms such as human-made bacteria that breaks down oil⁵⁵ and hybrid corn seed and plants,⁵⁶ and even genes.⁵⁷ Many people view these patents as a necessary incentive for research because they believe that patent rights encourage investment in research, the disclosure of research results, and the development of useful products.⁵⁸ Thus, the expanded scope of patentable subject matter, in addition to the transfer of patent titles to the research organizations, has led to an increase in scientific researchers receiving direct profits from their research. Yet as Congress and the courts have expanded the commercial

⁵² *Id.* Recently, the idea that a single gene can be related to a function has been put into question, thus raising even more questions about the validity of gene patents. Denise Caruso, *A Challenge to Gene Theory, a Tougher Look at Biotech*, N.Y. TIMES, July 1, 2007, § 3, at 3. Additionally, a lawsuit was recently filed challenging the patents that cover genes linked to breast cancer. See Complaint, Ass’n for Molecular Pathology v. United States Patent & Trademark Office, No. 08cv4515 (S.D.N.Y. May 12, 2009). Indeed, legislation has even been introduced in Congress to prohibit the patenting of genes. See Michael Crichton, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23; see also Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007). However, since gene patents are provided as an example of the way these controversies are expressed, this paper proceeds with the assumption that the patent office will continue issuing gene patents.

⁵³ Lori B. Andrews & Jordan Paradise, Essay, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. OF HEALTH POL’Y, L. & ETHICS 403, 404 (2005). These requirements include a “sufficient written description,” utility, novelty, and nonobviousness. *Id.*; see also 35 U.S.C. §§ 100-05 (2000). The written description requires a description of the invention, the process for making the invention, and the process for using the invention. ALAN L. DURHAM, PATENT LAW ESSENTIALS 85 (2d ed. 2004). Utility requires that the invention is useful to some extent, so long as the useful purpose is legal. *Id.* at 70-71. Finally, novelty requires that the invention is unique from previous inventions, *id.* at 90, while nonobviousness requires that the invention adds something to previous inventions that would not have occurred to the person of ordinary skill in the specific field of the invention, *id.* at 107. For a more thorough discussion of the requirements for a patent, see generally *id.* at 67-126.

⁵⁴ See AM. PATHOLOGISTS STATEMENT, *supra* note 40, at 6.

⁵⁵ See *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

⁵⁶ See *J. E. M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 127 (2001).

⁵⁷ See *supra* notes 47-53 and accompanying text.

⁵⁸ For example, with regards to the need for gene patents, John J. Doll, the director of the Biotechnology Examination Technology Center of the U.S. Patent and Trademark Office, has explained:

Without the incentive of patents, there would be less investment in DNA research, and scientists might not disclose their new DNA products to the public. Issuance of patents to such products not only results in the dissemination of technological information to the scientific community for use as a basis for further research but also stimulates investment in the research, development, and commercialization of new biologics. It is only with the patenting of DNA technology that some companies, particularly small ones, can raise sufficient venture capital to bring beneficial products to the marketplace or fund further research.

Doll, *supra* note 50, at 690.

nature of scientific research, they have failed to resolve the multitude of issues raised as a result of this commercial expansion.

II. PROBLEMS POSED BY THE COMMERCIALIZATION OF SCIENCE

Many people in varying fields have criticized the increasing commercialization of science.⁵⁹ Indeed, the arguments against gene patents are typical examples of the arguments against the trend toward the commercialization of research.⁶⁰ Additionally, the case of *Greenberg v. Miami Children's Hospital Research Institute, Inc.* provides an example of how these critiques can lead to conflicts between tissue donors and researchers.⁶¹ *Greenberg* suggests that since the commercialization of science is controversial, tissue donors need to be made aware of any proprietary uses of their donation in advance so that they can negotiate with the researcher if they oppose these commercial uses.⁶²

A. General Objections

Many of the initial concerns expressed in the wake of the Bayh-Dole Act continue to linger.⁶³ These initial concerns included the fear that exclusive licenses could lead to high prices and monopolies.⁶⁴ Since the patent owner could license the use of the patent to only one entity, many people were concerned taxpayers would be harmed because the entity receiving an exclusive license would have no competition and could charge high prices for a product that was developed as a result of publicly-funded research.⁶⁵ Additionally, people were also concerned the act might unjustifiably benefit foreign industry, which could license the patents despite not contributing any resources towards the development of the patent.⁶⁶ Finally, there were concerns that the involvement of non-profit academic universities with for-profit corporate entities would harm academic institutions by altering the areas of faculty research, abolishing collegiality, and encouraging researchers to ignore their other academic

⁵⁹ Certainly not everyone thinks that the commercialization of science is a bad thing. *See, e.g.*, Guide to Bayh-Dole, *supra* note 21 (“On a nation-wide basis, the results support the conclusion that the Bayh-Dole Act has promoted a substantial increase in technology transfer from universities to industry, and ultimately to the public.”). However, in order to understand why donors may be concerned about the potential uses of their donations, one must understand the objections donors may have to the commercialization of science. Thus, only the objections are addressed in this Note.

⁶⁰ *See infra* Part II.B.

⁶¹ In *Greenberg*, this conflict arose when the tissue donors expected the research to remain in the public domain, but the researcher patented the research results. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003).

⁶² *See infra* Part IV.C.

⁶³ *See, e.g.*, Campbell et al., *supra* note 1, at 13-17; Guide to Bayh-Dole, *supra* note 21.

⁶⁴ Guide to Bayh-Dole, *supra* note 21.

⁶⁵ *See id.*

⁶⁶ *See id.*

responsibilities, such as teaching.⁶⁷ The concern that the act might unjustifiably benefit foreign industry is the only concern that seems to have completely dropped out of the debate.

Indeed, just like the initial concerns expressed in the wake of Bayh-Dole, a substantial number of current concerns involve the changes to the research process and the academic community.⁶⁸ Specifically, because of technology transfer—the transfer of research results into products in the marketplace⁶⁹—research materials and information are no longer being openly shared among academic institutions.⁷⁰ This can be particularly damaging when any single institution lacks the materials to do appropriate research on a given issue.⁷¹ For example, institutions researching autism do not have a sufficient number of tissue samples to identify the gene responsible for the disease, yet researchers do not share their tissue samples because each researcher wants to be the one to discover the gene and patent it.⁷² Furthermore, when sharing does occur, it can be done in such a way so as to discriminate against the non-sharing organizations.⁷³ For example, the leading semiconductor companies swap and shuffle licenses in a way that effectively keeps their potential competitors out of the industry.⁷⁴

The effects of the commercialization of science on the progress of scientific knowledge also raise concerns.⁷⁵ The broad reach of patent rights⁷⁶ makes building upon others' research increasingly more difficult.⁷⁷ At best, this situation requires that researchers devote more of their budgets to licenses.⁷⁸ At worst, researchers are outright prevented

⁶⁷ Malinowski, *supra* note 1, at 54-55 (stating a concern university researchers would “shirk[] their academic responsibilities”); Campbell et al., *supra* note 1, at 13-17; Guide to Bayh-Dole, *supra* note 21.

⁶⁸ See, e.g., Petersen, *supra* note 6 (suggesting the connection between universities and industry threatens academic freedom).

⁶⁹ Guide to Bayh-Dole, *supra* note 21.

⁷⁰ See Malinowski, *supra* note 1, at 55; Campbell et al., *supra* note 1, at 13. In fact, the Bayh-Dole Act specifically is criticized for “increas[ing] the number and creativity of financial arrangements that give rise to conflicts of interest.” Gatter, *supra* note 6, at 619.

⁷¹ See Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 23 (2005) [hereinafter Andrews, *Benefits of Biobanks*].

⁷² *Id.*

⁷³ See Amy Harmon, *In the “Idea Wars,” a Fight to Control a New Currency*, N.Y. TIMES, Nov. 11, 2001, § 3, at 1.

⁷⁴ See *id.*

⁷⁵ Malinowski, *supra* note 1, at 55 (“[T]here is concern that over-patenting in biotechnology will result in license entanglements that will impede the advancement of research in the years to come, and impede medicinal applications with life and death consequences.” (footnote omitted)).

⁷⁶ See *supra* Part I.B.

⁷⁷ See Harmon, *supra* note 73; see also Andrews et al., *supra* note 47, at 1395.

⁷⁸ See, e.g., *supra* Part II.B. This raises concerns that these costs will be passed on to consumers. Due to concerns about the cost of access to therapeutic drugs, Congress asked the National Institutes of Health to prepare a plan to ensure the protection of the public's interests. NIH Response, *supra* note 25 (plan prepared to ensure the public's access to therapeutic drugs).

from doing the research.⁷⁹ Additionally, many difficulties can arise between these two extremes.⁸⁰

A 2006 report by the National Research Council of the National Academies, an organization that provides public policy advice on issues concerning science, technology, and health policies,⁸¹ found that in general, patents have not yet significantly slowed or blocked research.⁸² However, the report attributed this to a general lack of awareness among the research community regarding existing intellectual property rights.⁸³ It went on to warn that the lack of an effect on research could change dramatically if the research community becomes aware of its potential liability, particularly if patent holders begin to more actively exercise their patent rights.⁸⁴ Thus, although the commercialization of science has not yet significantly slowed the progress of scientific knowledge, it is conceivable that even one successful patent liability suit could significantly alter the effect that patents have on research.

Finally, the commercialization of science has also led to an increase in financial conflicts of interests.⁸⁵ People that criticize these conflicts claim they threaten the integrity of the research.⁸⁶ Specifically,

⁷⁹ Andrews et al., *supra* note 47, at 1395. Patent holders can refuse to give other researchers a license to use the patented material. *Id.* Alternatively, the patent holder may require an excessive fee for the license. *Id.*

⁸⁰ For example, DuPont's license terms for its genetically engineered mice required researchers licensing the mice to obtain permission from DuPont before new discoveries were disclosed or used in commercial applications. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698, 699 (1998). While some researchers accepted these restrictive terms and licensed the mice for use in their research, others rejected the terms, thus refusing to license the mice. *Id.*

⁸¹ The National Research Council, Welcome to the National Research Council, <http://sites.nationalacademies.org/nrc/index.htm> (last visited Jan. 31, 2009).

⁸² NATIONAL RESEARCH COUNCIL, *supra* note 37, at 125. While the National Research Council's report focused on genetic research, similar findings have also been reported in the biomedical field. See generally John P. Walsh, Ashish Arora, & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS. OF SCI., *PATENTS IN THE KNOWLEDGE-BASED ECONOMY* 285 (Wesley M. Cohen & Stephen A. Merrill, eds. 2003), available at <http://www.nap.edu/catalog/10770.html> (discussing the recent changes in patenting practices and affects of these changes in biotechnology).

⁸³ NATIONAL RESEARCH COUNCIL, *supra* note 37, at 125. Indeed, many researchers believed they did not need access to others' patent rights in order to do their research. *Id.* at 122. Additionally, few researchers reported searching to see if any patents may affect their research, despite universities increasingly notifying researchers that they should be doing such searches. *Id.*

⁸⁴ *Id.* at 125. This is particularly an issue since *Madey v. Duke University*, 307 F.3d 1351 (2002), in which the Federal Circuit made clear that in most instances universities are not protected from patent infringement suits by the common-law research exemption. *Id.* at 1362 ("Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects . . . [that] unmistakably further the institution's legitimate business objectives . . .").

⁸⁵ See Malinowski, *supra* note 1, at 55; Campbell et al., *supra* note 1, at 15-16.

