

HOW TO GET A FAIR SHARE: IP POLICIES FOR PUBLICLY SUPPORTED BIOBANKS

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I. INTRODUCTION

Medicine is no longer one size fits all. Hundreds of thousands of women in the United States take tamoxifen, a drug used in breast cancer treatment with unpleasant side effects; however, a genetic test can reveal whether the drug will even work for them.¹ Genetic testing might also help determine more accurately individualized dosing for the blood thinner warfarin; thousands of patients are hospitalized each year because of blood clots from an inadequate dose or internal bleeding from an overdose.² To obtain the benefits of personalized medicine, many have argued that large-scale participation in biobanks is necessary.³ For this article, the term “biobanks” includes repositories of biological materials or the data associated with them, including genetic databases, DNA databases, tissue or biological banks, and population collections.

Researchers often depend on governmental support in public biobanking.⁴ The terms “publicly supported biobanking” or “public biobanking” refer to biobanking research

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¹ Andrew Pollack, *Patient’s DNA May Be Signal to Tailor Medication*, N.Y. TIMES, Dec. 29, 2008, at A1, available at http://www.nytimes.com/2008/12/30/business/30gene.html?_r=1&adxnnl=1&adxnnlx=1232233315-YEB5g/eOVgNwmaCVXkj9NQ.

² *Id.*; Ryan P. Owen et al., *PharmGKB and the International Warfarin Pharmacogenetics Consortium: The Changing Role for Pharmacogenomic Databases and Single-Drug Pharmacogenetics*, 29 HUMAN MUTATION 456, 458-60 (2008).

³ See Francis S. Collins, *The Case for a U.S. Prospective Cohort Study of Genes and Environment*, 429 NATURE 475, 475-77 (2004); David Gurwitz et al., *A Call for the Creation of Personalized Medicine Databases*, 5 NATURE REV. 23, 23-25 (2006); Isaac S. Kohane & Russ B. Altman, *Health-Information Altruists — A Potentially Critical Resource*, 353 NEW ENG. J. MED. 2074, 2074-75 (2005).

⁴ See, e.g., Melissa A. Austin et al., *Monitoring Ethical, Legal and Social Issues in Developing Population Genetic Databases*, 5 GENETICS IN MED. 451, 452 (2003); Timothy Caulfield et al., *Trust, Patents and Public Perceptions: The Governance of Controversial Biotechnology Research*, 24 NATURE BIOTECH. 1352, 1352-54 (2006); Susanne B. Haga & Laura M. Beskow, *Ethical, Legal, and Social Implications of Biobanks for Genetics Research*, 60 ADV. IN GENETICS 505, 507-12 (2008).

collaborations involving (1) direct government support through funding, and (2) indirect government support by providing outreach programs to attract participants, or by allowing access to information, such as medical records, obtained through public funding. For public biobanking to be successful, broad segments of a population must provide access to their biological information, as the contributions underlying the discoveries are the foundation of the biobanks' value.⁵

Participants may have expectations of collective benefit beyond the advancement of science and may refuse to contribute if they feel they are being exploited.⁶ Even if participants, on an individual basis, are unaware or unconcerned with a biobank's intellectual property policies, governments negotiating access to data and providing support for biobanks should seek an equitable arrangement on their citizens' behalf.⁷ The imprimatur of government sponsorship, potential conflicts of interests, particularly in countries with socialized medicine, and costs associated with publicly supported projects highlight the importance of striking a fair deal among the government, researchers and participants in publicly supported biobanking.⁸

While recognizing the importance of ensuring informed consent, confidentiality and privacy in public biobanking,⁹ for this Article, I focus on how adopting measured intellectual property policies can ensure fairness while encouraging innovation.

What policies should apply to biobanks that make use of publicly supported projects involving medical data? The Bayh-Dole Act encourages the commercialization of inventions, allowing recipients of federal funding to license patents obtained using their federally supported research on an exclusive basis.¹⁰ However, because the law does not conclusively determine issues related to data access,¹¹ experimental use of patented discoveries¹² and benefit sharing,¹³

⁵ See Collins, *supra* note 3, at 475-77; Gurwitz, *supra* note 3, at 23-24; Kohane & Altman, *supra* note 3, at 2074-75.

⁶ See, e.g., Laura M. Beskow & Elizabeth Dean, *Informed Consent for Biorepositories: Assessing Prospective Participants' Understanding and Opinions*, 17 CANCER EPIDEMIOL. BIOMARKERS PREV. 1440, 1442-47 (2008); David E. Winickoff, *Partnership in U.K. Biobank: A Third Way for Genomic Property?*, 35 J. OF LAW, MED. & ETHICS 440, 441-50 (2007) (discussing biobank governance and benefit sharing in Iceland and the United Kingdom).

⁷ See Austin, *supra* note 4, at 452; Winickoff, *supra* note 6, at 446-49.

⁸ See, e.g. Mylene Deschenes & Clementine Sallee, *Accountability in Population Biobanking: Comparative Approaches*, 33 J.L. MED. & ETHICS 40, 41, 47 (2005); Austin, *supra* note 4, at 452-54; Caulfield, *supra* note 4, at 1352-53.

⁹ These are not insignificant challenges. See, e.g., Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS HUM. GENETICS 343, 349-59 (2007); Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays*, 4 PLOS GENETICS 1, 19 (2008) (“[S]haring only summary data does not completely mask identity” of individual participants).

¹⁰ Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200-212 (2000)). See Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, 15 INDUS. & CORP. CHANGE 1013, 1014 (2006); Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290-91 (2003).

¹¹ See, e.g., Rebecca S. Eisenberg & Arti K. Rai, *Harnessing and Sharing the Benefits of State-Sponsored Research: Intellectual Property Rights and Data Sharing in California's Stem Cell Initiative*, 21 BERKELEY TECH. L.J. 1187, 1189 (2006).

¹² *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

¹³ *Wash. Univ. v. Catalona*, 490 F.3d 667, 673-77 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008); *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1068-76 (S.D. Fla. 2003); *Moore v. Regents of the Univ. of Calif.*, 51 Cal. 3d 120, 134-46 (1990), *cert. denied*, 499 U.S. 936 (1991). See generally Cynthia M. Ho, *Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patient-Based*

publicly supported biobanks should consider these areas in their intellectual property policies. The benefits of policies providing increased transparency and non-monetary benefit sharing with participants must be balanced against potential diminished incentives for research and development.

