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Inalienably Yours?

The New Case for an Inalienable Property Right in Human Biological Material: Empowerment of Sample Donors or a Recipe for a Tragic Anti-Commons?

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Abstract

Modern biomedical research into the genetic component of common diseases calls for broad access to existing and novel collections of samples of human biological material, aka Biobanks. Groups of donors of these samples, however, increasingly claim a property right in their samples. They perceive the recognition of a personal property right in their biological material as the best means to serve two goals: to secure ongoing control over their samples after donation and to underpin their claim for a share in the proceeds that the research on their samples may yield. Given the objective of ensuring ongoing control, this property right is claimed to be inalienable. Recognition of a personal property right in one's biological material is problematic, especially where the requirement of inalienability seems at odds with the claim for a

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share of the profits. Yet, property rights in human biological material may be justified in a certain context, e.g. to enable subsets of patients to negotiate the terms and conditions of the research into their specific disorders. Biobanks, however, contain so many samples, which can be used for so many research purposes, that the unrestricted exercise of personal property rights by the sample donors will lead to a proliferation of rights. This proliferation is likely to deter or slow down both the creation of de novo Biobanks and the use of existing sample collections. Thus, recognising inalienable property rights in human biological material may lead to suboptimal use of these resources and create a classic 'anticommons property' scenario. It would also undermine the current trend to simplify existing informed consent requirements which aims to facilitate broad and previously unanticipated research on de novo and existing Biobanks. In addition, the tradition of altruistic participation in research and the notion that large-scale collections of human biological material are global public goods are arguments against recognising inalienable personal property rights in human biological material, at least in the context of Biobanks. To avoid uncertainty over the issue of who owns collected human biological material, the principle that the property rights in such material vest in the entity lawfully collecting and storing the material should be implemented in legislation. This way most individuals and their offspring will benefit more than when they heed the call to stand up for their property rights in their samples.

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Introduction: Mo(o)re Coming to a Court Near Your Biobank Soon?

Fourteen years have passed since the California Supreme Court denied John Moore a property interest in his removed bodily material.[1] In the meantime, repositories holding human biological material, such as national newborn screening-card collections or national pathology archives, have continued to grow exponentially, currently holding hundreds of millions of samples.[2] At the current time, these collections may assume a novel and previously unanticipated importance in that they can be linked and converted into so-called 'biobanks'; large-scale collections of human biological material and associated health data.[3] Biobanks are also being created *de novo* or 'from scratch' by the assembly of new collections of human material and associated health data from a representative part of a population, as in Iceland, Estonia and the UK, and as currently considered in the US.[4] There is even the initiative for an international and potentially global Biobank with the establishment of the Public Population Project in Genomics ("P3G") consortium.[5] The rationale behind the creation of Biobanks is that they are considered an invaluable tool to aid research into the interaction between genetic (nature) and environmental (nurture) factors in the development of common diseases- one of the "Grand Challenges" in the post-genomic era.[6]

The full scientific and commercial potential of a Biobank, however, may not be realised if there is uncertainty over the question of who owns the collected material. In order not to chill research and investment or the very creation of a Biobank, any uncertainty about clear title to the collected material must be resolved prior to its creation. In fact, resolving this uncertainty is more important for the future of Biobanks than resolving it in any particular way.[7] *De novo* Biobanks typically address the ownership issue by requiring sample donors to waive or assign any property rights in the material they supply to the Biobank. Existing repositories often lack such a waiver or assignment and they may lack appropriate consent of the sample donors for novel research questions. There is a current shift, however, towards acceptance of

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[1] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), *cert denied* 499 U.S. 936 (1991).

[2] According to a 1998 estimate of the U.S. National Bioethics Advisory Commission "at least 282 millions specimens (from more than 176 million individuals cases) are stored in the United States, and the collections are growing at a rate of over 20 million cases per year". National Bioethics Advisory Commission (NBAC), *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, Rockville, Maryland, August 1999.

[3] Aka "large-scale human genetic research databases", "gene banks" or "population databases".

[4] *E.g.* Icelandic Biobank, the Estonian Gene Bank, the UK Biobank, the International HapMap project including populations from Nigeria, China, Japan and the USA. For an overview see: M A Austin, S Harding and C McElroy, "Genebanks: A Comparison of Eight Proposed International Genetic Databases", (2003) 6 Community Genetics 37-45. For the US initiative see the NIH Request for Information: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-046.html.

[5] See http://www.p3gconsortium.org/

[6] F S Collins, E D Green, A E Gutmacher and M S Guyer, (2003) "A vision for the future of genomics research", 422 Nature, 840.

[7] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Ownership of Human Tissues and Cells-Special Report", OTA-BA-337 (Washington, DC: U.S. Government Printing Office, March 1987) (hereinafter "OTA"), at 4.

simplifying existing specific informed consent requirements for previously unanticipated research use, which would obviate the need for *re*-consent for each new research project and thus 'unlock' these repositories for broader research use.[8]

However, both property waivers and assignments and the trend towards broad consent, may be undermined by a countervailing trend. While courts and legislatures have long been reluctant to recognise property rights in human biological material, donors and commentators have recently reacquired a taste for the commodification thereof. This trend calls for patient empowerment through the recognition of an 'inalienable' personal property right of a person in his or her biological material. Property proponents are pleading in courts and urging legislators to create new property rights in human biological material as a means to secure ongoing control over their material after donation and to enable them to share in any benefits that may result from the research on the material they provide. One author has even calculated that an individual's DNA sample is worth USD 50,000, and has urged everybody to stand up for their property rights in their samples.[9] The fact that individuals supply a Biobank's base material seems to justify such a claim. Given the objective to ensure ongoing control, this property right is claimed to be inalienable. Under this 'inalienable property' model, waivers and assignments of property rights, as required by *de novo* Biobanks, are held void or voidable as against public policy. As a result, property rights in the collected material would vest in countless individuals. Also, this approach would render obsolete the trend towards simplifying consent for research on existing collections. While researchers would no longer be required to obtain specific re-consent for each new research project under this simplified consent model, they would be required to obtain such consent under the proposed property model.

The recent call to recognise property rights in samples on the one hand and the need to promote research on Biobanks on the other hand, urges a reconsideration of the question of whether individuals indeed have a personal property right in their collected biological material.[10] To do this, Part II will first summarise the present state of the law in a number of common law jurisdictions, including the inferences that can be drawn in this respect from the recently enacted UK Human Tissue Act 2004. Part III will describe the new arguments that are currently being made for recognising an inalienable property right in human biological material. Part IV will then revisit the issue of whether an individual has a property right in his biological material as such. While most commentators limit their discussion of this issue to the question of whether bodily material is alienable, this Article attempts to analyse whether human biological material fits each and all of the eleven standard incidents of personal property that have become the commonly accepted bundle of core property rights. This part also addresses the issue of whether personal property rights may be

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[8] B M Knoppers, "Biobanks: simplifying consent", 5 Nature Reviews Genetics, (2004), 485.

[9] J C Bear, "What is a person's DNA worth? Fair compensation for DNA Access", (2001) paper presented at 10th International Congress of Human Genetics in Vienna.

[10] This article will not discuss the question of who owns the *information* contained in a biobank, *i.e.* the medical and genetic information that can be derived from the materials and the associated health data. For an analysis of the multiple parties that could claim a database-right in the data contained in genomic databases see: J A Bovenberg, "Should Genomics Companies Set Up Database in Europe?", 18 Nature Biotechnology, 907, September 2000. Likewise, this article will not discuss privacy rights with respect to the information tha may be contained in biological material. As will be explained, the question whether or not to recognise property rights in human biological material does not affect the existence and exercise of privacy rights.

extended to encompass human biological material, if and when processed and cultured.

Part V will analyse the policy considerations pro and contra the recognition of property rights in human biological material. Part VI will examine the implications of recognising inalienable property rights in the specific context of a Biobank. I will argue that the recognition of property rights in human biological material in this context may lead to a proliferation of property rights that could result in the suboptimal use of this new resource. To articulate the adverse consequences of the potential proliferation of property rights, Part VI will apply the anticommons property theory to existing and *de novo* Biobanks. Anticommons property is associated with the '*tragedy*' that too many rightholders in a resource may block optimal use of such resource. It will be examined whether a Biobank could become anticommons property and if so, whether a Biobank Anticommons will be necessarily tragic. To put the analysis presented in this Article into context, it will be preceded by a typology of Biobanks in Part I.

Part I: What is a Biobank?

A biobank can be defined as a large-scale collection of human biological material of a representative part of a population and associated health, clinical and lifestyle data, including healthy and ill individuals, organised in a systematic way, to be stored long term, for multiple-purpose biomedical research ('Biobank'). The research objective distinguishes Biobanks from banks set up for therapeutic, transplantation or transfusion purposes. The size of a Biobank is deemed to enable statistically meaningful research aiding (population) studies into the causes of common complex diseases, drug reactions, the interplay between genetic status and the environment and public health questions. A Biobank provides a means of identifying the multifactorial causes of disease and showing how they interact with one another. Research using a Biobank should allow predictions of the risk of disease in populations, rather than predicting risk in individuals. Knowing the difference in risk in populations can provide direct evidence for the scope of prevention. Information from a Biobank may 'help specify meaningful subgroups of illness and improve the specificity [and] effectiveness of all kinds of healthcare'.[11] Also, Biobanks are thought to address a number of shortcomings associated with traditional case-control studies.[12]

Biobanks can be created and operated on a public, private or public-private footing.[13] They may be governed by specific legislation (Iceland, Estonia), and/or be subject to a specific regulatory framework (UK Biobank and the proposed US National Biospecimen Network). These frameworks set forth the terms and conditions of the governance of the resource, including but not limited to, issues of access to the bank, coding and anonimisation of personal data and donor's access to research results. In

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[11] UK Biobank, http://www.ukbiobank.ac.uk/why.htm, "Why is this needed and what are the benefits?" (2004)

[12] F S Collins, "The case for a US prospective cohort study of genes and environment", 429 Nature 475, 476.

[13] J A Bovenberg, "Ownership and Commercialisation of Large-scale Human Genetic Databases", OECD report on Biobanks, forthcoming.

addition, existing applicable federal, state and local rules will continue to apply, such as the EU data protection legislation and the US HIPAA Privacy Rule.

How can a Biobank be created?

As we have seen, there are basically two ways of creating a Biobank; either *de novo*, or by converting one or more of the many pre-existing collections of human biological material into a Biobank. Practically, most biobanks are 'hybrids' in that they combine novel collections of bodily material with existing data or the other way around. Examples of *de novo* collections are the Icelandic Biobank,[14] the Estonian Genebank[15] and the UK Biobank. Earlier this year, the United States National Institutes of Health issued a request for information regarding the design and implementation of a large-scale prospective cohort-study of genetic and environmental influences on common diseases.[16] The US Biobank is to include existing cohorts.[17] Examples of potential 'convertibles' are national collections of newborn screening cards and pathology archives. An international consortium linking national biobanks has been established in the form of the P3G consortium.[18] Most recently a call was made for a global human genome epidemiology initiative.[19]

A major difference between *de novo* Biobanks and pre-existing collections of human tissue is that the latter were not originally designed as Biobanks, and they may lack appropriate consent for previously unanticipated research questions. In addition, they are much more diverse in terms of the population included (affected and/or unaffected individuals, specific or general community), the nature and size of the biological specimens and related data collected, the context of the collection (clinical or research settings), the form of storage, and the underlying scientific purpose (ranging from screening programs, association studies, genetic epidemiology to pharmaco-genetics).[20]

What human biological materials go into a Biobank?

Biobanks contain certain types of human biological materials. Human biological materials can be defined to encompass 'the full range of specimens, from subcellular structures such as DNA, to cells, tissues (*e.g.* blood, bone, connective tissue, and skin), organs (*e.g.* liver, bladder, heart, kidney and placenta), gametes (*i.e.* sperm and ova), embryos, foetal tissues, and waste (*e.g.* hair, nail clippings, urine, faeces, and

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[14] For a description, see http://www.decode.com. This biobank is not to be confused with the Icelandic Health Sector Database, which is currently on hold.

[15] See http://www.geenivaramu.ee/.

[16] See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-046.html

[17] The Scientist, May 26, 2004, available at http://www.biomedcentral.com/news/20040526/04/

[18] See http://www.p3gconsortium.org/

[19] M J Khoury, "The case for a global human genome epidemiology initiative", 36 Nature Genetics (2004) 1027, see also http://www.cdc.gov/genomics/hugenet/default.htm.