⁸⁶ Malinowski, *supra* note 1, at 55 (stating that increases in financial conflicts of interest "jeopardize[] the integrity of research and the protection of human subjects"); see also Harmon, *supra* note 73 (stating critics complain that "intellectual property rights are regularly trumping social values like free speech or public health"). Indeed, even the scientific community itself recognizes the potential harm resulting from financial conflicts of interest, as many scientific journals require the

critics have observed a tendency for studies' outcomes to be favorable towards the researcher's, or research sponsor's, financial interests.⁸⁷ For example, a review of studies on calcium-channel antagonists, a compound used to treat cardiovascular disease, showed that 96% of the authors of studies supporting the use of the compound for treatment had financial ties with a manufacturer of the compound.⁸⁸ In contrast, only 60% of authors of neutral studies and 37% of authors of negative studies had financial ties with a manufacturer of the compound.⁸⁹ Financial conflicts of interest also raise the concern that researchers will forgo socially beneficial research that is not immediately profitable.⁹⁰ These critiques can be particularly harmful when directed at academic research, which is research performed at non-profit universities, because it undercuts the researchers' ability to evaluate hypotheses without any bias, including any financial bias.⁹¹ This ability is viewed as necessary to the integrity of academic research.⁹²

Thus, despite the government's endorsement of the commercialization of science through the Bayh-Dole Act and the expansion of patentable subject matter,⁹³ many people are still concerned about and criticize these changes. In fact, some scientists sympathetic to those concerns have taken efforts to keep their work in the public domain.⁹⁴ Thus, tissue donors who object to the use of their tissue for

disclosure of these conflicts in order for research to be published. See Richard M. Lebovitz, *The Duty to Disclose Patent Rights*, 6 NW. J. TECH. & INTELL. PROP. 36, 36-37 (2007), available at <http://www.law.northwestern.edu/journals/njtip/v6/n1/2/>.

⁸⁷ Petersen, *supra* note 6; Campbell et al., *supra* note 1, at 15-16. Sheldon Krimsky calls this phenomenon the "funding effect." Petersen, *supra* note 6.

⁸⁸ Henry Thomas Stelfox et al., *Conflict of Interest in the Debate Over Calcium-Channel Antagonists*, 338 NEW ENG. J. MED. 101, 101, 103 (1998).

⁸⁹ *Id.* at 103.

⁹⁰ See Charles Austin, *Churches Examine Genetic Research*, N.Y. TIMES, Nov. 14, 1982, § 1, at 39.

⁹¹ See Sheldon Krimsky, *The Funding Effect in Science and its Implications for the Judiciary*, 13 J.L. & POL'Y 43, 51 (2005) (stressing the importance of evaluating research results without any bias); Lawler, *supra* note 38, at 332 (stating a report on the University of California, Berkeley's collaboration with a large pharmaceutical company reported the deal "was a smashing success" and "that the university's academic soul was never for sale" but that critics of the report called it too narrow and self-serving); Delbanco, *supra* note 35 (criticizing the modern university for becoming too much like corporations).

⁹² See, e.g., Petersen, *supra* note 6 (Sheldon Krimsky "argues that the lure of profits is transforming universities so that they are no longer independent, disinterested centers of learning that the public has long depended on.").

⁹³ See *supra* Part I.

⁹⁴ For example, over 26,000 scientists vowed to boycott scientific journals that refused to place articles on a *free* on-line archive six months after publication. Harmon, *supra* note 73. The scientists, which included Nobel laureates, reasoned that the efforts of scientific journals "to control distribution of articles based on taxpayer-supported research [were] delaying scientific progress." *Id.* Other groups have developed open-source science initiatives, which seek to keep research results in the public domain. See, e.g., Andrew Pollack, *Open-Source Practices for Biotechnology*, N.Y. TIMES, Feb. 10, 2005, at C8 [hereinafter Pollack, *Open-Source Practices*] (describing the Biological Innovation for Open Society, or BIOS, initiative); Science Commons Homepage, <http://sciencecommons.org/> (last visited Jan. 31, 2009) [hereinafter Science Commons] ("Science Commons designs strategies and tools for faster, more efficient web-enabled scientific research. We

research ultimately used for commercial purposes could limit their donations to research in the public domain if they were aware of the researcher's intentions. Indeed, the reasons why a donor may wish to do so become even more evidence when gene patents are considered, as this area is particularly controversial.

B. *Objections as Applied to Gene Patents*

Gene patents in particular exemplify the adverse effects of the commercialization of science.⁹⁵ Gene patents are patents that cover the molecular structure of a portion of the genetic code and that structure's known function.⁹⁶ These patents are relevant to tissue donors because the research that underlies the patent application is done on donated tissues.⁹⁷

Critics raise many objections to gene patents. First, critics argue that genes are not patentable subject matter at all.⁹⁸ Notably, these critics argue that genes should not be patented because they are products of nature that occur without human manipulation.⁹⁹ Similarly, these patents have been criticized because the useful properties of genes are natural properties of the gene.¹⁰⁰ In other words, the scientist has not invented the useful properties of a gene.¹⁰¹

Second, gene patents are criticized because they lead to unreasonable healthcare costs.¹⁰² For example, the American College of Medical Genetics has expressed concerns that gene patents limit the

identify unnecessary barriers to research, craft policy guidelines and legal agreements to lower those barriers, and develop technology to make research, data and materials easier to find and use. Our goal is to speed the translation of data into discovery—unlocking the value of research so more people can benefit from the work scientists are doing.”). In other words, these groups try to keep research results freely available to the public. *See* BLACK'S LAW DICTIONARY 1265 (8th ed. 2004) (entry for “public domain”) (defining the public domain as “[t]he universe of inventions and creative works that are not protected by intellectual-property rights and are therefore available for anyone to use without charge”). Regardless of the method chosen, these groups are sending a clear message that they believe science will be best advanced if knowledge remains in the public domain rather than becoming commercialized by being sold for profit. *See, e.g.,* Harmon, *supra* note 73; Pollack, *Open-Source Practices, supra*; Science Commons, *supra*.

⁹⁵ Although the patent office has issued gene patents for some time now, objections are still made. For a more extensive survey of these issues, see generally Andrews & Paradise, *supra* note 53. Additionally, the regulations that the USPTO has put in place to evaluate gene patents provide an excellent review of the arguments made against gene patents and the USPTO's response to those arguments. *See generally* 66 Fed. Reg. 1092 (Jan. 5, 2001).

⁹⁶ *See id.* at 1095; *see also* Andrews & Paradise, *supra* note 53, at 405.

⁹⁷ Andrews & Paradise, *supra* note 53, at 409.

⁹⁸ *See, e.g., id.* at 403; Lindsey Singeo, Note, *The Patentability of the Native Hawaiian Genome*, 33 AM. J.L. & MED. 119, 124-25 (2007); Crichton, *supra* note 52; American College of Medical Genetics, Position Statement on Gene Patents and Accessibility of Gene Testing (Aug. 2, 1999), http://www.acmg.net/StaticContent/StaticPages/Gene_Patents.pdf [hereinafter *ACMG Position Statement*].

⁹⁹ Westhoff, *supra* note 47, at 7-8; ACMG Position Statement, *supra* note 98.

¹⁰⁰ Andrews & Paradise, *supra* note 53, at 405.

¹⁰¹ *Id.*

¹⁰² These costs can both be in terms of medical expenses and in terms of the prevention of the creation of improved health care techniques. *See* Greenfield, *supra* note 10, at 232-36.

accessibility of genetic tests, the quality of genetic tests available, and the number of medical professionals adequately trained to diagnose and properly care for genetic diseases.¹⁰³ These concerns are not unfounded. In a study evaluating the effects of patents on genetic testing services, researchers found that 25% of the laboratories had stopped performing a specific genetic test because of a patent, and 53% of the laboratories had decided not to develop a new genetic test for the same reason.¹⁰⁴ Thus, the costs of gene patents have reduced the availability of useful genetic tests to patients.¹⁰⁵ In fact, biotechnology companies themselves have even expressed concerns about the ramifications of gene patents for healthcare costs.¹⁰⁶

A third objection is that gene patents hinder research.¹⁰⁷ The American College of Medical Genetics argues that enforcement of genetic patents has led to either exclusive licenses that limit testing of a gene to a single laboratory or non-exclusive licenses with excessive fees.¹⁰⁸ These licensing agreements can effectively halt research by making it too expensive to study.¹⁰⁹ Research can also be halted when patent holders refuse to license the gene to other researchers.¹¹⁰ For example, one researcher abandoned a research project on women with early-stage breast cancer after the company owning the patents to two of the genetic mutations that cause breast cancer refused to license the tests necessary for the research.¹¹¹

¹⁰³ ACMG Position Statement, *supra* note 98; *see also* Malinowski, *supra* note 1, at 61 n.123 (“[S]ome commentators are asserting that intellectual property rights . . . are impeding access to resulting genetic tests for medical use . . .”); Crichton, *supra* note 52 (arguing countries without gene patents offer better genetic testing).

¹⁰⁴ Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. OF MOLECULAR DIAGNOSTICS 3, 3 (2003), available at <http://jmd.amjpathol.org/cgi/content/full/5/1/3>. The researchers noted that almost all laboratory directors felt the patents negatively effect clinical testing. *Id.*

¹⁰⁵ *Id.* at 8.

¹⁰⁶ *E.g.*, Andrew Pollack, *Is Everything for Sale?: Patenting a Human Gene As if It Were an Invention*, N.Y. TIMES, June 28, 2000, at C1 [hereinafter Pollack, *Patenting a Human Gene*] (“Dr. Robert I. Levy, senior vice president for science and technology at American Home Products, calls the gene patenting situations a ‘minefield.’ Finding out who owns rights to what takes an increasing amount of time . . . Royalties paid to holders of patents on genes, research mice and other tools can total 12 to 14 percent of the cost of a drug, he said, making some products uneconomical to produce.”).

¹⁰⁷ *See, e.g.*, ACMG Position Statement, *supra* note 98.

¹⁰⁸ *Id.* (stating gene patents have led to “monopolistic licensing that limits a given genetic test to a single laboratory, royalty-based licensing agreements with exorbitant up-front fees and per-test fees, [or] licensing agreements that seek proportions of reimbursement from testing services”).

¹⁰⁹ *See* Crichton, *supra* note 52. Crichton observes that the cost of the genetic sequence for Hepatitis C has encouraged many researchers to study topics that cost less. *Id.*

¹¹⁰ Andrews, *Benefits of Biobanks*, *supra* note 71, at 26.

¹¹¹ Kimberly Blanton, *Corporate Takeover Exploiting the US Patent System, A Single Company Has Gained Control Over Genetic Research and Testing for Breast Cancer. And Scientists, Doctors, and Patients Have to Play By its Rules*, BOSTON GLOBE, Feb. 24, 2002, Magazine, at 10. The researcher could have sent in samples to the company for testing, but elected not to because he prefers his own test, which would provide him with greater information than the results provided by the company. *Id.*

Finally, many people object to gene patents on moral grounds.¹¹² In 1995, religious leaders of over eighty faiths and denominations held a press conference expressing their view that since genes are a part of nature, they should not be patented.¹¹³ Although the precise nature of the objections varied by faith, the religions opposed to gene patents include Methodists,¹¹⁴ Southern Baptists,¹¹⁵ Episcopalians,¹¹⁶ Muslims,¹¹⁷ and Reform Jews.¹¹⁸ The common theme among these objections is that gene patents involve “the commodification of life” because they place a commercial value on human life and reduce life to a marketable product.¹¹⁹ Similarly, others have expressed the general view that genes should remain a part of our shared knowledge base.¹²⁰ Thus, people object to gene patents for several reasons. Given the myriad of issues a potential donor could have with gene patents, donors need some

¹¹² *E.g.*, Westhoff, *supra* note 47, at 8-9. These concerns also raise ethical issues when indigent and other vulnerable groups are involved. See Marina L. Whelan, Note, *What, if Any, Are the Ethical Obligations of the U.S. Patent Office?: A Closer Look at the Biological Sampling of Indigenous Groups*, 2006 DUKE L. & TECH. REV. 0014, ¶ 20 (2006), available at <http://www.law.duke.edu/journals/dltr/articles/pdf/2006DLTR0014.pdf>. Researchers frequently fail to consider the effect their research may have on these groups. *Id.* ¶ 10. In particular, researchers often fail to take into account indigenous groups’ belief that biological tissues are sacred and attempt to patent the genes they discover. *Id.* ¶ 10, 22. In one case, a Guayami woman’s tissue was used to develop a patented cell line without the permission of the woman or the tribe. *Id.* ¶ 13. This provoked protests from numerous groups, including the President of the Guayami General Congress and the Rural Advancement Foundation International. *Id.* ¶ 14. Ultimately the patent application was withdrawn. *Id.* These situations cause tension between researchers and critics, who argue that the researchers are exploiting the indigenous and other vulnerable groups. *Id.* ¶ 10. These critics are also concerned that the USPTO does not have the resources to deal with these issues. See Hatfield, *supra* note 43, at 6.