This Article examines policies that will embody the fairness essential for publicly supported biobanks to succeed. Part I discusses access to data and resulting research findings for approved researchers after a reasonable period of exclusivity. Part II addresses experimental use of patented discoveries for approved researchers. Part III discusses non-monetary benefit sharing for participants. I also examine recent legal developments, how selected biobanks address these issues, and additional considerations for public biobanks and their government partners in formulating intellectual property policies.

II. ADDRESSING ACCESS TO DATA

A. Allow Patents on Genetic Information, but Limit Restrictions on Access to Data

While data are technically not eligible for copyright or patent protection in the United States,¹⁴ obtaining a patent on a genetic sequence, single nucleotide polymorphism (SNP), or haplotype,¹⁵ for example, might limit the ability of other researchers to use that data for further research. An early example of international biobanking, the Human Genome Project (HGP), sought to determine the sequence of the more than 3 billion base pairs in human DNA and to use that sequence data to identify all human genes.¹⁶ In deciding how to address patent protection, the National Institutes of Health (NIH) issued a policy statement that raw genomic DNA sequences lack specific utility and should generally not be considered patentable subject matter.¹⁷ Despite this policy statement and a general understanding among researchers in the publicly funded HGP not to patent the information, nearly 20% of discovered human genes have been claimed in United States patents,¹⁸ though the validity of some of these patents is questionable.¹⁹ While research norms and the NIH's statement were sufficient to defeat efforts to restrict access to the data, including attempts by HGP's private-sector rival Celera, the HGP's

Discoveries, 7 DEPAUL J. HEALTH CARE L. 185, 225 (2004) (contracting of rights with patient groups).

¹⁴ See *Feist Publ'ns, Inc. v. Rural Tel. Servs. Co.*, 499 U.S. 340, 344-64 (1991); UNITED STATES PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2106 (8th ed. 2008); see also Eisenberg & Rai, *supra* note 11, at 1189.

¹⁵ SNPs are specific locations in the DNA sequence where individuals differ at a single nucleotide base. A haplotype is a pattern of nearby SNPs, inherited in blocks, on the same chromosome. National Human Genome Research Institute, International HapMap Project, <http://www.genome.gov/10001688> (last visited Feb. 28, 2009).

¹⁶ Francis S. Collins et al., *The Human Genome Project: Lessons from Large-Scale Biology*, 300 SCIENCE 286, 286-90 (2003); Oak Ridge National Lab, Human Genome Project Information, About the Human Genome Project, http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last visited Dec. 10, 2008).

¹⁷ National Human Genome Research Institute, NHGRI Policy Regarding Intellectual Property of Human Genomic Sequence (Apr. 9, 1996), <http://www.genome.gov/10000926> (noting, however, that the Bayh-Dole Act permits researchers to seek patent protection if they can demonstrate "convincing evidence for utility").

¹⁸ Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239 (2005).

¹⁹ See, e.g., *In re Fisher*, 421 F.3d 1365, 1378 (Fed. Cir. 2005) (finding claims to sequence information for genes of unknown function invalid for failure to disclose specific and substantial utility); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212-14 (Fed. Cir. 1991) ("It is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have [the claimed] activity.").

policies did not prevent commercialization efforts.²⁰ It is unclear “how much, if any, of the genome can be used freely for commercial purposes.”²¹

The HGP’s concerns about restricting access to data have been mitigated by the Federal Circuit’s decision in *In re Fisher*,²² which addressed the level of utility needed to obtain patent protection for DNA sequences that have been shown to correspond to portions of genes, even though the specific functions of the genes are unknown. Patent applicant Dane Fisher had claims directed to DNA fragments, known as “expressed sequence tags” (“ESTs”).²³ An EST corresponds to a portion of a gene being expressed; it can be used to identify an unknown gene and its location within a genome, but does not explain the function of the gene. In his patent application, Fisher sought to patent ESTs encoding portions of proteins in maize plants, although the purpose and use of the genes represented by the ESTs was not yet identified.²⁴ Fisher did not provide the structure or function of the gene or of the protein that the gene encoded; instead, he only stated that there were “a variety of ways” that the ESTs might be used without any supporting evidence that the uses were “presently beneficial.”²⁵ Because the ESTs claimed by Fisher corresponded to genes with no known functions, amounting to a “hunting license” for performing research that might not result in anything useful, the Federal Circuit held that the claimed invention did not have specific and substantial utility.²⁶ To show specific utility, an asserted use must “provide a well-defined and particular benefit to the public.”²⁷ For substantial utility, an asserted use must have “a significant and presently available benefit to the public.”²⁸ The utility standard set forth in *Fisher* thus precludes patenting sequence information for genes of unknown function.

Many biobanks have policies prohibiting restrictions on access to their underlying data. Some of the first collaborations sought to release data into the public domain, hoping to preclude patentability by creating prior art.²⁹ More recently, the UK Biobank, a medical research initiative and charity supported by various non-profit and government agencies, has stated it will require researchers to share results and supporting information from their analyses with “all researchers with appropriate scientific and ethics approval” as well as place all research findings using its data in the public domain, after a limited period of exclusivity.³⁰ The International HapMap Consortium, which seeks to determine patterns of DNA sequence variation to provide tools for disease risk factors, uses a click-wrap license to ensure that its underlying data will not

²⁰ See Donna M. Gitter, *Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases*, 43 Hous. L. Rev. 1475, 1500-01 (2007); Eisenberg & Rai, *supra* note 11, at 1201-02.

²¹ National Human Genome Research Institute, *The Human Genome Project Completion: Frequently Asked Questions*, <http://www.genome.gov/11006943> (last visited Dec. 10, 2008).

²² 421 F.3d at 1378.

²³ *Id.* at 1367-68.

²⁴ *Id.*

²⁵ *Id.* at 1367-68.

²⁶ *Id.* at 1373-74, 1376.

²⁷ *Id.* at 1371.

²⁸ *Id.*

²⁹ See Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 832 (2001) (discussing Merck’s collaboration with Washington University and the SNP Consortium’s efforts to place information in the public domain).

