OWNERSHIP AND COMMERCIALISATION OF HUMAN BIOLOGICAL MATERIAL (AND THE) IMPACT ON SCIENTIFIC AND MEDICAL RESEARCH

by

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A thesis submitted to the University of Southampton in fulfilment of the requirements for the degree of Doctor of Philosophy in Law

University of Southampton 2014

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Abstract

Health related biotechnological research is undoubtedly a significant social utility. Such research leads to development of drugs, diagnostics, and better understanding of the causes of diseases and illnesses that plague humanity. It also helps to drive economic growth.

Patenting and the commercialisation of the products of biotechnological research enterprise provide the necessary economic incentive to encourage investment, drive innovation and productivity in such enterprise. While significant profits are made from this enterprise, these profits are presently shared between researchers (and their employers) who develop the products and private companies that market the products in a commercial arena. Although human biological material is an essential raw material for most health related biotechnological research, the individuals who contribute this essential raw material ('sources') are largely excluded from partaking in the profits made from research enterprise.

While it is important to safeguard the profit interest of developers and marketers of products generated from biotechnological research enterprise in order to maintain the incentive to embark upon such ventures, the current two-dimensional approach to profit sharing is arguably untenable. It is inconsistent with notions of justice which form part of the fabric of a civilised society. Furthermore, sources are becoming aware of the potential commercial value of biological material as the matter continues to be debated in the public arena and they may refuse to participate in research if they perceive they are treated unjustly. This potential state of affairs could hinder research progress since its survival depends to a significant extent on the continued supply and availability of human biological material.

One supposition advanced here is that sources who contribute commercially valuable biological material towards research enterprise should be empowered by law to claim compensation for their contribution, or alternatively, to direct such compensation into further research, if they so wish. Furthermore, a source's interest in determining how and by whom his or her biological material is used should also receive more robust protection under the law than at present. Such an approach arguably enhances the ethics of research enterprise by helping to promote justice, dignity and autonomy for sources. It is proposed that a hybrid liability/property policy framework should be introduced for this purpose, a framework which should seek to safeguard the interests of sources of biological material, without discouraging innovation or eroding the economic incentive to conduct and invest in research. An attempt is made in this discourse to sketch the contours of one such model.

Acknowledgements

I developed an interest in this area of research some years ago, having stumbled upon Dr Remigius Nwabueze's research profile on the University of Southampton's website. I then proceeded to submit a research proposal to the University of Southampton, and thereafter embarked upon what was to be a challenging but ultimately rewarding doctoral journey. In undertaking the journey from inception to review and completion, I have incurred many debts. I am thankful to God for salvation through Jesus Christ, for inspiration and strength during this journey, and without whom I would not have completed this thesis.

I am grateful for the constructive criticism and helpful suggestions of Dr Remigius Nwabueze (supervisor) and Professor Hazel Biggs (advisor). I am also appreciative of the valuable feedback provided by Dr John Coggon following my upgrade examination. Collectively, the intellectual support from these academics enabled me to develop the breadth and depth at which I engaged with my chosen topic. I would like to appreciate the Richard Newitt Trust for their generous financial support during my doctoral study. I am also grateful to my Father, Semasa Ayihongbe, and brother, Sewhenu Ayihongbe for their financial and moral support, and willingness to discuss my doctoral work with me at all stages of study. Finally, I wish to record the debt of gratitude that I owe to the rest of my family, the RCCG Oasis of Life (Southampton) Church family and friends.

Chapters Outline

The primary objective of the present discussion is to propose and sketch the contours of an implementable policy framework for regulating interactions regarding human biological material supplied for biotechnological research, with particular emphasis on safeguarding the management and income entitlements of sources of human biological material. It proceeds on the basis that although the public utility inherent in biotechnological research dictates that policy makers maintain the economic incentive to conduct such research by facilitating an environment that is favourable to the commercial sector, this must be balanced against the interests of the sources of human biological material, without the contribution of whom most biotechnological research would not take place.

As with any legal construct, the proposed framework cannot exist in a vacuum and must be grounded upon established legal principles. Accordingly, and in order to provide a context within current legal discourse for the proposal advanced here, the following questions will be explored during the course of this discussion:

1. Theoretical characterisation: Do source ownership entitlements qualify as property interests under a normative understanding of property?

2. Legal characterisation: Are source ownership entitlements enforced as property interests under the law?

3. Should source ownership entitlements be protected? Should such protection include a legal characterisation of source ownership entitlements as property interests?

4. How should an implementable policy framework for the protection of source income entitlement and source management entitlement be construed?

The discussion consists of 5 chapters:

Chapter 1 is an introductory chapter that presents a synopsis of the issues that highlight the need for the proposed framework. It sets the stage for the analysis undertaken in succeeding chapters.

Chapter 2 examines the first question outlined above. Since the normative characterisation of both source income and source management entitlements as property interests is a necessary component of the proposed framework advanced for protecting both entitlements, Chapter 2 considers whether such entitlements qualify as property interests from a theoretical standpoint. This deliberation requires much broader analyses of whether source ownership entitlements and generally, ownership entitlements regarding biological material qualify as property interests. The analysis in chapter 2 led to the conclusion that both source ownership entitlements, ownership entitlements regarding biological material and indeed, excised biological material in itself, can qualify as property interests and property respectively under the various normative understandings of property, namely the bundle of rights perspective of property, some constructions of a bundle of rights-plus perspective and the reified perspective of property.

Chapter 3 explores the second question. Chapter 3 proceeds on the premise that while source income and source management entitlements might qualify as property interests under a normative understanding of property, it is a separate question and not simply a foregone conclusion, whether they are legal property interests. Chapter 3 seeks to determine the legal status of source ownership entitlements by exploring decided cases and relevant statutory provisions. It notes that source management entitlement seems to be largely protected by liability rules but suggests that the current safeguards are insufficient because it either has limited scope and does not protect all classes of sources (the restriction of remedies for breach of fiduciary duty and lack of informed consent to doctor-patient relationship) and where it does offer universal protection under a criminal based liability framework, it largely serves to vindicate the state's interest in crime reduction and maintaining public order, rather than the victim's (the source's) interest. The legal position regarding source income entitlement is less certain. With regard to the question of whether source income and management entitlements are legal property interests, chapter 3 concludes that while recent cases indicate a preparedness of the courts to admit source ownership entitlements in general into the category of property, they do not represent a coherent body of jurisprudence upon which to determine the matter and there remains

uncertainty under the law as to whether source ownership entitlements are legally protectable property interests.

Chapter 4 considers the third question. The chapter is divided into two distinct sections (Part I and II) simply to improve its accessibility to the reader. Part I examines the case for increasing the current safeguards under the law for the protection of source management entitlement. It also analyses the arguments raised by those who object to the legal recognition of source income entitlement. Part II presents the arguments in support of the legal recognition of source income entitlement. Chapter 4 concludes that while there seem to be a general concession among commentators that a source's management entitlement need to be protected more robustly than at present, such a concession does not exist in respect of source income entitlement. However, after deducing that the concerns raised by those opposed to the legal recognition of source income entitlement are not insurmountable and can in fact be addressed by the appropriate regulatory and legislative framework, the chapter concludes that source income entitlement should be enforced under the law.