¹¹³ Richard Stone, *Religious Leaders Oppose Patenting Genes and Animals*, 268 SCIENCE 1126, 1126 (1995). This viewpoint is not necessarily linked to any one religion, but rather is also a general moral argument that some critics make. See, e.g., Pollack, *Patenting a Human Gene*, *supra* note 106.

¹¹⁴ The Methodist Church created a genetic task force which in 1992 “concluded that ‘exclusive ownership rights of genes as a means of making genetic technologies accessible raises serious theological concerns.’” Stone, *supra* note 113, at 1126.

¹¹⁵ The Executive Director of the Southern Baptist Convention’s Christian Life Commission stated that “granting patents on genes or organisms ‘represents the usurpation of the ownership rights of the Sovereign of the universe.’” *Id.*

¹¹⁶ A former Episcopal minister stated that companies should not be able to make profits off our “common human heritage.” *Id.* (internal quotation marks omitted).

¹¹⁷ The Executive Director of the American Muslim Counsel stated “[t]he engineering of humans and human genes raises serious concerns for Muslims.” *Id.* (internal quotation marks omitted).

¹¹⁸ A Rabbi associated with the Religious Action Center of Reform Judaism recognized that while “Jewish tradition has always stressed a reconciliation of religion and science,” the patenting process of human genes and living organisms was not necessary for a healthy biotechnology industry. *Id.* (internal quotation marks omitted).

¹¹⁹ See, e.g., *id.* Stone defines the “commodification of life” as “the reduction of life to its commercial value and marketability.” *Id.* (internal quotation marks omitted).

¹²⁰ *E.g.*, *Stifling or Stimulating—The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. On Courts, the Internet, and Intellectual Property of the H. Judiciary Comm.*, 110th Cong. 8 (2007) (statement of Lawrence Sung, J.D., Ph.D., Law School Professor and Intellectual Property Law Program Director, University of Maryland, School of Law, Baltimore, MD) (“[G]enes are simply something that we have a sense should be part of the public common.”).

mechanism to provide them with a choice whether their tissue will be used for commercial purposes.

C. *Greenberg v. Miami Children's Hospital: An Example of How Donors' and Researchers' Interests May Conflict*

The opposing viewpoints regarding the commercialization of scientific research resulted in a conflict between donors and a researcher in *Greenberg v. Miami Children's Hospital Research Institute, Inc.*¹²¹ In this case, a group of nonprofit organizations and individuals donated money, tissue samples, and other materials to a researcher in the hopes that he would discover the gene responsible for Canavan's disease,¹²² a genetic disease that primarily affects Jewish children.¹²³ The nonprofit organizations and individuals expected that the ongoing research would remain in the public domain,¹²⁴ where it would be freely available to other researchers.¹²⁵ However, the researcher patented the gene responsible for Canavan's disease and a screening test for the gene shortly after it was discovered.¹²⁶ This meant that any other researcher that wanted to research the disease must first obtain a license from the patentee.¹²⁷ As a result, the patent allowed the researcher to restrict research related to the gene or any of the gene's mutations.¹²⁸

Once the nonprofit organizations and individuals learned about the patent, they brought suit, alleging, inter alia, lack of informed consent, conversion, and unjust enrichment.¹²⁹ The court dismissed the lack of informed consent claim, concluding that such a duty would "chill medical research."¹³⁰ However, the court did not provide much evidence to support its claim that requiring researchers to disclose financial interests would chill research.¹³¹ Indeed, the *Greenberg* plaintiffs criticized this in their motion for reconsideration, stating that "[t]he Court's conclusion that extending the duty of informed consent to

¹²¹ 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

¹²² *Id.* at 1067.

¹²³ Canavan's disease "is a relatively rare, but always fatal, inherited, degenerative brain disorder that primarily affects children of eastern and central European Jewish . . . descent." Canavan Foundation, *What Is Canavan Disease?*, <http://www.canavanfoundation.org/canavan.php> (last visited Jan. 31, 2009).

¹²⁴ *Greenberg*, 264 F. Supp. 2d at 1067.

¹²⁵ See BLACK'S LAW DICTIONARY 1265 (8th ed. 2004) (defining "public domain" as "[t]he universe of inventions and creative works that are not protected by intellectual-property rights and are therefore available for anyone to use without charge").

¹²⁶ *Greenberg*, 264 F. Supp. 2d at 1067.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.* at 1067-68. Plaintiffs also alleged breach of fiduciary duty, fraudulent concealment, and misappropriation of trade secrets. *Id.* at 1066. However, these causes of action are not discussed in depth here because the vast majority of the literature has focused on the informed consent, conversion, and unjust enrichment claims.

¹³⁰ *Id.* at 1070-71.

¹³¹ *Id.* at 1070.

include disclosure of financial interests ‘would chill medical research’ is an issue that demands factual development and expert testimony and which [we] can [establish] as demonstrably untrue.”¹³²

The court also dismissed the conversion claim, reasoning that the donors had no legally cognizable property interest in the donated tissue.¹³³ The court rejected the donors’ argument that they had a property interest in their tissue samples because the biological tissues “were donations to research without any contemporaneous expectations of return of the body tissue and genetic samples.”¹³⁴ Accordingly, the only claim to survive summary judgment was an unjust enrichment claim.¹³⁵ This claim was ultimately settled by the parties in a settlement that provided the researcher would continue collecting licensing royalties on genetic testing, but would permit other researchers to do research on the gene without collecting licensing royalties.¹³⁶

Despite the *Greenberg* court’s purported interest in furthering science, many legal analysts and scientists have concluded that the *Greenberg* result is detrimental to the advancement of scientific research.¹³⁷ Most notably, the court cited the fear that enabling donors to have a say in what happens to their body parts after the donation occurred would give them too much “dead-hand control,”¹³⁸ and that such continuing control by donors over the use of their donated tissues would ultimately stifle science.¹³⁹ However, the *Greenberg* court failed to

¹³² Plaintiffs’ Motion and Memorandum of Law for Reconsideration of Order Dismissing Count I of Plaintiffs’ Complaint ¶ 5, *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003) (No. 02-22244-CIV-MORENO), 2004 WL 2247051. Additionally, the *Greenberg* opinion has been critiqued as “an internally inconsistent ruling that fails to provide donors or researchers much useful guidance.” Russell Korobkin, “*No Compensation*” or “*Pro Compensation*”: *Moore v. Regents and Default Rules for Human Tissue Donations*, 40 J. HEALTH L. 1, 11 (2007) [hereinafter Korobkin, *Default Rules*].

¹³³ *Greenberg*, 264 F. Supp. 2d at 1074-76.

¹³⁴ *Id.* at 1074.

¹³⁵ *Id.* at 1072-73, 1077.

¹³⁶ Although the settlement was confidential, a press release stated that it “provides for continued royalty-based genetic testing by certain licensed laboratories and royalty-free research by institutions, doctors, and scientists searching for a cure.” Canavan Foundation, *Joint Press Release* (Sept. 29, 2003), http://www.canavanfoundation.org/news/09-03_miami.php.

¹³⁷ See, e.g., Baird, *supra* note 10, at 336-37 (suggesting that the case may harm “the perceived trust between researcher and patient—a relationship of trust and confidence without which research collaborations would fail”); see also Hanes, *supra* note 12, at 412 (making a similar criticism of the *Catalona* case, discussed *infra* Part III.B, stating that it may “negatively affect tissue donation”).

¹³⁸ In property law, the notion of dead-hand control refers generally to the notion that a decedent could continue to control the distribution of his or her wealth in such a manner that it would continue to control the behavior of living beneficiaries, and that certain types of dead-hand control should be restricted. See BLACK’S LAW DICTIONARY 426 (8th ed. 2004) (entry for “deadhand control”). Here, the court used the phrase to create an analogy between a decedent continued control over beneficiaries after death and a tissue donor’s continued control over the researcher’s conduct regarding the tissue sample after the donation has been made. See *Greenberg*, 264 F. Supp. 2d at 1071.

¹³⁹ *Greenberg*, 264 F. Supp. 2d at 1071 (stating “this extra duty would give rise to a type of dead-hand control that research subjects could hold because they would be able to dictate how medical research progresses”).

realize that the lack of donor control itself may in fact stifle science by reducing the number of people willing to donate their biological tissues to research.¹⁴⁰ This makes *Greenberg* a particularly interesting backdrop for examining the possible effects of solutions attempting to balance the interests of both donors and researchers.

III. AN ANALYSIS OF PROPOSED SOLUTIONS

Greenberg demonstrates how the increasing commercialization of science can lead to conflicts between donors and researchers. Indeed, donors' interests must be protected and balanced against both the researchers' and the public's interest in furthering science.¹⁴¹ However, the court's analysis of the *Greenberg* claims—and the subsequent discussion following that decision—raises the question of whether the existing legal framework sufficiently balances these interests. In particular, the majority of scholarship has focused largely on unjust enrichment, enhanced property rights in donated tissues, and informed consent.¹⁴² The following presents some of the arguments made by scholars in favor of each of these doctrines and then analyzes the effect each doctrine would likely have on researchers and donors.

A. Unjust Enrichment

The unjust enrichment cause of action is particularly important since it was the sole cause of action to survive summary judgment in *Greenberg*.¹⁴³ The court, applying Florida law, stated that the elements of unjust enrichment were, “(1) the plaintiff conferred a benefit on the defendant, who had knowledge of the benefit; (2) the defendant voluntarily accepted and retained the benefit; and (3) under the circumstances it would be inequitable for the defendant to retain the benefit without paying for it.”¹⁴⁴ Since unjust enrichment is an equitable doctrine, damages will vary based on the facts of the individual case, but

¹⁴⁰ After all, there are a number of reasons donors may object to the use of their tissues for commercial purposes. See *infra* Part II.A-B. If donors have no control over the use of their tissue, they may choose not to donate at all, thus reducing the number of tissue samples available for research. See Eric B. Chen, *Who Owns the Property Rights to Your Genetic Material?*, 13 U. BALT. INTELL. PROP. L.J. 1, 9 (2004); Whelan, *supra* note 112, ¶ 4.

¹⁴¹ See Michele Goodwin, *Formalism and the Legal Status of Body Parts*, 2006 U. CHI. LEGAL F. 317, 359-60 (2006) (“That Congress wanted biotechnology to thrive cannot in contemporary terms be interpreted as granting the biotech industry immunity from judicial scrutiny.”).

¹⁴² Some scholars also select a combination of several models. See, e.g., Gitter, *supra* note 10, at 338-44 (proposing a combination of a property interest and a liability rule); Baird, *supra* note 10, at 347-48 (proposing a combination of the informed consent and benefit-sharing models).

¹⁴³ *Greenberg*, 264 F. Supp. 2d at 1077.