[20] C Sallée and B M Knoppers, "Existing Human Genetic Research Databases", OECD report on HGRD's, forthcoming.

sweat, which often contains shed skin cells)'.[21] Most human materials are made of or carry cells which are the basic structural units of living organisms. Some human materials contain 'non cell' fractions such as serum, the 'non cell' fraction of blood, which may carry enzymes and minerals and other materials.

Pre-existing repositories may contain a variety of human biological material, such as pathological tissue or the blood drops on Guthrie cards. By definition, a Biobank cannot state in advance the complete range of analyses that will be performed on the collected material. Consequently, the collection, processing and storage of the samples in *de novo* Biobanks is designed so as to ensure the widest possible range of analyses that can be carried out on the samples in the future. In principle, a Biobank could be fed with all sorts of human biological material: hair, nails, and, indeed, blood, sweat and tears. In practice, the three most advanced *de novo* Biobanks - Iceland, Estonia and the UK Biobank - have chosen to take blood samples. The 0.5 million participants in the UK Biobank, for example, will be asked to contribute 40 mls of blood. The constituent fractions of blood are plasma, buffy coat, serum and red cells. Prior to storage, the blood samples will be fractionated and aliquoted in different storage formats to protect the long term integrity of the samples. The samples of each participant will also undergo a default series of biochemical measurements. Whole blood will be stored for subsequent DNA analysis. In addition to blood, UK Biobank will also be collecting urine samples from the participants. Urine contains a number of bodily products, reflecting the overall metabolic status of an organism and can reveal important information pertaining to the presence of pathologies or biological stressors.[22] For the avoidance of doubt, the Biobanks that are the subject of this article are used for biomedical research, and not for transplantation or therapeutic uses. They typically contain blood and regenerative tissue (except sperm and ova), *i.e.* tissue that can be replaced by the body after removal. They typically do not contain organs, bone, sperm, ova, embryos or foetal tissue and, therefore, are not to be confused with organ banks, sperm banks and the like.

On what basis are samples transferred to a Biobank?

Participation in a *de novo* Biobank is on a voluntary basis and requires informed consent. Typically, consenting participants are required to waive any property claims in the biological material they supply to the bank or to assign such rights to the bank. The informed consent form used for the Estonian Gene Bank, for example, makes the gene donor declare that he is aware of the fact that his tissue sample may have some commercial value and that the right of ownership of the tissue sample shall be assigned to the foundation owning the bank.[23] Consent forms for some existing collections may contain a similar waiver or assignment. These waivers and assignments seem to pre-empt any complications following from the recognition of a personal property right in human biological material.

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[21] National Bioethics Advisory Commission, "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance", Rockville, Maryland, August 1999, Volume, Report and Recommendations, at 22.

[22] UK Biobank, "Sample Handling and Storage Subgroup Protocol and Recommendations, version 1.0, 7 July 2004, for comment (hereinafter UK Biobank Sample Protocol), at 21.

[23] Estonian Gene Donor Consent Form, Annex 1 Regulation No 125, Dec 17, 2001, Minister of Social Affairs, section 3.

However, 'property waivers and assignments', whether granted in the context of existing collections or *de novo* Biobanks, may not work for a number of reasons. First, property proponents argue that a property right in human biological material is 'inalienable'. For them, 'inalienability' is a necessary corollary of recognising personal property rights in human biological material. If human biological material were alienable, then individuals could transfer their property rights and thus dispose, rather than retain, *on-going* control over their samples. In this vein, any waiver or assignment of property rights is considered either legally void or voidable as against public policy, or owing to 'power asymmetry' between the sample donor and the recipient institution or 'undue influence' exercised by the institution over the sample donor.[24] According to one commentator:

> *[No] such assignation of rights should be legally permissible. Thus, while individuals or communities might choose not to exercise their (property) rights, they cannot give them away.* [25]

As to existing collections, many of them do not provide for 'property waivers' in respect of the collected material. And in the event waivers have been obtained, they are unlikely to be 'blanket waivers'; their scope is likely to be related to the scope of the informed consent given for the research concerned. In brief, the issue of personal property rights in the human biological material collected in Biobanks must be addressed.

Part II: Who owns human biological material? The present state of the law

The question of whether an individual has a property right in his material collected in a Biobank is, obviously, preceded by the preliminary question of whether an individual has a personal property right in his or her biological material as such. Both legislatures and courts have long been reluctant to recognise such a right.

In the US no federal property right in human biological material has been adopted, in spite of various pleas to that effect. While the National Organ Transplant Act prohibits the sale of any human organs for use in human transplantation,[26] no federal law prohibits the sale of blood for transfusion, research or manufacturing.[27] Similarly, states banning commercial dealings in respect of organs generally make an exception for regenerative tissue.[28] Various states have considered legislative proposals[29], but

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[24] D E Winickoff and R N Winickoff, "The Charitable Trust as a model for Genomic Biobanks", N Engl J Med (2003) 349;12, 1181.

[25] G Laurie, *Genetic Privacy, a Challenge to Medico-Legal Norms*, (2002) (hereafter referred to as Laurie, *Genetic Privacy*, at 318.

[26] National Organ Transplant Act, 42 U.S.C.A. paragraph 274e(a) 2000.

[27] R Rao, "Property, Privacy, and the Human Body", 80 B.U.L.Rev. (2000), 359 at 373.

[28] D M Gitter "Ownership of human Tissue: A Proposal for federal Recognition of Human Research Participants' property Rights in Their Biological Material", (2004) 61 Washington and Lee Law Review, 257 and M A Shields, "Liability for conversion and misappropriation of genetic material" , at 267, fn. 34.

[29] M M Lin, "Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy Act", (1996) 22 American Journal of Law and Medicine 109, at 112-118, ("hereafter referred to as: Lin").

only one state, Oregon, has adopted legislation explicitly recognising that 'an individual's genetic information and DNA sample are the property of the individual except when the information or sample is used in anonymous research'.[30] This provision, however, has been repealed and replaced by a more comprehensive set of privacy rights with regard to the collection and use of genetic samples.[31]

In the UK, no legislation exists which directly addresses the issue of whether a person can claim a property right in his biological material. The 1961 Human Tissue Act only makes lawful the use of parts of bodies of a deceased person for therapeutic or research purposes in the event such person had consented to such *post mortem* use.[32] The implication of this Act is that the person consenting to the use of any body parts after death for research donates these parts free of all claims. On the other hand, it has been argued that the Human Organ Transplants Act, the Human Fertilisation and Embryology Act 1990 and section 25 of the National Health Services Act (1977) seem 'implicitly to adopt a property approach'.[33] The Human Tissue Act 1961 and the Human Organ Transplants will be repealed and replaced by the Human Tissue Act 2004 which received Royal Assent on November 15, 2004.[34] The purpose of the Human Tissue Act 2004 is to provide a comprehensive framework for issues relating to whole body donation and the taking, storage and use of human organs and tissue. Notably, the Act makes *consent* and not *personal property rights* the fundamental principle underpinning the lawful storage and use of, *inter alia*, human body parts and tissue. The Act is silent on the issue of whether an individual can claim a property right in biological material removed from his body. Part 2 of the Act contains a prohibition of commercial dealings in human material, which appears to endorse a 'non-property' approach. However, the prohibition is limited to dealings in material which is 'intended to be used for the purpose of transplantation'.[35] Also, the prohibition does not apply to material 'which is the subject of property because of an application of human skill'.[36] In this provision, the Act explicitly acknowledges that at least the person applying skill on human biological material can claim a property right to the material concerned.

In Australia, the Human Tissue Acts set forth consent conditions for the *donation* rather that the *sale* of human blood, regenerative tissue and non-regenerative tissue.[37] No statute exists addressing the property status of genetic samples.[38]

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[30] ORS 659.715.

[31] Senate Bill 114, s. 15, passed by the Senate on May 22, 2001, available at: http://pub.das.state.or.us/LEG_BILLS/PDFs_2001/ESB114.pdf.

[32] Human Tissue Act 1961, as amended by Anatomy Act 1984 (c.14), s.13(2)(c) and Statute Law (Repeals) Act 1974 (c.22), Sch. Pt. XI.

[33] Nuffield Council of Bioethics, Human Tissue Ethical and Legal Issues, 1995, at 70.

[34] Human Tissue Act 2004; the substantive provisions of the Act will come into force on days appointed by the Secretary of State by order. Full implementation is not expected to be before April 2006 (Human Tissue Act 2004, Explanatory Notes, 69).

[35] Human Tissue Act 2004, s. 32 subsection (1) and subsection (8).

[36] Human Tissue Act 2004, s. 32(9).

[37] Australian Law Reform Commission *"Essentially yours"* (2003), available at http://www.austlii.edu.au/au/other/alrc/publications/reports/96/ (hereinafter: "ALRC"), at 5478.

[38] ALRC, at 527.

The courts in the above common law jurisdictions have traditionally held that neither a human corpse nor parts of a corpse can be the subject of property rights.[39] This position, however, is subject to a number of exceptions, especially where courts have found that body parts and bodily substances, such as urine and blood samples, are capable of being stolen, thus implying that these samples have property status.[40] One early Australian case, *Doodeward v Spence,*[41] concerned an action for recovery of a two headed-foetus preserved in a jar of alcohol. The 'owner' had bought it at an auction and was subsequently prosecuted for publicly exhibiting the specimen for gain, 'to the manifest outrage of public decency'.[42] While reaffirming that a corpse could not be the subject of property, the Australian High Court held that a corpse or a part thereof could be subject to a right of possession, where it had come lawfully into someone's possession, who had subsequently bestowed some ('perhaps not much') work and skill upon it. In *Re v Kelly* the same principle was applied to body parts removed from the body.[43] Kelly, an artist, had removed a number of human body parts from the Royal College of London without its permission and without the intention of returning them. All the specimens taken had been preserved or fixed by college staff, and most of them had been the subject of further dissection so as to reveal the inner workings of the body. The court dismissed the appeal against the conviction for theft holding that the parts of a corpse could be "property" for the purposes of section 4 of the Theft Act 1968, 'if they had acquired different attributes by virtue of the application of skill, such as dissection or preservation techniques, for exhibition or teaching purposes.'[44]

Under existing common law, the following two elements must be established for a person or institution to acquire a possessory property right in human biological material. First, the organisation or person using the biological material must have lawful authority to do so. Second, that organisation must apply some work or skill to the preservation of the sample. It is not clear how much work is required. The two-headed foetus had simply been placed in alcohol, which, by the standards of the dissenting judge, meant that 'no skill or labour has been exercised on it'.[45] While the Criminal Court in *Re v Kelly* recognised anatomical specimens as the property of the institution because it had preserved, fixed or dissected them, the preservation of a deceased's brain in paraffin wax has been held not to constitute sufficient work or skill.[46] One test to determine whether sufficient skill has been applied could be whether the work has resulted in the material acquiring an 'actual pecuniary value', as Griffith, J considered in *Doodeward v Spence.*[47] Another test could be to assess

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[39] A Campbell-Tiech, A corpse in law, British Journal of Haematology (2002) 117, at 809.

[40] ALRC, at 528.

[41] *Doodeward vs Spence* (1908, 6 CLR 406), 415.

[42] *Doodeward vs Spence* (1908, 6 CLR 406). See also P Skegg, Human corpses, Medical Specimens and the Law of Property, (1976) 4 Anglo-American Law Review 412.

[43] *R v Kelly* [1999] Q.B. 621

[44] *R v Kelly* [1999] Q.B. 621, 631.

[45] *Doodeward vs Spence* (1908, 6 CLR 406), Higgins, J, 417.

[46] Dobson v North Tyneside HA, [1996] 4 All E.R. 474. Also see Skene, "Proprietary rights in human bodies, body parts and tissue: regulatory contexts and proposals for new laws", 22 Legal Studies: the Journal of the Society of Public Teachers of Law, (2002) 103, at 125, fn 120.

