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BIOSOCIALITY, REIMAGINED: A GLOBAL DISTRIBUTIVE JUSTICE FRAMEWORK FOR OWNERSHIP OF HUMAN GENETIC MATERIAL

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> "It is now essential to find legal rules that can take account of the fact that the human body, more than a thing, is a tangible and intangible complex, dissociable from the subject that shelters (or sheltered) it, in the service of diverse interests, not necessarily divergent, but that must be prioritized appropriately."[2]

Genomic biobanks—repositories of human genetic material for research use—serve increasingly important functions in contemporary global society. Biobanks collect, store, process, and distribute biological specimens and associated data collected from patients and research participants, facilitating research that connects these data with clinical responses.[3] In other words, aggregating genetic material in these banks allows researchers to better understand disease epidemiologically and to develop modalities for treatment that act precisely and efficiently.

The assemblage of personal health information and human DNA represents exciting possibilities for managing and mitigating suffering on a global scale. However, the practice of biobanking is complicated by the complex relationship between altruistic notions of research for the greater good, and flows of capital between funders, researchers, and markets. Furthermore, biobanks illustrate what some have called a "new distributive politics of biomedical research," in which "the commodification of persons . . . has challenged the ontological, ethical, and political underpinnings of the social contract between researchers and their human subjects."[4] The basic dilemma is twofold. First, how should capital accumulated from the sales of biotechnological products

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2. Florence Bellivier & Christine Noiville, *The Circulation of Human Body Parts and Products: When Exclusive Property Rights Mask the Issue of Access*, *in* BIOBANKS AND TISSUE RESEARCH: THE PUBLIC, THE PATIENT, AND THE REGULATION 211 (Christian Lenk, Judit Sándor, & Bert Gordijn eds., 2011).

3. Jennifer Girod & Katherine Drabiak, *A Proposal for Comprehensive Biobank Research Laws to Promote Translational Medicine in Indiana,* 5 IND. HEALTH L. REV. 217, 219 (2008).

4. David E. Winickoff, *Partnership in U.K. Biobank: A Third Way for Genomic Property?* 35 J.L. MED. & ETHICS 440, 440 (2007).

developed from donated human genetic material (HGM) be allocated? Second, and even more fundamentally, to whom should property rights in HGM be assigned?

The present Article will explore this dilemma through several parts. Part I will provide an overview of biobanks, including explorations of underlying scientific, historical, and sociocultural functions. This part will also present the ethical, legal, and social issues implicated by the practice of biobanking—especially when on a national or international scale. Next, Part II will outline the United States' legal framework for both ethical regulation of human subject research, and the allocation of property rights in HGM.

In addition to the dominant United States model, various alternative paradigms for ownership over HGM have attempted to balance competing interests between exclusion and access; private and public; altruism and ownership; and individual and community. These models will be surveyed in Part III, and both the dominant Western paradigm,[5] as well as alternatives based on diverse cultural values, will be critiqued. Subsequently, Part IV will reframe the property rights dilemma in the context of distributive justice. Here I will argue that new modes of "biosociality" have entered into modern global society, such that scientific understandings of human genetics have reshaped social and cultural dynamics.[6] Based on the importance of collective rights in genetic group identities, the Western framework for the assignment of property rights over human genetic material provides an inadequate basis for the realization of distributive justice.

Thus, Part V will propose that, prior to determining which model should govern property rights in human genetic material, we must reimagine the Western paradigm for property ownership. My contention is that in order to actualize distributive justice, we must reframe the ownership debate in collective, rather than individual, terms. In so doing, national and international tangible and intellectual property law regimes should recognize that groups of people who share common genetics also share interests in their own genetic material, as well as any biotechnological products created using their DNA samples.

5. In extremely simplified terms—which will be sufficient for the purposes of this Article—the Western paradigm is one of private, rather than collective, ownership of property. *See* Harold Demsetz, *Toward a Theory of Property Rights II: The Competition Between Private and Collective Ownership*, 31 J. LEGAL STUDIES S653, S667 (2002) (overviewing the rise of private ownership in the West, beginning in Ancient Greek states and the Roman Empire, and increasing in significance as a result of the industrial revolution and economic specialization.).

6. *See* Marianne Sommer, *DNA and Cultures of Remembrance: Anthropological Genetics, Biohistories and Biosocialities*, 5 BIOSOCIETIES 366 (2010).

Therefore, these groups should, at minimum, be afforded access to, and some of the privileges and benefits associated with, the ownership of such products.

I. BIOBANKS: THE SCIENCE, THE HISTORY, THE ISSUES

Conceptually, the practice of biobanking is rooted in the so-called "new genetics" movement, which, according to its proponents, will "lay the groundwork for 'personalized' medicine by allowing a better match between the drug and the individual genetic profile, while 'empowering' the individual by offering greater certainty about their health status and more options in healthcare decisions."[7] In the context of public health, biobanks are seen as generators of population-based preventive interventions, since they compile data surrounding individual genetics, lifestyle, and the impact of environment on disease.[8] For both individual and population-based applications, biobanks are broadly defined as collections of human biological material, in association with personal medical, genealogical, environmental, and lifestyle information. Biobanks exist in many different forms within clinical, research, and judiciary settings.[9]

Notwithstanding this diversity, all biobanks implicate controversial questions. These ethical, legal, and social issues (ELSI) have been broadly discussed. For instance, in the United States, the National Human Genome Research Institute's 2011 ELSI Congress identified three pivotal factors currently shaping genomic research, its clinical translation, and its societal implications: (1) the increasingly blurred boundary between research and treatment; (2) uncertainty, i.e., the indefinite, indeterminate, and incomplete nature of much genomic information and the challenges that arise from making meaning and use of it; and (3) the role of negotiations between multiple scientific and non-scientific stakeholders in setting the priorities for and direction of biomedical research.[10] These factors illustrate broad, thematic challenges that the biomedical community and policymakers will likely be forced to grapple with in the near future.