Chapter 5 examines the fourth question. The chapter scrutinizes existing proposals advanced as alternative policy frameworks to the current legal approach regarding source ownership entitlements. It notes that while existing proposals are excellent alternatives to the current system, they are far from complete solutions and it is possible to enhance them to provide a more effective solution. Chapter 5 outlines the hybrid liability/property framework that is advanced in this discussion and assesses its efficacy. The chapter concludes that while the proposed framework is not without its limitations, it is a more effective compromise than the current system and existing proposals to the extent that it better protects key interests of sources of human biological material, namely source income and management entitlements, while still facilitating an environment in which biotechnological research can flourish.

CHAPTER 1 INTRODUCTION

Rationale

This discussion is concerned with protecting source ownership entitlements regarding biological material supplied either for specific health related[1] research projects or supplied for health related research following removal for therapeutic purposes. A case is not advanced for protecting all source ownership entitlements but, rather, the focus is on protecting both source management entitlement and source income entitlement in excised biological material.

To enhance the accessibility of this discussion, it is useful to consider the definition of some key terms at this early stage of the discussion. The term 'source ownership entitlement' is invoked to denote the various entitlements that a person may have with regard to biological material removed from his or her body (excised biological material) which are protected from interference by others and which others must respect.[2] The 'source' in this context is the individual from whom the biological material was removed.[3] 'Source management entitlement' is defined here as the ability of a source to determine how and by whom his or her biological material is used[4] and 'source income entitlement' denotes the ability of a source to derive a monetary benefit from foregoing personal use of his or her biological material[5]. With regard to source income entitlement, it should be noted that while references are made to 'compensation' and 'payment', a subtle distinction is made between 'compensation/payment' as in a 'purchase' (payment made in direct exchange for an

[1] As opposed to research for instance, to develop cosmetic and enhancement products.
[2] J Wall, 'The Legal Status of Body Parts: A Framework' (2011) 31 OJLS 783, 785.
[3] Biological material used for research can be material 'left over' after a diagnostic procedure or operation; material donated as part of a research project accompanying medical treatment; or material provided specifically for a research project quite unconnected with medical treatment. Tissue provided by a living donor is usually preferable for research purposes, compared with tissue from a deceased donor; however, some forms of tissue, such as brain tissue, may be very hard or impossible to obtain during life. (Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (Nuffield Council on Bioethics (11 October 2011) para 1.13).
[4] Wall (n 2). See also, AM Honoré, 'Ownership' in AG Guest (ed), Oxford Essays in Jurisprudence (1st Series, OUP, 1961) 107, 112-124.
[5] Ibid.

object, for example, a certain amount for a pint of blood) and a 'reward' (material advantage gained by a person as a result of contributing biological material, that exceeds payment for the losses they incurred in donating).[6] The latter is adopted in the present discussion. Thus, any monetary payment to sources of human biological material should be understood in terms of a reward for the person's act of providing biological material, a form of recognition for their act of contributing to the research enterprise, rather than a purchase of the biological material itself.[7]

The definition attributed to the term 'biological material' in this discussion consists of any collection of human cells or sub-cellular components separated from a human body.[8] This definition includes solid organs, blood components and tissue samples.[9] Gametes and embryos have been excluded from this definition of biological material[10] because the public policy concerns raised by gametes and embryos differ from those raised by non-reproductive biological material. Public policy concerns are relevant to the extent that they determine the nature of the limitations placed upon the exercise of a particular entitlement and the provisions included in the policy framework for protecting that entitlement.[11] An attempt to include all three categories of biological material will potentially widen the scope of this discussion to the extent that the depth at which relevant issues specific to each category of biological material is analysed may be negatively impacted. In essence, it may reduce the capacity to fully explore relevant issues relating to each class of biological material.

[6] Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 3) 2, paras 30 and 6.27.
[7] Ibid.
[8] R Hardcastle, *Law and the Human Body: Property Rights, Ownership and control* (Hart Publishing; 2007) 1.
[9] Tissue is defined as:
'A collection of cells of similar structure organized to carry out one or more particular functions. For example, in animals nervous tissue is specialized to perceive and transmit stimuli. An organ, such as a lung or kidney, contains many different types of tissues.' E Martin and RS Hine (eds), *OXFORD DICTIONARY OF BIOLOGY* (4th edn, OUP, 2000) 592.
[10] Hardcastle (n 8).
[11] *Moore v Regents of the University of California* (Moore SC) 793 P 2d 479 (Cal SC 1990) [510].

The general theme pursued in this discussion is that of source welfare maximisation (promotion of source interests) as a means of enhancing the ethics and sustainability of health related biotechnological[12] research. In simple terms, the survival of most health related biotechnological research (hereinafter referred to as 'biotechnological research') depends to a large extent on the supply of biological material by human sources because human biological material is an essential tool in most of this type of research since it provides the raw material for such research.[13] Accordingly, the promotion of the interests of sources of human biological material is arguably crucial in maintaining the supply of biological material because it would likely form an incentive for those sources to contribute their biological material for use in research. Expressed differently, if people perceive that their interests are not being protected then they would likely refuse to make their biological material available for use in research. This sentiment is underpinned by theoretical expositions of the concepts of justice and relative deprivation,[14] and recent events such as the Arab spring uprisings[15] and civil unrest in Greece[16] and other European countries[17], where it has

[12] Biotechnology is defined here as: 'The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.' It includes techniques such as cellular infusion, cell/tissue culture engineering, DNA/RNA sequencing and genomics. (The Organisation for Economic Co-operation and Development (OECD), 'Biotechnology Policies –Statistical Definition of Biotechnology': <http://www.oecd.org/sti/biotech/statisticaldefinitionofbiotechnology.htm> accessed 19 June 2014)

[13] Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 3) 38 and generally from 35-42.

[14] M Maiese, 'Distributive Justice' Beyond Intractability. G Burgess and H Burgess (eds), Conflict Information Consortium, University of Colorado, Boulder. Posted: June 2003 <http://www.beyondintractability.org/bi-essay/distributive-justice> accessed 19 June 2014. See also M Deutsch, 'Justice and Conflict' in *The Handbook of Conflict Resolution: Theory and Practice*, M Deutsch and PT Coleman eds, (San Francisco, Jossey-Bass Publishers, 2000) 43; WG Runciman, Relative deprivation and social justice : A study of attitudes to social inequality in twentieth-century England (University of California Press, 1966); I Walker, HJ Smith, Relative Deprivation: Specification, Development, and Integration (Cambridge University Press, 2001).

[15] About.com, Middle East Issues, 'Arab Spring Uprisings': <http://middleeast.about.com/od/humanrightsdemocracy/tp/Arab-Spring-Uprisings.htm> accessed accessed 19 June 2014; See also, BBC News World, 'Arab uprisings: Country by country – Egypt': <http://www.bbc.co.uk/news/world-12482291> accessed 19 June 2014.

[16] N Kitsantonis and R Donadio 'Greek Parliament Passes Austerity Plan After Riots Rage': <http://www.nytimes.com/2012/02/13/world/europe/greeks-pessimistic-in-anti-austerity-protests.html?pagewanted=all&_r=0> accessed 19 June 2014; See also, BBC News Europe, 'Athens clashes as Greek police fire tear gas' <http://www.bbc.co.uk/news/world-europe-19724284> accessed 19 June 2014.