[47] *Doodeward vs Spence* (1908, 6 CLR 406), 415.

whether the material had acquired, by virtue of the application of skill, different attributes, as contemplated by the Criminal Court in *Re v Kelly.* In general, it should be noted that most case law to date has dealt with limited fact situations in which the courts have only recognised a limited, possessory ownership right for specific purposes.[48]

In the US, there are only a few reported cases dealing with disputes over property rights to human biological material. They involve disputes between researchers and a corporation over the acquisition and ownership of established *cell lines* rather than ownership of 'raw' human biological material.[49] Until recently, the only case squarely addressing the issue whether a tissue donor has a property interests in his excised cells was the landmark decision of the California Supreme Court in *Moore*. In 1976 John Moore underwent treatment for a rare form of hairy-cell leukemia at the Medical Centre of the University of California at Los Angeles. His physician, Dr Golde, recommended surgical removal of his abnormally large spleen, without, however, disclosing to Moore his 'prior formed intent' to obtain portions thereof for research purposes. In a series of postoperative visits, Golde withdrew substantial amounts of blood and other samples, cultured a cell line from Moore's T-lymphocytes and discovered that the cells had a unique ability to produce a protein that might be used to develop an anti-cancer agent. While the Regents of the University of California filed a patent application for the cell line, Golde, in spite of repeated representations to Moore that there was no commercial value to his bodily substances, negotiated agreements for commercial development thereof, earning him, according to the legend, millions of dollars. When Moore found out what had happened to his excised cells, he filed suit against, inter alia, Dr Golde and the University of California. Moore claimed, *inter alia*, an interest in the products developed by using his tissue on the basis of a tort of 'conversion'- an intentional exercise of dominion and control over personal property that so seriously interferes with the right of another to control that property that the tortfeasor may justly be required to pay the other the full value of the property.[50] This claim forced the California Supreme Court to consider whether Moore had a property interest in his excised cells.

The California Supreme Court held that Moore had no such property interest. The court first found that there was no case holding that a person retains a sufficient interest in excised cells to support a cause of action for conversion.

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[48] ALRC, 527-529 and Skene, "Proprietary rights in human bodies, body parts and tissue: regulatory contexts and proposals for new laws", 22 Legal Studies: the Journal of the Society of Public Teachers of Law, (2002) 103, 105-110.

[49] *Miles, Inc. v Scripps Clinic and Research Foundation*, 810 F. Supp1. 1092 and *United States v. Arora*, 860 F. Supp. 1091. For a survey of the current state of US case law see M M Lin, "Conferring a Federal Property right in Genetic Material: Stepping into the Future with the Genetic Privacy Act", (1996) 22 American Journal of Law and Medicine 109, at 112-118, D M Gitter "Ownership of human Tissue: A Proposal for federal Recognition of Human Research Participants' property Rights in Their Biological Material", (2004) 61 Washington and Lee Law Review, 257 and M A Shields, "Liability for conversion and misappropriation of genetic material", Annotation of *Greenberg v. Miami Children's Hospital*, 121 A.L.R.5th 315. In addition to the reported cases, there are a few reported instances in the US which have been settled out of court. For a description of these case histories, see OTA, at 24.

[50] 18 Am. Jur. 2nd Conversion § 1.

It then rejected Moore's argument that "[i]f the courts have found a sufficient proprietary interest in one's persona, how could one not have a right in one's own genetic material, something far more profoundly the essence of one's human uniqueness than a name or a face?". According to the court, this analogy misconceived the nature of the genetic materials and research involved in the case at hand. The court pointed out that the goal and the result of the research was to produce lymphokines, a protein which, unlike a name or a face, has the same molecular structure and function in every human being. In addition, the court considered that the particular genetic material which is reponsible for the natural production of lymphokines 'is also the same in every person; it is no more unique to Moore than the number of vertebrae in the spine or the chemical formula of hemoglobin'.[51] The reason Moore's cells were unique was that they overproduced lymphokines, because they were infected by a virus, HTLV-II (Human T-cell leukemia virus type II).[52]

Next, the court refused to accept the argument advanced by the Court of Appeals that '[a] patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress.[53] In retort, the Supreme Court held that it was not 'necessary to force the round pegs of "privacy" and "dignity" into the square hole of "property" in order to protect the patient, since the fiduciary-duty and informed-consent theories protect these interests directly by requiring full disclosure.'[54]

The next consideration that made Moore's property claim problematic for the court was a California statute, which restricted how excised cells may be used and required their eventual destruction. Thus, the court reasoned, 'the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to "property" or "ownership" for purposes of conversion law.'[55]

The court further argued that the patented cell line and the products derived from it could not be Moore's property 'because the patented cell line were both factually and legally distinct from the cells taken from Moore's body.'[56] According to the court, Moore's claim that 'he owned the cell line and the products derived from it were inconsistent with the patent, which constitutes an authoritative determination that the cell line is the product of invention.'[57]

Having found that Moore had no property rights in his excised cells under existing law, the court then refused to extend the theory of conversion, for a number of policy reasons.[58] First, the court did not want to impose a strict-liability tort duty on scientists to investigate the consensual pedigree of each human cell sample used in research. To impose such a duty would create a potential obstacle to research

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[51] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), 490.

[52] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), 491, and n. 30.

[53] *Moore v. Regents of University of California*, 249 Cal. Rptr., 494, 508.

[54] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), 491.

[55] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), 492.

[56] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), 492.

[57] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), 493.

[58] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), 493-497.

stemming from uncertainty about legal title to biological samples and hinder research by restricting access to the necessary raw materials. Second, the court considered that the case made by Moore for a property right in his biological material was better suited to legislative resolution. Third, the tort of conversion was deemed unnecessary to protect patients' rights, because physicians would face liability if they breached existing disclosure obligations, a mechanism which did not unnecessarily hinder research.

The court concluded that the use of excised human cells in medical research did not amount to a conversion. The court made it clear however, that it was not prepared to bar any role a property approach could have in the protection of human beings.[59] *Moore* was shortly followed by the District Court of Florida in *Greenberg v. Miami Children's Hospital*,[60] which decision will be discussed *infra.*

Part III: The new case for property rights in human biological material

While courts and legislatures have long been reluctant to recognise property rights in human biological material, sample donors and commentators have recently reacquired a taste for the commodification of human biological material. They are pleading in courts and urging legislatures to create new property rights in human biological material, as a means to secure ongoing control over their material and to enable them to share in the benefits they expect will be generated by the subsequent research on their material. The plea for recognising property right in human biological material is not new. In 1995, for example, Annas et al. published a draft US model Genetic Privacy Act (the 'GPA').[61] The GPA contained a provision to the effect that 'an individually identifiable DNA sample is the property of the sample source.'[62] The authors of the GPA provided the following rationale:

> *By establishing an individually identifiable sample as the property of the sample source,*
>
> *the GPA not only serves the interests of those who would want to maintain exclusive control over their DNA, but also enables those who desire to share or transfer such control to do so … Owning one's DNA sample allows transfer of control of the sample in accordance with property law principles.*[63]

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[59] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990) 493. The court did rule however, that Moore's third amended complaint stated a cause of action for breach of fiduciary duty or lack of informed consent.

[60] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003).

[61] G J Annas, L H Glantz, P A Roche, "Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations", (1995) 23 Journal of Law, Medicine and Ethics 360-66 ("hereafter referred to as: Annas, Glanz & Roche, *Genetic Privacy Act*"), at 362.

[62] Model Genetic Privacy Act and Commentary, Section 104, G J Annas, L H Glantz, P A Roche, Health Law Department; Boston University School of Public Health; 80 East Concord Street; Boston, MA 02118, February 28, 1995.

[63] Annas, Glanz & Roche, *Genetic Privacy Act*, at 363.

As we have seen, however, to date no such statutory property rights are available. Yet, as Laurie has put it, 'the voices in support of property in the person are becoming louder and the ears on which they fall will not always be deaf'.[64] In his 2002 'Genetic Privacy, A Challenge to Medico-Legal Norms', Laurie made the following case for recognising personal property rights in human biological material:

> *A personal property paradigm could, in fact, serve an all-important role in completing the picture of adequate protection for the personality in tandem with other protections such as autonomy, confidentiality and privacy. However, the added value of a property model lies in its ability to empower individuals and communities and to provide the crucial continuing control over samples or information through which ongoing moral and legal influence may be exerted.*[65]

Support for his prediction can be found with a number of patient groups and commentators[66] and can be illustrated by the following examples.[67]

A recent example of a patient advocacy group claiming property rights over their tissue is PXE International, Inc. ('PXE'). PXE is a non-profit organisation incorporated by a patient advocacy group, representing the interests of individuals affected by pseudoxanthoma elasticum (PXE), a genetic disorder causing calcification of elastic tissue. PXE is a global organisation that coordinates and funds a consortium of nineteen research labs, provides patient support, directs a blood and tissue bank and maintains a database of thousands of individuals.[68] In order to steer researchers toward working on finding the gene associated with PXE disease, PXE entered into a contract with researchers. Under the contract, PXE is entitled to retain ownership rights in any patent application arising from the research, including a profit share in any revenue to be generated by such inventions, a right of control ensuring broad and affordable availability of genetic tests, and a right to influence future licensing of the intellectual property.[69] In essence, the PXE agreement implies that PXE and/or its members possess a property right in their biological material. To date, neither party to the contract has challenged its enforceability on the ground that the individuals do not have a property right in their excised material pursuant to *Moore*. PXE's example has been followed by patient groups such as Cure Autism Now and the Juvenile Diabetes Research Foundation.[70]

On October 30, 2000, another patient advocacy group, the parents of children with Canavan disease, the Canavan Foundation and the National Tay-Sachs&Allied

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[64] Laurie, *Genetic Privacy*, at 324.

[65] Laurie, *Genetic Privacy* at 316.

[66] See *e.g.* A D Moore, "Owning Genetic Information and Gene Enhancement Techniques: why privacy and property rules may undermine social control of the human genome", 14 Bioethics (2000) 2, Lin supra fn 23, Laurie, *Genetic Privacy,* at 315 and 319.

[67] For an in depth analysis of the current movements towards a property model in ourselves, s*ee* Laurie, *Genetic Privacy*, at 319-324.

[68] See www.pxe.org.

[69] Gitter, at 317, referring to Kolata.

[70] Gitter, at 318, referring to Genetic Alliance.

Diseases Association, filed a six-count complaint against Miami Children's Hospital Research Institute Inc. and its researcher, Dr Reuben Matalon, asserting, *inter alia*, conversion and seeking damages and equitable and injunctive relief. As Moreno, District Judge, put it, 'this case presents an unfortunate dilemma set against the backdrop of a historic breakthrough in the treatment of a previously intractable genetic disorder'.[71] The plaintiffs had encouraged a team of scientists to pursue research into Canavan disease, a fatal genetic disorder with no known cure. Using financial resources, blood, urine and tissue samples, autopsies and confidential medical information contributed by the patients and their families, the team identified the Canavan gene mutation and developed a genetic screening test for the disease. After the team was recruited by the Miami Children's Hospital Research Institute, their continued work led the Hospital to file a patent application for the gene associated with Canavan disease, its various mutations and related applications, including carrier and prenatal testing.[72] According to the plaintiffs the Hospital threatened centers that offered Canavan testing with possible enforcement actions regarding the recently-issued patent and restricted public accessibility through negotiating exclusive licensing agreements and charging royalty fees.[73]

In count V of their complaint, plaintiffs alleged that they had a property interest in their body tissue and genetic information, and that they owned the Canavan registry in Illinois which contained contact information, pedigree information and family information for Canavan families worldwide. They claimed that the hospital and Matalon had converted their names and the genetic information by utilising them for the hospitals' 'exclusive economic benefit'.[74] The Florida District Court, however, declined to recognise a property interest for the body tissue and genetic information voluntarily given to the Hospital. The court held that these were donations to research without any contemporaneous expectations of return of the body tissue and genetic samples. The court approvingly cited the California's Supreme Court's finding in *Moore* that a donor has no property interest at stake after he has made his donation.[75]

The court also reasoned that limits to the property rights that attach to body tissue had been recognised in Florida state courts and that the property right in blood and tissue samples evaporates once the sample is voluntarily given to a third party. The court also rejected plaintiff's reference to *Pioneer Hi-Bred v. Holden Foundation*.[76] In this case the Southern District Court of Iowa had held that a corn seed company's property interest in the genetic message contained in a corn seed variety is property protected by the laws of conversion. The *Greenberg* court pointed out that the *Pioneer* court had recognised that, 'where information is gathered and arranged at some cost and sold as a commodity on the market, it is properly protected as property.'[77] The

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[71] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003), 1066.

[72] US patent No. 5,679,635 issued to the hospital in October 1997.

[73] Complaint, paragraph 30.

[74] Complaint, paragraph 65.