³⁰ U.K. BIOBANK, ETHICS AND GOVERNANCE FRAMEWORK, at 13 (2007), <http://www.ukbiobank.ac.uk/docs/EGF20082.pdf>.

be patented.³¹ However, if a researcher associates a SNP or haplotype with disease risk or drug response, the data-release policy does not prohibit patenting, “as long as any ensuing patent is not used to prevent others’ access to the HapMap data.”³² PharmGKB, a public genotype-phenotype resource seeking to impact how medicine is delivered and “catalyze scientific discovery in both pharmacogenetics/pharmacogenomics and biomedical informatics,” similarly prohibits commercialization of its data in its terms of data use.³³

Public biobanks should limit researchers’ abilities to place restrictions on access to their data and resulting research findings, allowing meaningful access to other researchers with appropriate scientific and ethics approval and after a limited period of exclusivity to allow for publication, development and patenting.

Requirements for data sharing for certain publicly funded research projects have already been implemented, though not in the specific context of publicly supported biobanks. The NIH requires researchers to submit a plan for data sharing in grant applications for more than \$500,000 of funding, as “data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health.”³⁴ The availability of public funding eases concerns about providing adequate incentives for research and development. Challenging questions about how to ensure access to data while maintaining confidentiality have been, and should be, explored.³⁵

Biobanks have expressed concern about researchers obtaining and enforcing patents using their data. For example, the nonprofit Coriell Institute for Medical Research is undertaking a Personalized Medicine Collaborative “to understand why people often respond differently to treatments and to discover presently unknown genes.”³⁶ Representatives from Coriell state that they want data from the Collaborative “to be accessible for discovery, to push the envelope on new knowledge. . . . [It] should be used in a manner to gain new knowledge rather than for patents on DNA.”³⁷ Navigenics, a consumer genomics company, has applied for patents for the use of SNPs to calculate susceptibility for disease, but states that any such patents will be licensed “on a non-exclusive, non-discriminatory basis.”³⁸ MalariaGEN, a Malaria Genomic Epidemiology Network of research groups collaborating on large-scale investigations, permits intellectual property protection if the discovery is directly relevant to clinical application, immediate licensing is highly likely, and protection is needed as a stimulus for further

³¹ International HapMap Consortium, *International HapMap Project*, 426 NATURE 789, 793 (2003).

³² *Id.*

³³ PharmGKB, Mission Statement, http://www.pharmgkb.org/home/pharmgkb_mission_statement.jsp (last visited Dec. 22, 2008); PharmGKB, Terms and Conditions of Data Use, <http://www.pharmgkb.org/home/policies/web-data.jsp> (last visited Dec. 22, 2008) (terms require agreement to “use the data for research purposes only and not with any intent to . . . offer all or any part of the data for sale as a commercial item”).

³⁴ NIH, FINAL NIH STATEMENT ON SHARING RESEARCH DATA (Feb. 23, 2003), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

³⁵ See, e.g., Eisenberg, *supra* note 10, at 1024-29; Gitter, *supra* note 20, at 1492-1519.

³⁶ Coriell Institute for Medical Research, Participation in the Coriell Personalized Medicine Collaborative Offered at No Cost, <http://www.coriell.org/index.php/content/view/92/257/> (last visited on Dec. 16, 2008).

³⁷ Telephone Interview with Joseph L. Mintzer, Executive Vice President and Chief Operating Officer, and Courtney Sill, Director of Communications, Coriell Institute for Medical Research (Nov. 25, 2008); Email from Courtney Sill, Director of Communications, Coriell Institute for Medical Research (Jan. 8, 2009, 05:56 PST) (on file with author).

³⁸ Navigenics, Inc., Our Policy Regarding Gene Patents, http://www.navigenics.com/visitor/what_we_offer/our_policies/gene_patents/ (last visited Feb. 26, 2009).

development.³⁹

The extent to which measured restrictions on the patentability of genetic information would deter investment and innovation has been the subject of debate.⁴⁰ In light of this uncertainty, public biobanks should refrain from imposing restrictions on the patentability of genetic information. However, they should limit restrictions on access to their data and resulting research findings, allowing access to approved researchers and after a limited period of exclusivity.

B. *Allow Patents on Correlations, but Limit Restrictions on Access to Data*

In addition to concerns about access to data and patenting genetic information, patents on correlations between genetic or phenotypic attributes and treatment have been widely discussed. This Article does not conclude whether restrictions on these types of patents are appropriate, but rather suggests that recent developments in patent law will likely narrow the scope of eligible subject matter, hampering the ability to obtain these types of patents. Biobanks should not place further restrictions on the ability to obtain patent protection for genetic information or correlations, as the deterrent effect on research and investment is too great.

The Federal Circuit's recent *en banc* opinion in *In re Bilski*⁴¹ may raise obstacles to the patenting of correlations. Correlation claims are a type of "process" claim.⁴² In addressing subject matter eligibility of process claims under 35 U.S.C. § 101, the Supreme Court has allowed claims that cover a particular application of a fundamental principle, but has refused to allow claims that would preempt substantially all uses of the fundamental principle.⁴³

To determine whether a claim is sufficiently narrow to cover a particular application of a fundamental principle as opposed to preempting it, the court in *Bilski* used the "machine-or-transformation" test.⁴⁴ Under the "machine-or-transformation" test, a process may be patented if it is tied to a particular machine or transforms materials to a different state or thing.⁴⁵ The court in *Bilski* further held that "mere field-of-use limitations," such as attempting to limit use of a formula to a particular technological environment, or "insignificant extra-solution activity," such as adding a conventional extra step to a formula, does not convert an otherwise ineligible process into one that is patentable.⁴⁶ The court also recognized that the test might need adjustment or even abandonment to accommodate "emerging technologies," as future developments in technology may present difficult challenges to its application.⁴⁷

³⁹ MalariaGEN, *A Global Network For Investigating the Genomic Epidemiology of Malaria*, 456 NATURE 732, 736 (2008).

⁴⁰ See, e.g., John H. Barton, *Emerging Patent Issues in Genomic Diagnostics*, 24 NATURE BIOTECH. 939, 940 (2006); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1676-83 (2003); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698-701 (1998); Jon F. Merz & Michelle R. Henry, *The Prevalence of Patent Interferences in Gene Technology*, 22 NATURE BIOTECH. 153, 153-54 (2004).

⁴¹ 545 F.3d 943 (Fed. Cir. 2008) (*en banc*).

⁴² *Id.* at 949.