¹⁴⁴ *Id.* at 1072.

in certain circumstances the disgorgement of profits acquired from the patenting of research may be a potential form of relief.¹⁴⁵

Despite the fact that some scholars find unjust enrichment claims and other liability theories desirable to protect donors whose tissues are used for commercial purposes because they are flexible and can thus cover numerous situations,¹⁴⁶ these theories pose three key problems. First, these claims are exceptionally broad and provide no clear guidance for researchers wishing to avoid liability.¹⁴⁷ Ironically, it is the broadness of unjust enrichment claims that makes the doctrine so desirable to some scholars.¹⁴⁸ These scholars find the broadness appealing because it provides flexibility for achieving an appropriate balance between donors' and researchers' competing interests.¹⁴⁹ Yet this broadness also results in a lack of certainty for both donors and researchers.¹⁵⁰

While technically researchers have no positive duty under existing law to inform tissue donors of any potential proprietary uses of the resulting research,¹⁵¹ the result of unjust enrichment actions like the one brought in *Greenberg* is the creation of a *de facto* informed consent requirement.¹⁵² In other words, it provides an equitable remedy where there are no complementary legal guidelines or framework. While these actions will likely result in researchers disclosing potential proprietary uses,¹⁵³ the use of unjust enrichment claims means that researchers have no clear guidelines regarding what must be disclosed or the procedures

¹⁴⁵ Univ. of Colo. Found. v. Am. Cyanamid Co., 153 F. Supp. 2d 1231, 1243-44 (D. Colo. 2001). Researchers at the University of Colorado developed a reformulation technique for prenatal vitamins that they intended to freely release into the public domain. *Id.* at 1242. The researchers intended for Cyanamid to use their work to develop improved prenatal vitamins, but they also intended for other manufacturers of prenatal vitamins to use their work. *Id.* However, Cyanamid patented the technique by falsely claiming that it was a Cyanamid researcher who developed it. *Id.* In a preliminary ruling on the issue of damages, the court stated that in the context of a situation where "an inventor [is] deprived of his prerogative *not* to patent, or to refuse to allow another to patent, his inventions," the disgorgement of profits is an appropriate remedy. *Id.* at 1242-44. It is possible that in a situation where tissue donors intend to keep the results of research on their tissues in the public domain, but the researcher patents those results, a court would similarly find that the disgorgement of profits is an appropriate remedy.

¹⁴⁶ See, e.g., Greenfield, *supra* note 10, at 237; Larry I. Palmer, *Should Liability Play a Role in Social Control of Biobanks?*, 33 J.L. MED. & ETHICS 70, 77 (2005).

¹⁴⁷ See Gitter, *supra* note 10, at 337-38.

¹⁴⁸ See, e.g., Greenfield, *supra* note 10, at 237; Palmer, *supra* note 146, at 72.

¹⁴⁹ E.g., Greenfield, *supra* note 10, at 237 ("Although not limitless, . . . examples of potential claims illustrate the far-reaching possibilities of the unjust enrichment claim to deter the practice of patenting human genetic material."); Palmer, *supra* note 146, at 72 (noting the importance "of liability rules in arriving at the appropriate institutional balance between research goals and promises versus individual and group desires to have some degree of social control over the research enterprise").

¹⁵⁰ This vagueness has led one author to state that unjust enrichment claims are "too ad hoc . . . to be relied upon for future research participants." Gitter, *supra* note 10, at 338.

¹⁵¹ See Greenfield, *supra* note 10, at 248-49.

¹⁵² See Korobkin, *Default Rules*, *supra* note 132, at 13.

¹⁵³ See Palmer, *supra* note 146, at 72 (noting the purpose of a liability action is to encourage information disclosure).

necessary to accomplish disclosure.¹⁵⁴ Rather, appropriate disclosure determinations can be made only after-the-fact.¹⁵⁵ Although this flexibility can be attractive, as it allows for disclosure to vary with “changing social mores and attitudes,”¹⁵⁶ it comes at the clear expense of researcher certainty. As a result, unjust enrichment claims do not adequately protect researchers’ interest in efficiency, as the researchers must determine what disclosures are appropriate.¹⁵⁷ Additionally, unjust enrichment claims do not adequately protect donors’ interests in receiving the appropriate disclosures since there are no clear guidelines.

Second, unjust enrichment claims require that donors discover that their tissues have been used for a commercial purpose.¹⁵⁸ Although this issue poses a challenge to any plaintiff, it is particularly problematic in the case of unjust enrichment precisely because researchers do not have an affirmative or explicit duty to disclose any potential proprietary uses.¹⁵⁹ If the researchers do not disclose this information, or if they disclose too little information, some donors may erroneously assume that the research will remain in the public domain.¹⁶⁰ Thus, these donors will be at an even greater disadvantage than donors who make no assumptions that the research will remain in the public domain because they will not be aware of the possibility that their tissues will be used for profitable purposes.

Finally, despite the flexibility of equitable relief, unjust enrichment claims may still not provide plaintiffs with the relief they desire. Although the disgorgement of profits is one potential form of relief,¹⁶¹ this remedy likely will be rarely granted. Since unjust enrichment is an equitable doctrine, courts may take into account whether it is just for the defendants to keep the profits.¹⁶² In making this determination, courts have suggested that disgorgement of profits is most

¹⁵⁴ This contradictory position of the *Greenberg* court has been noted by scholars. *See, e.g., Greenfield, supra* note 10, at 227 (“The judge declined to extend a ‘duty of informed consent to the researcher’s economic interests’ and yet the lack of disclosure to the plaintiffs of the defendants’ intent to patent and profit from the research was considered unjust.”).

¹⁵⁵ *Palmer, supra* note 146, at 77.

¹⁵⁶ *Id.*

¹⁵⁷ Alternatively, the researcher could disclose everything. However, this would be undesirable for the researcher because of the added expense it would create. Similarly, it would be undesirable for the donor because it could result in important information about significant conflicts of interest being buried by a substantial number of relatively small conflicts of interests that have little to no effect on the donor’s decision to donate.

¹⁵⁸ *See, e.g., Lori Andrews, The Battle Over the Body, TRIAL, Oct. 2006, at 22, 26* [hereinafter *Andrews, Battle Over the Body*] (“[M]ost people whose tissue is mined for patentable genes do not even know they have been donors.”).

¹⁵⁹ *See Greenfield, supra* note 10, at 248-49.

¹⁶⁰ Although there will be donors that are neutral on this issue, there is reason to believe a significant amount of tissue donors, if made aware of the issue, would prefer to donate their tissue samples to research remaining in the public domain. *See supra* note 8 and accompanying text.

¹⁶¹ *E.g., Univ. of Colo. Found. v. Am. Cyanamid Co., 153 F. Supp. 2d 1231, 1243-44 (D. Colo. 2001); San Bernardino v. Walsh, 69 Cal. Rptr. 3d 848, 855-57 (Ct. App. 2007).*

¹⁶² *Walsh, 69 Cal. Rptr. 3d at 855-56.*

appropriate where the defendant acted in a particularly culpable manner, such as when the defendant acts in conscious disregard of others' rights.¹⁶³ Additionally, monetary damages are inadequate for donors, such as the *Greenberg* plaintiffs, that are seeking to have the research results remain in the public domain.¹⁶⁴

Thus, unjust enrichment claims are appealing because they are broad and flexible.¹⁶⁵ However, they also pose significant problems, as they fail to provide clear guidelines regarding what information must be disclosed.¹⁶⁶ Furthermore, unjust enrichment claims will only protect donors that already are aware that their tissues may be used for profitable purposes.¹⁶⁷ Finally, unjust enrichment claims may not provide adequate remedies for plaintiffs.¹⁶⁸

B. *Property Interests and Conversion*

Another proposed way to protect donors' interests is providing tissue donors with a property interest in their tissues.¹⁶⁹ This property interest would grant tissue donors more control over their donations,¹⁷⁰ including enabling tissue donors to bring an action of conversion if their tissues are used for unauthorized uses.¹⁷¹ Proponents of a property interest argue that this is consistent with how people view their bodies, as people intuitively feel they own their bodies.¹⁷² These scholars also argue that a property interest is also consistent with the current trend to view genetic materials as property.¹⁷³ For example, researchers increasingly

¹⁶³ For example, in *American Cyanamid*, the court stressed the "extreme culpability" of the defendants in its decision to grant disgorgement of profits. 153 F. Supp. 2d at 1244. Similarly, in *Walsh*, the court reasoned that "a person acting in conscious disregard of the rights of another should be required to disgorge all profit." 69 Cal. Rptr. 3d at 856.

¹⁶⁴ Baird, *supra* note 10, at 337.

¹⁶⁵ See *supra* notes 143-145 and accompanying text.

¹⁶⁶ See *supra* notes 146-157 and accompanying text.

¹⁶⁷ See *supra* notes 158-160 and accompanying text.

¹⁶⁸ See *supra* notes 161-164 and accompanying text.

¹⁶⁹ See, e.g., Andrews, *Battle Over the Body*, *supra* note 158, at 24.

¹⁷⁰ Baird, *supra* note 10, at 345; see also Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 748 (2004) (noting "property promises powerful protections").

¹⁷¹ Conversion is "[t]he wrongful possession or disposition of another's property as if it were one's own; an act or series of acts of willful interference, without lawful justification, with an item of property in a manner inconsistent with another's right, whereby that other person is deprived of the use and possession of the property." BLACK'S LAW DICTIONARY 356 (8th ed. 2004). In *Greenberg*, the court dismissed the plaintiffs' claim for conversion because the donors lacked a property right in their tissues. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003). Thus, recognizing a property interest in their tissues may make these claims justiciable. Goodwin, *supra* note 141, at 371.

¹⁷² See, e.g., Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES, Apr. 16, 2006, § 6, at 38. At the same time, a similar argument is made by opponents to property rights in biological tissues. See e.g., Goodwin, *supra* note 141, at 318 (arguing property rights are against "the established normative view of the body as a sacred, inalienable object").

¹⁷³ Suter, *supra* note 170, at 746.

view genetic materials and information as property because of potential patent property rights.¹⁷⁴

Finally, some scholars argue that recognizing a property interest in tissues is important because it may permit donors to sell their tissues.¹⁷⁵ These scholars contend that the sale of tissue donations would ensure the tissues were used for the most efficient use.¹⁷⁶ They also contend that it is only fair that the donor profits from the sale of their tissues because all of the other parties involved profit from the research.¹⁷⁷ Thus, the argument that tissue donors should have a property interest and be able to sell their bodily tissues reflects the general movement towards the commercialization of scientific research in past years.¹⁷⁸

Although the granting of explicit property rights may appear to be a sufficient method to protect donors' interests, it does not work for donors that generally object to the commercialization of science. For example, recognizing a property interest in a donor's bodily tissues may be an uncomfortable form of protection for donors who object to the increasingly commercial nature of scientific research.¹⁷⁹ In short, the granting of a property interest would increase the total number of market transactions by adding yet another party that may receive compensation.¹⁸⁰ Additionally, granting a property interest in the donor's bodily tissues invokes the same moral and religious objections that have been expressed with gene patents.¹⁸¹ Indeed, one of the primary arguments against granting donors with property rights in their biological tissues is that it commodifies, or commercializes, life.¹⁸²

Not all scholars who argue that property rights are necessary to protect donors agree that tissue donors should be allowed to sell their tissues.¹⁸³ Scholars who argue for a property right that does not permit tissue donors to sell their tissues ground their arguments in the idea that

¹⁷⁴ *Id.* at 745-46.

¹⁷⁵ Gitter, *supra* note 10, at 262-63; Gary E. Marchant, *Property Rights and Benefit-Sharing for DNA Donors?*, 45 JURIMETRICS J. 153, 165 (2005). Similarly, benefit sharing has been proposed. Chen, *supra* note 140, at 10. This model provides for a licensing scheme where patients give up their personal property claims to their tissues in exchange for a small percentage of the commercial profits generated from the research results. *Id.* This model assumes that tissue donors must and do accept the commercialization of research. *See, e.g., id.*

¹⁷⁶ Marchant, *supra* note 175, at 165. These scholars argue that the sale of tissues ensures that the bodily tissue goes to the researcher that values it the most. *Id.* However, this position assumes that the researcher that values the tissue the most will put it to the most efficient use. *Id.*

¹⁷⁷ *Id.*; Suter, *supra* note 170, at 757.

¹⁷⁸ Suter, *supra* note 170, at 745; *see also supra* Part I.

¹⁷⁹ *See supra* Part II.

¹⁸⁰ *See supra* Part II.

¹⁸¹ *See* Gitter, *supra* note 10, at 277; *see also supra* notes 112-120 and accompanying text.

¹⁸² *See, e.g.,* Yael Bregman-Eschet, *Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 25 (2006) (stating property rights in biological tissues "disregard[] personhood values and interest in the self").