[75] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003), 1074-1075..

[76] *Pioneer Hi-Bred vs. Holden Foundation* 1987 WL 341211 (S.D.Iowa, Oct.30, 1987), aff'd, 35 F.3d 1226 (8th Cir.1994),

[77] 264 F. Supp 2nd1064 (S.D. Fla. 2003).

Greenberg court saw this reasoning as providing 'more support for property rights inherent in the Hospital's research rather than the donations of plaintiffs' DNA'.[78] The court also distinguished a litany of cases in other jurisdictions that had recognised that body tissue can be property in some circumstances on the ground that they did not involve voluntary donations to medical research.[79]

Additionally, plaintiffs had cited a Florida statute on genetic testing in support of their contention that persons who contribute body tissue for researchers to use in genetic analysis do not relinquish ownership of the results of the analysis. The *Greenberg* court, however, found the statute inapplicable under a common law theory of conversion, 'because by its plain meaning, it only provides penalties for disclosure or lack of informed consent if a person is being genetically analysed.[80] Even assuming, arguendo, that the statute did create a property right in genetic material donated for medical research purposes, the *Greenberg* court found it 'unclear whether that would confer a property right for conversion, a common law cause of action.'[81]

Finally, the court held that the facts alleged did not sufficiently allege the elements of a *prima facie* case of conversion, as the plaintiffs had not alleged how the Hospital's use of the Registry in their research was an expressly unauthorised act. Plaintiffs had failed to allege the circumstances or conditions that were attached to the defendants' use of the Canavan Registry. The court also rejected plaintiffs claim that the fruits of the research, namely the patented material, was commercialised, on the following ground:

> *If adopted, the expansive theory championed by Plaintiffs would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital. At the core, these were donations to research without any contemporaneous expectations of return.*[82]

The court did permit, however, a cause of action for unjust enrichment, recognising 'a continuing research collaboration that involved Plaintiffs also investing time and significant resources in the race to isolate the Canavan gene'.[83]

The apparent inconsistency between the judicial precedents established in *Moore* and *Greenberg* on the one hand and the PXE agreement on the other hand, recently caused another commentator to call for the adoption of a property model. Proposing 'Federal

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[78] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003), 1075.

[79] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003), 1075.

[80] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003), 1075.

[81] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003), 1075.

[82] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003), 1076.

[83] According to a September 29, 2003 joint press release, the parties have reached a settlement which provides for continued royalty-based genetic testing by certain licensed laboratories and royalty-free research by institutions, doctors, and scientists searching for a cure; available at http://www.canavanfoundation.org/news/09-03_miami.php.

Recognition of Human Research Participants' Property Rights in Their Biological Material', this commentator proposes a hybrid property/liability approach.[84] The property component of this model would entitle individuals to invoke property rights in their biological material when they negotiate *in advance* over any rights in the use of their material. The liability component of this model would entitle individuals who had *not* negotiated in advance, to bring an action for conversion when researchers had withheld from them vital information that would have facilitated their ability to bargain for such rights. Applied to Biobanks, participants in *de novo* Biobanks would be entitled to negotiate with the entity governing the bank over any rights in the use of their material. Applied to existing collections of human biological materials, the entities governing those repositories could face actions for conversion if they have withheld from them information that might have caused them to bargain over any rights in the use of their material.

Part IV: Can human biological material be owned? Legal analysis

The above cases and controversies call for a reconsideration of the issue of whether individuals have property rights in their biological material. One way to shape this reconsideration is by taking the approach a court is likely to adopt when called upon to determine whether a property right in a novel object ought to be recognised. Such a court will typically want to examine two questions. First, does the object fit the characteristics of property? Second, are there any policy reasons in favour or against granting such right?[85] The following paragraph will discuss the first question. The second question will be examined in the next paragraph. For the avoidance of doubt, the object of discussion is limited to the type of material that typically goes into a Biobank: blood and certain types of regenerative tissue.

In order to be able to answer the first question, the concept of property will be defined. In the past, personal property has been defined as the relationship between a person and an object and described as the 'sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe'.[86] In less hyperbolic terms, property has nowadays come to be characterised as a 'bundle of rights', governing the infinite number of potential relations and non relations that people may have with each other over any given resource.[87] The bundle of rights is not fixed. There is however, a core list of standard incidents proposed by Honoré that is commonly accepted as making up the bundle of personal property rights or 'full ownership'. According to Honoré this concept is common to all 'mature' legal systems, and he draws his examples from both common law and civil law jurisdictions. Generally, if a person controls all or most of these rights in respect of an object, he is considered the owner of that object.[88]

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[84] D M Gitter "Ownership of Human Tissue: A Proposal for federal Recognition of Human Research Participants' property Rights in Their Biological Material", (2004) 61 Washington and Lee Law Review, 257 ("hereafter referred to as: Gitter")

[85] *E.g.* the California Supreme Court in *Moore*.

[86] Attributed to Sir William Blackstone, *Commentaries on the Laws of England,* Oxford 1775.

[87] M A. Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets", (1998) 111 Harv. L. Rev. 621, ("hereafter referred to as Heller"), at 662.

[88] *E.g.* Heller, 663-664, referring to L C Becker, Property rights: Philosophical Foundations 7-23 (1977); S R Munzer, A Theory of Property 24 (1990) at 27, n. 14 and A Reeve, Property 14-21 (1986).

The core bundle that constitutes ownership includes the following incidents or 'sticks':[89]

i. the right to exclusive possession;

ii. the right to personal use and enjoyment:

iii. the right to manage use by others;

iv. the right to the income from use by others;

v. the right to the capital value, including alienation, consumption, waste, or destruction;

vi. the rights to security (that is, immunity from expropriation)

vii. the power of transmissibility by gift, devise, or descent;

viii. the lack of any term on these rights;

ix. the duty to refrain from using the object in ways that harm others;

x. the liability to execution for repayment of debts; and

xi. residual rights on the reversion of lapsed ownership rights held by others.

Applying the sticks to human biological material

Most commentators discussing property rights in human biological material are content to discuss the question of whether such material is alienable, *i.e.* whether it can be sold. However, the most obvious avenue of inquiry to assess whether an individual can have property rights in his biological materials seems to be to analyse whether human biological material fits each and all of the eleven standard incidents of property. The advantage of this approach is that, once the standard case of full ownership has been analysed, all contradictions and implications are easier to identify and assess.

(i.) The right to exclusive possession. The right to possess is 'the right to have exclusive physical control of a thing, or to have such control as the nature of the thing admits'.[90] The remedies available to the owner are designed to enable the plaintiff either to retain or get back the thing owned. One characteristic of human biological material seems to render the application of the right of possession illusory. At least some human material is ubiquitous: we scatter millions of samples around us every day; when we get a haircut, when we shed skin cells, when we lick a stamp on an envelope, and so on. In practice, exclusive physical control of these types of biological material thus scattered around seems nearly impossible. Yet, while the remedy available to exercise the right to possession may not secure effective 'control' for at least some types of material, there seems to be no reason as to why human biological material could not be subject to a right of exclusive physical control. For example, such remedy would empower an individual to bring an action for recovery of the drops of 'his' blood stored on a Guthrie card in a newborn screening card

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[89] A M Honoré, "Ownership", in A.D. Guest (ed), *Oxford Essays in Jurisprudence* 107-128, ("hereafter referred to as: Honoré").

[90] Honoré, at 113.

collection- that is assuming this possessory right has not accrued to the institution holding the collection.

(ii) The right to use. The right to use refers to 'personal use and enjoyment', excluding the rights to management and income discussed below.[91] The permissible types of use constitute an open list and, moral objections aside, there seems to be no reason why an individual could not exercise this right in respect of his biological material. In fact, this right seems to co-incide with a person's right to autonomy over his body. To be sure, any *harmful* use could be prohibited, as discussed *infra.* In practice, only a limited number of individuals may have the requisite knowledge and technology to actually use their sample personally for research purposes in any meaningful way. Craig Venter for example, was probably unique in that he was able to use his own DNA sample in his successful effort to sequence the human genome.[92]

(iii) The right to management. The right to manage is the right to decide how and by whom the thing owned shall be used.[93] The right implies the power to license acts which, without such authorisation, would otherwise be unlawful. The right also implies the power to permit others to use one's things, to define the limits of such permission and to contract in respect of the exploitation of the thing. Thus, the right to management indeed provides a basis for an individual to exercise on-going control over the use of his biological material by third parties. It allows individuals to decide whether or not to license research acts and to define the terms of such permission. In practice, the fact that human biological material can be used for an infinite number of research purposes, and the fact that researchers are unable to state in advance what uses they will make of the material may make the exercise of the right to management problematic. Yet, conceptually that is no reason why this right could not apply and is, perhaps, even an additional reason why it should apply to human biological material.

(iv) The right to the income. 'Income may be thought of as a surrogate of use, a benefit derived from forgoing personal use of a thing and allowing others to use it for reward'.[94] Practically, a person who supplies a drop of blood for research does not really forego personal use of his biological material; he will continue to produce a life-time supply of genetically identical material. Yet, conceptually, the fact that an individual is his own continuous supply of her biological material is not, *per se*, a reason to deny her the right to exploit her materials. Statutory prohibitions aside, there is no reason why an individual could not exact a reward from a researcher willing to use his biological material. In practice, however, absent rare genes or a rare disorder as in *Moore*, researchers allowed to use the material are unlikely to be willing to pay any reward for such a right to use for the reasons set forth below, under (v).

(v) The right to the capital. 'The right to the capital consists in the power to alienate (*i.e.* 'sell') the thing and the liberty to consume, waste or destroy the whole or part of it'.[95] *Prima facie* there are no reasons why an individual could not alienate his biological material.[96] However, alienation of an object implies the transfer of the full

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[91] Honoré, at 116.

[92] M Ridley, Nature via Nurture, at 1.

[93] Honoré, at 116.

[94] Honoré, at 117.

[95] Honoré, at 118.

[96] Which does not mean that there could be no moral or policy objections against that possibility.

bundle of rights to the new owner, including the right to the capital. So, while alienation would enable an individual to exercise his right to the capital value of his biological material, the logical consequence thereof is that he can no longer exercise on-going control over his material.

Obviously, a person alienating his biological material could seek to impose limitations on the use of the material by the new owner. However, if you demand consideration in exchange for your sample, can you expect those paying such consideration to accept your on-going control over that sample? Why should a researcher who has paid for certain biological material, accept that the seller retains the right to claim it back or have it destroyed at will? Anyone who is required to pay 'quids' for material will want to receive a proper 'quo'. If an individual chooses to 'commodify' his biological material, the logical extension thereof is that he 'has to deliver'; he cannot have his cake and eat it. As a result then, in the words of Thomas Murray, 'Putting a price on the priceless, even a high price, actually cheapens it'.[97] Compounding this issue is that the transfer of *exclusive* rights to human biological material is problematic, if not impossible to enforce. Any individual 'possesses' or, indeed, 'is' his own life-time supply of biological material, which enables him to 'sell' genetically identical material not just to one, but to an infinite number of new 'owners'.

Another complication triggered by the right to the capital is that the use of most human biological material as such is unlikely to generate any income and, hence, the proper consideration will be hard to assess. Typically, property proponents claim a share of the profits to be made with the sale of any products derived from the research on their material. In doing so, they equate the value of a person's sample to a percentage of future profits to be made by the company marketing the end product.[98] Such an equation, however, is flawed because the only way to determine the market value of a commodity is in the market place, as a result of supply and demand.[99] That could, indeed, mean that someone having 'unique' genes, like John Moore or the community of PXE patients, could negotiate a monopoly price. However, the invisible hand of the market will most likely bring down the price of 'common material' to a minimum. Also, some donors might be willing to donate their samples for free, whether for altruistic reasons or in expectation of other, more indirect benefits such as better health care for their (grand-) children. Recognition of a property right in human biological material would not provide for any mechanisms to exclude such a 'coalition of the willing' from the market place for human biological material. Notwithstanding this complication, however, the fact that the material may have only limited or even no commercial value does not, *per se*, mean that it cannot be subject of a property right.

(vi) The right to security. The right to security or immunity from expropriation reflects the notion that the owner 'should be able to look forward to remaining owner

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[97] Thomas H. Murray, Discover, March 1986, cited in OTA, at 126.

[98] *E.g.* John Moore sought a percentage of the proceeds from the sale of the cell line produced from his cells.