[17] B Gonzalez and A Khalip, 'Europe Austerity Protests: Strikes Sweep Southern Europe In Response To Cuts': <http://www.huffingtonpost.com/2012/11/14/europe-austerity-protests-strikes-greece-italy-france_n_2129091.html> accessed 19 June 2014; See also, BBC News Europe, 'Violent clashes as

been shown that where people feel that their interests are not being protected, they are prone to rebel against the establishments and social institutions that are perceived to instigate or perpetuate such apparent injustice.[18] These concepts are examined in detail in chapter 4 (II) of this discussion. Since biotechnological research offers significant social utility in aiding public health because it has paved the way for the development of many drugs, diagnostics and therapies that the modern society has come to rely upon[19], policy makers ought to act to prevent the occurrence of factors that could potentially impede its progress, in this case, a possible decline in the willingness of the public to contribute biological material for research uses. One way of doing this could be to review the adequacy of the safeguards, if any, currently available to protect source management and source income entitlements.

A specific context in the biotechnological research venture where injustice arguably exists is in the distribution of economic benefits in those instances where the research product is marketed in a commercial arena and a profit is made. Essentially, the emergence of biotechnology[20] has led to technological advances in science which have transformed the ability of scientific and medical research to develop health enhancing products such as diagnostics and drug therapies[21] and products with

austerity protests grip EU cities': <http://www.bbc.co.uk/news/world-europe-20320993> accessed 19 June 2014.

[18] For a discussion of the notion of relative deprivation, see Maiese (n 14), Deutsch (n 14), Runciman (n 14), Walker and Smith (n 14).

[19] Economy Watch, 'Biotechnology in Medicine': <http://www.economywatch.com/business-technology/biotechnology/biotechnology-in-medicine.html> accessed 19 June 2014; EuropaBio, 'How can Biotechnology benefit you?': <http://www.europabio.org/how-can-biotechnology-benefit-you> accessed 19 June 2014.

[20] For a definition of biotechnology, see the Organisation for Economic Co-operation and Development (OECD), 'Biotechnology Policies –Statistical Definition of Biotechnology' (n 12).

[21] EuropaBio (n 19):

> Healthcare biotech is already benefiting more than 350 million patients around the world through the use of biotech medicine to treat and prevent every day and chronic illnesses including heart attacks, stroke, multiple sclerosis, breast cancer, cystic fibrosis, leukaemia, diabetes, hepatitis and other rare or infectious diseases.
>
> Healthcare biotech is estimated to account for more than 20% of all marketed medicines and it is estimated that by 2015, 50% of all medicines will come from biotech.

See also, Economy Watch (n 19); Biotechnology Industry Organization, 'What is Biotechnology?': <http://www.bio.org/articles/what-biotechnology> accessed 19 June 2014; The Organisation for

therapeutic potential such as specialised cell lines.[22] While these products generate significant financial returns when marketed,[23] at the time of writing, the profits are exclusively shared between researchers (and their sponsors/employers) who develop the products, and private companies (biotechnology, pharmaceutical, medical device companies)[24] that invest in marketing the products in a commercial arena- the source of human biological material who contributes the essential raw material[25] is excluded from obtaining financial gain. The circumstances surrounding the 'HeLa' cell line and the 'Mo' cell line illustrate this arguably unjust practice.

Economic Co-operation and Development (OECD), 'Biotechnology Policies –Biotechnology, Innovation and Health': <http://www.oecd.org/sti/biotech/biotechnologyinnovationandhealth.htm> accessed 19 June 2014.

[22] Researchers in the medical and scientific community can use human cells to develop a cell line. Cell lines are often used in research in place of primary cells (cells taken directly from the human body) because amongst other things, they are capable of reproducing indefinitely and thus, provide an unlimited supply of material for research. In contrast, primary cells generally reproduce a few times and then die. See Life technologies, 'Introduction to Cell Culture': <http://www.lifetechnologies.com/uk/en/home/references/gibco-cell-culture-basics/introduction-to-cell-culture.html> accessed 19 June 2014; G Kaur and JM Dufour, 'Cell lines: Valuable tools or useless artifacts' (2012) 2 Spermatogenesis 1, 1; C Devine, 'Tissue Rights and Ownership: Is a Cell Line a Research Tool or a Person. (2010) The Columbia Science and Technology Law Review. <http://www.stlr.org/2010/03/tissue-rights-and-ownership-is-a-cell-line-a-research-tool-or-a-person/> accessed 19 June 2014.

[23] See Devine (ibid).

[24] Collectively, these three types of companies are largely referred simply as 'biotechnology companies' or the 'biotechnology industry' during the course of this discussion.

[25] (Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 3) 36-38:

> Whole organs, such as the kidneys, heart, liver, lungs, pancreas and the small bowel may be donated after death either for transplantation or for research. Other organs, such as the brain, large bowel, bladder and prostate, are not currently transplanted but may still be donated for research purposes.[25]
> It is also possible to donate some organs during life: at present the organs provided by living donors are primarily kidneys, but liver lobes may also be donated, and partial donations of the lung have taken place in the past.
> A very wide range of tissue (footnote omitted) such as corneas, skin, bone, heart valves, tendons and cartilage, may be donated for transplantation or research. While many of these forms of tissue may only be donated after death, some such as bone may be provided by living donors: for example heads of femur removed during an operation to replace a hip joint are sometimes processed and 'recycled'(footnote omitted) for research uses.(footnote omitted)
>
> In clinical trials of new medicines, for example, vital information about the effects of the medicine on an individual is obtained from samples of blood and other materials provided by research participants. However, blood and tissue are also used much more widely in medical research, from early drug 'discovery' – such as using human tumour samples to discover possible targets for treatment – to later clinical development where samples may be used to identify which subgroups of the patient populations respond best to the new medicine.

The HeLa cell line was the first 'immortal cell line' created by researchers and was developed from cells removed from the body of Henrietta Lacks, a woman suffering from 'a particularly virulent strain of cervical cancer.'[26] These immortal cell lines offer significant utility to researchers 'because of their ability to grow indefinitely and to survive being divided and shared; these traits allow [researchers] to engage in more productive research.'[27] The development of these cells has given rise to notable improvements in research and experimentation because 'unlike most cells, these cells do not die of old age…'[28]Since its creation in the 1950s, researchers have used HeLa cells in developing both the polio vaccine and drugs that treat Parkinson's disease and leukaemia. The cells from the line have also been used in space to aid research on the 'effects of zero gravity on human tissue'. [29] On the whole, '[researchers] have produced more than two thousand pounds of these cells, the sales of which have generated millions in profits.'[30]

While Lacks' death meant that she could not directly be compensated for her contribution to the research enterprise, her relatives were not offered any compensation in acknowledgment of Lacks' crucial contribution, nor were they offered compensation for their own direct contributions to the research.[31] The recent agreement between researchers (United States of America National Institutes of Health) and the Lacks Family would appear to reinforce this continued 'no compensation' approach taken by researchers. Under the agreement, distribution and access to complete DNA sequences from Henrietta's cancer cells will be restricted to scientific researchers funded by US government grants.[32] Requests from