7. Herbert Gottweis & Alan Petersen, *Biobanks and Governance: An Introduction*, *in* BIOBANKS: GOVERNANCE IN COMPARATIVE PERSPECTIVE 3 (Herbert Gottweis & Alan Petersen eds., 2008).

8. *Id.*

9. *Id.* at 5.

10. Gail E. Henderson et al., *What Research Ethics Should Learn from Genomics and Society Research: Lessons from the ELSI Congress of 2011*, 40 J.L. MED. & ETHICS 1008, 1009 (2012).

Meanwhile, more specific ELSI have also been identified in the context of large-scale biobanking initiatives. For instance, K.L. Hoeyer of the Department of Public Health at the University of Denmark noted that "[t]he larger the biobank, the more complex the social maneuvering."[11] According to Hoeyer, the shift in scale towards larger initiatives has organizational, communicative, epistemic, and cultural effects.[12] These social impacts reflect changes in the relationship between individuals, states, and markets, which in turn lead to legal challenges related to (1) the need for harmonization of the rules governing biobank research; and (2) the need for legal agreement on the extent to which body parts can be considered property, and who is entitled to benefits derived from such property.[13] This Article will focus on this latter need—defining the parameters of the property right in human genetic material.

The ELSI surrounding biobanks—especially when large-scale—are common to all countries in which these repositories have been created. However, especially peculiar legal challenges have arisen in the United States, due to its patchwork of federal and state laws, created by legislatures in some instances, and by judges in others. Under the fragmented American framework, the ethical issues that genomic research implicates tend to be governed by federal statutory law. In contrast, the legal issues have almost exclusively been relegated to state courts, which have applied the laws of their separate jurisdictions to create a complicated scaffolding for the assignment of property rights in human biological materials.

II. COMMODIFICATION OF THE BODY: HUMAN GENETICS, MEDICAL RESEARCH, AND AMERICAN LAW

In the United States, two separate legal frameworks exist to address the practices surrounding biobanking of human genetic material. Federal statutes and regulations broadly govern ethics in research involving human subjects, as well as protection of the confidentiality of

11. Klaus Lindgaard Hoeyer, *Size Matters: The Ethical, Legal, and Social Issues Surrounding Large-Scale Genetic Biobank Initiatives*, 21 NORSK EPIDEMIOLOGI 211, 212 (2012).

12. *Id. See also* Anne Cambon-Thomsen, *The Social and Ethical Issues of Post-Genomic Human Biobanks*, 5 NATURE REVIEWS: GENETICS 866, 866 (2004) (arguing that in all countries, biobanking has raised similar issues, including: (1) the tension that exists between the rights of individuals or groups and the routes towards research progress; (2) the need to provide adequate informed consent; (3) the difficulty of reconciling the non-commercial use of human body parts with the growing role of commercial biobanks; and (4) how best to ensure the optimal and transparent use of biobanks while defining the rights of priority or researchers and companies over samples and data).

13. Hoeyer, *supra* note 11, at 213–14.

personal health information. Meanwhile, the allocation of property rights for ownership of human genetic material has been conducted through the jurisprudence of individual courts at the subnational level. The result is a tenuous status quo in which no national standard for the assignment of property rights in HGM exists, and in which global dynamics are not considered.

A. Regulation of Ethical Issues: Federal Statutory Law

Nearly all research involving human subjects in the United States is governed by a set of federal regulations known collectively as the "Common Rule."[14] The Common Rule's mélange of regulations outline the basic provisions for Institutional Review Boards (IRBs), informed consent, and Assurances of Compliance for all fifteen participating departments and agencies.[15] The new collection of biological materials or information from a person for research purposes, including biobanking, triggers the Common Rule, as does any research not involving new information if it uses "identifiable private information" about an individual.[16]

Similarly, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") covers research uses of "protected health information" ("PHI") associated with the specimens that biobanks contain, but does not apply to the specimens themselves.[17] HIPAA's Privacy Rule prevents a covered entity from disclosing an individual's PHI for research purposes without express authorization. The Privacy Rule does not apply to data that have been de-identified through statistically-approved methods or if most personally identifying information has been removed.[18] However, some categories of information which link an individual to a particular population group (e.g., race, ethnicity, socioeconomic status) may remain intact and still be considered legally

14. 45 C.F.R. § 46.101 (2005). The Common Rule was initially published in 1991, and codified in separate regulations by 15 federal departments and agencies. The Department of Health and Human Services regulations are those which are contained in 45 C.F.R. pt. 46.

15. *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEPT. OF HEALTH & HUMAN SERVICES, *available at* http://www.hhs.gov/ohrp/humansubjects/commonrule/ (last visited Apr. 20, 2013).

16. 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 (1999).

17. 45 C.F.R. § 160.103. *See also* Girod & Drabiak, *supra* note 3, at 221.

18. *See Summary of the HIPAA Privacy Rule*, U.S. DEPT. OF HEALTH & HUMAN SERVICES, *available at* http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html (last visited Apr. 20, 2013).

de-identified, a fact that may leave open the possibility for discrimination[19] if data are misused.[20]

As currently written the Common Rule and HIPAA do not adequately address the unforeseen uses of previously collected genetic material, a problem that biobanks exacerbate. The issue is primarily one of giving adequate informed consent to research subjects, when information or material collected for one purpose is later determined to have value for additional, previously unforeseen purposes. In these instances, obtaining fresh informed consent for new research with previously collected materials has substantial costs, such as difficulties in locating donors, or the potential that they might refuse to consent to the new use of their donated materials.[21]

Due to the inadequacies of the current framework, proposals have been advanced to reform the Common Rule and HIPAA to require discussion about the potential for unforeseen uses of genetic materials as a component of informed consent.[22] The need for such reform is acute in the context of the United States' property rights paradigm for human DNA. The U.S. model for ownership of HGM affords essentially no rights to the individuals who "donate" their tissues for research uses. Thus, adequate informed consent should be understood as the minimum level of recognition for the rights of donors of HGM.