[99] Of course, a tissue donor could ask to be paid *by way* of a profit share. However, the value of such a share can only be based on the value determined by supply and demand for the tissue in question, just like the *number* of employee share options is not related to the company's profit, but corresponds to the value of the employee in the market place.

indefinitely if he so chooses and he remains solvent'.[100] There seems to be sufficient reason to grant an individual the 'security stick' in his biological material. This right reinforces the principle of autonomy and informed consent in that any transmission of material should be consensual. What's more, the right to security is, unlike the consensual right to informed consent, a general right, availing not only against a contractual counterpart but also against others. Yet, it may have an adverse implication. The right to security is consistent with 'the existence of a power to expropriate or divest in the state or public authorities'.[101] This is not a general power to expropriate any property for any purposes. Such a general power would, even when subject to paying adequate compensation, be fatal to ownership.[102] However, when limited to certain classes of objects, and to specific limited purposes, in the public interest, expropriation is possible, subject to the state or said authorities paying adequate compensation. In other words, if human biological material is private property, the State could expropriate such property, for example for purposes of research in the general interest, provided adequate compensation is paid. Needless to say, such power of expropriation does not promote the exercise of on-going control of a person over his biological material.[103]

(vii) The incident of transmissibility. Transmissibility means that an interest does not stop with the death of the owner, but can be transmitted to the owner's successors, whether by gift, devise or descent. An interest which is transmissible to the holder's successors enables them to enjoy the thing after the holder's death. Although transmissibility can stop short at the first, second or third generation, an owner's interest is characterised by *indefinite* transmissibility. There is no limit on the possible number of transmissions, though the nature of the resource in question may well limit the actual number.[104] There seems to be no reason why human biological material could not be subject to the incident of transmissibility. Upon the death of an individual, any property interests in his biological material would pass on to his heirs or any persons designated by him. The fact that both outside and within the dead body, human biological material only has a limited life span, if any, does not seem to make that any different. In deceased form, it can still be preserved and used.

(viii) The incident of absence of term. The absence of term means 'unlimited' duration in that it is not certain to determine on a fixed date or on the occurrence of a contingency. Ownership is considered an 'indeterminate' interest to which no term is set, unlike, for example, copyright which lapses 70 years after the death of the holder. Should the owner live for ever, he would continue in the enjoyment of his property right for as long as the thing remains in existence. As Honoré points out, however, even indeterminate interests are determinable, because the owner or his successor may lose their interest in the event of bankruptcy or execution sale.[105] There seems to be

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[100] Honoré, at 119.

[101] Honoré, at 119.

[102] Honoré, at 119.

[103] This kind of expropriation for public interest research purposes is not to be confused with existing powers to forgo consent to bodily searches for forensic purposes, mandatory vaccination programmes and the like, which do not entail any form of expropriation.

[104] Honoré, at 121.

[105] Honoré, at 122.

no reason why human biological material could not be subject to the incident of absence of term, as there seems to be no fixed date or contingency the occurrence of which would call for the determination of a property right in human biological material, apart from the events of bankruptcy or execution sale.

(ix) The prohibition of harmful use. An owner's liberty to use the thing he owns as he chooses is subject to the limitation that such use does not harm others. No matter how freely you may use your car, you are not allowed, for one thing, to 'drink and drive'. Although most limitations are familiar and obvious, what use qualifies as 'harm' is open to debate. In the case of human biological material, it is hard to conceive of any use by its 'owner' that would be harmful to anybody else, except for cases involving the intentional transmission of diseases, such as having unsafe sex when diagnosed HIV-positive. Rather, in certain circumstances it is a *refusal* to use one's material that may be harmful to others. A PXE patient who refuses to hand over his tissue to PXE Inc., may not act in the interests of the community of PXE patients and, in a way, cause them harm. As Becker has noted, '[H]armful use may shade into a requirement for productive use.'[106] It would probably go too far, however, to qualify such a refusal to use as an infliction of harm. Most likely, the principle of autonomy would prevail in that no one could be forced to participate in scientific research. To the extent, however, that harmful use could be made of human biological material, there seems to be no reason why no prohibitions could be imposed on the use of those materials. Thus, there is no reason why this incident could not apply to human biological material.

(x) The liability to execution. Liability to execution means that an owner's interest can be taken away from him to satisfy any overdue debts owed third parties, whether by execution of a judgement debt or on insolvency.[107] According to Honoré, executability constitutes one of the standard ingredients of the liberal idea of ownership.[108] It is a question, though, whether human biological material could be subject to executability. Conceptually, in essence, this liability is only an extension of the right to the capital and the income. If an individual has the right to the capital and the income in respect of his biological material, then his material is inherently liable to execution. Technically, it would also be feasible to take a tissue sample from an insolvent and put it on the auction block or 'liquidate' it by way of trade sale, under any legally required supervision. However, the ubiquity and the potential for lifetime supply of human biological material trigger some serious and thorny practical and conceptual questions. Absent unique features such as Moore's lymphocytes, the taking of one blood sample is unlikely to satisfy any material debts. Could then a debtor be forced to have his blood taken and sold until all debts have been paid or until he dies? To what extent and in which way, should this execution take into account the state of health of the debtor involved? These questions seem to rule out the application of executability to human biological material. Yet this application would not be totally absurd, as illustrated by a US tax case. The case concerned a donor who earned her living by repeatedly selling her rare blood.[109] The tax court determined that the payments received by the donor for the sale of her blood were taxable as income,

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[106] L C Becker, Property rights: Philosophical Foundations (1977) at 19.

[107] Honoré, at 123.

[108] Honoré, at 123.

[109] See R Rao, "Property, Privacy and the Human Body", 80 B.U.L.Rev. 359, 372.

subject to ordinary business expenses incurred by her creating this product. In this way, payments received or receivable in exchange for donations of blood for other purposes, such as research, would be subject to the incident of executability.

(xi) The residual right. The residual right is the right on the reversion of lapsed rights held by others. This characteristic of ownership means that the owner is the ultimate residuary. When the rights of holders of lesser interests lapse, the 'owner' acquires these rights. This seems an appropriate right in the context of human biological material. It enables individuals to retain residual rights in their material after any 'lesser' rights, such as a right to use it for research purposes, have lapsed. However, the impact of this characteristic should not be overstated. It only applies in the situation that the owner has allowed lesser rights in his materials. It does not provide for any residual rights in human biological materials after alienation, transmission, expropriation or execution.

Have Your Stick?

By way of an interim conclusion, the above inquiry suggests that while the application of some rights from the core bundle to human material is conceivable, human biological material as such does not fit comfortably in a number of rights from the property bundle. Notably, the power to alienate, the right to security and the liability to execution give rise to contradictions and potentially adverse implications. In order to obviate the implications of *full* ownership, property proponents propose to remove those incidents of property from the 'bundle of rights' that are considered inappropriate in the context of human biological material.[110] Munzer, for example, has proposed a 'finer grained taxonomy' and a classification of body rights into personal rights and weak and strong property rights.[111] For example, one could take out the 'alienation stick' so as to secure that no sample donor could ever be deemed to have 'given away or 'sold out' his property interest in his material, regardless of whether any compensation has been received. Under this approach of 'inalienability', any waiver of property rights in human biological material, as required by *de novo* Biobanks, would be illegal, invalid and unenforceable. Similarly, one could take out the liability to execution, and the power of the government to expropriate, which would otherwise be implied in the right to security.

For various reasons, however, this eclectic approach is not satisfactory. First, as a result of imposing all desirable limitations, the bundle of property rights would be stripped of a number of core rights. Just how many of the standard incidents may be removed from the bundle before we stop calling it property, is a contentious issue. According to Honoré, while all incidents are necessary for full ownership; none of them is a necessary constituent of ownership *per se*.[112] People may own objects in various restricted senses, for example when one has the right to management and income of one's house, but only a restricted right to use and capital, due to leasing and mortgage agreements. Also, each of the sticks is subject to differing scopes, restrictions and definitions. It has been argued that a number of *subsets* of the eleven

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[110] S R Munzer, A Theory of Property (1990) at 54-55. See also ALRC, at 535.

[111] S R Munzer, A Theory of Property (1990) at 49.

[112] Honoré, at 112-113. See also L C Becker, Property rights: Philosophical Foundations (1977) at 19-20.

incidents may constitute a variety of what may reasonably be called ownership: the right to capital alone, as it is the most fundamental of the standard incidents; any subset including the right to capital, the right to security, possession, use, income or management plus any other element or set of elements.[113] Thus, 'property law is capable of modifying the bundle of rights, including the fundamental right of alienation, so as to accommodate moral and policy concerns.[114] And as Radin has pointed out, some things may be given away but not sold (*e.g.* organs). She has labelled this category of things 'market-inalienable'.[115] In fact, that is precisely what the courts did in *Moore* and *Greenberg*.

Categorising human biological material as 'market-inalienable' property would simply eradicate the problem that, otherwise, alienation would result in loss of control. If you would have all standard property rights in your biological material without, however, the right to alienate it, you could indeed exercise ongoing control. But solving one problem, market-inalienability creates another. By precluding the sale of human biological material, it would inhibit the achievement of the other goal property proponents aim to achieve, *i.e.* to invoke property rights as the underpinning of the claims for profit-sharing. Somehow, the twin goals of 'ongoing control' on the one hand and 'profit-share' on the other hand, are contradictory, if not mutually exclusive.

A second objection to the eclectic approach would be that the extension of only a limited subset of property rights to human biological material will obscure rather than clarify the legal status thereof.[116] Absent clear statutory provisions, there will be uncertainty as to which incidents of property are removed from the bundle. Any clear legislation in this respect will require consensus as to what exactly is considered an inappropriate incident; the notion that there are 'ethical concerns' about granting full ownership does not help very much as it does not specify those concerns.

Property rights in human biological material *if and when cultured?*

Another fundamental question the eclectic approach cannot solve is the complication that arises in the context of research on human biological material. Such research requires at least some form of processing of the material involved, ranging from storage on FTA/Isocode paper to the creation of entire cell lines. Most human biological material can be fractionated into their constituent components and specific biomolecules such as DNA or proteins can be isolated. Some of these components are labile, and in order to enable research need to be preserved upon excision from the body using stabilizing agents. Live cells are stable at room temperature for up to 48 hours but must be either cultured or cryopreserved in liquid nitrogen at –180 degrees

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[113] L C Becker, Property rights: Philosophical Foundations (1977) at 19-20.

[114] M Litman and G Robertson, " The Common Law Status of Genetic Material", in Legal Rights and Human Material, Ed. Bartha Maria Knoppers, Timothy Caulfield, and T. Douglas Kinsella (1996), at 64.

[115] M J Radin, Market-Inalienability, 100 Harvard L. Rev. (1987) 1849, at 1853.

[116] The clarification claim is somewhat disingenuous anyway. It was the very threat of uncertainty that the recognition of a property interest in human tissue would bring about, which tilted the court in *Moore* towards denying such interest. Also, it is probably this judicial decision that provided the required certainty, at least in the jurisdiction concerned (California), but probably in other jurisdictions as well: the Florida district court in *Greenberg v. Miami Children's Hospital* approvingly cited *Moore*.

Celsius in order to remain viable.[117] Primary cell cultures may be derived directly from solid human tissue or blood. Cell culture involves growing cells under artificial conditions, such as in the laboratory, either attached to some type of artificial surface or suspended in a special solution. As soon as a sample is cultured, it may not be representative of the total specimen used, and the longer the sample is in culture, the less it is like the original specimen.[118] A primary culture can be transformed into an immortal cell line using different techniques. Cells that have adapted to continuous culture cannot be considered entirely representative of the total population of the original isolate, and they may continue to change over time. Biobanks will typically not immortalise the donated material. As a distinct feature, the UK Biobank draft protocol proposes the taking of an additional 5ml of blood of a random sample of 10,000 participants for subsequent immortalisation of peripheral blood lymphocytes.[119]

The above triggers the question of whether, and under what conditions, the standard property incidents, jointly or separately, extend automatically to human biological material, if and when processed or cultured by others. While mere processing of biological material might not be sufficient to confer (limited) property rights, their artificial culture most likely is. This applies *a fortiori* to cell cultures and cells from which an immortal cell line has been derived. Such cell line, can hardly be considered to 'be' the original cell; the longer the sample is in culture, the less it is like the original specimen.[120] It is equally hard to consider the cell culture or a cell line as 'the fruits' of the original material, to which fruits the owner of that material would be entitled under the theory of accession.[121] Rather, a subset of accession theory- specification- would apply, vesting full title in the person who added the most value to the final product.[122] In brief, property rights do not automatically extend to any derivative products produced by others. If such extension were to be accepted, then John Moore would have title to the cell line produced from his excised cells. Such entitlement, however, seems only justified if Dr Golde and the Regents would be paid for the value they added to the original cells by producing the cell line.