⁴³ *Id.* at 952-53; *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (holding that application of algorithm in rubber molding process was patent-eligible subject matter); *Gottschalk v. Benson*, 409 U.S. 63, 67-72 (1972) (holding a method for converting binary-coded decimal numbers into pure binary numbers to be not patentable).

⁴⁴ *Bilski*, 545 F.3d at 954.

⁴⁵ *Id.* at 956.

⁴⁶ *Id.* at 957.

⁴⁷ *Id.* at 956.

The case of *Lab. Corp. of America Holdings v. Metabolite Lab. Inc. (Lab. Corp.)*,⁴⁸ which pre-dated the *Bilski* decision, involved patent claims directed to assaying bodily fluids for an elevated level of homocysteine, and correlating the level of homocysteine with a vitamin deficiency. Although the Court dismissed its original writ of certiorari as improvidently granted, Justice Breyer explained in his dissent that he would have found the claim at issue invalid.⁴⁹ If the “machine-or-transformation test” of *Bilski* were applied to assess patentability, the claim at issue would appear to fail the first prong, as the assay is not tied to a specific machine,⁵⁰ and it is unclear whether the claim would be sufficiently transformative to satisfy the second prong. Demonstrating physical transformation seems questionable because no specific assay method is required by the claims.⁵¹ However, using the broadest definition of a “transformation,” the method “transforms” bodily fluid into information about elevated levels of homocysteine and vitamin deficiency, which are representative of physical objects or substances.⁵²

Unlike *Lab. Corp.*, the *Bilski* decision addressed a business method patent, which involves preemption of an abstract idea or mental process.⁵³ The machine or transformation test of *Bilski* will likely need modification when applied to claims directed to biological methods, where the fundamental principle in question is often a natural phenomenon or law of nature; a transformation may more easily be shown for claims involving biological processes than business methods.⁵⁴ Recently, however, the Federal Circuit strictly applied *Bilski* to a biological method claim in *Classen Immunotherapies, Inc. v. Biogen IDEC (Classen)*.⁵⁵ In a one-paragraph, nonprecedential decision, the court found that claims for evaluating vaccine schedules, which include the step of immunizing patients,⁵⁶ failed *Bilski*’s machine or transformation test.⁵⁷

The *Bilski* decision may pose significant barriers to patenting correlations and diagnostic methods if it is strictly applied to claims involving biological methods, as it was in *Classen*.⁵⁸ As an example, many claims in the controversial breast cancer genetic screening patents owned by Myriad could be called into question.⁵⁹ Several of these patents claim methods to identify mutations that are not tied to any particular machine or apparatus.⁶⁰ Claims that are limited to a

⁴⁸ 548 U.S. 124, 125 (2006) (per curiam) (writ of certiorari dismissed as improvidently granted).

⁴⁹ *Id.* at 134-38 (Breyer, J., dissenting).

⁵⁰ *Id.* at 129 (describing the claims, which do not require the use of any test for the assay).

⁵¹ *Id.* However, the assay mentioned by Metabolite in its appellate brief requires reducing the bonds between the homocysteine molecules and the compounds to which they are chemically bound, which would likely satisfy the transformation requirement. Brief for Respondents at 3, *Lab. Corp.*, 548 U.S. 124 (2006) (No. 04-607), 2006 WL 303905.

⁵² *Bilski*, 545 F.3d at 963; see also Posting of Dennis Crouch to Patently-O Blog, <http://www.patentlyo.com/patent/2008/11/applying-bils-1.html> (Nov. 10, 2008).

⁵³ *Id.* at 949, 951 (claims at issue directed to methods for hedging risk in commodities trading).

⁵⁴ *Lab. Corp.*, 548 U.S. at 136 (Breyer, J., dissenting) (“[T]o use virtually any natural phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter.”); see also Posting of Christopher M. Holman to Patently-O Blog, <http://www.patentlyo.com/patent/2008/11/applying-bilski.html> (Nov. 4, 2008).

⁵⁵ 2008 U.S. App. LEXIS 25661, at *2 (2006) (Fed. Cir. Dec. 19, 2008) (nonprecedential).

⁵⁶ U.S. Patent No. 6,638,739 (filed Apr. 18, 2002); U.S. Patent No. 6,420,139 (filed Jul. 6, 2000); U.S. Patent No. 5,723,283 (filed May 31, 1995).

⁵⁷ *Classen*, 2008 U.S. App. LEXIS 25661, at *2.

⁵⁸ For a discussion about the *Bilski* decision’s potential impact on innovation incentives, see *Bilski*, 545 F.3d at 976-81, 989-95 (Rader, J., dissenting).

⁵⁹ See *infra* notes 63-65 and accompanying text.

⁶⁰ See U.S. Patent No. 6,124,104 col. 169 l. 46 (filed Mar. 20, 1998) (methods for “diagnosing a predisposition for

machine or type of analysis would likely satisfy the “machine” prong of the *Bilski* test, though even such limitations could also be viewed as field of use restrictions.⁶¹ Any extra-solution activity of a diagnosis, for example, might be held insignificant.⁶² As discussed above with regard to the example of *Lab. Corp.*, it is unclear whether Myriad’s diagnostic patents would be found to meet the “transformation prong” of the *Bilski* test, unless it could be shown that they transform bodily fluids into a different state or thing. The uncertainty of whether these types of claims are patentable may have a significant impact on research and development in these areas.

Heightened requirements of utility and subject matter eligibility will likely limit the scope of patents that are granted on genetic information and correlations. Biobanks should avoid placing any additional restrictions on the ability to obtain these types of patents, as they will likely deter research and investment. However, biobanks should consider adopting policies that prohibit researchers from restricting other approved researchers’ access to the underlying data and resulting research findings, after a reasonable period of exclusivity to allow for publication and patenting.