[26] Devine (n 22). 'researchers continued to collect genetic material for the purposes of HeLa cell development from these family members long after Lacks died, under the guise of routine cancer screening diagnostics.' (ibid).
[27] Ibid.
[28] Ibid.
[29] Ibid.
[30] Ibid.
[31] Ibid. 'Researchers continued to collect genetic material for the purposes of HeLa cell development from these family members long after Lacks died, under the guise of routine cancer screening diagnostics.' (ibid).
[32] D Kroll, 'Ethical Justice, But No Financial Rewards, For The Henrietta Lacks Family' (2013) Forbes: <http://www.forbes.com/sites/davidkroll/2013/08/08/ethical-justice-but-no-financial-rewards-for-

researchers will now be reviewed by a six-person panel that includes two Lacks family representatives.[33] Additionally, publications developed from such research will now be accompanied by an acknowledgment of Henrietta Lacks as the source of the cells.[34] While the agreement does arguably represent an attempt by researchers to better promote source interests, particularly, source management entitlement in excised biological material, it does not make provision for monetary compensation for the Lacks Family.[35]

Similarly, the Mo-cell line (developed from biological material removed from the body of John Moore, a patient receiving treatment for hairy-cell leukaemia) has been used to produce biologically important substances such as lymphokines, which offer significant utility in treating blood diseases, cancers, immune system deficiencies, and other blood factors that are used in developing specialised blood cells.[36] However, as in Lacks' case, the researchers who generated the Mo-cell line from Moore's excised biological material did not offer to compensate him in acknowledgement of his valuable contribution to the research enterprise. In fact, they contested Mr Moore's civil court action which he issued in an attempt to claim the value of his contribution. The case of *Moore*[37] is discussed in greater detail in subsequent chapters.

Before proceeding further, it should be noted that although this discourse seeks to advocate for the interests of sources of human biological material and for the current pendulum of benefits flowing from biotechnological research ventures to be

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the-henrietta-lacks-family/2/> accessed 19 June 2014. See also, E Callaway, 'Deal done over HeLa cell line - Family of Henrietta Lacks agrees to release of genomic data' (2010) 500 Nature International weekly journal of science 132, 132.

[33] Ibid.

[34] Ibid.

[35] Ibid.

[36] Appellant's Opening Brief [5], *Moore v Regents of the University of California*, App. No. B021195 (California Court of Appeal August 1987), cited in MT Danforth, 'Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits' (1988) 6 Yale L. & Pol'y Rev. 179, 179.

[37] *Moore* SC (n 11), *Moore v Regents of the University of California* [1988] 202 Cal. Rptr. 494.

re-balanced in a manner that better protect the interests of sources, an exercise of caution is necessary to ensure that the biotechnology industry is not portrayed simply as exploiters of the public's generosity because such a view would not be entirely accurate. The simple fact is that the biotechnology industry makes significant social and economic contributions to society both in the UK and globally.[38] Aside from its contribution in aiding public health as illustrated above, the industry also helps to meet other national strategic objectives by training a scientifically competent workforce, creating new knowledge and technologies, and maintaining an ongoing and vibrant innovation stream that drives economic growth.[39] However, due to space constraints, the present discussion simply acknowledges the economic benefits of biotechnological research and makes reference to it where relevant but it does not engage in a substantial analysis of the actual economic contributions of biotechnological research ventures to society. Rather, the discussion largely emphasizes the social (health) benefits that flow from biotechnological research ventures.

[38] For an illustration of the social and economic contributions of biotechnology, see:
London Stock Exchange Group, 'Biotech & Healthcare': <http://www.lseg.com/resources/1000-companies-inspire-britain/biotech-healthcare> accessed 19 June 2014;
The Association of the British Pharmaceutical Industry, 'The pharmaceutical industry's contribution to the UK economy and beyond': <http://www.abpi.org.uk/about-us/objectives/Documents/UK%20economy%20and%20beyond.pdf> accessed 19 June 2014;
The Association of the British Pharmaceutical Industry, 'Monthly Annual Total (MAT) trade balance': <http://www.abpi.org.uk/industry-info/knowledge-hub/uk-economy/Pages/mat-trade-balance.aspx> accessed 19 June 2014;
Biotechnology Industry Organization, 'The Economic Contributions of the Biotechnology Industry to the U.S. Economy': <http://biotechwork.org/pages/FileStream.aspx?mode=Stream&fileId=87d27f43-4cf4-db11-b900-00c09f26cd10> accessed 19 June 2014;
Biotechnology Industry Organisation, 'The Economic Contributions of the Biotechnology Industry': <http://www.bio.org/articles/economic-contributions-biotechnology-industry> accessed 19 June 2014; E Zika, I Papatryfon, O Wolf, M Gomez-Barbero, A J Stein, A Bock, 'Consequences, Opportunities and Challenges of Modern Biotechnology for Europe': <http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_200704_biotech.pdf> accessed 19 June 2014;
European Business and Technology Centre, 'Indian Biotechnology Sector – Overview': <http://ebtc.eu/pdf/Indian_Biotechnology_Sector-Overview_VO1.pdf > accessed 19 June 2014.

[39] American Society for Biochemistry and Molecular Biology, 'Toward a Sustainable Biomedical Research Enterprise' <https://www.asbmb.org/uploadedFiles/Advocacy/About_the_PAAC/SBRE%20Final_JMB%20.pdf> accessed 19 June 2014.

It is intended that the focus of this discussion will be on the law and legislative policies in the United Kingdom. However, where the British Jurisprudence does not exist or is under developed, it is envisaged that the focus may shift to comparable common law jurisdictions such as the United States of America (USA) and Australia and cases from these jurisdictions may then be relied upon. To add an empirical perspective to the debate surrounding source income entitlement, empirical evidence will be examined from case studies of regulatory systems that permit compensated living organ donation (Iran),[40] and those involving controlled experiments and observational studies studying generally the impact of incentive on the donation of biological material (Sweden, Switzerland, United Kingdom, United States).[41] It is hoped that the empirical investigation will assist by providing a basis upon which to deduce the potential state of affairs that could result from the legal enforcement of source income entitlement in the United Kingdom.

One of the proposals made in this discussion is that the legislator ought to provide a more robust policy framework to fully safeguard source management entitlement than the provisions currently contained within the Human Tissue Act 2004 (HTA 2004)[42], especially in consideration of the argument that the ability of a person to manage his or her biological material is fundamental to that person's autonomous life, his liberty[43] and the expression of his personhood[44]. It is suggested that the enhanced framework for protecting source management entitlement could be incorporated as supplementary provisions to the HTA 2004. However, since legal frameworks cannot be reached in a vacuum and must be grounded upon established

[40] AJ Ghods, 'Renal transplantation in Iran' (2002) 17 Nephrol Dial Transplant 222, 222–228. Also see AJ Ghods, 'Ethical issues and living unrelated donor kidney transplantation' (2009) 3 Iranian Journal of Kidney Diseases 183, 183-91; AJ Ghods and S Savaj, 'Iranian Model of Paid and Regulated Living-Unrelated Kidney Donation' (2006) 1 Clin J Am Soc Nephrol 1136, 1136 -1145; A Bagheri, 'Compensated kidney donation: an ethical review of the Iranian model' (2006) 16 Kennedy Institute of Ethics Journal, 269, 269-82.

[41] N Lacetera, M Macis and R Slonim 'Will there be blood? incentives and substitution effects in pro-social behavior (2009) *IZA Discussion Papers*: No. 4567, 20; L Götte and A Stutzer, 'Blood donations and incentives: evidence from a field experiment' (2008) IZA Discussion Papers, No. 3580.