As we have seen, the present state of the law tends towards the opposite position; if an organisation or person uses human biological material with lawful authority, he will obtain a possessory right if he applies some work or skill to the preservation of the sample. It is not clear how much work is required. Applying the 'alcohol' threshold set forth in *Doodeward v Spence*, the storage proceedings for blood and urine proposed by, for example, the UK Biobank, seem to pass both the 'skill or labour test', as would the techniques enabling the immortalisation of peripheral blood lymphocytes. In line with this case law, under the UK Human Tissue Act 2004 human biological material is not regarded 'as from a human body if it is created outside the

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[117] UK Biobank Sample Protocol, at 14.

[118] OTA, at 5.

[119] UK Biobank draft scientific protocol 2003, section 2.3.5.1 and UK Biobank Sample Protocol, section 4.2.6., at 30.

[120] OTA, at 33.

[121] OTA, at 83.

[122] OTA, at 84.

human body'. According to the Explanatory Notes to the Act, this includes cell lines.[123]

Part V: Should human biological material be owned? Policy arguments in support of a property model

Having analysed the legal question of whether human materials fit the characteristics of property, we can now turn to the second question a court will address, *i.e.* whether there are any policy reasons in favour or against granting personal property rights in human materials. The recent call in support of property rights in human material seems to be motivated by the following considerations.

First, the doctrines currently protecting a person's interest in his tissue are considered inadequate. Privacy rights are said to only confer 'negative' rights and not to amount to 'a right of positive entitlement'.[124] Recognising a property right in human material is considered to facilitate the exercise of continuing, indeed positive control by an individual over what happens to his tissue after donation. The concepts of informed consent and breach of fiduciary duty, relied upon by the court in *Moore*, are also held to be inadequate. The rights and remedies provided under these doctrines do not avail against those outside the scope of the patient-physician relationship. As we have seen, an essential characteristic of a property right is that it can be asserted, not only against the original recipient of the material, but also against any subsequent users who have never been in a (contractual, informed consent) relationship with the donor. In addition, it is argued that the amount of damages available under these theories will not motivate physicians to disclose any financial interests.[125] Absent a property right in biological material, courts and juries are expected to award relatively low compensatory and punitive damages. Also, under these theories, 'research participants will be left without a remedy, because the harm they suffered affected not their medical interests but rather their dignity and autonomy'.[126]

The second factor relates to considerations of equity and justice. It is considered 'unprincipled' that intellectual property rights on 'genetic inventions' allow commercial companies to make six-digit profits, while the individual, as the supplier of the raw material, is denied a piece of the cake.[127] Because the contribution of human biological material is just as indispensable in the research process as the use of other supplies, such as reagents and equipment, it is claimed to be unjust to deny research participants compensation, where the suppliers of other materials are being paid for their deliveries. One commentator suggests that such compensation should not only be due upon commercialisation of any derived biological product, but from the moment the researchers begin to use that material.[128] The 'but for' argument

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[123] Explanatory Notes to the Human Tissue Act 2004, commentary on Part 1, section 1 under 10 and section 32 under 48.

[124] Laurie, *Genetic Privacy,* at 300.

[125] Gitter, at 306.

[126] Gitter, at 307.

[127] Laurie, *Genetic Privacy*, at 315. Gitter, fn. 40: 'Moreover, a willing research participant frequently neither rues the fact that commercial products were developed from the tissue nor desires return of the tissue, but simply wishes for a share in the profits".

[128] Gitter, at 296.

supporting equitable claims for compensation was also put forward by Mosk J in his dissenting opinion in *Moore*:

> *[N]o one can question Moore's crucial contribution to the invention-an invention named, ironically, after him: but for [emphasis added] the cells of Moore's body taken by defendants, there would have been no Mo cell line…[F]or all their expertise, defendants do not claim they could have extracted the Mo cell line out of thin air.*[129]

Recognising property rights in human biological material would allow individuals to share in the profits that may be generated by the use of their samples.

The third factor is that the recognition of a property right would reinforce the trust that the participants must have in biomedical research and without which such research is doomed to fail. The facts in *Moore* painfully illustrate how this trust could be lost when a patient finds out that his repeat visits to the hospital did not serve his well being but the disguised commercial interests of his physician. A property right in their materials would provide donors with clear and enforceable legal remedies to redress any abuse, misuse or underuse of their samples.

A fourth argument has been formulated by one commentator as follows:

> *[R]esearch participants also merit property rights in their genetic material because… participants face risks associated with biomedical research... [R]esearch participants must contend for the potential harm resulting from the medical procedures they undergo in the experimentation process, the loss of privacy, the dangers of negative consequences from the release of their medical information, and the risk of learning emotionally disturbing information about their health.*[130]

The fifth argument advanced by several property proponents is that a property right in human biological material will not chill but rather stimulate research. It has been submitted that those previously reluctant to come forward with their material, would have an incentive to do so if they would be financially rewarded for their contribution.[131] Thus, property rights would enable the allocation of human biological material to the highest bidder.[132]

The sixth factor is clarification. Proponents of property rights in human biological materials claim that these rights will clarify the legal status of those materials, which they claim is presently unclear. Property rights define the relationship between donors and recipients and provide for clear remedies in the event they have been violated, such as an action for return or destruction of samples, injunctive relief or damages.[133]

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[129] *Moore v. Regents of the University of California,* 793 P.2d 479 (Cal.1990), 511.

[130] Gitter, at 297.

[131] Laurie, at 324.

[132] Gitter at 292, Lin at 131-132.

[133] ALRC, at 531.

Should human biological material be owned? Policy arguments against a property model

A number of countervailing arguments can be made against the case for property rights in human biological material. First, historically, property rights in the human body and its parts have been considered inappropriate, as articulated in the principle of 'non commerciality' of the human body and its parts, and set forth in various international instruments.[134] The idea, for example, that an individual could offer his tissue for sale on eBay, is regarded by some as an infringement on human dignity. Similarly, the application of related incidents of property rights as seizure and foreclosure are considered by some an affront to human dignity.

Second, recognising a property right in human biological material would undermine the traditional notion of altruistic participation in research for the benefit of society at large. Neither the traditional, 'pre-biotech' pharmaceutical industry nor the medical devices industry could have sold a single product without the involvement of hundreds of thousands of healthy volunteers and patients in the trials that are legally required to obtain and maintain market authorisations for these products. Yet, to date, research participants typically neither demand a share of any profits nor claim control rights over the sale of products. It is easy to imagine scenarios that would occur were this tradition abandoned. John Moore, by way of a speculative example, could have been charged for the use of any diagnostics by Hairy Cell Leukemia (HCL) Inc., and/or other groups of former research participants involved in the testing of the device, or the use of the diagnostic might have been denied, pending the outcome of the negotiations of such groups over control rights and benefit sharing.

Such scenarios are not purely hypothetical and there is no reason why such groups would act any differently than commercial entities in their licensing policies. As Gitter points out, patient groups might exercise control over 'their' research results in such a way as to maximise the group's benefit, while limiting access to these results to people suffering from other disorders.[135] For example, there is, according to Gitter, 'evidence that the gene associated with PXE might also relate to hypertension and cardiovascular disease'.[136] PXE reportedly realises that it could "make a killing (*sic*) because who cares if we're making the costs of cardiovascular treatment huge".[137] PXE Inc. has, however, asserted that the group would resists bettering their own fortunes at the expense of patients suffering from other diseases, claiming that it did 'not just represent people with PXE, we represent anybody who has anything'.[138] Such a statement, however, does not amount to a binding and enforceable access policy. In fact, PXE Inc. does acknowledge that, in practice, 'the group would insist upon licensing deals that would maximise the access of PXE patients to a future diagnostic or test or treatment'.[139] The irony of this position, of course, is the fact that PXE

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[134] *E.g.* Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997. Article 21.

[135] Gitter, at 323.

[136] Gitter, at 323.

[137] Gitter, at 323, citing the president of PXE International.

[138] Gitter at 323.

[139] Gitter, at 323.

patients are, most likely, not immune from other diseases, for which yet other groups could claim property rights. In brief, if the property rights model were to be adopted, we might all end up having to swap licenses and set off royalty payments before consulting our physician.

Third, the long standing tradition of altruistic donation evokes the fundamental question of whether the donation of a tissue sample is so inherently different from other, traditional forms of participating in 'non genetic' research, as to justify special compensation and control rights? A closer analysis of the argument set forth above may illustrate this point:

> *[R]esearch participants also merit property rights in their genetic material because… participants face risks associated with biomedical research... [R]esearch participants must contend for the potential harm resulting from the medical procedures they undergo in the experimentation process, the loss of privacy, the dangers of negative consequences from the release of their medical information, and the risk of learning emotionally disturbing information about their health*[140].

There can be no denying that each of these risks applies equally, if not, *a fortiori,* to those participants in 'non-genetic', traditional clinical research. The trouble 'traditional' trial subjects have to go through may well exceed the trouble of donating 40 mls of blood and a jar of urine to a Biobank. As a practical matter, the distinction between the contribution of human biological material and other forms of participation in research will be hard to implement, since biomedical research typically involves not just analysis of human biological material, but a whole range of other investigations as well.

Fourth, the 'but for' argument *per se* does not and cannot provide an inherent justification of a property claim. Using this argument, anyone involved in the research and development process of a drug could stake a claim to the end results; the supplier of the chemical reagents, the secretary posting the patent application, all trial subjects involved in the various phases of clinical safety tests and post-marketing surveillance and the regulator issuing the market authorisation. And here too, the 'but for' argument could easily spill over into other areas of research participation and healthcare. Using the argument, every patient could claim a portion of their physician's income since 'but for' their visit and 'but for' their condition, the physician could not have earned his income. Again, this is not a hypothetical scenario. The plaintiffs in *Greenberg* alleged that Dr. Matalon had personally profited from his research on their biological material by receiving a substantial federal grant to undertake further research on the gene patent.[141]

Fifth, recognising property rights to enable patients to claim part of the benefits resulting from any derived products could undermine the solidarity which underpins systems of health care in countries having national health-insurance systems. Under these systems, the costs of medical care, including prescription drugs, are largely reimbursable. So, eventually, any profits in the biomedical sector are paid for out of

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[140] Gitter, at 297.

[141] *Greenberg vs Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp 2nd1064 (S.D. Fla. 2003).

the collective premiums. Any profits payable to a subset of patients with a specific disorder goes at the expense of those who are paying the premiums. In the final analysis, the most equitable and just solution may be for the government to simply levy taxes on the corporate income generated by industry and redistribute the proceeds, subject to democratic control.

Sixth, a number of commentators are willing to ignore the fundamental difference between property rights and patents, when they use the patentability of biological inventions as an argument to support property rights in human biological material. Their reasoning is motivated by the alleged 'unprincipledness', which allegedly allows biotechnology companies to make a profit while denying a property interest to the supplier of the base material. Intuitively, one can only sympathise with such an observation. A patent however, is not property but a reward for an invention in the form of a limited and temporary monopoly to exploit the invention.[142] In the long run, to ignore the fundamental differences between the concepts of personal property and patents and their built-in checks and balances, may prove counterproductive.

Seventh, the concern that the doctrines of informed consent and autonomy are inadequate may be better addressed at a more appropriate level. Most of the interests that a property right is claimed to more adequately protect are actually better served by the laws specifically designed to serve those interests; data protection laws and clinical trial legislation, for example, contain adequate and enforceable remedies to protect individuals against abuse of the personal information derivable from their material. The Australian Law Reform Commission, for example, concluded that the preferred starting point for any comprehensive reform of the law relating to the collection, storage, use of, and access to, genetic samples was to build on existing information and health privacy legislation. The Australian Inquiry recommended that this could be done by ensuring that privacy laws cover the handling of genetic samples, as well as the genetic information derived from them.[143] Most recently, the UK Human Tissue Act 2004 has made *consent* and not *personal property rights* the fundamental principle underpinning of the lawful storage and use of, *inter alia*, human body parts and tissue.