¹⁸³ *See* Suter, *supra* note 170, at 757.

the concept of property is flexible.¹⁸⁴ Specifically, the commercialization of human tissue is not a necessary result of recognizing a property interest in bodily tissues.¹⁸⁵ In other words, these scholars argue it is possible to provide for a property right that would allow for donors' control over their tissues by providing for a conversion action without permitting donors to exert control over their tissues by selling them.¹⁸⁶

On its face, this suggestion appears to resolve any concerns donors may have about a property interest in biological tissues commodifying life and adding to the commercial interests of researchers. However, the ability to freely sell property, and thus commercialization, is the norm of property law, not the exception.¹⁸⁷ Thus, even if donors were provided a property right without the ability to sell their tissues, concerns remain about the inherent market values associated with property rights.¹⁸⁸ Since people associate market values with property rights, a property right will still have the effect of making people comfortable with viewing biological tissues as a commercial item.¹⁸⁹ In other words, regardless of whether donors are permitted to sell their body tissues, recognizing a property right brings with it an assumption that those items that are property are most appropriately allocated through market mechanisms.¹⁹⁰ Therefore, there is a significant risk that recognizing a property right in donors' tissues, even if that right explicitly prevents donors from selling their tissues, may still commodify life.¹⁹¹

On the other hand, even if courts were to recognize that donors have a property interest in their tissues,¹⁹² it may not provide donors

¹⁸⁴ See Korobkin, *Default Rules*, *supra* note 132, at 4; Baird, *supra* note 10, at 345.

¹⁸⁵ See Baird, *supra* note 10, at 345.

¹⁸⁶ See, e.g., Suter, *supra* note 170, at 757.

¹⁸⁷ *Id.* at 748.

¹⁸⁸ See *id.* at 803 (“[A]llowing genetic information to be a commodity in some instances might drive us to think of it *solely* as a commodity.”); see also Goodwin, *supra* note 141, at 318 (arguing that recognizing a property right in body tissues “would violate the established normative view of the body as a sacred, inalienable object”).

¹⁸⁹ *Id.*

¹⁹⁰ E. RICHARD GOLD, *BODY PARTS: PROPERTY RIGHTS AND THE OWNERSHIP OF HUMAN BIOLOGICAL MATERIALS* 9 (1996). E. Richard Gold explains that there are three aspects of this assumption:

The first of these is that different objects are valuable to us, and ought to be distributed, according to different modes of valuation. The second component is that, whatever these different modes of valuation are, they can be translated into or thought of in terms of a market price. Third, the market will allocate the object in accordance with the most significant of these modes of valuation, using market price as a guide.

Id.

¹⁹¹ See Gitter, *supra* note 10, at 312 (“[W]idespread societal acceptance of the notion that research participants possess a property interest in their tissue will lead individuals to expect compensation . . .”).

¹⁹² In reality, this is rather unlikely, as current biotechnology jurisprudence has rejected the notion of the body as property. See Goodwin, *supra* note 141, at 319. It is much more likely that

much protection. As noted previously, donors may not be aware that their donations may be used for commercial purposes.¹⁹³ Without being aware of this possible use of their tissues, many donors who might want to negotiate to ensure their tissues are not used for proprietary research will not realize that they need to do so.¹⁹⁴ Thus, recognizing a property interest does not help donors that are unaware that the researcher may benefit financially from the research results,¹⁹⁵ but who would object to this gain if asked.

This is particularly evident in light of the decisions by the district court and the Eighth Circuit in *Washington University v. Catalona*.¹⁹⁶ In *Catalona*, Washington University filed a declaratory action against a former researcher, Dr. Catalona, seeking a declaration of ownership over biological materials in a biorepository,¹⁹⁷ which contains tissue sample donations from which DNA can be obtained for research.¹⁹⁸ The donors and Dr. Catalona argued that Dr. Catalona should be granted possession of the biological materials.¹⁹⁹ They reasoned the materials were donated with the “intent” that they would be used for Dr. Catalona’s research.²⁰⁰ Additionally, the donors argued they “retained ownership rights in their donated biological materials and [could] withdraw said materials and have them transferred . . . via their discontinuation of participation in any research at [Washington University] and their signing of Dr. Catalona’s consent form.”²⁰¹

such an interest would be the result of legislation, which would be able to specify the nature of the interest and thus *may* provide more protection.

¹⁹³ See Andrews, *Battle Over the Body*, *supra* note 158, at 26.

¹⁹⁴ These donors could choose not to have their tissue donations used for proprietary uses for a number of reasons. For an overview of objections to the commercialization of science, see *supra* Part II.

¹⁹⁵ Most donors will recognize that the researcher will benefit financially from the research in terms of the researcher’s salary from his or her employer. Similarly, many donors will also likely recognize that the researcher may receive indirect financial benefits if the research results are important to the research community. For example, a successful research project may increase the researcher’s reputation in the community or result in the researcher gaining tenure at an educational institution, both of which may ultimately result in a salary increase. However, the key concern for the purposes of this Note is that donors will not be aware of direct financial benefits the researcher may receive. These direct financial benefits include, for example, royalty fees received from licensing patents developed as a result of the research.

¹⁹⁶ *Washington Univ. v. Catalona (Catalona I)*, 437 F. Supp. 2d 985 (E.D. Mo. 2006), *aff’d*, 490 F.3d 667 (8th Cir. 2007).

¹⁹⁷ *Id.* at 987. Dr. Catalona began gathering prostate cancer samples during his employment at Washington University. Skloot, *supra* note 172. Washington University obtained the samples years before the litigation arose. *Id.* However, when Dr. Catalona took a position at Northwestern University, he sent a letter to many of the donors in the biorepository with a release form instructing Washington University to release the samples upon the doctor’s request. *Catalona I*, 437 F. Supp. 2d at 993.

¹⁹⁸ Bregman-Eschet, *supra* note 182, at 8. These biorepositories are also referred to as “DNA banks or biobanks.” *Id.*

¹⁹⁹ *Catalona I*, 437 F. Supp. 2d at 994. Interestingly, Dr. Catalona abandoned the argument that he owned the materials. *Id.* at 994 n.11.

²⁰⁰ *Id.* at 994.

²⁰¹ *Id.*

Ultimately, both the District Court and the Eighth Circuit determined that Washington University owned the tissues because the donors had made a valid inter vivos gift.²⁰² Under Missouri law, Washington University “bear[ed] the burden to prove by clear and convincing evidence there was (1) present intent of the donor to make a gift, (2) delivery of the property by the donor to the donee, and (3) acceptance of the gift by the donee.”²⁰³ The courts found that Washington University met its burden in proving these elements,²⁰⁴ which are typical elements for an inter vivos gift.²⁰⁵ Importantly, the Eighth Circuit stated that the donors’ ability to withdraw from the study did not mean the transfer was not absolute.²⁰⁶ Rather, it recognized that a valid inter vivos gift may be made subject to the donor’s later exercise of an express revocation right.²⁰⁷

Thus, *Catalona* demonstrates that in order for a property model to adequately protect donors’ interests, the donors must be aware that their tissues may be used for profit-creating purposes. Once aware, the donors could potentially negotiate with the researcher to ensure that their tissues were not used for certain uses.²⁰⁸ For example, they could

²⁰² *Id.* at 997; *Washington Univ. v. Catalona (Catalona II)*, 490 F.3d 667, 676 (8th Cir. 2007). In other words, the donors made a valid gift during their lifetime. BLACK’S LAW DICTIONARY 710 (8th ed. 2004) (entry for “inter vivos gift”). The District Court first applied Missouri property law to reach its conclusion that the university owned the tissues, noting “exclusive possession and control of personal property is *prima facie* evidence of ownership, and anyone else claiming such property bears the burden of proof.” *Catalona I*, 437 F. Supp. 2d at 994. Since Washington University met both of these criteria, the donors had the burden of proving their ownership interest. *Id.* Not surprisingly, the court determined that the donors had not met this burden. *Id.* at 997. The court reasoned:

Both the *Greenberg* and the *Moore* cases found the research participant to be a “donor” who had parted with any semblance of ownership rights once their biological materials had been excised for medical research. Both courts reviewed relevant caselaw, addressed policy considerations, and addressed the implications of applicable federal and/or state laws dealing with biological materials. The Court finds their analysis to be persuasive, and in light of its own review of applicable Missouri law, finds that WU has met its burden in establishing ownership of the subject materials and that the RPs have not put forth adequate evidence to challenge WU’s ownership claim.

Id. However, the Eighth Circuit never addressed this argument. It found that the university owned the tissues as a result of a valid *inter vivos* gift. *Catalona II*, 490 F.3d at 676.

²⁰³ *Catalona II*, 490 F.3d at 674.

²⁰⁴ *Catalona I*, 437 F. Supp. 2d at 994; *Catalona II*, 490 F.3d at 674-77.

²⁰⁵ For example, the *Restatement (Third) of Property* states:

(a) To make a gift of property, the donor must transfer an ownership interest to the donee without consideration and with donative intent.

(b) Acceptance by the donee is required for a gift to become complete. Acceptance is presumed, subject to the donee’s right to refuse or disclaim.

RESTATEMENT (THIRD) OF PROPERTY § 6.1 (2003).

²⁰⁶ *Catalona II*, 490 F.3d at 675.

²⁰⁷ *Id.* (stating “an inter vivos gift nevertheless may be subject to a condition allowing the donor to exercise a particular revocation right in the future”).

²⁰⁸ Although negotiation suggests contract, this condition also could be a permissible condition on the donation. *See, e.g., id.*

negotiate a provision that the tissues could not be used for commercial uses. However, without this negotiation, courts would likely follow the *Catalona* court's lead and find that the donation was a valid and generally unrestricted inter vivos gift.²⁰⁹ This is because the Missouri law regarding inter vivos gifts is sufficiently similar to other inter vivos gift requirements that a court could analogize to the *Catalona* case.²¹⁰ Since courts have been reluctant to grant donors control over their tissues,²¹¹ subsequent courts would likely make this analogy and hold the donors made an inter vivos gift and thus do not retain control over the use of their donations.

Finally, granting property interests in donated tissues is also harmful to the progress of research because it increases researchers' transaction costs.²¹² For example, researchers would face the costs of negotiating donor compensation, including the time and effort required and the increased costs of a potential holdout requesting a very high compensation rate.²¹³ This increase in transaction costs may also trickle down and harm society by slowing the progress of scientific knowledge.²¹⁴ In particular, the increased costs to researchers may decrease investment in biotechnology research, and as a result slow important medical advancements.²¹⁵ Thus, the property solution is inadequate because it poses significant burdens on the researcher and violates potential ethical and moral beliefs of the donor.

C. *Informed Consent*

Some scholars also suggest that informed consent might be used to protect donors.²¹⁶ This doctrine, which was originally developed to protect research participants' autonomy, or individual choice,²¹⁷ requires mandatory disclosure by the researchers to the research participant—in this case, the tissue donor.²¹⁸ Currently, both state and federal laws govern the disclosures the researcher must make in order to obtain

²⁰⁹ See, e.g., *id.* at 676.

²¹⁰ See RESTATEMENT (THIRD) OF PROPERTY § 6.1 (2003).

²¹¹ See, e.g., *Catalona II*, 490 F.3d at 673-77; *Tilousi v. Ariz. State Univ.*, No. 04-CV-1290-PCT-FJM, 2005 WL 6199562, at *4-*5 (D. Ariz. Mar. 3, 2005); *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1074-96 (S.D. Fla. 2003); *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 487-97 (Cal. 1990).

²¹² *Bregman-Eschet*, *supra* note 182, at 25; *Gitter*, *supra* note 10, at 279.

²¹³ *Gitter*, *supra* note 10, at 279-80.

²¹⁴ *Id.* at 277.

²¹⁵ *Id.*

²¹⁶ See, e.g., Kevin L. J. Oberdorfer, Note, *The Lessons of Greenberg: Informed Consent and the Protection of Tissue Sources' Research Interests*, 93 GEO. L.J. 365, 386 (2004).

²¹⁷ Russell Korobkin, *Autonomy and Informed Consent in Nontherapeutic Biomedical Research*, 54 UCLA L. REV. 605, 611 (2007) [hereinafter *Korobkin, Nontherapeutic Biomedical Research*].