III. AVAILABILITY OF PATENTED DISCOVERIES FOR EXPERIMENTAL USE

Patent holders are often perceived, accurately or not, as overreaching in the assertion of their intellectual property rights. A widely-referenced example supporting this perception is Myriad’s assertion of its patents related to genes *BRCA1* and *BRCA2*. Myriad has attempted to restrict tests performed outside its laboratories, including those for determining additional variations in genes that can signal susceptibility to breast cancer, impeding research and development of more comprehensive screening approaches.⁶³ Despite Myriad’s objections, laboratories in Europe continued their efforts in research and development, discovering new defects in genes related to breast cancer susceptibility.⁶⁴ These researchers were perhaps emboldened by vigorous protests against Myriad’s restrictive licensing requirements in Europe, as well as in Canada.⁶⁵ To promote fairness, and to encourage comprehensiveness and the pace

breast cancer...by detecting a germline alteration in the *BRCA2* gene”); U.S. Patent No. 6,033,857 col. 169 l. 47 (filed Mar. 20, 1998) (methods for “diagnosing a predisposition for breast cancer ... comparing the germline sequence of the *BRCA2* gene ... with the germline sequence of the wild-type *BRCA2* gene”); U.S. Patent No. 5,753,441 col. 155 l. 16 (filed Jan. 5, 1996) (methods for “screening germline . . . comparing germline sequence of a *BRCA1* gene ... with germline sequences of wild-type *BRCA1* gene”). In these patents, the dependent claims list a variety of methods for executing the independent claims.

⁶¹ *Bilski*, 545 F.3d. at 957.

⁶² *See id.*

⁶³ *See, e.g.*, Brian Goldman, *HER2 testing: The Patent “Genee” is Out of the Bottle*, 176 CAN. MEDICAL ASS’N J. 1443, 1443-44 (2007); Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. AMER. MEDICAL ASS’N 1379, 1379-88 (2006) (finding that 17% of study participants with negative commercial genetic test results for *BRCA1* and *BRCA2* carried previously undetected genetic mutations that predispose them to breast cancer); Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 134-36, 138-39 (2002) (discussing flaws in Myriad’s approach to *BRCA* testing).

⁶⁴ *See, e.g.*, Ken Ernhofer, *Ownership of Genes at Stake in Potential Lawsuit*, CHRISTIAN SCIENCE MONITOR, Feb. 27, 2003, available at <http://www.csmonitor.com/2003/0227/p07s03-woam.html>; Williams-Jones, *supra* note 63, at 138-40.

⁶⁵ *See, e.g.*, Heather Kent, *British Columbia Sidesteps Patent Claim, Transfers BRCA Gene Testing to Ontario*, 168 CAN. MED. ASS’N J. 211, 211 (2003); Goldman, *supra* note 63, at 1444; Williams-Jones, *supra* note 63, at 138-44. More recently, Myriad’s licensee in Australia, Genetic Technologies (GTG), requested that eight public testing laboratories in Australia agree to refer testing for *BRCA1* and *BRCA2* to GTG. Adam Cresswell, *A Price on Your*

of discovery, public biobanks should consider addressing experimental use in their intellectual property policies.

Some genes are the subject of multiple patents covering diagnostic methods, SNPs, cell lines, and other constructs containing the gene.⁶⁶ These overlapping rights may act as barriers to entry, chilling research and potentially blocking any improvements that might otherwise result.⁶⁷ While the scope of the regulatory use exemption has been expanded to cover uses reasonably related to the submission of information to the FDA,⁶⁸ and the norm may be to ignore the existence of patents,⁶⁹ the decision in *Madey v. Duke University*⁷⁰ and the increasing overlap between public and private research⁷¹ suggest the need for public biobanks to address experimental research use that falls outside of the regulatory exemption.

In *Madey v. Duke*, the patent holder Dr. John Madey had previously directed a research lab for Duke University and alleged that the university continued to use his patented equipment after he resigned.⁷² In reversing the district court's grant of summary judgment in favor of Duke based on the experimental use defense, the Federal Circuit held that an act does not qualify for the "strictly limited experimental use defense" if it "is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."⁷³ The court found that Duke's status as a for-profit or non-profit institution was not dispositive; the use of patented inventions in research projects at a university would "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty."⁷⁴

Although there was hope that the Supreme Court might clarify the scope of the experimental use defense in *Merck v. Integra*, it declined to do so.⁷⁵ The Court instead focused on the regulatory use exemption, stating that it extends to "all uses of patented compounds that are reasonably related to the development and submission of *any* information" to the FDA under a federal law regulating the use of drugs.⁷⁶ In this case, the use of RGD peptides for determining "the best drug candidate to subject to future clinical testing under the FDA processes" fell within

Genes, THE AUSTRALIAN, July 30, 2008, available at <http://www.theaustralian.news.com.au/story/0,25197,24097920-28737,00.html>.

⁶⁶ Jensen & Murray, *supra* note 18, at 239.

⁶⁷ See, e.g., Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577-79 (2002) (30% of U.S. laboratories in survey reported discontinuing or not developing genetic testing for haemochromatosis in light of patents covering these tests); Barton, *supra*, note 40, at 939 (discussing implications of diagnostic gene patents on the transition from the one gene, one function model of analysis to the many genes, many functions model); Burk & Lemley, *supra* note 40, at 1610-14; Heller & Eisenberg, *supra* note 40, at 698-701; Rai & Eisenberg, *supra* note 10, at 295-97. *But see* F. Scott Kieff, *IP Transactions: On the Theory & Practice of Commercializing Innovation*, 42 HOUS. L. REV. 727, 740-43 (2005).

⁶⁸ See *Merck KGaA v. Integra Lifesciences I, Ltd.* (Merck v. Integra), 545 U.S. 193, 208 (2005) (clarifying the scope of the regulatory use exemption by holding that the use of patented compounds is protected by § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce "the types of information that are relevant to an IND [Investigational New Drug Application] or NDA [New Drug Application]").

⁶⁹ See Eisenberg, *supra* note 10, at 1018-20; Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 21-22 (2008).

⁷⁰ 307 F.3d 1351 (Fed. Cir. 2002).

⁷¹ See Eisenberg, *supra* note 10, at 1014; Rai & Eisenberg, *supra* note 10, at 296.

⁷² 307 F.3d at 1352-53.

⁷³ *Id.* at 1362.

⁷⁴ *Id.*

⁷⁵ 545 U.S. at 205 n.7 (2005).

⁷⁶ *Id.* at 202 (emphasis in original).

the scope of the regulatory use exemption.⁷⁷ The *Integra* case thus broadened the ability to use patented inventions as research tools when there is a reasonable belief that the experiments will produce information relevant to a regulatory submission to the FDA.