In brief, both legal and policy concerns caution against the recognition of property rights in human biological material *as such*. The next question then is whether an individual should be able to claim a property right in his material in the specific context of a Biobank and, particularly in respect of *de novo* biobanks, and whether a waiver of any property right in human material is valid, binding and enforceable.

Part VI: Property rights in human biological material in Biobanks

As we have seen, a Biobank is based on the collection, storage and use of hundreds of thousands of samples. These samples will be used in hundreds of future research projects. Some of these projects may, in turn, lead to the formulation of yet other research projects. Let us just imagine what would happen if the participating individuals could exercise property rights in their samples. Imagine research project X

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[142] Assuming that patents are not improperly awarded and the invention truly meets the criteria for patentability. A discussion of whether that is currently the case in the area of 'genetic inventions' is beyond the scope of this Article.

[143] ALRC, Recommendation 8-2 (at 286) and Recommendation 20-2 (at 539).

proposed to be conducted using all the samples of Biobank Y. Seeking 'ongoing control', donors will exercise their right to the management of their samples, which may lead to the following: x thousand donors say yes; x thousand others say no; x thousand others say only if we get feedback; x thousand donors say only if we don't get feedback; and/or x thousand donors claim back their material.

Similarly, seeking to share in the benefits, donors will exercise their right to the capital value of their samples, which could easily lead to the following. X thousand donors accept a 5 % profit share; x thousand donors do not settle for less than 10%; x hundred donors claim to have lucky genes or to exhibit special conditions so they claim joint ownership of any related patents; x thousand donors insist on free genetic counselling; and/or x thousand others prefer free personalised medicine. A practical illustration can be found in the debate over the proper benefits due to the population in exchange for the creation of the Icelandic Biobank.[144] Another example is the failure of the stakeholders in a US Biobank (the Framingheart Study) to reach agreement on the terms and conditions for the digitisation and exploitation of the collected data by a private company, which was willing to fund an ethics advisory board and a science education program in Framingham schools, as well as a separate fund to benefit the city.[145]

The above complications only relate to two of the eleven standard incidents of property. And they relate to only one research project. Now imagine the implications of the exercise, in one way or the other, of the other nine incidents for multiple projects. UK Biobank, for example, expects some hundreds of projects to be conducted on the UK Biobank per year. Even if, as has been proposed,[146] the projects would be announced on a website maintained by the operator of the Biobank in question, any meaningful exercise of property rights by a participant faced with, let's say, 250 announcements per year (5 per week), seems unlikely. At best, it would provide an illusory perception of 'ongoing control'. On top of this, Biobanks could conceivably be faced with the prospect of a bailiff foreclosing either material or contractual rights to future royalties, which donors may have pledged to secure their debts.

Recognising property rights, even only a limited subset of the standard incidents, for the owners of biological material in the context of a Biobank is likely to create a proliferation of property rights.[147] A Biobank would face the prospect of hundreds or more 'Moore' cases for each of the hundreds of projects each year. Assuming that this prospect does not prevent the Biobank from being funded and created in the first place, this proliferation of property rights would inevitably require costly transactions to acquire those rights, preceded by countless negotiations about the terms of the

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[144] H T Greely, "Iceland's plan for Genomics Research: Facts and Implications", 40 Jurimetrics J. 153-191 (2000) and Potts, "An examination of the Bargain Made between Iceland and deCODE Genetics with implications for Global Bioprospecting", 7 Va. J.L. & Tech. (2002) 8.

[145] Rosenberg, R, *Questions still linger on Heart Study access* Boston Globe, February 1, 2001:D4.

[146] D E Winickoff and R N Winickoff, "The Charitable Trust as a Model for Genomic Biobanks, N Engl J Med 349;12, 1181.

[147] It is important to realize that this proliferation is not a logistical problem. Biobanks are typically designed in such a way as to be able to trace and communicate with research participants and to honor specific requests for withdrawal of participation. The mere possibility of being able to communicate with research participants in itself cannot resolve the array of issues to be dealt with as a result of the proliferation of rights.

collection, storage and use of the samples. The transactions would have to address a wide array of issues: the purpose of the transfer or donation, the right to use the biological material, a specification of use, the consideration due, the term of the agreement, breach, compensation, expiration, events of default, the right to modify the sample, use and access thereto by third parties, the production of derivative products such as cell lines, intellectual property rights and so on. And even if a sufficient number of sample suppliers would agree to the use of their samples for project X, such an agreement is unlikely to be considered a 'done deal'. As we have seen, property proponents have argued that either waivers or assignments of property rights in human biological material would either be void, due to asymmetries of power between the donor and the recipient or due to undue influence exerted by the institution on the donor, and has to be prohibited by statute.[148]

Property rights in Biobanks: reversing the trend towards simplified consent

A second drawback resulting from recognising property rights in human biological material in a Biobank is that it would effectively undercut the current trend towards accepting general consent for (population-based) research on existing large-scale collections. Under this model, existing specific informed consent requirements for previously unanticipated research uses would be replaced by a more general consent, which would obviate the need for *re*-consent for each new research project. This would enable researchers to 'unlock' these repositories that would otherwise be prone to underuse.[149] This trend is fortified by the proposed ethical Guidelines for Access to Banked DNA, issued by the World Health Organisation.[150] These guidelines provide that existing stored specimens, such as those in hospital departments or collections of blood spots on newborn screening cards, should not be subject to new rules for consent or re-contact. The guidelines also state that a blanket informed consent, which would allow use of a sample in future projects, is the most efficient approach. This trend has been reinforced by the recent opinion of the German National Ethics Council in its Opinion on 'Biobanks for Research'.[151] The opinion has been heralded as an 'enlightened, pragmatic and practical approach, still respecting basic ethical principles'.[152] However, the gains from this trend- unlocking existing collections for biobank research- may be short-lived if the call for personal property rights in the samples concerned is heeded. While researchers would no longer be required to obtain specific re-consent for each new research project under this simplified consent model, they would be required to obtain such consent under the proposed property model.

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[148] D E Winickoff and R N Winickoff, ibid, at 1181 and Laurie, *Genetic Privacy*, at 318.

[149] B M Knoppers, "Biobanks: simplifying consent", 5 Nature Reviews Genetics, (2004), 485.

[150] WHO, *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services*, 1998, WHO/HGN/GL/ETH/98.1

[151] German National Ethics Committee, *'Biobanks for Research'*, Opinon (2004), available at kontakt@ethikrat.org.

[152] B M Knoppers, "Biobanks: simplifying consent", 5 Nature Reviews Genetics, (2004), 485.

The Tragedy of the Anticommons

To gain further insights into the adverse effects of property rights in human biological material in the context of a Biobank, it may be helpful to turn to Heller's theory of *anticommons property*. The theory is a useful tool in understanding the widespread intuition that when too many holders have an exclusive right in a resource, the use of the resource is likely to be suboptimal. As Heller notes, *anticommons property* can best be understood as the mirror image of *commons property*. Commons property has been defined as the situation in which multiple owners are each endowed with the privilege to use a given resource and no one has the right to exclude another. This situation may lead to a 'Tragedy of the Commons' in that the resource will be overused to the point of exhaustion. The metaphor of the Tragedy of the Commons was introduced by Garrett Hardin who gave the following example.[153] Multiple herdsmen enjoy the privilege to graze their sheep on a pasture open to all of them. Each herdsman will try to maximise his number of sheep, with each extra sheep earning him +1. While each extra sheep will lead to overgrazing the pasture, the effects of overgrazing are shared among the herdsmen. As a result, the actual *loss* to an individual herdsman of adding one more sheep on the pasture is not -1 but a *fraction* of -1. Since, as we saw, each herdsman will seek to maximise his number of sheep, while not suffering the full adverse consequences thereof, the pasture will inevitably be overgrazed. In other words, people often overuse commonly-held resources, because they have no incentive to conserve them if no one has the right to exclude others from using such resources. Other examples given by Hardin include depleted fisheries and pollution. The metaphor of the Tragedy of the Commons has been a powerful argument for the privatisation of commons property, in the form of creating private property rights which create incentives for conservation of the resource.

However, while *under*-assignment of property rights for a commonly-held resource will lead to *over*-utilisation of the resource, *over*-assignment of property rights in a resource may result in *under*-use of such resource. Unbridled privatisation in the form of granting rights to multiple owners may lead to a proliferation of fractional property rights. Such a proliferation would leave no one with an effective privilege to use the resource. One of the examples discussed by Heller is the 'Post-Earthquake Reconstruction of Kobe Japan'. Although $30 billion had flowed into the city to rebuild it after the earthquake, much of the city lay in rubble for a long time, because "a single angry tenant can block urban renewal. And does".[154] Under Japanese post-war property laws, land in Kobe had been divided to the point where there are thousands of parcels the size of a US garage and a building 'can be based on a plot that is actually dozens of smaller parcels thrown together by developers.'[155] In one block of Kobe, over 300 renters, lessees, landowners, and subletters owned often overlapping claims, and each one had to agree before rebuilding could go forward. According to a city official, it was 'like trying to get thousands of little corporate presidents to agree on one plan'.[156] An obvious solution would have been for the

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[153] G Hardin, "The Tragedy of the Commons", 162 Science (1968) 1243, 1244-1245.

[154] Heller, at 684, quoting Jathon Sapsord, *Quake-Hobbled Kobe Shows how Land Law Can Paralyze Japan*, Wall St.J., Dec.12, 1996, at A1.

[155] Heller, at 684..

[156] Heller, at 684.

government to intervene and buy the land under laws of eminent domain. However, as Heller points out, Japanese authorities frequently decline to seize property because this would violate the nation's historical and cultural preference for harmony and consensus.[157]

This mirror image of the Tragedy of the Commons has been named, naturally, the Tragedy of the Anticommons. Anticommons property has been defined as 'a property regime in which multiple owners hold effective rights of exclusion in a scarce resource'.[158] The anticommons can also be expressed in terms of the bundle-of-rights metaphor. According to Heller, 'an object is held as anticommons property if one owner holds one of Honoré's core rights in an object and a second owner holds the same or another core right in the object, and so on, with no hierarchy among these owners' rights or clear rules for conflict resolution'.[159] The '*tragedy*' is that 'rational individuals acting separately may collectively waste the resource by underconsuming it compared with a social optimum.'[160] Anticommons property can appear whenever governments create new property rights, in particular when they create too many rights and too many decision-makers who can block use.[161] As Heller demonstrated, a powerful application of anticommons appeared in transition economies, where store-fronts remained empty in spite of privatisation, due to the proliferation of property rights. Another example is land use, when parcels may become uneconomically small after successive partitions.[162] The Anticommons property model has also been used to gain insights into the effects of privatisation of upstream biomedical research in the US. Privatisation of fundamental biomedical research, in combination with over-assignment of patent rights on gene fragments, threatens to enable everyone involved in the product development process to set up a 'tollbooth' on the road towards the production of life-saving innovations.[163] As a result, such production is slowed down or may become prohibitively expensive. The metaphor has also been used to articulate the adverse implications of unrestricted recognition of database rights in genomic databases.[164]

Property rights in material stored in Biobanks: creating another Anticommons?

The anticommons metaphor also helps articulate the adverse consequences resulting from recognising property rights in human biological material in the context of Biobanks.[165] It helps explain why commodification of human biological material may

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[157] Heller, at 685.

[158] Heller, at 668.

[159] Heller, at 670.

[160] Heller, at 677.

[161] Heller, at 624-625.

[162] Heller, 665, fn 201.

[163] M Heller and R S Eisenberg, "Can Patents Deter Innovation: the Anticommons in Biomedical Research", 280 Science (1998), 5364, at 698-701.

[164] J A Bovenberg, "Should Genomics Companies set up Database in Europe?" 18 Nature Biotechnology (2000), 907.

[165] See also C H Harrison, Neither Moore Nor the Market, 28 American Journal of Law and Medicine, (2002) at 86.

cause a tragedy by potentially blocking, delaying or restricting the collection, storage and use of large-scale collections of such material. As a result the true value of these collections may not be realised. As we have seen, agreement on the terms of use will be hard to achieve. Absent such agreements, prospective researchers may be deterred from conducting research on the collected material by the prospect of a mass tort action based on conversion by the individuals who supplied the base material. Industry may be deterred from researching material which carries the potential of a future claim for profits. It is important to note in this respect that, by definition, an anticommons is a property regime in which multiple owners hold effective rights of exclusion in a scarce resource. Such rights do not only include property rights but may also include informal control rights, such as the ability to delay regulatory approvals,[166] or, in the context of biomedical research on Biobanks, overly narrow informed consent requirements.