²¹⁸ See *id.* at 610; Oberdorfer, *supra* note 216, at 368-69.

informed consent.²¹⁹ These required disclosures include an explanation of the research procedure, the potential risks, and the potential benefits.²²⁰ Additionally, the federal regulations governing research involving humans,²²¹ generally referred to as the Common Rule,²²² also permit optional disclosures of information. Optional disclosures may occur when the Institutional Review Board (IRB), the institutional organization in charge of ensuring research is ethically acceptable,²²³ requires the disclosure of information in order to protect research participants' rights.²²⁴

Informed consent is an appealing solution for donors. The doctrine's historical recognition of the importance of research participants' autonomy²²⁵ nicely complements the idea that donors should have a choice regarding the proprietary use of their tissues. In addition, informed consent ensures that donors are aware their tissues may be used for profit-making purposes, such as gene patents, since this information would be disclosed.²²⁶ Furthermore, informed consent requirements also typically impose a relatively minor burden on researchers. Despite the *Greenberg* court's conclusion that requiring researchers to disclose the potential commercial uses of science would have a devastating impact on science, few scholars have been able to identify these harmful effects.²²⁷

²¹⁹ Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 611. This brief overview of informed consent focuses on informed consent in the nontherapeutic research situation. For a summary of informed consent law in both the treatment and research contexts, see generally Grimm, *supra* note 10.

²²⁰ More specifically, the Common Rule requires that researchers disclose:

[T]he description, purpose, duration, and experimental nature of the study; any reasonably foreseeable risks or discomforts to the subject; any reasonably expected benefits to the subject or to others; appropriate alternative procedures or treatments that might be advantageous to the subject; the extent of privacy and confidentiality of records identifying the subject; the availability of compensation or treatment for possible injuries; contact information in case the subject has questions or concerns; and the right to withdraw from the study at any time without penalty.

Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 610. One author has suggested that the lack of an explicit requirement reflects the fact that scientific research has changed immensely since the Common Rule was created. See Andrews, *Benefits of Biobanks*, *supra* note 71, at 25.

²²¹ See 45 C.F.R. §§ 46.101-.124 (2006).

²²² See Oberdorfer, *supra* note 216, at 367.

²²³ Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941, 953 (2006).

²²⁴ In particular, an "IRB may require that [other] information . . . be given to the subjects when . . . the information would meaningfully add to the protection of the rights and welfare of subjects." 45 C.F.R. § 46.109.

²²⁵ See *id.* at 611.

²²⁶ Granted, informed consent forms are often criticized for being extremely long and difficult to understand. See, e.g., Boyle, *supra* note 11, at 60-61; Gatter, *supra* note 6, at 614-15. However, disclosure of researchers' financial interests in the informed consent form at least provides the information and increases the chances that the donor is aware of these potential uses.

²²⁷ One author went so far as to characterize the court's conclusion as "inapt" and "backward." Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 618. Even an

In fact, one scholar determined that the only potential harm that could occur from the disclosure of a researcher's financial interests would be a reduction in the number of tissue donations.²²⁸ This could occur if a significant number of donors refused to donate their samples to researchers that would profit from them.²²⁹ However, granting donors with a degree of control over their tissue samples may actually open up a new source of donors for those researchers that do not intend to profit from their research.²³⁰

Another burden imposed upon researchers by an informed consent requirement is that researchers would be required to develop a system to keep track of the donor's wishes with regards to the sample's use.²³¹ Currently, researchers do not document any information regarding the donors' intentions for the use of tissue samples.²³² However, oftentimes other types of information about the donor, such as the donors' health records, are stored with the tissues because this information is necessary for the planned research.²³³ As a result, although researchers may find it inconvenient to devise a system to track donors' wishes, this requirement would pose a rather minimal burden on researchers in light of the fact that they already store other information about the donor with the tissue donations. Thus, informed consent permits donors to determine whether their tissue donations will be used for profit-making purposes without generally imposing a significant burden on researchers.

However, informed consent is not a panacea as there are several problems with the current informed consent laws. Indeed, many scholars in favor of requiring disclosure of financial interests acknowledge

author that agreed with the court's dismissal of the informed consent claim recognized that requiring disclosure would place little burden on researchers. See Oberdorfer, *supra* note 216, at 377-78.

²²⁸ See Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 618-19.

²²⁹ *Id.* Indeed, at least one court has refused to accept a decrease in participants as a justification for nondisclosure of information. *Id.* at 619 n.60. That court reasoned that promoting the progress of science by not informing a donor about an aspect of the research, such as the researcher's financial interests, undermines the principle of autonomy that underlies informed consent. See, e.g., *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 844 (Md. 2001) (rejecting "[t]he fact that if such information was furnished, it might be difficult to obtain human subjects for the research" as a justification for nondisclosure of information); see also Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 619.

²³⁰ See Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 618-19. As researchers continue to profit from research, donors will increasingly become aware that their tissues may be used for profitable research. Extending one study's findings to the general public, about 1/3 of potential donors opposes the use of their tissues for profitable research. See *supra* note 8 and accompanying text. If those donors are unable to control whether their tissue is used for profitable research, they will most likely elect not to donate. E.g., Chen, *supra* note 140, at 9. However, if the donors can control whether their tissue is used for profitable research, they will still be able to donate their tissues to research that the researcher will not profit from.

²³¹ See Skloot, *supra* note 172.

²³² *Id.*

²³³ See Henry T. Greely, *Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information*, 34 WAKE FOREST L. REV. 737, 739-41 (1999).

modifications to existing law are necessary since current laws do not require that donors consent to profitable uses of research.²³⁴ In fact, neither the current federal nor state informed consent laws require that researchers disclose any potential profit-making uses of the research results to donors.²³⁵ The federal Common Rule contains no explicit requirement that researchers disclose their financial interests.²³⁶ As a result, any financial disclosures would be optional under the provisions *permitting* the IRB to require additional disclosures.²³⁷ In addition, state common law actions for lack of informed consent do not clearly require financial disclosure.²³⁸ These actions typically only require disclosure of the material risks of physical harm to the research participant as a result of the participant's involvement in the research.²³⁹ Common law actions for lack of informed consent do not typically cover the emotional or economic harms that would result from the non-disclosure of a researcher's financial interests.²⁴⁰

Thus, since neither set of regulations explicitly requires that researchers disclose their financial interests, current federal or state

²³⁴ E.g., Jackson, *supra* note 47, ¶¶ 38-45; Oberdorfer, *supra* note 216, at 386-89.

²³⁵ See Oberdorfer, *supra* note 216, at 366.

²³⁶ Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 610. In fact, some scholars argue that although the current case law virtually requires researchers to put such terms into their informed consent forms, there is a risk in doing so absent an explicit legal duty because they may violate the "no waiver" provision found in the Common Rule. Korobkin, *Default Rules*, *supra* note 132, at 13. This provision states that:

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

45 C.F.R. § 46.116 (2006). The Office for Human Research Protections (OHRP), the body responsible for offering guidance to research institutions regarding interpretation of the federal regulations, see OHRP Fact Sheet, Nov. 8, 2008, <http://www.hhs.gov/ohrp/about/ohrfactsheet.htm>, has interpreted the no waiver provision to mean that it would be improper for researchers to insert a clause in their informed consent forms that is too general. Office for Protection from Research Risks (OPRR), Cooperative Oncology Group Chairpersons Meeting, "Exculpatory Language" in Informed Consent (Nov. 15, 1996), <http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm> [hereinafter Exculpatory Language]; see also Korobkin, *Default Rules*, *supra* note 132, at 13. However, these guidelines go on to say that specific language, such as, "Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur," is permissible. Exculpatory Language, *supra*. However, permissible provisions, as opposed to required provisions, do not adequately protect donors' interests.

²³⁷ See notes 222-224 and accompanying text.

²³⁸ In fact, the state common law doctrine of informed consent most likely does not require disclosure of financial interests. Oberdorfer, *supra* note 216, at 366; see also Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1070-71 (S.D. Fla. 2003) ("declin[ing] to extend the duty of informed consent to cover a researcher's economic interests").

²³⁹ Oberdorfer, *supra* note 216, at 379; see also Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 851 (Md. 2001) (stressing the importance of protecting research participants from physical harm). This focus is likely due to the fact that informed consent originally developed as a cause of action in a therapeutic context, where the research participant directly benefits, and the general requirements reflect this. Grimm, *supra* note 10, at 57-58; Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 611.

²⁴⁰ Oberdorfer, *supra* note 216, at 379.

regulations cannot be relied upon to ensure donors are aware of the potential profitable uses of the research.²⁴¹ Without explicit disclosure requirements, researchers have demonstrated that they are reluctant to provide this information, and when they do it is often vaguely phrased.²⁴² For example, one informed consent form simply states, “You will receive no reimbursement for donating tissue,”²⁴³ without going on to explain the financial rewards that the researchers may receive.

Moreover, even if the Common Rule did mandate disclosure of researchers’ financial interests as scholars have proposed,²⁴⁴ informed consent would still not adequately protect donors. This is because the federal Common Rule does not apply to all research.²⁴⁵ Specifically, Common Rule provisions govern research on humans only when the research is federally funded, or when the research institution has assured the federal government that the Common Rule requirements will be followed.²⁴⁶ The scope of the federal regulations is expanded by the U.S.

²⁴¹ See Skloot, *supra* note 172. This is particularly interesting considering many professional organizations have passed guidelines requiring disclosure of the potential commercial uses of research. Andrews, *Benefits of Biobanks*, *supra* note 71, at 25. For example, the American Medical Association’s Code of Ethics provides:

Physicians contemplating the commercial use of human tissue should abide by the following guidelines: (1) Informed consent must be obtained from patients for the use of organs or tissues in clinical research. (2) Potential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials. (3) Human tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material. (4) Profits from the commercial use of human tissue and its products may be shared with patients, in accordance with lawful contractual agreements. (5) The diagnostic and therapeutic alternatives offered to patients by their physicians should conform to standards of good medical practice and should not be influenced in any way by the commercial potential of the patient’s tissue.

Am. Med. Ass’n, Code of Ethics E-2.08 Commercial Use of Human Tissue, *available at* <http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf> (last visited Mar. 24, 2009) [hereinafter AMA Code of Ethics]. This suggests a general recognition that donors should be made aware of these uses. However, there are only guidelines, and as such, do not generally provide for a justiciable cause of action. See Skloot, *supra* note 172.

²⁴² See Skloot, *supra* note 172. Rebecca Skloot gives several examples of current informed consent provisions:

The norm is still a sentence or two saying leftover blood and tissue can be used for education and research. When it comes to profits, some consent forms come right out and say, “We may give or sell the specimen and certain medical information about you.” Others skip disclosure or say, “You will receive no reimbursement for donating tissue.” Still others admit confusion: “Your sample will be owned by [the university]. . . . It is unknown whether you will be able to gain (participate in) any financial compensation (payment) from any benefits gained from this research.”

Id.

²⁴³ *Id.*

²⁴⁴ See, e.g., Oberdorfer, *supra* note 216, at 386.

²⁴⁵ Skloot, *supra* note 172 (observing that “[i]n the end, much of tissue research is not governed by the Common Rule”); see also Gatter, *supra* note 6, at 587. For an overview of the Common Rule’s requirements, see *supra* note 220.

²⁴⁶ Korobkin, *Nontherapeutic Biomedical Research*, *supra* note 217, at 612. Notably, there are a few states that have incorporated the Common Rule into state law. See Lisa C. Edwards,

Food and Drug Administration regulations, which cover research that involves pharmaceutical drugs and medical devices.²⁴⁷ These Food and Drug Administration regulations impose disclosure requirements that are similar to those imposed by the Common Rule,²⁴⁸ and thus would expand the scope of a federal mandate to disclose financial interests to include research involving pharmaceutical drugs and medical devices not covered by the Common Rule.²⁴⁹ As a result, the Common Rule and its accompanying federal regulations apply to much research involving human participants, but it does not cover all research.²⁵⁰ Thus, if the scope of informed consent was expanded by modifying the federal regulations to mandate disclosure of researchers' financial interests, there may still be donors who do not receive adequate informed consent.