B. Definition of the Property Right: State Case Law

The question of ownership of human genetic material in the United States arguably begins with the story of Henrietta Lacks, a poor African American woman who died of a virulent form of cervical cancer in the 1950s.[23] Biological samples containing Ms. Lacks' genetic material were taken during the course of her treatment, and researchers subsequently capitalized on the aggressive nature of her cancer cells to

19. Note, however, that in 2008 Congress passed the Genetic Information Nondiscrimination Act (GINA), which was "the first preemptive antidiscrimination statute in American history." GINA prohibits genetic-information discrimination in health insurance and employment contexts. Jessica L. Roberts, *Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act,* 63 VAND. L. REV. 439, 441 (2010).

20. Girod & Drabiak, *supra* note 3, at 222–25.

21. Greely, *supra* note 16, at 740.

22. *See id.* at 752–56. Specifically, Greely proposes that the following issues be discussed at the time of obtaining informed consent: (1) permission for unforeseen research; (2) recontact; (3) withdrawal; (4) time limits; (5) availability of information or materials to third parties; (6) implications for groups; and (7) commercial uses.

23. For a detailed account of Ms. Lack's life and legacy, *see* REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS (2010).

develop a method for reproducing human cells in a laboratory.[24] The cell line derived from this research, "HeLa," has had an enormous impact in biomedicine, leading to the polio vaccine, cancer treatments, and new methods for in vitro fertilization.[25] Despite the substantial capital that has circulated due to the creation of the HeLa cell line, the Lacks family has not shared in this wealth. Ironically, the clinical applications of HeLa are inaccessible to Henrietta's surviving children, who cannot afford health insurance.[26]

Subsequently, courts in multiple states have reaffirmed the denial of donors' property rights in their own tissue, and hence have prevented donors from sharing in any economic benefits from biotechnologies developed from samples of their genetic material. The legal doctrine originated in California, in *Moore v. Regents of the University of California*.[27] The case began with John Moore's treatment for leukemia at UCLA Hospital, over the course of which physicians removed his spleen and took samples of tissue and blood. The doctors did not disclose to Mr. Moore that his cells were unusual, nor that their use in research could lead to exciting—and potentially profitable—discoveries.[28] Researchers used these cells to establish the "Mo" cell line, the value of which has been estimated in the billions of dollars.[29]

Mr. Moore brought suit against his treating physicians and the hospital, alleging that the use of his cells in potentially lucrative research constituted a conversion of his personal property, among other claims.[30] The California Supreme Court ultimately rejected Mr. Moore's conversion claim, reasoning that Moore did not retain an ownership interest in his cells following their removal from his body.[31] Although *Moore* is only binding precedent in California, the case has had a foundational impact on how property rights in human genetic material are construed throughout the United States. Courts in other states have

24. Robin Feldman, *Whose Body is it Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law*, 63 STAN. L. REV. 1377, 1381 (2011).

25. *See* SKLOOT, *supra* note 23, at 3.

26. *See* Robin McKie, *Henrietta Lack's Cells Were Priceless, But Her Family Can't Afford a Hospital*, THE GUARDIAN (Apr. 3, 2010), *available at* http://www.guardian.co.uk/world/2010/apr/04/henrietta-lacks-cancer-cells (last visited June 4, 2015).

27. 793 P.2d 479 (Cal. 1990).

28. *Id*. at 480–83.

29. Feldman, *supra* note 24, at 1381.

30. Moore initially stated thirteen causes of action, but only the breach of fiduciary duty and lack of informed consent, and the conversion claims made it to the California Supreme Court. *Moore*, 793 P.2d at 482.

31. *Id*. at 488–89.

reached similar conclusions, tending to value the inputs of medical research over the interests of research participants.[32]

In *Greenberg v. Miami Children's Hospital Research Institute, Inc.*,[33] a Florida federal district court rejected a conversion claim brought by tissue donors against a physician who received the donors' genetic materials, used them to isolate the gene causing Canavan disease, and then obtained a patent on the genetic sequence identified.[34] The *Greenberg* court asserted that "Plaintiffs have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion,"[35] cited *Moore*, and then went on to conclude that "limits to the property rights that attach to body tissue have been recognized in Florida state courts."[36]

Likewise, in *Washington University v. Catalona*,[37] the U.S. Court of Appeals for the Eighth Circuit upheld the district court's finding that patients who were invited to participate in genetic research by providing tissue to a biorepository at Washington University were "donors" and that the samples collected were "inter-vivos" gifts from the patients to the institution.[38] Critics have argued that the decisions in *Greenberg* and *Catalona* are problematic because they confuse informed consent with donation, failing to recognize that research participants should not reasonably be expected to behave like donors in other situations, who might understand that they are engaged in an arms-length negotiation.[39]

These cases illustrate the "traditional assumption" that research participants who provide genetic material are donors, individuals who receive no financial compensation for their samples, receive no share of revenues from any commercial products resulting from research relying on their donated samples, have no patent rights to patentable discoveries that use their donated DNA, and have little or no say about what is done with their samples beyond whatever restrictions were included in their informed consent agreement.[40] This theory of prop-

32. *See* Gail Javitt, *Why Not Take All of Me? Reflections on the Immortal Life of Henrietta Lacks and the Status of Participants in Research Using Human Specimens*, 11 MINN. J.L. SCI. & TECH. 713, 741 (2010).

33. 264 F.Supp.2d 1064, 1066 (S.D. Fla. 2003).

34. *Id*. at 1067.

35. *Id*. at 1074.

36. *Id.* at 1075.

37. *Washington University v. Catalona (Catalona II)*, 490 F.3d 667, 668 (8th Cir. 2007).

38. *Id*. at 673–74.