[42] *Human Tissue Act* 2004, 2004 Chapter 30.

[43] J Christman, Self-ownership, Equality and the Structure of Property Rights' (1991) 19 Political Theory 28, 34.

[44] Wall (n 2) 793.

legal principles, it is submitted that such a framework could comprise a liability/property framework that borrows from both liability and property rules because both legal principles address the limitations of each other. For instance, due to the special status and dignity accorded by society to the human body and biological material removed from the human body,[45] it is important that the chosen framework for protecting entitlements regarding excised biological material is implemented in a way that is not contrary to public policy. One of the advantages of liability rules over property rules in this regard is that they are able to take consideration of relevant ethical issues such as an individual's entitlement to control the actions of professionals and their organisation, considerations which are not necessarily reflected in a property approach[46]. Likewise, in cases of interference with source ownership entitlements, a property framework enables a source of biological material to claim a wide range of remedies that are unavailable for breach of liability rules.[47]

Currently, source income entitlement in respect of excised biological material supplied for research uses is not enforced under the law. This legal position is arguably untenable in view of the significant profit that is made by researchers and commercial companies involved in biotechnological research enterprise. The current system of benefit sharing that encourages sources of biological material to be 'pure altruists' and allows all other parties involved in biotechnological research to be 'pure capitalists' is evidently unjust if justice is considered as a matter of equity, equality or even reciprocity. From an equity-focused perspective, it is possible to argue that 'the suppliers of biological material that are critical to making scientific

[45] *Moore* SC (n 11) [498] (Arabian J).
[46] LI Palmer, 'Should Liability Play a Role in Social Control of Bio banks? (2005) 33 JL Med Ethics 70, cited in RN Nwabueze, 'Donated Organs, Property Rights and the Remedial Quagmire' (2008) 16 Med L Rev 201.
[47] RN Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (2013) J Med Ethics 1, 1 [Published Online First: January 31 2013 doi: 10.1136/medethics-2012-100815]; DM Gitter, 'Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material' (2004) 61 Wash. & Lee L. Rev. 257; Wall (n 2) 802: "Nwabueze, Powloski and Mason and Laurie all provide arguments that suggest that the wide range of remedies that property rules are able to provide will be more effective at protecting ownership entitlements than the remedial consequences that follow from a breach of liability rules."

advancement possible should receive compensation' for their input[48] Also, on grounds of equality, the law should, arguably, recognize the source's right to do with his biological material what recipient researchers can lawfully do with the biological material: when researchers and companies are making profits from their contributions to research using the source's biological material, the contributor of biological material should not be left out.[49] Additionally, 'the issue [could] be seen 'as one of reciprocity [to the extent that] the person from whose body the [biological material] is taken should share in the rewards resulting from his or her contribution.'[50]

The apparently unjust current system is attributable to the refusal of the courts and legislators to enforce source income entitlement regarding excised biological material under a property rule or a liability construct. This is because of concerns that such recognition will threaten the survival of socially useful medical research and fears that such recognition might lead to a market in biological material, which, it is argued, would objectify and commodify human beings; and undermine the dignity and sanctity of the person.[51] While these may represent legitimate concerns, they are not insurmountable. They could be addressed with the appropriate policy framework (for example, liability models or hybrid liability/property models).

Also, sources are becoming aware of the commercial value of their biological material as issues relating to biological material are discussed in the public forum[52].

[48] R Steinbrook, 'Egg Donation and Human Embryonic Stem Cell Research' (2006) 354 N. ENG. J. Med. 324, 325 (citing an interview with B Steinbock); R Korobkin, *"No Compensation" or "Pro Compensation": Moore v. Regents and Default Rules for Human Tissue Donations* (2007) 40 (1) Journal of Health Law, 11.

[49] M Dodson and R Williamson, 'Indigenous Peoples and the Morality of the Human Genome Project' (1999) 25 Journal of Medical Ethics 204, 207-208.

[50] TH Murray 'Who Owns the Body? On the Ethics of Using Human Tissue for Commercial Purposes' (1986) 8 (1) IRB: Ethics and Human Research, 1, 1.

[51] RN Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (Ashgate Publishing, 2007) 91.

[52] See generally Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 3) J Boyle, 'To Pay or Not to Pay, That is the Question: Finding an intermediary solution along the Moore

Therefore, in order to help to preserve the survival of biotechnological research, it is important that sources are compensated for their contribution towards research enterprise; if not, sources might consider they are being exploited because everyone except the source is compensated, and they could potentially be discouraged from supplying biological material, which would ultimately hinder research that aids public health.

It is suggested that source income entitlement ought to be enforced under the law in order to help to promote justice for sources. It is submitted that a liability/property based compensation framework could be introduced for that purpose and the new compensation framework could be implemented as supplementary provisions to the HTA 2004. In order to invoke the property protection advanced in this discussion and for a source to be able to claim property-based remedies where there has been interference with the source's management entitlement and/or income entitlement, it would be necessary to recognise both source management and source income entitlements as legally protectable property interests.

It should be noted that a definitive position is not taken in this discussion regarding compensation in the context of the supply of biological material for transplant purposes, neither is an attempt made to engage in any significant manner with the issues raised in that context. A distinction, however, is made between the research and transplant context in order to illustrate that the offer of compensation in the research context does not raise the same ethical and policy concerns potentially raised in the transplant context. Firstly, supply of biological material for research does not present the degree of 'removal risks' that is inherent in the transplant context because the type of biological material used for research is usually regenerative, not necessary for human health or in the case of diseased tissue, already removed from the individual source for diagnostic and therapeutic

Spectrum' (2002) 7 Journal of Medicine & Law 55, 64; D Dickenson, *Body Shopping: Converting Body Parts to Profit* (Oneworld, 2008) 35; Gitter (n 47) 341.

purposes.[53] Thus, the individual source does not need to undergo further surgery to make the biological material available for research. Secondly, the requirement for compensation in the research context will not give rise to the type of unethical bargaining that could potentially result if such a provision was introduced in the transplant context.[54] The recipient patient of an organ in the transplant context will usually face imminent death and though a patient in need of a tissue transplant may not face imminent death, he or she will likely face some health difficulties.[55] There are evidently important ethical and policy reasons for prohibiting compensation in view of the foregoing conditions. These include 'the possibility that high-income patients will bid up the prices of human [biological material] beyond the reach of middle- or low-income people,'[56] such potential inequality in access to health services is morally objectionable and might ultimately lead to social unrest and disorder. However, 'the law does not have the same interest in procuring for researchers human tissue samples free of charge… certainly, society benefits to the extent that [researchers] can obtain access to human tissue at low cost, but the relationship between such research and the preservation of life is more attenuated.'[57]

Also, the motivational factors that influence the decision to donate are arguably different in both transplant and research contexts. The continued role of altruism in donation for transplant purposes is encouraged 'as underpinning important communal values that express something very significant about the kind of society in which we wish to live.'[58] In this connection, 'an altruistic basis for donation helps underpin a communal, and collective, approach to the provision of bodily material needed by others for the preservation or improvement of their health.'[59] Such an approach is arguably in the public interest in the transplant scenario than a pure

[53] Gitter (ibid) 313; 299 n 164.
[54] Ibid.
[55] Ibid.
[56] Ibid.
[57] Ibid.
[58] Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 3) viii, 132 and para 6.75.
[59] Ibid.

payment model because it will generally help to ensure that the value placed on the health of all members of society is not dependent upon their economic status, and 'the poor' in society will not be denied access to health services because they cannot afford it.