The Federal Circuit recently interpreted the scope of the regulatory use exemption narrowly in *Proveris Scientific Corp. v. Innovasystems, Inc.*⁷⁸ The case concerned whether the regulatory use exemption protected defendant's use of the patented device, which characterized aerosol sprays used in drug delivery devices.⁷⁹ The patented device was used in the development of FDA regulatory submissions, but was not itself subject to the FDA pre-market approval process.⁸⁰ The Federal Circuit held that because a competing device would have no regulatory barriers to entry after the patent expired, the regulatory use exemption was not designed to provide relief for the defendant.⁸¹

Thus, experimentation that is not for idle amusement or reasonably related to regulatory submissions to the FDA is not protected under either defense. As Judge Newman noted in her dissent from the Federal Circuit's *Integra* decision, basic research should be protected under the common law research exception, such that the regulatory exemption under § 271(e) picks up where the common law exception leaves off.⁸² Currently, basic research taking place in the gap referenced by Judge Newman is not protected. Also, using patented inventions in experimentation that is not reasonably related to an FDA regulatory submission is unprotected. For example, tests developed by laboratories for use in-house, such as those using genetic information to determine the effectiveness and dosing of drugs, are not subject to FDA approval.⁸³ Public biobanks should consider adopting policies that allow for these types of experimental use for approved researchers.

Although the regulatory or experimental use defenses fail to protect basic research in the circumstances discussed above, obtaining injunctions against unauthorized experimentation is no longer a given. In *eBay v. MercExchange*, the Supreme Court held that the decision to grant or deny an injunction "must be exercised consistent with traditional principles of equity," rejecting the "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances."⁸⁴ Thus, courts must apply the traditional four-factor test, requiring a plaintiff to show (1) irreparable injury; (2) inadequate alternative remedies, such as monetary damages; (3) the balance of hardships favors the plaintiff; and (4) the public interest will not be harmed by granting injunctive relief.⁸⁵

Despite the rejection of the general rule favoring injunctive relief in patent cases, the possibility of obtaining a permanent injunction is still considerable.⁸⁶ Difficulty negotiating licenses for overlapping patents covering the same gene, or the number of licenses needed to

⁷⁷ *Id.* at 205.

⁷⁸ 536 F.3d 1256 (Fed. Cir. 2008).

⁷⁹ *Id.* at 1258-59.

⁸⁰ *Id.*

⁸¹ *Id.* at 1260-66.

⁸² *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (2003), corrected by 2003 U.S. App. LEXIS 27796, at *52 (Fed. Cir. June 6, 2003), vacated, 545 U.S.193 (2005).

⁸³ Brandon Keim, *Lawless Gene-Testing Industry Needs a Sheriff*, WIRED, Apr. 3, 2008, http://www.wired.com/medtech/drugs/news/2008/04/gene_testing.

⁸⁴ *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-94 (2006).

⁸⁵ *Id.* at 391.

⁸⁶ See Univ. of Houston Law Ctr., U.S. Patent Litigation Statistics (Jeffery Johnson et al., eds.), <http://www.patstats.org/Patstats3.html> (last visited Mar. 30, 2009) (noting that permanent injunction rulings after *eBay* had a 75% grant rate in 2006-2007 and a 69% grant rate in 2008).

develop diagnostic tests used in an array, might be sufficient to show significant hardship and defeat an injunction.⁸⁷ However, in light of the strong public interest in encouraging innovation through a functioning patent system, it is unclear how often courts will issue injunctions or effectively require compulsory licensing in these types of situations.⁸⁸

Policies discussing experimental use are rare. Researchers have relied on the uncertain historical tendency, pre-*Madey*, that companies will not assert their patents against experimental users, or researchers may have decided not to undertake research in a particular area because of patents.⁸⁹ In light of the uncertainty surrounding the regulatory use and experimental use defenses, the blending of public and private research collaborations, and the possibility of injunctive relief, biobanks should consider requiring that researchers agree to allow experimental use by approved researchers after a reasonable period of exclusivity.

A policy authorizing experimental use will not solve potential hold-up problems where a patent holder attempts to block use of an improvement or extract prohibitive licensing fees. However, requiring licensing of patented technology for improvements or prohibiting “reach through” claims, where a patent holder asserts an interest in research findings, would too greatly deter researcher involvement and investment, as the value of an improvement is difficult to assess prior to its creation.⁹⁰ While recognizing the potential for hold-ups, financial incentives for non-exclusive licensing of enabling technologies and the reduced probability of obtaining injunctive relief may be sufficient to spur negotiation.⁹¹ Thus, publicly supported biobanks should not require licensing of patented technologies for improvements, but should allow experimental research use of the data and resulting discoveries by approved researchers and after a limited exclusivity period.

IV. BIOBANKS WITH BENEFITS

⁸⁷ See, e.g., Turna Ray, *Whole-Genome Sequencing Poses ‘Serious Challenge’ to US Patent System, HHS Finds*, PHARMACOGENOMICS REPORTER, Dec. 10, 2008, http://www.pgxreporter.com/issues/6_48/features/151206-1.htm; Barton, *supra* note 40, at 941 (“[D]iagnostic patents, when used, for example, in a multipurpose array, would be hard to enforce by injunction, because of the great hardship of being unable to combine all the relevant tests in a way valuable to the practitioner”).

⁸⁸ See, e.g., Andrew W. Torrance, *Patents to the Rescue - Disasters and Patent Law*, 10 DEPAUL J. HEALTH CARE L. 309, 326–46 (2007). For an interesting proposal that the National Institutes of Health should have more legal authority to guide the patenting and licensing activities of its grantees, see Barton, *supra* note 40, at 941 (suggesting that the NIH and “other similar donors impose on genetic research a self-denying injunction about patents that would effectively require licenses”). See also Rai & Eisenberg, *supra* note 10, at 303-13.

⁸⁹ See, e.g., Merz, *supra* note 67, at 577-79.

⁹⁰ See generally Richard Li-Dar Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J. L. & TECH. 251, 318-29 (2007) (discussing a compulsory licensing system that determines reach-through royalties based on the contribution that patented research provides to the improvement); Vida Foubister, *Gene Patents Raise Concerns for Researchers, Clinicians: Firm’s Patents on Breast Cancer Genes Raise Additional Concerns*, A.M.A. News, Feb. 21, 2000, available at <http://www.ama-assn.org/amednews/2000/02/21/prsb0221.htm> (discussing an agreement between the National Cancer Institute and Myriad including a “reach through” clause prohibiting any assertions of an interest in research findings).