39. Javitt, *supra* note 32, at 745.

40. Gary E. Marchant, *Property Rights and Benefit-Sharing for DNA Donors?,* 45 JURIMETRICS J. 153, 155 (2005).

erty law—conceptualizing individuals who provide samples of genetic material for biomedical research or to biobanks as "donors"—could appropriately be termed the "Moore model." While it currently embodies the status quo for ownership of HGM in the United States, the Moore model is by no means the only way to understand property rights in the human body.

III. WHO OWNS WHOM: PROPERTY RIGHTS FRAMEWORKS FOR HUMAN GENETIC MATERIAL

The question of to whom property rights in human genetic material should be granted has broader implications than the allocation of legal privileges and economic benefits, although such assignments are themselves tremendously impactful. More fundamental, though, are the various debates that the allocation of property rights in human DNA provokes. These areas of contention manifest diverse sociocultural values, and implicate significant historical trends surrounding economic globalization and the worldwide encroachment of Western conceptualizations of property ownership.[41] The areas of debate—exclusion v. access; private v. public; altruism v. property; individual v. collective—are encapsulated in the various proposed models for ownership of human genetic material. However, each model assigns value differentially, and therefore the selection of one over the others has vast impact over the distribution of benefits, capital, and ultimately, power, in global society.

A. The American Status Quo: The Moore Model

The precedent set by *Moore* and reaffirmed by subsequent case law constructs a donation model for research participation, which has been historically operative in the United States. This "traditional assumption"[42] holds that research participants are donors of the biological samples that they provide, and these individuals therefore waive all property rights as terms of participation in a study. Indeed, typically the terms of this waiver are made explicit. For instance, the informed consent form for Beth Israel Deaconess Medical Center in Boston contains the following provision:

41. *See, e.g.,* Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 455–460 (2006) (discussing the clash of values between the Western desire for strong patent rights for the promotion of innovation and alternative perspectives calling for the protection of traditional knowledge for, e.g., spiritual and cultural reasons).

42. Marchant, *supra* note 40, at 155.

> You also understand and agree that the tissue you donate as a participant in this research program becomes the permanent property of the Beth Israel Deaconess Medical Center. Beth Israel Deaconess Medical Center has no program to compensate you in the event product testing or commercial development takes place.[43]

The Moore model presumes that research participants agree to provide samples of their genetic material based on altruistic motivations. Thus, in *Moore*, the court's majority had no difficulty in concluding that the plaintiff "clearly did not expect to retain possession of his cells following their removal," and so retained no ownership interest in his genetic material after it was extracted from his body.[44] Additionally, the Moore model is predicated on the furtherance of economic rationale—such as incentivization of innovation—rather than on public or collective rights.

B. The European Model: State Ownership

The largest-scale biobanks to date have been established in Europe, in addition to a limited number of other industrialized nations. Several countries or subnational units have established or are establishing large biobanks representing huge populations, including Austria, Estonia, France, Great Britain, Germany, Iceland, Lativa, Norway, Singapore, Sweden, and Quebec.[45] These government-sponsored, population-based biobanks have experimented with different schemes for ownership of the human genetic material that they contain. However, even where ownership of a population biobank database is partly or fully in the hands of a private company, the rights to the "human material" contained within these databases frequently remains in the public domain, vis a vis the state.[46]

Thus, the European model differs from the Moore model in that ownership of HGM contained in European-population biobanks is typically bifurcated, simultaneously allowing for individual and collective property rights. For instance, the U.K. Biobank has been lauded for "staking out a new imagination of the genomic biobank as a common-

43. *Id*. (citing Beth Israel-Ardis Consent Form, at 4).

44. *Moore*, *supra* note 27, at 136–37; *but see Moore*, *supra* note 27, at 154 (Broussard, J., dissenting) (reframing the question for establishing a conversion claim as such: "the pertinent inquiry is not whether a patient generally retains an ownership interest in a body part after its removal from his body, but rather whether a patient has a right to determine, before a body part is removed, the use to which the part will be put after removal.").

45. Gottweis & Petersen, *supra* note 7, at 5; *see also* Mark A. Rothstein, *Expanding the Ethical Analysis of Biobanks*, 33 J.L. MED. & ETHICS 89, 97 (2005).

46. Sarah Wilson, *Population Biobanks and Social Justice: Commercial or Communitarian Models?: A Comparative Analysis of Benefit Sharing, Ownership and Access Arrangements*, 8 TRAMES 80, 86 (2004).

pool resource."[47] But the European model does not wholly depart from the theoretical underpinnings of the Moore model. Indeed, although the example of the U.K. Biobank is intriguing in that its contents are publicly owned, it still "emphasises the ownership and property rights of the research institution above that of the individual participants."[48] While such a paradigm shifts the Moore model's focus from exclusively private rights based on economic rationale, it may not fully assuage concerns over distributive justice.

C. The Free Market Model

In contrast to the European model, which at least acknowledges the importance of collective property rights, some have proposed that privatization should go even further than conceived of in the Moore paradigm. These proposals call for an open market in which all individuals would enjoy the ability to sell their own genetic materials to the highest bidder. The market model would presume that "any valuable object will be more efficiently distributed through a series of voluntary market transactions than through other allocation systems. Thus, the information encoded in an individual's genome should be exchangeable through the free market."[49] In contrast to the understanding of biomedical research subjects as donors, market theory conceptualizes participants as competitors in an economic sphere in which human genetic material is a valuable commodity.

Although it perpetuates the dominant Western value system for property ownership, the free market approach could entail many distributive advantages. Unlike the European model, a free market could facilitate benefit sharing, potentially increase the supply of available donors, and augment public confidence in genetic research.[50] Yet, financially compensating all donors could implicate ethical and practical problems, such as inappropriate inducement to participate in research, and determining the fair market value of human biological specimens.[51] Additionally, the free market approach may not be appropri-

47. Winickoff, *supra* note 4, at 441.

48. Wilson, *supra* note 46, at 86.

49. Catherine M. Valerio Barrad, *Genetic Information and Property Theory,* 87 NW. U. L. REV. 1037, 1081 (1993).

50. Marchant, *supra* note 40, at 169.

51. *Id*. at 169–70; *but see* Marshall B. Kapp, *A Legal Approach to the Use of Human Biological Materials for Research Purposes*, 10 RUTGERS J. L. & PUB. POL'Y 1, 26 (2013) (discussing proposals for Genetic Bills of Rights that have been introduced in Massachusetts and Vermont, which would recognize that human biological material has a fair market value. Such legislation could make it easier to determine what this value should be).

ate for many countries whose social and economic values do not align well with neoliberal economic theory.