However, where altruism is recognised as a central motivational factor in the transplant context[60] and the introduction of a non-altruistic system where compensation is offered, might therefore present a risk of undermining altruism and negatively impact upon altruistic donations, this is not so in the research scenario. If the accepted definition for an altruistic action is 'one that is motivated by concern for the welfare of the recipient of some beneficent behaviour,' then it is arguable that altruism, on a strict application of the foregoing definition, is not a factor that significantly influences a source's decision to contribute biological material in the research context. This is because at the time when biological material is transferred from the source to the recipient researcher, the welfare or 'well-being of immediate others is absent because it is unknown or too far into the future'[61] and 'while material donated for research will be used with the aim of improving health in the long term, the connection between the donation and that outcome is both extended and uncertain.'[62] Furthermore, 'while research results may benefit many in the long term, the very uncertain nature of such research means that such beneficiaries seem very remote.'[63]In this connection, the source's contribution of biological material for research uses cannot really be motivated out of concern for the welfare of the recipient of the biological material. 'Participants may certainly feel a sense of contributing to society for the common good but are less likely to envisage their actions as an act of altruism towards specific (if unknown) others.'[64] Interestingly, the immediate recipient of biological material in the commercial research context seeks to profit from it and it is probably safe to assume that sources do not donate

[60] Ibid, 132.
[61] Ibid, 142.
[62] Ibid, 145.
[63] Ibid.
[64] Ibid.

out of concern for commercial users of biological material or because they wish to assist such users in their profit endeavours. In view of the above-mentioned distinctions between donation for transplant and research purposes, a case for source compensation in the research context is therefore not intolerable or far-fetched, and arguably justified.

Novelty

The debate relating to the recognition of ownership entitlements has predominantly focused on the undesirable state of affairs that could potentially result from a property framework.[65] Supporters of a property based framework have generally proposed property rules as the underlying legal principle upon which a framework should be formulated but have not generally considered how a framework incorporating property rules should be implemented in practice, particularly in the context of the United Kingdom (UK).

The few commentators who have considered the workability of a property framework in practice and have suggested alternative frameworks to address its shortcomings, such as Gitter,[66] Harrison[67] and Boyle,[68] have only considered their proposals in the context of the United States (US). They have incorporated mechanisms specific to the US jurisdiction, albeit that some general ideas and principles are applicable to the UK context. Both liability and property rules are identified here as the appropriate legal principles upon which to base a framework for protecting source management and income entitlements and unlike previous commentary, a UK-specific framework that incorporates the chosen legal principles is proposed in this discourse.

Proposed hybrid models which purport to borrow from both liability and property rules such as that of Gitter[69] are quintessentially property models and suffer many of the difficulties associated with the property model. For instance, Gitter's proposed framework is plagued with the bargaining problems associated with a property

[65] C Harrison, 'Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue' (2002) 28 Am. J.L. & Med. 77, 78.
[66] Gitter (n 47) 338-341.
[67] Harrison (n 65) 93-100.
[68] Boyle (n 52) 74-77.
[69] Gitter (n 47) 338-341.

framework to the extent that it gives all sources a bargaining entitlement and so researchers will be required to bargain with each individual source for use of excised biological material. This will potentially increase transaction costs incurred by researchers and compound the difficulties already inherent in the biotechnology enterprise.[70] The framework proposed in this discussion is considered to better incorporate property and liability rules in protecting the chosen ownership entitlements and it also addresses many of the drawbacks of the current donative model, the pure property approach and the shortcomings of some suggested alternatives to the property approach.

Few advocates for source income entitlement have distinguished between different classes of sources, in terms of their relative contributions to the research enterprise and the value of their contributions to the research enterprise. Permitting all sources of biological material to exercise their income entitlement by bargaining with researchers, or claim the content of their income entitlement by obtaining compensation for use of their biological material may prove quite problematic for researchers for the reasons outlined above in respect of Gitter's model. This might prove unsustainable for research in the long run. Furthermore, although a marketable research product can sometimes be developed from an individual specimen, this does not represent the norm. Rather, research enterprises usually involve collections of biological material supplied by several sources and while the collections may have considerable value, each individual biological specimen may be worth very little of itself. [71] Thus if researchers have to pay all sources, they may end up paying out and not receiving anything in return. Researchers would need to recoup the increased transaction costs so they can stay in business -the likelihood is that the costs will be recouped by making the price of the research product high.[72] This could ultimately increase treatment and diagnostics costs and potentially

[70] TP Dillon, 'Source Compensation for Tissue and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits' (1989) 64 Notre Dame L. Rev. 628, 635; Gitter (n 47) 281.
[71] Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 3) 194, para 7.18; U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology: Ownership of Human Tissues and Cells – Special Report (OTA-BA-337, 1987) 8.
[72] Dillon (n 70) 639-640.

undermine public health. Where the ultimate product is something other than a 'treatment or diagnostics', for instance, a cell line, which could be used in furthering medical knowledge or developing a product for diagnosis, such transaction costs might hamper scientific advancement and development of future diagnostic and therapeutic products because researchers could recoup their increased transaction costs by making the price of the cell line high. The price in such cases might potentially be beyond the reach of some non-commercial researchers who may seek to use the cell line in further research but might not have the comparatively generous budget that commercial researchers have at their disposal.

The debate is underpinned by a substantial body of theoretical expositions regarding the future state of affairs that could result from the legal recognition of source ownership entitlements. However, the literature is generally grounded in assumptions and speculations; there is little or no empirical study of many potential outcomes that have been discussed. These include: the impact of offering financial incentives to sources of biological material on their decision to contribute biological material towards research enterprise, on altruistic donations, on the potential exploitation of sources by researchers, on the value placed by individuals on their health (in other words, would prospective sources of biological material elevate financial concerns over health because of the offer or promise of financial gain?); the impact of the current system of 'no financial gain for sources but financial gain for other contributors involved in biotechnology research enterprise' on the public's perception of justice in biotechnological research enterprise, and on their willingness to participate in such enterprise; the potential impact of different 'pro-source compensation' policy frameworks on the economic incentive to invest in, or to conduct biotechnological research. These issues need to be explored in order to assist policy makers in devising an informed and robust legislative and regulatory framework that meet the needs of all stakeholders involved in biotechnological research and to promote the wider public interest for society in such research, namely, its therapeutic potential in aiding public health and its contribution to economic growth. While the present discussion seeks to examine the result from

empirical studies of other contexts beyond the biotechnological research framework in order to offer an instructive empirical perspective to the debate regarding the legal recognition of source ownership entitlements, it remains necessary to explore the above-mentioned lines of enquiry in the specific context of biotechnological research enterprise.

CHAPTER 2 THEORETICAL CHARACTERISATION: DO SOURCE OWNERSHIP ENTITLEMENTS QUALIFY AS PROPERTY INTERESTS UNDER A NORMATIVE UNDERSTANDING OF PROPERTY?