Finally, modifying current informed consent requirements to mandate disclosure of researchers' financial interests is problematic because "true informed consent"²⁵¹ will impose significant burdens on researchers in some situations. Specifically, true informed consent will be burdensome in situations where researchers are unable to adequately disclose their financial interests at the time of the donation, when informed consent is initially obtained.²⁵² Researchers will be unable to give adequate disclosure when they are unaware of their specific financial interests.²⁵³ For example, the researcher may not anticipate that the research results would lead to a commercial use, such as a patent, until the research results are clear. This issue could also arise in the context of stored tissues, where a new commercial use may be discovered years later.²⁵⁴ True informed consent requires specific information, which blanket provisions, such as, "This research may be used for commercial purposes," do not provide.²⁵⁵ Thus, in order to obtain true informed consent, these researchers would be required to re-

Note, *Tissue Tug-of-War: A Comparison of International and U.S. Perspectives on the Regulation of Human Tissue Banks*, 41 VAND. J. TRANSNAT'L L. 639, 647 (2008).

²⁴⁷ 21 C.F.R. § 50.1(a) (2007).

²⁴⁸ See 21 C.F.R. §§ 50.1-27.

²⁴⁹ Research involving pharmaceutical drugs or medical devices automatically is covered by the U.S. Food and Drug regulations. See 21 C.F.R. § 50.1(a). However, it may not be covered by the Common Rule in cases where the research is entirely privately funded and occurs at an institution that has not assured the federal government that all research will comply with the Common Rule requirements. See *supra* notes 245-246 and accompanying text.

²⁵⁰ For example, it would not cover privately-funded research that is not regulated by the U.S. Food and Drug Administration, such as research on the genetic causes of a particular disease, at an institution that has not assured the federal government that the Common Rule requirements will be followed. See *supra* notes 245-249 and accompanying text.

²⁵¹ See Daniel S. Strouse, *Informed Consent to Genetic Research on Banked Human Tissue*, 45 JURIMETRICS J. 135, 142 (2005).

²⁵² See Greely, *supra* note 233, at 738-41 (describing how this issue generally applies to stored tissue samples).

²⁵³ See *id.* at 740-41.

²⁵⁴ When tissue samples are taken, they may be used for unforeseeable research. Strouse, *supra* note 251, at 136. Thus, these studies could result in unexpected commercial uses.

²⁵⁵ See *id.* at 142-43.

contact the donors once these uses became clear.²⁵⁶ However, such a requirement would be extremely costly for the researchers, especially since the researcher may not be able to contact some donors in order to obtain their consent.²⁵⁷ In short, requiring researchers to obtain true informed consent would conflict with the current federal policy to encourage researchers to engage in profitable uses of their research,²⁵⁸ as well as impose significant burdens on these researchers.

Therefore, informed consent is an appealing solution for donors because it provides them with the information necessary to make a choice about the commercial use of their tissues.²⁵⁹ However, this disclosure is not currently required by state or federal informed consent laws,²⁶⁰ and modifying the federal Common Law to mandate disclosure of financial interests would be insufficient because the federal Common Law does not apply to all research.²⁶¹ Additionally, although informed consent generally does not impose a significant burden on researchers,²⁶² it can impose a significant burden when researchers are unaware of their specific potential financial interests at the time of the donation.²⁶³

IV. A PROPOSED UNIFORM DISCLOSURE OF FINANCIAL INTERESTS ACT

It is clear that an increasingly commercial scientific research regime requires that donors have some degree of control over the use of their tissues for profitable purposes.²⁶⁴ As a result, scholars have analyzed several potential causes of action to protect donors.²⁶⁵ Of these, unjust enrichment seems to be the main cause of action that courts permit donors to use to prevent the use of their tissues for commercial purposes.²⁶⁶ However, unjust enrichment is ultimately unsatisfactory to both donors and researchers because it does not impose a clear, explicit duty of disclosure on researchers.²⁶⁷ In order for donors to actually make

²⁵⁶ *See id.*

²⁵⁷ *Id.* at 143. For a general discussion of informed consent issues posed by stored tissues and a proposed solution, see Greely, *supra* note 233.

²⁵⁸ *See supra* Part I.

²⁵⁹ *See supra* notes 225-226 and accompanying text.

²⁶⁰ *See supra* notes 234-243 and accompanying text.

²⁶¹ *See supra* notes 244-250 and accompanying text.

²⁶² *See supra* notes 227-233 and accompanying text.

²⁶³ *See supra* notes 252-258 and accompanying text.

²⁶⁴ Skloot, *supra* note 172 (“[A] growing number of activists . . . are arguing cases and pushing for federal regulations that would change the status quo by granting people rights to control their tissues.”).

²⁶⁵ *See supra* notes 10-11.

²⁶⁶ *See Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1077-78 (S.D. Fla. 2003) (dismissing all of plaintiffs’ claims except for unjust enrichment claim).

²⁶⁷ *See supra* Part III.A; *see also* Greenfield, *supra* note 10, at 249; Korobkin, *Default Rules*, *supra* note 132, at 13.

a choice about whether to permit the use of their tissues for commercial purposes, disclosure is necessary.

A modified version of property rights is also unsatisfactory for these donors because it also does not demand disclosure.²⁶⁸ Furthermore, recognizing property rights in donors' bodily tissues risks commodifying body tissues.²⁶⁹ Finally, property rights may have detrimental effects on the scientific research process.²⁷⁰ Given these issues, and the lack of certainty of the full ramifications of recognizing a property interest in donors' tissues,²⁷¹ such an extreme step should not be taken unless no other alternatives provide an adequate solution.

Informed consent initially appears to be a plausible solution because it poses a relatively small burden on the researcher²⁷² and provides donors with disclosure.²⁷³ However, true informed consent would be difficult to achieve since some researchers are unaware of their financial interests at the time informed consent is typically obtained.²⁷⁴ These researchers would only be able to provide a statement describing the potential for the research results to be used for commercial purposes, which many scholars contend does not constitute truly informed consent.²⁷⁵ Furthermore, the current informed consent requirements are inadequate because they do not mandate disclosure of potential commercial uses of research such as patents.²⁷⁶

As a result, this Part argues that a legislative solution is necessary to sufficiently balance the interests of both researchers and donors.²⁷⁷ This solution would consist of two parts: a disclosure requirement and an enforcement mechanism for donors whose tissue has been used for commercial purposes without the donors' permission. Finally, this legislative scheme must be implemented in a manner such that it applies to all research.

²⁶⁸ See *supra* notes 192-211 and accompanying text.

²⁶⁹ See *supra* notes 175-191 and accompanying text.

²⁷⁰ See *supra* notes 212-215 and accompanying text.

²⁷¹ See Goodwin, *supra* note 141, at 370-71.

²⁷² See *supra* notes 227-233 and accompanying text.

²⁷³ See *supra* notes 225-226 and accompanying text.

²⁷⁴ See *supra* notes 252-258 and accompanying text.

²⁷⁵ See, e.g., Strouse, *supra* note 251, at 142-43.

²⁷⁶ See *supra* notes 234-243 and accompanying text.

²⁷⁷ Although this legislative solution is largely based on informed consent, this Note will refer to it as a disclosure mechanism in recognition of the argument that true informed consent would require disclosure of the specific financial interests. See e.g., Strouse, *supra* note 251, at 142-43.

A. *The Proposed Legislative Scheme*

1. Mandatory Disclosure Requirements

The proposed legislative solution would require researchers to disclose potential commercial applications of the research, such as the potential for patents,²⁷⁸ within the existing informed consent form. The extent of the required disclosure would vary based on the foreseeability of the future commercial applications.²⁷⁹ If the researcher could reasonably expect that the research would result in specific commercial applications, the researcher would be required to disclose those specific financial interests. For example, if research intended to determine a particular gene responsible for a disease, and the researcher intends to obtain a gene patent if the gene is discovered, then the researcher would be required to include a disclosure statement stating, “The results of this research may result in a gene patent.”²⁸⁰

Since researchers are not always aware of the commercial uses that may result from a study,²⁸¹ researchers that want to leave open the possibility of using the results for unspecific commercial purposes may meet the disclosure requirements by explaining to the donor that the tissue may be used for future proprietary uses and describing what this may entail. Thus, a statement such as, “This study may result in the development of commercial uses, in which the researcher may have a financial stake,” would be insufficient because it does not sufficiently inform the donor how the research may result in commercial uses.²⁸² Instead, a more specific statement is required, such as, “This study may result in the development of commercial uses from which the researcher may profit. Although no current commercial uses are anticipated, unexpected uses may arise. For example, the researcher may profit by licensing a patent, or developing a medical product, that results from the research.”

Requiring researchers to specifically disclose all reasonably foreseeable commercial uses in addition to permitting sufficiently specific blanket disclosure statements of the potential commercial uses attempts to balance the interests of both researchers and donors. On the one hand, these statements adequately protect donors because they alert the donor to the possibility that the tissues may be used for commercial

²⁷⁸ For a further explanation of these potential commercial uses, see *supra* Part I.

²⁷⁹ Professor Greely has proposed similar disclosure requirements in addressing the problems that have arisen regarding informed consent for stored tissues. See Greely, *supra* note 233, at 755-56.

²⁸⁰ This scenario is adapted from the facts of *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1066-68 (S.D. Fla. 2003).

²⁸¹ See *supra* notes 252-258 and accompanying text.

²⁸² Thus, the vast majority of current financial disclosure provisions would be insufficient. See *supra* note 242.

purposes, and when feasible, those purposes are identified, thus permitting the donor to express any objections.²⁸³ This would permit donors with objections to enter into negotiations with the researchers, or, if the researchers are uninterested in negotiating with the donor, the donors could seek out other researchers with similar views.²⁸⁴ At the same time, researchers are not required to do the impossible and anticipate every possible commercial use of the research results.²⁸⁵ Additionally, researchers are not required to re-contact donors every time a potential new profitable use of the research arises.²⁸⁶

Furthermore, these disclosure requirements are largely consistent with the current federal policy regarding permissible financial disclosures, which allows financial disclosures so long as they are sufficiently specific.²⁸⁷ These disclosure requirements simply go a step further by mandating the disclosure of direct financial interests in the research. Additionally, mandatory disclosure is consistent with many medical and research organizations' policy positions, which urge the disclosure of financial interests.²⁸⁸ However, this solution provides consistent disclosure requirements across all research areas.²⁸⁹ Furthermore, mandatory disclosure of direct financial interests in research is reconcilable with the federal government's policy of

²⁸³ For a description of these potential objections, see *supra* Part II.

²⁸⁴ For example, these donors may prefer to donate their tissues to "open-source" research projects, such as those associated with the Biological Innovation for Open Society initiative, that intend to keep their results in the public domain. See Pollack, *Open-Source Practices*, *supra* note 94.

²⁸⁵ See *supra* notes 256-257 and accompanying text.

²⁸⁶ See *id.*

²⁸⁷ See *supra* note 236. State policies are not addressed here because most states have not expressed a clear policy. Rather, courts have had to deal with these issues when they arise. See, e.g., *Wash. Univ. v. Catalona (Catalona II)*, 490 F.3d 667, 672-73 (8th Cir. 2007) (donors seeking to retain control over possession of their tissues); *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 480 (Cal. 1990) (use of tissues for commercial purposes in the therapeutic research context); *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1066-68 (S.D. Fla. 2003) (use of tissues for commercial purposes in the non-therapeutic research context).