D. Open Access Models

A less extreme approach is embodied in models that would provide for open access to biobanked information. Open access models may retain the basic Moore framework; however, they also emphasize the importance of, at least, allowing for open, unrestricted access to data generated by research that has utilized donated DNA. To promote distributive justice, open access, coupled with enhanced informed consent protocols, can be understood as the minimum benefit to which donors are entitled, since "[a]ccess constraints on patented 'health technologies'—medicines, diagnostic agents, and agricultural innovations—may severely compromise human well-being."[52]

Providing rapid and unrestricted access to the research data accrued by large-scale biobanks is a form of "benefit sharing."[53] This concept advocates for the creation of mechanisms to ensure that the advantages stemming from genomic research are enjoyed by whole population groups, rather than by researchers or their host institutions alone.[54] The sharing of benefits derived from research with donated human genetic materials has been frequently recognized as a means for the advancement of distributive justice.[55] Open access models can promote the well-being of the individuals and communities on which scientific progress relies, by simultaneously preventing "parasite patenting of primary data," and by promoting quick and efficient dissemination of research results, even if donors of HGM are not actually recognized as rights holders.[56]

The intersection of distributive justice and open access to research results implicates not only theoretical questions of ownership of human genetic material, but also the parameters of international IP

52. Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 919 (2009).

53. Yann Joly, Clarissa Allen & Bartha M. Knoppers, *Open Access as Benefit Sharing? The Example of Publicly Funded Large-Scale Genomic Databases*, 40 J.L. MED. & ETHICS 143, 143 (2012).

54. *Id.*

55. *See* Lori B. Andrews, *Harnessing the Benefits of Biobanks,* 33 J.L. MED. & ETHICS 22, 27 (2005).

56. Joly, et al., *supra* note 53. Notably, some authors have argued that current open access/open source models do not adequately address the problem of parasitic patenting. *See, e.g.,* 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, 1492 (2007) (proposing that "creators of future large-scale, publicly funded genomic databases ought to implement a nonexclusive, nonroyalty-bearing licensing policy for [biobanked] data.").

law regimes. The American patent system values strong individual property rights and private ordering of ownership, and these values have been internationalized through multilateral agreements such as the 1992 Trade Related Aspects of Intellectual Property Agreement (TRIPS).[57] However, it is interesting to consider how "distributive safeguards" might be integrated into this paradigm, thus enhancing access to patented health technologies for low-income and other marginalized populations.[58]

For instance, it has been proposed that the public institutions which contribute large amounts of "scientific capital" —i.e., money, labor, and bodily materials—to life sciences research are uniquely positioned to create a "distributive commons" for patented health technologies.[59] Legally, this shared ownership structure could conceptually resemble a public-private tenancy in common, combining the productive power of the private sector with publicly-oriented distributive safeguards.[60] Since both public and private institutions have legitimate claims to patented health technologies,[61] a legal framework granting shared ownership over the downstream uses of these technologies would be reasonable and appropriate. By recognizing open access to biobanked data, advantages of the current patent law scheme could be retained, while communitarian well-being could be enhanced.

E. Quasi- / Semi-Patents Models

Similarly, another potential means to achieve benefit-sharing ends on a broad, system-wide scale could entail modifying extant international legal framework for patent eligibility by limiting the ability of researchers to obtain protections for biotechnologies derived from HGM. One proposal for patent law reform would incorporate two ownership models for the contents of biobanks, distinguishing human genetic specimens from the annotative information associated there-

57. Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 AM. J. INT'L L. 641, 643 (2004) (noting that the United States assumed the leadership role in pressing for the adoption of TRIPS and that the agreement requires countries to extend patent protection to bioengineered goods with the potential imposition of trade sanctions if they do not comply).

58. *See* Lee, *supra* note 52 at 1014.

59. *Id.* at 918.

60. *Id.* at 926–27.

61. *Id.* at 1014.

with.[62] According to this approach, biobanked tissue would still be technically owned by the entity responsible for maintaining the tissue and the database.[63]

However, this entity would enjoy rights to only a few "sticks" in the rhetorical "bundle." In contrast to the Moore model, biobanks would exist in a semicommons, in which member researchers would have access to all relevant tissue and datasets to enable efficiency and effectiveness.[64] Meanwhile, tissue information would be situated as a "pure commons" within the biobanking semicommons, with de-identified information available to all members of the semicommons, including researchers and tissue donors.[65] Thus, it is argued that imagining biobanks as operating within a liberal semicommons would allow more benefits to inure to tissue donors, without drastically altering the extant patent law frameworks. Yet, even if construed as a semicommons, it is unlikely that the information-access benefits that research donors would enjoy would fully address distributive justice concerns.

F. Economic Benefit Sharing Models

Ultimately, the need to achieve distributive justice in the context of biobanking demands more than access to information, although such transparency would indeed be an improvement over the status quo in the United States. Multiple ideas about how to share the economic benefits of biotechnologies developed from donated genetic materials have been advanced. Yet there is little agreement about which model would be most feasible. Furthermore, many critics have voiced caution over the possibility of "undue inducement;" the notion that individuals might be inappropriately lured to participate in research if they are offered direct, financial returns on their involvement.[66] But the accuracy of such concerns may be increasingly questioned, as "[r]esearch participants' constitutive exclusion from access to the vast profits that accrue to researchers and companies is . . . growing difficult to defend and describe in conventional ethical languages of gift and a diffuse public good."[67]

62. Ken Gatter, *Biobanks as a Tissue and Information Semicommons: Balancing Interests for Personalized Medicine, Tissue Donors and the Public Health*, 15 J. HEALTH CARE L. & POL'Y 303, 335 (2012).