Introduction

To provide an indication of the range of ownership entitlements that a person might have in a resource, it is useful to consider Honoré's exposition regarding the concept of 'ownership'. In his important paper, interestingly titled *Ownership*,[1] Honoré identifies eleven incidents of a full liberal concept of ownership and provides an in-depth account of each incident. Honoré was of the view that a person must hold most (but not necessarily all) of these incidents in respect of an object in order to establish a full liberal concept of ownership in that object[2]. These incidents include the right to possess (to have exclusive control over the object; the right to use (to exercise personal use of the object); the right to manage (to determine how and by whom the object is used); the right to income (to derive a benefit from foregoing personal use of the object); the right to security (assurance that the person will remain owner of the object); the right to capital (the power to alienate and liberty to consume the object), the right of transmissibility (the ability to transfer ownership interests to another); the right to absence of term (presumption of indeterminate length of ownership); the duty to prevent harm (inability to use the object in harmful ways); the liability to execution (liable to have the object seized in payment of debt) and the incident of residuary (rights may expire or be abandoned so as to vest in someone else).[3]

Honoré's incidents of ownership are adopted as indicative but not exhaustive of the range of entitlements that a person may have with regard to his or her biological

[1] AM Honoré, 'Ownership' in AG Guest (ed), Oxford Essays in Jurisprudence (1st Series, OUP, 1961) 107, 112-24.
[2] M Quigley. 'Property and the body: Applying Honoré' (2007) 33 Journal of Medical Ethics 631, 631-634.
[3] Ibid. Also, see J Wall, 'The Legal Status of Body Parts: A Framework' (2011) 31 OJLS 783, 785.

material. These entitlements are called ownership entitlements in this discussion simply for descriptive purposes and should not be confused with 'ownership' or an 'ownership' interest (defined below). The law does not currently recognise and enforce many of these entitlements in favour of individuals in respect of biological material removed from the body. The only entitlement really recognised by the law in respect of biological material is source management entitlement, which is protected under the *Human Tissue Act* 2004[4] and to a limited degree under the common law principle of bodily integrity[5]. As mentioned in the previous chapter, the primary issue raised in this discussion comprise the legal protection of source income entitlement and increased protection for source management entitlement. Since the normative characterisation of both income and management entitlements as property interests is a necessary component of the proposed policy framework for protecting both entitlements, it is prudent to consider whether such entitlements, (that is, entitlements relating to biological material) qualify as property interests from a theoretical standpoint. A useful starting point is the line of enquiry that explores the debate surrounding what constitutes property and whether entitlements relating to biological material fit into that classification.

What is Property?

There appears to be a difference between the popular conception of property and the legal conception of property. In illustrating this difference, Ackerman wrote:

> If there is anything that a lawyer remembers from his legal education, it is that laymen are deeply confused in their property talk; that the law of property

[4] *Human Tissue Act* 2004, 2004 Chapter 30.
[5] *Collins v Wilcock* (1984) 1 WLR 1172 [1177].

> concerns itself with bundles of user-rights, not with the awkward idea that things belong to particular people.[6]

In essence, the popular conception of property which is sometimes referred as the 'layperson's understanding of property' is that that the term 'property' relates to things. This view perceives property as predominantly including tangible things such as land, furniture and vehicles but also intangible things such as copyrights, patents and trademarks.[7] However, the commonly espoused conception of property among lawyers would appear to be an antithesis of the popular conception because lawyers prefer to understand property as consisting of a set of legal relations or a bundle of rights rather than as 'things'. These relations could exist between persons and things, or among persons with or without reference to things. In other words, property refers more to rights, which could be exercised with or without reference to things as opposed to the things themselves.[8] The advantage of a perception of property as rights rather than things is that it provides the framework with some flexibility. Such a flexible framework is suitable for analysing legal issues relating to non-traditional forms of property such as biological material, one's person[9] one's race[10] and traditional knowledge[11]. In addition to the above conceptions of property, there is also a school of thought that views property as a basis of expectations that a person can reasonably hold in his dealings with others.[12]

[6] B Ackerman, *Private Property and the Constitution* (New Haven: Yale University Press, 1977) 115.
[7] SR Munzer, *A Theory of Property* (New York: Cambridge University Press, 1990) 16; CB Macpherson, *Property: Mainstream and Critical Positions* (Toronto: University of Toronto Press, 1978) 2. Also see Ackerman (ibid) 11; RN Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (Ashgate Publishing, 2007) 7.
[8] Nwabueze (ibid) 12.
[9] MJ Radin, *Reinterpreting Property* (Chicago: The University of Chicago Press, 1993) 1-71.
[10] J Chen, 'Embryonic Thoughts on Racial Identity as New Property' (1997) 68 *U. Colo. L. Rev*. 1123
[11] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 3-4.
[12] J Bentham, 'Security and Equality of Property' in Macpherson ed (n 7) 51. Also see H Demetz, 'Toward A Theory of Property Rights' (1967) 57 Am. EC. Rev. 347, 347

Devising a precise definition for property has proved problematic for academics because the meaning of property often changes in response to developments in the socio-economic circumstances of a particular society[13] and consequently, there is no single precise universal definition for the concept of property[14]. Macpherson observed for instance that property was generally understood to constitute rights over things up to the late part of the seventeenth century when the popular conception of property as material objects emerged. The change in the meaning of property, according to Macpherson, emerged with the spread of the full capitalist market economy from the seventeenth century onwards, where the old limited rights in land and other valuable things were replaced by virtually unlimited rights[15].

In this regard, he observes:

> As rights in land became more absolute, and parcels of land became more freely marketable commodities, it became natural to think of the land itself as the property. And as aggregation of commercial and industrial capital, operating in increasingly free markets and themselves freely marketable overtook in bulk the older kinds of moveable wealth based on charters and monopolies, the capital itself, whether in money or in the form of actual plant, could easily be thought of as the property. The more freely and pervasively the market operated, the more this was so. It appeared to be the things themselves, not just rights in them that were exchanged in the market.[16]

A particular society could be deemed to consider property as rights rather than things when that society recognises that a person may have the physical possession

[13] See JR Singer and J Beermann, 'The Social Origins of Property' (1993) 6 Can. J.L. & Juris 217.
[14] See LC Becker, *Property Rights: Philosophical Foundations* (London: Routledge, 1977) 2-4; J Waldron, *The Right to Private Property* (Oxford: Clarendon Press, 1988) 28-30; JW Harris, *Property and Justice* (Oxford: Clarendon Press, 1996) 6-8; RA Posner, *Economic Analysis of Law* (5 edn New York: Aspen, 1998).
[15] Macpherson (n 7) 7.
[16] Ibid.

of a thing without being the property owner.[17] This is exemplified in the context of rented accommodation where a tenant by virtue of his tenancy agreement is entitled to occupy a house, although he is not the owner of the house.

There are two dominant paradigms in which the concept of property is understood in academic literature. They include the reified perspective and the bundle of rights theory.