⁹¹ See, e.g., PAUL GOLDSTEIN, INTELLECTUAL PROPERTY: THE TOUGH NEW REALITIES THAT COULD MAKE OR BREAK YOUR BUSINESS 188-89 (2007); Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 627 (2005) (“enabling technologies are more valuable...when many firms compete to exploit and improve them,” providing examples of the Axel and Cohen-Boyer patent licenses).

In determining intellectual property policies, publicly supported biobanks should consider whether to provide non-monetary benefit sharing, allowing participants to benefit from the discoveries made using their contributions. For example, the UK Biobank has stated that it will reinvest any income it receives from intellectual property fees back into the resource.⁹² Non-monetary benefit sharing policies can encourage acceptance, promote fairness, and maintain trust.

The United States generally does not provide for compensation for donation of biological materials, though there are limited exceptions.⁹³ Unlike the donation of blood, ova or sperm, which is generally seen as valuable on an individual basis and often receives compensation, donations from individuals to public biobanks are generally most valuable when pooled.⁹⁴ The alleged value of the plaintiff's individual contribution in *Moore v. Regents of the University of California*,⁹⁵ where John Moore claimed a property right in the cell line derived from his spleen, is more the exception than the rule in public biobanking. In denying Moore's claim, the court expressed concern about inefficiencies and transaction costs associated with giving individuals property rights in their respective contributions,⁹⁶ and that concern could become significantly greater in large-scale population studies.

This is not to say that the interests of individual participants are, or should be, irrelevant in biobanking. Benefit sharing can mitigate feelings of unfairness that participants might otherwise have, feelings that might hinder acceptance and trust in public biobanking.⁹⁷ Few cases have addressed whether participants retain rights to their tissue after it has been removed. In *Greenberg v. Miami Children's Hospital*, the court denied participant families whose children suffered from a rare genetic disorder a property right in bodily tissues and genetic information, where they sought to ensure widespread access to the resulting test for the Canavan gene.⁹⁸ The court in *Washington University v. Catalona* similarly held that once participants have donated biological samples with valid consent, they do not have an ownership right and cannot direct, transfer, or control their use.⁹⁹

In light of the decisions in *Moore*, *Greenberg*, and *Catalona*, participants in research collaborations have engaged in contractual self-help. One example is the nonprofit foundation PXE International, which collects tissues and information from individuals affected by, or carriers of, a rare connective tissue disorder called pseudoxanthoma elasticum ("PXE").¹⁰⁰ By

⁹² U.K. BIOBANK, *supra* note 30, at 18.

⁹³ See, e.g., Michele Goodwin, *Altruism's Limits: Law, Capacity, and Organ Commodification*, 56 RUTGERS L. REV. 305, 385-94 (2004); Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U.L. REV. 359, 365-87, 447-58 (2000).

⁹⁴ See Henry T. Greely, *The Control of Genetic Research: Involving the "Groups Between,"* 33 HOUS. L. REV. 1397, 1410 (1997); Collins, *supra* note 3, at 475-77; Kohane & Altman, *supra* note 3, at 2074.

⁹⁵ 51 Cal. 3d 120 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

⁹⁶ *Id.* at 146 ("If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery").

⁹⁷ See Cori Hayden, *Taking as Giving: Bioscience, Exchange, and the Politics of Benefit-Sharing*, 37 SOC. STUD. SCI. 729, 729-58 (2007).

⁹⁸ 264 F. Supp. 2d 1064, 1074-76 (S.D. Fla. 2003). The group of families had provided bodily tissues, organ samples of a deceased child, data, and funding to researchers for almost seven years. *Id.* at 1066-67.

⁹⁹ 490 F.3d 667, 675 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008).

¹⁰⁰ Paul Smaglik, *Tissue Donors Use Their Influence in Deal Over Gene Patent Terms*, 407 NATURE 821, 821 (2000); Sharon F. Terry et al., *Advocacy Groups as Research Organizations: The PXE International Example*, 8 NATURE REV. GENETICS 157, 157-64 (2007); PXE International, Homepage, <http://www.pxe.org/english/view.asp?x=1> (last visited Jan. 3, 2009).

prohibiting restrictions on approved researchers' access to the underlying data after a reasonable period of time, advocacy groups can attempt to ensure that secrecy will not slow the pace of discovery.¹⁰¹ Several other research foundations have adopted the PXE model in setting up tissue and data banks, negotiating with researchers, and creating diagnostic tests.¹⁰²

While recognizing that the PXE model may work best for well-organized and informed groups of patients seeking research collaboration for rare diseases, publicly supported biobanks can emulate some of its advantages, encouraging acceptance and embodying fairness, by offering non-monetary benefits to participants.¹⁰³ For example, collaborations can funnel a portion of their profits back into research or healthcare infrastructure, such as helping to fund clinics or provide access to discoveries at a reduced rate. Providing these types of benefits to the population being studied fosters goodwill, encouraging acceptance and maintaining trust.¹⁰⁴ Some of these arrangements might contradict *Moore* as against public policy because they could increase transaction costs in research.¹⁰⁵ However, contrary to the court's concern in *Moore* about overwhelming transaction costs,¹⁰⁶ non-monetary benefit sharing with participants may help reduce friction by engaging participants with substantial non-financial motivations.

Some scholars have proposed that biobanks should be based on an agreement modeled on the charitable trust, which would create a trust to hold title to samples and allow access to researchers with terms benefiting participants.¹⁰⁷ Significant financial challenges may inhibit the viability of incorporating certain aspects of charitable trusts, as companies engaged in an extended and expensive commercialization process depend on the exclusivity inherent in the patent reward to recover their costs.¹⁰⁸ Publicly supported biobanks should still consider implementing non-monetary benefit sharing as a way of fostering trust and fairness, such as by providing participants with relevant information and access to discoveries resulting from the biobanks' data at a reasonable rate.