63. *Id.* at 341.

64. *Id.*

65. *Id.* at 342.

66. *See, e.g.*, Cori Hayden, *Taking as Giving: Bioscience, Exchange, and the Politics of Benefit-Sharing*, 37 SOCIAL STUDIES OF SCI. 729, 739 (2007).

67. *Id.* at 740.

Yet, even if frameworks for economic benefit sharing are to be considered for implementation, it remains unclear which would best serve the ends of capitalism and distributive justice simultaneously. Proposals have included the idea of royalty-distribution,[68] or the issuance of a single share of "subject-class" stock in any tied-in biotech venture to all participants in a research trial.[69] Others have discussed the extension of the "direct negotiation" model,[70] in the context of fostering joint ventures based on contract law between biobanks and tissue donors.[71]

Importantly, these myriad proposals for economic benefit sharing operate in terms of equity, "definitively stop[ping] short of offering property rights as a kind of benefit itself."[72] Therefore, benefit sharing frameworks typically avoid any discussion of potential participation by tissue donors in a market for their biological specimens.

G. Hybrid Models: Proposals for Comprehensive Reform

Perhaps the most pragmatic yet radical proposals for reforming property law with respect to the ownership of human genetic material are those which have attempted to strike a more equitable balance between the interests of various stakeholders. Such approaches are based on the argument that "[n]either the Moore-based donation paradigm nor the market-based alternative is sufficiently satisfactory to quiet professional and social concerns."[73] Additionally, these hybrid models attempt to go beyond approaches for open access or economic

68. *See, e.g.*, Jon F. Merz et al., *Protecting Subjects' Interests in Genetic Research*, 70 AM. J. HUMAN GENETICS 965, 968–69 (2002). The authors state that "[e]ntities involved in the commercial aspects of research (including companies and universities that develop intellectual property portfolios from which royalty revenues can be earned) should be expected, as a matter of public policy and research ethics practice, to openly negotiate with foundations and disease-associated advocacy group [*sic*] and to resolve issues regarding ownership control of downstream use, limits on financial profit-taking from inventions, equitable profit sharing, and other acknowledgements of all contributions before the research is done. *Id.* at 970.

69. Hayden, *supra* note 66, at 742.

70. The direct negotiation model is best exemplified by the work of the organization PXE International. As an advocacy group for individuals with pseudoxanthoma elasticum ("PXE"), a rare connective tissue disorder, the organization recruits researchers, but only those who agree to abide by PXE's terms. The terms of these contracts provide that PXE International will enjoy co-ownership of any patent that ensues from study of the tissues that the biobank provides. Organizational decisionmaking is guided by patients and the relatives of patients, who represent the population with the largest stake in locating therapies and cures. PXE INTERNATIONAL, http://www.pxe.org (last visited June 4, 2015).

71. *See, e.g.*, Andrews, *supra* note 55, at 27.

72. Hayden, *supra* note 66, at 743.

73. Charlotte H. Harrison, *Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 23 AM. J.L. & MED. 77, 78 (2002).

benefit sharing, by allocating rights in HGM to biomedical research donors.

Following this logic, Harrison proposes a model that would maintain a general rule of donation for HGM at the time it is acquired and provide an objective, non-market mechanism for compensation after research use for unusual cases in which samples prove to have significant commercial utility, and thereby the potential to generate substantial profits.[74] The "objective, non-market mechanism" that Harrison proposes would be a statutorily-established compensation tribunal that would "use statutory standards to calculate the measure of compensation to be paid" to a donor if and when her tissues are determined to have exceptional market value.[75]

Alternatively, Boyle proposes a "trust system" which would offer a mechanism to promote altruism while allowing compensation for specific individuals who contribute a "great deal" to a research study.[76] Boyle's model *would* confer a property interest to individual donors, which would be granted by a governmental commission that would create an inter vivos trust, at the time of donation, on behalf of the donee, "in case his tissue has significant commercial value in the future."[77] In contrast, Winickoff and Winickoff's "charitable trust" model would position the biobank as a trust with the public as the beneficiary and the biobank's managers as trustees, who would assume all of the legal obligations that such a position entails.[78]

Alternatively, Gitter argues that research participants should have the opportunity to bargain with researchers autonomously.[79] Thus, Gitter proposes that "Congress enact legislation permitting and regulating the sale of human tissue used for research purposes, and establish a tort of conversion in the event that a scientific researcher wrongfully exercises dominion over a research participant's tissue."[80]

74. *Id.* at 79.

75. *Id.* at 97.

76. Joyce Boyle, *To Pay or Not to Pay, That is the Question: Finding an Intermediary Solution Along the Moore Spectrum*, 7 MICH. ST. U. J. MED. & L. 55, 74 (2002).

77. *Id.* at 75.

78. David E. Winickoff & Richard N. Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 NEW ENGLAND J. MED. 1180, 1182 (2003); *see also* David E. Winickoff & Larissa B. Neumann, *Towards a Social Contract for Genomics: Property and the Public in the 'Biotrust' Model*, 3 GEONOMICS, SOC. & POL'Y 8, 8 (2005) (attempting to clarify how "thorny questions around property rights, the right to withdraw from research, access to materials, and funding might be handled within . . . a charitable trust structure").

79. 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, 270 (2004).

80. *Id.* at 268.