²⁸⁸ See, e.g., TASK FORCE ON FIN. CONFLICTS OF INTEREST IN CLINICAL RESEARCH, ASS'N OF AM. MED. COLLEGES, PROTECTING SUBJECTS, PRESERVING TRUST, PROMOTING PROGRESS II 11 (2002), available at <http://www.aamc.org/research/coi/2002coireport.pdf> (requiring all financial conflicts of interests be disclosed to the IRB, which then should determine which are disclosed to research participants); TASK FORCE ON RESEARCH ACCOUNTABILITY, ASS'N OF AM. UNIVS., REPORT ON INDIVIDUAL AND INSTITUTIONAL FINANCIAL CONFLICT OF INTEREST ii (2001), available at <http://www.aau.edu/research/COI.01.pdf> (providing the following guidelines for dealing with financial conflicts of interest: "1) *disclose* always; 2) *manage* the conflict in most cases; 3) *prohibit* the activity when necessary to protect the public interest or the interest of the university"); AMA Code of Ethics, *supra* note 241, E-2.08 ("Physicians contemplating the commercial use of human tissue should abide by the following guidelines: . . . (2) Potential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials. (3) Human tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material."); see also Andrews, *Benefits of Biobanks*, *supra* note 71, at 25.

²⁸⁹ Different organizations codes apply in different contexts. For example, the Association of American Medical Colleges' position would apply to research performed by its member medical schools, whereas the Association of American Universities' position would apply to research performed by its member medical schools. See *supra* note 288.

encouraging the commercial use of scientific research,²⁹⁰ since it does not prevent commercial uses, but rather permits donors with objections to such uses to express them.

2. Enforcement Mechanisms

In order for the mandatory disclosure requirements to be effective, donors must be able to enforce the requirements when donors' tissues are used for commercial purposes without their express permission. This Note argues that a donor that wishes to bring an action for failure to obtain permission must prove three elements: (1) the donor's tissues were used in research by the defendant, (2) the research in which the tissues were used resulted in a commercial use, and (3) the donor did not consent to the use of the biological tissues for commercial research, either because the researcher did not adequately disclose these uses or because the tissues were used in disregard of the donor's refusal to consent to commercial uses. These requirements are loosely based off the traditional elements of informed consent actions.²⁹¹ However, they are modified because the traditional informed consent action is designed to remedy a physical harm.²⁹² In contrast, the donor harmed by a commercial use of research has suffered a harm that is better classified as a "dignitary harm[]." ²⁹³ Thus, these requirements are intended to ensure the donor did in fact suffer a cognizable harm as a result of the defendant's conduct. In order to be harmed under this mandated disclosure regime, there must be a commercial use of the research.

If the donor succeeds in proving these requirements, there are a number of remedies that may be available to the donor. The donor may be able to prove general damages if he or she has suffered physical or economic harm. For example, the donor may experience economic harm if the donor participated in research on a particular genetic disorder and now is unable to receive the screening test for that genetic disorder without paying an exorbitant fee. However, since the donor will often be

²⁹⁰ See *supra* Part I. Indeed, the Department of Health and Human Services has issued guidelines for when researchers may want to disclose financial interests. See 69 Fed. Reg. 26,393, 26,395-97 (May 12, 2004).

²⁹¹ In particular, the traditional common law action for informed consent requires:

(1) [A researcher's] duty to disclose material risks; (2) the failure to disclose or inadequate disclosure of those risks; (3) as a direct and proximate result of the failure to disclose, [the research participant] consented to [research] to which she otherwise would not have consented; and (4) [the research participant] was injured by the proposed [research].

Oberdorfer, *supra* note 216, at 371.

²⁹² See *supra* notes 238-240 and accompanying text.

²⁹³ See Dina Mishra, Comment, *'Tis Better to Receive: The Case for an Organ Donee's Cause of Action*, 25 YALE L. & POL'Y REV. 403, 408 (2007). For example, a research subject may think, "It's my blood, damn it. How can they use it without my permission?" Greely, *supra* note 233, at 758.

unable to prove physical or economic harm where the sole injury is the emotional harm of having the donated tissues used for unauthorized commercial uses,²⁹⁴ statutory damages should also be provided, which the donor could elect as an alternative to proving general damages. The statutory damages would be calculated by dividing the total profits received by the researcher by the total number of donors used for the research.²⁹⁵ In situations where the failure to disclose was intentional, the donor would be entitled to treble damages.²⁹⁶ Regardless of the relief received, a donor that is successful on the merits would be entitled to attorney's fees.²⁹⁷

Additionally, donors may also be able to obtain equitable remedies, such as an injunction or disgorgement of profits, when the court determines that justice so requires.²⁹⁸ These remedies should be limited in use to circumstances where the researcher's conduct is particularly culpable.²⁹⁹ For example, if a researcher knows that the research may result in a patent or other commercial use but intentionally fails to disclose this information to donors, an injunction or disgorgement of profits may be appropriate. In these circumstances, these severe remedies are necessary to deter particularly culpable abuses by researchers. Thus, the application of these remedies would not significantly differ from their traditional applications by courts.³⁰⁰

B. Implementation of the Legislative Proposal

In order for donors' interests to be fully protected, disclosure must be required by all researchers.³⁰¹ Ideally, this would occur by the federal government passing the legislative proposal. However, this would

²⁹⁴ For example, in *Greenberg*, the plaintiff's harm was that they "were . . . denied the benefits of their prolonged efforts in contributing time, information, monies and blood, tissue, urine and autopsy samples toward research that they thought was designed for non-commercial purposes for the good of the public at large." Complaint ¶ 39, *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003) (No. 02-22244-CIV-MORENO).

²⁹⁵ Admittedly, this amount may be low in situations where the researcher has not received much money in profits or in situations where there have been many donors. However, this formula is selected because it would require that the researcher disgorge all profits if every donor brought an action.

²⁹⁶ In other words, the donor would receive three times the damages determined by the initial statutory calculation. See BLACK'S LAW DICTIONARY 419 (8th ed. 2004) (entry for "damages").

²⁹⁷ These attorney's fees will hopefully encourage donors to bring actions against researchers even where their ultimate recovery may be relatively low.

²⁹⁸ Thus, plaintiffs are not foreclosed from the flexible equitable remedies provided by an unjust enrichment action. See *supra* Part III.A. However, since clear disclosure requirements are defined, see *supra* Part IV.A., researchers are not subject to the uncertainty of unjust enrichment actions. See *supra* notes 146-157 and accompanying text.

²⁹⁹ In other words, when the researcher's conduct is particularly blameworthy. See BLACK'S LAW DICTIONARY 407 (8th ed. 2004) (entry for "culpable").

³⁰⁰ For a discussion of courts' application of the disgorgement of profits remedy, see *supra* notes 161-164 and accompanying text.

³⁰¹ See *supra* notes 241-250 and accompanying text.

be inconsistent with the federal government's current policy of only regulating federally-funded and FDA regulated research.³⁰² Since the federal government is presumably unlikely to change this policy, a more plausible solution is to initially seek to amend the Common Rule to conform to the proposed disclosure requirements.³⁰³ This would result in the protection of most donors.³⁰⁴

Ideally, in order to ensure protection of all donors, the states should then be encouraged to also enact the proposed legislative solution. Although this raises the possibility that state and federal laws may conflict,³⁰⁵ this outcome is unlikely. Much research is already governed by both state and federal laws.³⁰⁶ Currently, there has not been a problem with these sets of laws conflicting.³⁰⁷ Furthermore, a research organization should be able to comply with both sets of rules unless they conflict. In order for the rules to conflict, the state would have to prohibit the researcher from disclosing certain financial conflicts. Given the vast consensus that these conflicts should be disclosed,³⁰⁸ this outcome is unlikely.

³⁰² See *supra* notes 244-250 and accompanying text. Additionally, the federal government may not have the power to pass such a policy. The Interstate Commerce Clause, U.S. CONST. art. I, § 8, cl. 3, may not grant Congress the power because most research occurs within a single state using participants from that state. Only the research results are then entered into interstate commerce.

³⁰³ Like the other provisions of the Common Rule, Congress has the power to do this because it has the power to restrict the use of federal funds. U.S. CONST. art. I, § 8, cl. 1; see also *South Dakota v. Dole*, 483 U.S. 203, 206-07 (1987) (explaining that the power of Congress to attach strings to federal funds is very broad).

³⁰⁴ Admittedly, it would only protect most donors, not all donors. See *supra* notes 244-250 and accompanying text. Nonetheless, it would be better than the current system. Indeed, Congress should expand the scope of coverage by additionally providing that the disclosure provision applies to all tissue samples. Currently, tissue samples that are completely anonymous may not be subject to the Common Rule. See Michael D. Volk, Jr., Christine Meis McAuliffe & May Mowzoon, *Genebank Management: A Review of Salient Ethical, Legal, and Social Issues*, 45 JURIMETRICS J. 205, 218 (2005). However, making samples anonymous does not prevent the harm that donors experience when their tissues are impermissibly used for commercial purposes. Thus, anonymous samples should also be subject to mandatory disclosure requirements.

³⁰⁵ State and federal laws may conflict if the state legislature does not enact the proposed act but rather drafts its own legislation on the issue.

³⁰⁶ The research is always governed by the state informed consent law. See, e.g., *supra* notes 238-240 and accompanying text. In addition, many of those research projects are also governed by the federal Common Rule. See *supra* notes 245-250 and accompanying text.

³⁰⁷ Indeed, when state and federal laws differ, it is often because the state laws are more stringent than the federal regulations. Compare *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001) (holding that "in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is *any* risk of injury or damage to the health of the subject" (emphasis added)), with 45 C.F.R. § 46.404 (2007) (permitting research on children that poses only "*minimal* risk" so long as the child's assent and the parent's or guardian's permission is obtained (emphasis added)).

³⁰⁸ See *supra* notes 287-290 and accompanying text.

C. *Additional Protection Using Contracts*

A possible criticism is that these disclosures will not provide donors with sufficient protection because donors will not have sufficient bargaining power to negotiate with the researcher. Indeed, in the case of individuals, the researcher may present this disclosure as a “take-it-or-leave-it” provision. Unless the donors’ tissues are particularly valuable,³⁰⁹ the donors may lack bargaining power since the researchers are able to acquire the same materials from another donor. However, donors are still adequately protected. Even if they are unable to negotiate with one researcher, they may still seek out a researcher that would use their tissues in the manner they desire. Furthermore, groups of donors, such as patient advocacy organizations, may have sufficient bargaining power to negotiate with the researchers.³¹⁰ Disclosure will facilitate these negotiations by ensuring that the groups are aware of the potential uses of their tissues.³¹¹ Thus, they will be able to initiate negotiations if they desire to change the terms of the use.

V. CONCLUSION

Scientific research is increasingly being used for profitable purposes.³¹² At the same time, there are many reasons why donors may object to the use of their donations for these uses.³¹³ As a result, donors’ interests must be protected. However, these protections must also take into account researchers’ interests. Currently, most of the proposed solutions do not adequately balance the researchers’ and donors’ interests. As a result, this Note proposes a mandatory disclosure regime.³¹⁴ This regime would inform donors of potential commercial uses.³¹⁵ At the same time, the regime would impose a relatively slight burden on researchers.³¹⁶ Finally, the regime provides a cause of action through which donors can enforce the mandatory disclosure

³⁰⁹ For example, the donors’ tissues may have a unique characteristic that makes those particular tissues valuable to the researcher. *See, e.g.*, *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 481-83 (Cal. 1990) (researchers were initially aware that Moore’s cells were valuable).

³¹⁰ For example, PXE International, a patient advocacy group for pseudoxanthoma elasticum (PXE), was able to successfully negotiate with researchers. *See Baird, supra* note 10, at 335. PXE International was able to negotiate a portion of the patent rights in return for access to its tissue bank and database of family information. *Id.* Its purpose in entering into these negotiations was to ensure affordable access to any advancements resulting from the research, such as a test for the disease. *Id.*

³¹¹ For example, the *Greenberg* plaintiffs would have likely negotiated with the researcher before the research began if they had been aware that the researcher contemplated commercial uses. *See Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003).

³¹² *See supra* Part I.

³¹³ *See supra* Part II.

³¹⁴ *See supra* Part IV.

³¹⁵ *See supra* Part IV.A.1.

³¹⁶ *See supra* notes 227-233 and accompanying text.

requirements.³¹⁷ Thus, unlike other proposed solutions,³¹⁸ this regime achieves a balance between donors' and researchers' interests while granting donors some control over the commercial use of their tissue donations.

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³¹⁷ See *supra* Part IV.A.2.

³¹⁸ See *supra* Part III.

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