Will a Biobank Anticommons be Tragic?

It is important to note that an anticommons is 'not necessarily tragic'.[167] Anticommons property is only tragic if it *endures* once it has emerged. For a variety of reasons, most Anticommons are transient since most Anticommons property will normally be rebundled into useful private property. This rebundling can be brought about by market mechanisms, informal institutions or government intervention. As regards market mechanisms, people usually start trading their initial endowments and rearrange them until resources are put to their highest-valued uses.[168] For example, as Heller and Eisenberg have put it, 'copyright collectives have evolved to facilitate licensing transactions so that broadcasters and other producers may readily obtain permission to use numerous copyrighted works held by different owners. Similarly, in the automobile, aircraft manufacturing, and synthetic rubber industries, patent pools have emerged, sometimes with the help of government, when licences under multiple patent rights have been necessary to develop important new products.'[169]

Informal institutions may evolve because Anticommons property theory is partly based on the assumption of rational-self interested persons. This assumption may not reflect the motives of people in the real world.[170] In practice, 'close-knit communities' may develop informal norms and institutions to manage resources and avoid tragedies, for example, co-operation among multiple tenants of an apartment block. [171] Finally, Anticommons property could be rebundled into useful private property by government intervention, *e.g.* when the governments redefines, abolishes or confiscates previously granted property rights.

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[166] Heller, at 665, fn 199.

[167] Heller, at 673.

[168] Heller, at 625.

[169] M Heller and R S Eisenberg, "Can Patents Deter Innovation: the Anticommons in Biomedical Research", 280 Science (1998), 5364, at 698-701.

[170] Heller, at 675.

[171] Skene, "Proprietary rights in human bodies, body parts and tissue: regulatory contexts and proposals for new laws", 22 Legal Studies: the Journal of the Society of Public Teachers of Law, (2002) 103, at 117.

However, these solutions may not work in the context of human biological material, for a number of reasons. The market mechanism may fail because sample donors are unlikely to start trading their property rights in their samples, as long as they do not want to give up 'ongoing control and perceive their rights as inalienable. Also, the number of parties to deal with, - up to half a million or more, as well as the number of deals, - up to a few hundred per year, would drive up transaction costs beyond the financial capacity of public or even private research. Adding to the transaction costs would be the costs of administering the agreements over time. In addition, the actual compensation payable to the participants is likely to add significant costs, even if it were assumed that your DNA sample is worth only a fraction of USD 50,000. Moreover, bargaining may fail due to 'holdouts'. Just like the angry tenant in Kobe could, by himself, block the reconstruction of the entire block, an angry individual or group of individuals could potentially paralyse sensible use of the Biobank.

Furthermore, the emergence of standard license terms would be hard to achieve, due to the heterogeneity of participants. While members of a copyright collective will primarily seek to maximise royalties, participants in a biological material collective will have a wider array of interests. And these interests will diverge widely among participants, since they all have divergent economic and healthcare needs, divergent moral opinions and religious convictions, and divergent ethical and cultural backgrounds. This heterogeneity will require costly case-by-case negotiations on the terms and conditions of use of their collected material. Worse, these negotiations could lead to different terms for different groups for the storage of their biological material in one and the same Biobank. This would undermine the very purpose of a Biobank, *i.e.* to create a large enough resource to do statistically meaningful research. The emergence of standard licensing terms will also be impeded by participants' cognitive bias; individuals may be prone to overvalue their biological material. This is not merely a hypothetical problem. We have already seen claims, right or wrong, that any individual's DNA sample is worth USD 50, 000. And, with hindsight, even the action brought by John Moore for a share in the proceeds of his rare cells, may have been motivated by an overvaluation of his rare cells. Notably, many a commentator of *Moore* has misrepresented some of the highly emotive facts in this case. Although it is true that some drug companies were initially interested in the cells because of their association with cytokines, they eventually pursued other avenues. And while Dr Golde is reported to have sold a patent over the cell-line for USD 15 million, the patent in fact was issued to the University of California which, according to Professor Henry Greely of Stanford Law School, decided not to maintain it. The cell line is still offered for sale, for USD 425, by the American Type Culture Collection (ATCC), a global not for profit bioresource institution. While it is true that Dr. Golde had some financial interests in the cell lines, according to Greely 'no one ever made a dime off the patent'.[172]

The mechanism of government intervention may fail as well. As we have seen, one implication of recognising personal property rights in human biological material would be that it becomes subject to expropriation. Yet, the taking by the government of property rights in human biological material is unlikely. It would require the establishment of 'adequate compensation'. Even assuming this could be done, the government is unlikely to be prepared to compensate hundreds of thousands of sample donors, if only for lack of resources. As a matter of principle, governments may be

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[172] Venting his spleen, *CMAJ* 1998;159:1451 © Richard Cairney.

declined to expropriate human biological material, in view of considerations of personal autonomy, just as the Japanese government frequently declines to expropriate for the sake of harmony and consensus.

Informal institutions, finally, may work, precisely because the individuals concerned might not act as 'rational-self interested' persons. Irrational behavior may particularly occur in the area of research participation, where it has long been the norm to participate and donate material for free. In this perspective, participants in a Biobank do not exercise their property rights for altruistic reasons. Paradoxically, then, it would be the tradition of altruistic participation that would prevent a Biobank Anticommons, - which is caused by the replacement of that tradition by a property rights model, from turning into a tragedy. However, the formation of such a coalition of willing participants would require their waiving or their assigning their property interest in their biological material. As we have seen such waiver or assignment would run counter to the proposed 'inalienability' of these interests. In a sense, the sample collection formed by PXE Inc. may form an example of such an informal institution. Theoretically, the group faced its own Anticommons, in that individual PXE patients could have claimed property rights in their material. Apparently, they have resolved the issue. Yet, while informal institutions may arise in the context of dedicated special interest groups, they are unlikely to evolve in the context of large-scale Biobanks. By definition, these banks comprise material from a very large and a very diverse 'constituency', from which material is assembled not for hypothesis driven research into a specific, genetic disorder, but for the broad purpose of population-based research into the causes of multiple common diseases.

How to avoid a tragic Biobank Anticommons?

When market mechanisms, governmental intervention and informal institutions fail, it is unclear what other mechanisms are available to convert Anticommons property into a useful resource. As Heller notes, this question is underdeveloped in the literature on the economics of property rights.[173] One obvious solution advanced by Heller is for governments 'to convey a core bundle of property rights to a single owner, rather than rights of exclusion to multiple owners'.[174] This single owner would be the entity operating the Biobank. Obviously, no one could be forced to donate his or her biological material to a Biobank, ever. Individuals contemplating to participate in a *de novo* Biobank could even be given the opportunity to have themselves tested and, in the event they have rare and potentially commercially valuable material, they could decide not to participate and try to sell or transfer their materials to somebody else, an option John Moore and the Greenbergs was denied. However, once a donation is made, upon informed consent, it should be unconditional, for free and for as long as the Biobank exists; any residual individual property interests in the material in the Biobank should be denied. A Biobank would thus earn clean title, unaffected by any individual residual property interests, to store and use the collection of material, in accordance with its terms and mission, and in the interests of all involved, including, but not limited to, the individuals donating material. Obviously, the unconditional donation of a sample would not prevent an individual or a group of patients, from

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[173] Heller, at 678.

[174] Heller, 688.

donating, selling or transferring his material, on whatever basis, to anyone else, for any conceivable purpose.

This option is less radical than it may appear. As we have seen, existing case law hints in the same direction. A similar approach has been proposed by Skene, be it that his proposal to reject a general principle that people have a property interest in their body parts and tissues seems to permit conditions to be imposed on the initial consent.[175] Notably, the rejection of any individual property rights would not affect the exercise by research participants of any 'non-property' protections offered by law against the abuse of samples or the information contained therein, such as privacy rights. Given the particularly sensitive nature of this collection of nature and nurture data, these laws could even be enhanced. The Estonian legislation establishing the Estonian Gene Bank, for example, contains an express prohibition against genetic discrimination. In addition, donors could be given specific rights in respect of their material, such as the right to know or not to know the results of any analysis.[176] The prime general interest to be served by the Biobank would be the promotion of research. To that end, Biobanks should be subject to principles of good governance, including, but not limited to, the following: they should be accessible for research purposes only; all research must pass ethical and scientific review; and any benefits must flow back to the resource. In essence, this approach aims to solve the adverse implications of individual ongoing control and 'individual claims for a benefit share by providing for 'collective' ongoing control and 'collective' benefit-sharing.

We began this inquiry with the statement that the full scientific and commercial potential of a Biobank, may not be realised if there is uncertainty over the question of who owns the collected material. Having considered this statement, any residual uncertainty should be eliminated altogether by the codification of the principle that the property rights in biological material vest in the entity lawfully collecting and storing the material.[177]

Anticommons and Common heritage

Denying property rights, even in a watered down version, in human biological material in the context of a Biobank would thwart the emerging pleas in favour of an inalienable property model for human biological material to enable ongoing control and a profit-share. However, the arguments against a property model are not limited to the metaphor of the Tragedy of the Anticommons. Additional support can be found in the notion, set forth in a number of international declarations, that the human genome is, in a symbolic sense, the heritage of mankind[178] and that Biobanks are a global public good.[179] These proclamations are commonly understood to serve as an

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[175] Skene, "Proprietary rights in human bodies, body parts and tissue: regulatory contexts and proposals for new laws", 22 Legal Studies: the Journal of the Society of Public Teachers of Law, (2002) 103, at 118.

[176] *See, e.g.* the enumeration of donor rights in the legislation governing the creation and use of the Estonian Gene Bank, Chapter 2, specifically paragraph 11.

[177] See also Skene, at 125.

[178] UNESCO, Universal Declaration on the Human Genome and Human Rights, 1997.

[179] HUGO**,** Statement on Genomic Databases, Human Genome Organization 2003.

argument against misappropriation of the human genome, genetic samples and associated genetic data by industry.

I would argue, however, that the notion of the human genome and Biobanks as a 'common heritage', a global public good, should also serve as a barrier to the recognition of personal property rights for the individual suppliers of the 'raw material', at least in the context of the large-scale collection, storage and use of human biological material. The idea of a common or global public good is a two-edged sword in that it both wards off overly broad patent claims on 'genetic inventions', and a proliferation of proprietary claims by individuals to their biological material, each of which would hinder reaping the full fruits of this resource.

Conclusion

The emergence of Biobanks, on the one hand, and the call for property rights by donors in their human biological material, on the other hand, urges a reconsideration of the issue of who owns these materials. Recognising property rights in human biological material, while conceivable from a legal perspective, is problematic, especially where such rights are considered to be inalienable. In addition, on balance the various policy implications of recognising property rights outweigh the considerations in favour of such a right.

Nevertheless, recognising property rights in human biological material may be appropriate in certain contexts, for example to enable specific patient groups to negotiate the terms and conditions of research into their specific disorder. In the final analysis, courts are likely to adopt a contextual approach and the way they will resolve the issue in a particular case will be influenced by the manner in which it is framed. To inquire whether PXE patients should be able to dictate the terms of use of the tissue repository they set up, is likely to evoke a positive response, as is the inquiry of whether the Greenbergs are entitled to compensation for their 'blood, sweat and tears'.

To inquire, however, whether each individual research participant should be able to block or profit from each use of the biological material he has provided to a Biobank, should invite at least a mixed and qualified response. The potential of a tragic anticommons in both existing sample collections and *de novo* Biobanks cautions against the granting of unqualified and inalienable property rights in human biological material in that context. For both existing, large-scale repositories of human material and *de novo* Biobanks, the Tragedy would be that they cannot be converted into respectively cannot be used as a Biobank and that they will be prone to underuse. A second drawback of adopting an unqualified property approach would be that it would effectively undercut the current trend towards simplifying existing informed consent requirements for (populations-based) research on existing large-scale collections. To avoid uncertainty over the issue of who owns collected human biological material, the principle that the property rights in such material vest in the entity that has lawfully collected and stored the material, should be implemented in legislation. This approach would also coincide with the widespread notion that these collections are a global public good. As the steward of the collection, the entity operating the Biobank is to act in accordance with provisions of good governance, in the interest of its beneficiaries, including not only the community of sample donors but also the public at large and future generations. This way most individuals and their offspring will

benefit more than when they heed the call to stand up for their property rights in their samples.