Finally, Conley et al. turn away from the historical language of the law of tangible property and trusts to propose a trade secret model for genomic biobanking.[81] The Conley model authors conducted a study in which participants tended to describe their DNA in ways that were reminiscent of the legal definition of a trade secret.[82] Hence, the authors propose a biobank-participant contract, under which participants' rights and researchers' obligations would be defined on a case-by-case basis, with the resulting agreement enforceable by courts.[83]

Although each of these alternative frameworks for ownership of human genetic material has merit, none should be implemented until a fundamental prerequisite is met. That is, the ownership debate should first be broadly reframed in terms of distributive justice. As Marchant has noted in calling for a "new ethic" of genetic donation, "[w]e will all (hopefully) share in the ultimate benefits of genetic research, and therefore it may only be fair that we all do our part in making those benefits possible."[84] While I agree that a "new ethic" is required before reforming the legal framework of human DNA ownership, I believe that Marchant's proposal misses the mark. Rather than shifting societal value toward augmented altruism, focusing on the actions of the individual participant, I argue that the very notion of biosociality[85] should be reformulated. Under such a re-valuation, the benefits of biomedical research would, in part, inure to groups. Property rights in human genetic material would be re-imagined, collectivized.[86]

IV. AN ARGUMENT FOR DISTRIBUTIVE JUSTICE

Distributive justice can be understood as a "normative principle favoring equality of access in resource allocation" in contrast to the "more commonplace utilitarian objective of allocating resources to maximize aggregate welfare."[87] In the context of biobanking, distributive justice refers to a systematic concern for ensuring access to the

81. John M. Conley et al., *A Trade Secret Model for Genomic Biobanking*, 40 J.L. MED. & ETHICS 612, 613 (2012).

82. *Id.* at 614.

83. *Id.* at 623.

84. Marchant, *supra* note 40, at 173.

85. "Biosociality" refers to forms of collective action that arise in relation to the biological self. Mark L. Flear, *"Together for Health"? How EU Governance of Health Undermines Active Biological Citizenship*, 26 WIS. INT'L L.J. 868, n.5 (2008).

86. The "collectivization" of the research subject refers to discussions "in which the notion of community as a protectable collective has been ricocheting vigorously between the aboriginal and the associational, the conceptual spaces of the fourth and first worlds, ethnic groups and patient groups, nations and families." Hayden, *supra* note 66, at 744.

87. Lee, *supra* note 52, at 921.

resources generated by biotechnology to those who cannot afford market prices.[88] The story of Henrietta Lacks offers an example of the dearth of distributive justice in the United States' model for ownership of human genetic material. As discussed in Part II of this Article, although the HeLa cell line has generated billions of dollars in profits, Lacks' family is still too poor to afford health insurance.[89] Thus, if one of Lacks' children or grandchildren suffered from a condition that could be treated through a HeLa product, she would likely not be able to gain access to it, unable to pay the market price. Distributive justice seeks to redress this unfortunate irony.

In order to begin to realize distributive justice in the context of biotechnological development, we must question the Western notion that the rights associated with property ownership are vested primarily in private individuals. Instead, we might imagine that for certain forms of property, models of ownership which locate rights in groups or collectives would be more appropriate. Human genetic materials may be considered one form of collective or shared property, since no individual person possesses genetic material entirely distinct from that of other people in, for example, his family.[90]

Furthermore, inapposite to an understanding of research subjects as autonomous individuals, "due to the (shared) nature of genetic material and the information it provides, families, disease communities, populations or 'ethnic groups', and even entire nations . . . are the subjects of genetics research."[91] Indeed, the Western paradigm for ownership of human genetic material ignores almost entirely the groups that exist between the national governments that regulate research and the individuals who participate in research studies.[92] Ironically, though, research in human genetics is actually about these "groups between"—ethnic groups, disease organizations, and families. Yet the extant legal framework – at least in the United States – gives these groups no formal direction over research studies about them.[93]

88. *Id.*

89. *See* McKie, *supra* note 26.

90. Natalie Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research*, 23 HARV. J.L. & TECH. 119, 132 (2009) (noting that the "shared nature of genetic information may necessitate new procedures for obtaining familial consent for public disclosure of genetic information" since family members also have a stake in the confidentiality of the samples provided by consenting tissue donors).

91. Hayden, *supra* note 66, at 744.

92. Henry T. Greely, *The Control of Genetic Research: Involving the "Groups Between"*, 33 HOUS. L. REV. 1397, 1398 (1997).

93. *Id*. at 1398–99.

Nevertheless, some have proposed that biobanking—even within the confines of current governance structures—could be leveraged to empower population groups who have been excluded from the genomics revolution.[94] These groups—termed "health care have-nots" ("HCHNs")—include those without economic means or a loud political voice, who have been traditionally marginalized in clinical research, such as children, women, and many minority groups.[95] Several strategies could currently be employed to share benefits with populations of HCHNs, ranging from specific technology transfer arrangements to the generalized channeling of revenue into public health basic needs such as vaccines, clean water, and sanitation.[96]

Yet, the most fundamental need is to recognize that rather than individual research participants, these groups—the HCHNs, as well as other groups between, such as disease organizations—should be at the heart of distributive justice proposals. In other words, "it is communities or groups (even populations and nations) *rather than individuals* that serve as the viable subjects of benefit-sharing."[97]

V. REDEFINING HUMAN GENETIC PROPERTY IN THE CONTEXT OF DISTRIBUTIVE JUSTICE

In order to maximize distributive justice in the context of biobanking, thereby promoting enhanced equality in access to the fruits of health technologies, the ownership debate must be reframed in collective, rather than individual, terms. Implicit in this reconceptualization is the recognition that groups of people who share common genetics also share interests in any biotechnological products that are created using their DNA. Therefore, we should re-envision how the property rights associated with human genetic material are allocated, departing from a paradigm of individual ownership, legally acknowledging a genetic reality.

A. A New Bioethics in United States & International Patent Law

To comprehensively reconceptualize American property law theory in the context of ownership of human genetic material would be a daunting undertaking. However, initial steps could be taken to intro-

94. Michael J. Malinowski, *Could Biobanking be a Means to Include "Health Care Have-Nots" in the Genomics Revolution?*, 9 DEPAUL J. HEALTH CARE L. 1005, 1008 (2005).

95. *Id*. at 1005–06.

96. *Id*. at 1019–20.