Many research collaborations have adopted some form of benefit sharing policies with their participants. Some non-profit endeavors, such as the Coriell Personalized Medicine Collaborative and the Personal Genome Project, provide free genetic analysis and information about relevant discoveries to their participants.¹⁰⁹ Even commercial genetics services, partnering

¹⁰¹ Some of these contracts provide for joint ownership, which likely is too great a disincentive for most researchers. See, e.g., Ho, *supra* note 13, at 225. At least one advocacy group has sought to control licensing and availability by seeking joint inventorship on patents with patient-participants; however, patient involvement would rarely rise to the level of contribution necessary for joint inventorship. See Press Release, PXE International, U.S. Patent Office Issues First Gene Patent to Patient Advocacy Group: Co-Inventors Include Non-Scientist "Mom" (Aug. 24, 2004), <http://www.pxe.org/english/view.asp?x=1412&id=74>; Ho, *supra* note 13, at 225-26.

¹⁰² See Terry, *supra* note 100, at 161-63.

¹⁰³ Providing benefit sharing with participants was endorsed over a decade ago by the North American Regional Committee of the Human Genome Diversity Project (HGDP). North Am. Regional Comm. of the HGDP, *Model Protocol*, 33 HOUS. L. REV. 1431, 1452-61, 1466-68 (1996-1997).

¹⁰⁴ *Id.*

¹⁰⁵ See Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371, 374-75, 378-80 (2007).

¹⁰⁶ 51 Cal. 3d 120, 146 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

¹⁰⁷ See generally David E. Winickoff & Richard N. Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 NEW ENG. J. MED. 1180, 1180-84 (2003) (discussing the benefits and structure of the charitable trust model for biobanks).

¹⁰⁸ See, e.g., Jeffrey Otten, Heidi R. Wyle & Gregory D. Phelps, Letter to the Editor, *The Charitable Trust as a Model for Genomic Biobanks*, 350 NEW ENG. J. MED. 85, 85-86 (2004).

¹⁰⁹ See Personal Genome Project, Important Considerations, <http://www.personalgenomes.org/considerations.html> (last visited Jan. 2, 2009); Coriell, *supra* notes 36-37. See also Marshfield Clinic Research Foundation,

with non-profit research institutes, provide information about developments to their participants.¹¹⁰ One commercial genetics service, Navigenics, maintains that any resulting patented discoveries will be made available to participants at a reasonable rate.¹¹¹

How much benefit sharing is fair? An early example is Iceland's authorization of a private company, deCODE, to create a national medical records database for genetic research.¹¹² The promise of free drugs and diagnostics during the patent period to participants and the creation of jobs in Iceland was seen as an insufficient benefit in exchange for access to the country's medical records, though questions about the validity of informed consent, privacy, and lack of community involvement contributed largely to the concerns about the database.¹¹³ Similarly, a genomics company's proposal to build a private genome project with data from the Framingham Heart Study and pay 5% of profits to a community development fund was not sufficient to keep a deal with Boston University from collapsing, although promising exclusive access to certain data for paying clients, with a lower level of data access for academic researchers, was likely the main reason for its rejection.¹¹⁴

Given that one reason participants contribute to biobanks is a desire to promote public welfare,¹¹⁵ the amount of benefit sharing may be less significant to them than assuring transparency and advancing discoveries through prohibiting restrictions on data, allowing experimental use of patented discoveries, and providing non-monetary benefits that embody fairness.

At a minimum, public biobanks should provide participants with medically relevant information, provided they have opted-in to receive it.¹¹⁶ Public biobanks should consider adopting policies to ensure access to drugs and diagnostics discovered using donated samples at a reasonable rate for participants. Biobanks could also offer participants the option to have any remuneration for their contributions donated to provide for further research, improve the health care infrastructure within the community, or assist the charity of their choice. In addition to

Personalized Medicine Research Project, http://www.marshfieldclinic.org/chg/pages/default.aspx?page=chg_pmrp_faqs (last visited Jan. 3, 2009) ("Project researchers also plan to send a newsletter to all study participants with updates and information... [A]ny revenue resulting from the project will be used only to pay research expenses, fund additional research and education, provide incentives to discoverers ..., donate to health care-related charities or community health care programs, or finance other purposes consistent with the not-for-profit mission of Marshfield Clinic and its Research Foundation.").

¹¹⁰ GenomeWeb staff reporter, *23andMe Inks Collaboration with Parkinson's Institute*, GENOMEWEB DAILY NEWS, May 14, 2008, available at <http://www.genomeweb.com/issues/news/146921-1.html>; Navigenics-Welcome to the Scripps Genomic Health Initiative, <http://www.navigenics.com/scripps> (Dec. 12, 2008); Navigenics, Inc., Membership Benefits, <http://www.navigenics.com/healthcompass/MembershipBenefits/> (Jan. 2, 2009); 23andMe, 23andWe Research, <https://www.23andme.com/research/> (Jan. 2, 2009).

¹¹¹ See Navigenics, Inc., *supra* note 38 (discussing "a universal royalty model for licensing gene patents").

¹¹² See Henry T. Greely, *Iceland's Plan for Genomics Research: Facts and Implications*, 40 JURIMETRICS 153, 161 (2000).

¹¹³ See *id.* at 176-91; Martin Enserink, *Physicians Wary of Scheme to Pool Icelanders' Genetic Data; Database of Health Records Would Be Granted to Private Company for Analysis*, 281 SCI. 890, 890-91 (1998); Winickoff, *supra* note 107, at 1182.

¹¹⁴ See Ronald Rosenberg, *Questions Still Linger on Heart Study Access*, BOSTON GLOBE, Feb. 21, 2001, at D4 (stating that "paying customers... would have exclusive access to the analyses and other digitized data the company generated"); Winickoff, *supra* note 107, at 1182.

¹¹⁵ See Winickoff, *supra* note 107, at 1181-82.

¹¹⁶ See, e.g., Greely, *supra* note 9, at 359-60 (suggesting researchers may have a duty to provide medically relevant information to willing participants).

avoiding the distasteful appearance of profiting from one's disease, non-monetary benefit sharing also raises fewer ethical questions about commodification of the human body.¹¹⁷

V. CONCLUSION

This paper has reviewed how publicly supported biobanks should consider addressing selected intellectual property issues. Because of uncertainty about access to data, experimental use and benefit sharing, public biobanks should address these areas in their intellectual property policies. However, restrictions on patent protection related to genetic information or requiring licensing for improvements will impose too significant a burden on research and investment. By addressing these issues, public biobanks will foster the fairness essential to the success of personalized medicine.

¹¹⁷ See, e.g., Goodwin, *supra* note 93, at 385-94; Rao, *supra* note 93, at 453-60.