97. Hayden, *supra* note 66, at 746 (discussing the position of Merz, et al. (2002) and the HUGO Ethics Committee) (emphasis in original).

duce a bioethics of distributive justice into the extant intellectual property law framework in the relatively near future. For instance, the U.S. Patent Office ("USPTO") apparently does not conduct any review of the source of the biological material in patent applications involving genetic resources.[98] Since the USPTO has yet to implement any sort of "Model Ethical Protocol" or other form of "ethical review," proposals such as the "Carvalho Requirement" have been advanced.[99]

The Carvalho Requirement would establish as a prerequisite for patentability of biotechnologies the "requirement that applicants for patents in the field of biotechnology disclose the source of the genetic resources eventually used as raw materials or tools in the inventive activity."[100] The disclosure of the source of genetic resources can be understood as a safeguard against the improper assertion by researchers of rights over biological material collected from vulnerable populations, such as indigenous groups.[101] Any reconsideration of the role that ethics play in patent law should not be limited to the United States. Indeed, in an increasingly global economy the role of ethics should be considered on a worldwide basis, given the backdrop of multilateral IP agreements such as TRIPS.[102]

Furthermore, mechanisms for protecting the "groups between" are especially important given the practice of transnational genetic sampling from indigenous groups. Concerns have principally been expressed over "biocolonialism," a phenomenon in which "isolated indigenous groups have become an ever-limited and rare 'source' for the research community,"[103] especially researchers from industrialized nations such as the United States. Generally, it has been argued that "developed countries' patent-based systems and the developing countries' sovereign-based systems have overreached in permitting or asserting ownership rights over genetic material."[104] Thus, the patent offices in wealthy, industrialized countries should take international implications into account when setting the guidelines for patent examiners' evaluation of patents in human genetic material, especially when

98. Marina L. Whelan, *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. 14, 20 (2006).

99. *Id*. at 23.

100. Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J. L. & POL'Y 371, 374 (2000).

101. Whelan, *supra* note 98, at 26.

102. Ho, *supra* note 41, at 526.

103. *Id*. at 525.

104. Safrin, *supra* note 57, at 641–42.

that material is sourced from vulnerable populations in the developing world.[105]

Beyond the protections that could result from the introduction of a new bioethical framework within national patent offices, some commentators contend that a new international regime is necessary to realize distributive justice in biomedical research. For instance, Baird has proposed an "individual/community property rights model," to be enacted through a prospective international agreement under which each country would adopt legislation to become compliant with five principles related especially to informed consent and benefit sharing.[106] These principles include provisions that grant individuals ownership rights over the tissues which they may freely decide to "donate," and that conceptualize donated tissue as community property.[107] Global adoption of Baird's model—or even serious consideration of its implications in countries like the United States—may be unlikely. Yet it is important to recognize that advances in modern biotechnology will necessarily dictate the evolution of contemporary tangible and intellectual property legal frameworks at some future moment.

At such a time, it will be fundamental to consider how the issue of ownership of human tissue relates to broader sociocultural questions, "such as struggles over the role of the state, philanthropy, and the private sector in allocating resources; questions about the relationship between entitlements and rights; and perhaps most vividly, questions about how new forms of privatization seem to give rise to a range of 'public-izations' or processes of producing collectives, the implications of which are far from self-evident."[108]

In other words, although the debate over property rights in human genetic material represents one conversation about how legal paradigms could be shifted from a focus on the individual to the collective, such discussions are potentially numerous. Thus, frameworks for how property rights over human genetic materials are allocated should

105. *Id.* at 675.

106. Melanie Baird, *When and Why Does What Belong to Whom? A Proposed Model for the International Protection of Human Donors of Biological Material*, 32 CAN.-US. L.J. 331, 347 (2006).

107. The principles as fully enumerated are: (1) Informed consent is obtained from all who donate tissue; (2) Each individual may independently decide whether or not to donate *their tangible property*, their tissue, to research; (3) Donated tissue is viewed as community property and a percentage of any profits made from the commercialization of this shared property must be allocated; (4) Each country will establish an administrative agency, an arbitration panel, a tribunal, or a similar objective, non-profit body . . . [which will] select projects and organizations that best represent the community of interest of tissue donors. Allocated profits will be shared between those selected; (5) The same non-profit agency described in (4) shall have the authority to grant compulsory licenses. *Id*. at 347–48 (emphasis added).

108. Hayden, *supra* note 66, at 753.

be reimagined in a manner consistent with principles of distributive justice. In so doing, provisions from the alternative models of ownership discussed in Part IV of this Article should be considered. Until this future manifests, the voices of members of vulnerable populations should be better translated into international law and policy, through efforts of community empowerment and participatory democracy.[109] A distributive justice foundation may then be laid, if only in theory.

CONCLUSION

The diverse practices surrounding the phenomenon of biobanking—including biomedical research and derivative health care technologies—offer tremendous promise for the propagation of greater social good. Indeed, if done according to sound bioethical principles, biobanking initiatives could help to alleviate the suffering resultant from illness and disease, while also promoting distributive justice through benefit sharing. To best achieve these ends, it is likely that current models for ownership of human genetic material will need to be radically redesigned. In so doing, human genetic material should be conceptualized as community, rather than individual, property. The human body may thus be understood as a "tangible and intangible complex,"[110] with the ownership interests therein allocated between tissue donors and communities, but not inherently vested in researchers, institutions, governments, or corporations.

109. For an example of how participatory democracy may be leveraged to achieve such ends, see Vence L. Bonham, et al., *Community-Based Dialogue: Engaging Communities of Color in the United States' Genetics Policy Conversation*, 34 J. HEALTH POL. POL'Y & L. 325 (2009) (discussing the Communities of Color Genetics Policy Project, which engaged individuals from African American and Latino communities of diverse socioeconomic levels in the process of "rational democratic deliberation" on ethical and policy issues including genome research).

110. *See* Bellivier & Noiville, *supra* note 2.