Reified theory of Property

The Reified perspective focuses on the exercise of control and dominion over tangible objects[18] or the alteration of a thing from its naturally occurring state by the expenditure of labour[19]. In other words, being in physical possession of an object indicates the existence of property interests in the object, so an individual is said to have property in a thing that belongs to that individual, such as a car or a book. Additionally, once a person exercises control or dominion over an object or changes a thing from its naturally occurring state then it is that person's property. Therefore, where no one takes physical possession of a particular object then the object is the property of no one *(res nullius)*.[20] An application of this view is illustrated in everyday normality where for instance, wild birds, wild beasts, fish in the river or in the sea; do not belong to anyone until they are captured.[21] Once they are captured then they become, as a rule, the property of the captor and for as long as the captor keeps possession of his captives, he is regarded as having property in them but if

[17] Ibid.
[18] D Litowitz,'Reification in Law and Legal Theory' (2000) 9 *S. Ca. Interdis. LJ.* 401.
[19] J Locke, 'The Second Treatise on Civil Government' (1689), cited in GA Cohen, *Self-Ownership, Freedom and Equality* (Cambridge: Cambridge University Press, 1997) 209. Also, see RN Nwabueze, 'Biotechnology and the New Property Regime in Human Bodies and Body Parts' (2002) 24 Loy. L.A. Int'l & Comp. L. Rev. 19, 40.
[20] JA Strahan, *Law of Property* (3rd edn London: Stevens & Sons Ltd, 1901) 3.
[21] Ibid.

they escape completely out of his possession then they become no one's property and will become the property of the first person that recaptures them.[22]

By reason of its restriction to physical objects, the reified perspective may not represent a suitable framework for analysing legal issues relating to 'creations of the mind' such as intellectual property.[23] Nevertheless, in comparison to the 'bundle of rights' theory, which is discussed below, the reified perspective has the advantage of certainty and simplicity in clearly distinguishing between a thing and rights exercised with respect to a thing that qualify as property and property rights respectively.[24] Many writers in the nineteenth century such as Blackstone, Strahan and Austin[25] invoked the reified perspective to explain the nature of property rights. For example, Blackstone in his *Commentaries on the Law of England* provided a definition of property that has been applied by many property scholars[26]. Blackstone states:

> There is nothing, which so generally strikes in the imagination and engages the affections of mankind, as the right of property; or that 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.[27]

[22] Ibid.
[23] Nwabueze, 'Biotechnology and the New Property Regime in Human Bodies and Body Parts' (n 19) 39- 41. Also, see Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 68; L Thurow 'Globalization: The Product of a Knowledge-Based Economy' (2000) 570 The Annals 19; MA Holman and SR Munzer, 'Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags' (2000) 85 Iowa L. Rev. 735; RH Stern, 'The Bundle of Rights Suited to New Technology' (1986) 47 U. Pitt. L. Rev. 1229.
[24] RN Nwabueze, 'Legal Paradigms of human tissues' in C Lenk, N Hoppe, K Beier and C Wiesemann, *Human Tissue Research: A European Perspective on the Ethical and Legal Challenges* (Oxford: Oxford University Press, 2011) 90; Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7), 28-29.
[25] J Austin, *The Province of Jurisprudence* Determined (London: John Murray, Albermarle Street, 1863), Lecture xlvii.
[26] D Kennedy, 'The Structure of Blackstone's Commentaries' (1979) 28 Buffalo L. Rev. 209; K J Vandevelde, 'The New Property of the Nineteenth Century: The Development of the Modern Concept of Property' (1980) 29 Buffalo L.R. 325-367.
[27] W Blackstone, *Commentaries on the Laws of England*: volume 2 (London: A. Strahan, 1809) 2.

Before proceeding further, it is crucial to note that although Blackstone refers to a 'sole and despotic dominion,' this should not be taken to mean that property rights are absolute because they are not.[28] Depending on the policy objectives of the legal system, the law through legislation and regulation usually places limitations on the exercise of property owners' rights of property.[29] For instance, a landowner may be unable to use his land as he sees fit because the land is subject to an easement or a restrictive covenant. Blackstone's reference to a 'sole and despotic dominion' should instead be understood as referring to an owner's right to exclude others from using his property without the need to perform any social function.[30] Although not directly concerned with Blackstone's definition, Macpherson indicated a similar interpretation when he writes:

> Modern Private Property is indeed subject to certain limits on the uses to which one can put it: the law commonly forbids using one's land or buildings to create a nuisance, using any of one's goods to endanger lives, and so on. But the modern right, in comparison with the feudal right which preceded it, may be called an absolute in two senses: it is a right to dispose of, or alienate, as well as to use; and it is a right which is not conditional on the owner's performance of any social function.[31]

Like Blackstone, Strahan's commentary on the nature of property rights was also thing-focused. In his commentary, Strahan observes:

> The next point to be noted in this description of the right of ownership is that it must subsist over a thing; and the thing it subsists over must be a determinate thing, that is, an actually existing physical object…We cannot in this sense own a debt, or a patent, or a copyright, all of which are mere creations of the law,

[28] CM Rose, 'Canons of Property Talk, or, Blackstone's Anxiety' (1998) 108 *Yale L.J*. 601. Ackerman (n 6) 97-103.
[29] JW Ely, The Guardian of Every Other Right (Oxford: Oxford University Press, 1992) 17-25.
[30] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 29.
[31] Macpherson (n 7) 10.

> without any physical embodiments over which physical power can be exercised. Accordingly, strictly speaking, such rights are not property…[32]

A common starting point when analysing the reified perspective's treatment of entitlements relating to biological material is to consider Locke's labour added theory of property. Locke states:

> Though the earth and all inferior creatures, be common to all men, yet every man has a *property in his person*: this nobody has any right to but himself. The labour of his body, and the *work* of his hands, we may say, are properly his. Whatsoever then he removes out of the state that nature hath provided, left it in, he hath mixed his *labour* with and joined to it something that is his own, and thereby makes it his property. It being by him removed from the common state nature hath placed it in, it hath by this labour something annexed to it, that excludes the common right of other men: for this labour being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to…[33] (Italics in the original)

Two interpretations of Locke's statement could potentially be distinguished. Locke's theory could arguably provide a foundation for the belief that an individual has a property right in his body and in this regard, he also has a property right in the products derived from its labour, products which include excised biological material.[34] On the other hand, it is also possible that Locke was not actually saying that we have a property right in our bodies but rather, that an individual has a property right in his actions, as a moral agent, but not necessarily in his physical

[32] Strahan (n 20) 13.
[33] J Locke, *Second Treatise of Government,* (CB Macpherson ed, first published 1690, Indianapolis: Hackett Publishing Co. 1980) 19.
[34] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 67-68.

body.[35] On this view, it is because an individual has a property right in his actions that he also has a property right to the products or wealth derived from his actions.[36] What belongs to the individual is the labour but not the body, the work but not the hands that he used to carry out the work.[37] A person has title to the fruits of the labour of his body because his labour is an expression of his agency and status as a person.[38] He only has title to what he has laboured to create. He does not have property in his body merely because he inhabits his body. Only God has title in a person's body because God alone created the person's body.[39] The more plausible interpretation of Locke's theory is the latter because Locke clearly distinguished between a person and his body and between the labour of a person's body and the body itself. [40] This is reflected where he states: 'every man has property in his own person; this nobody has any right to but himself… The labour of his body and the work of his hands we may say are properly his.'[41]

Applying the latter interpretation of Locke's theory to the context of excised biological material, it could be suggested that an individual does not have a property right in his excised biological material because he did not work to create it and so he cannot be said to have acquired a property right, for instance, in the specialised cell lines or therapeutic products derived from research using the excised biological material.[42] The researchers on the other hand could be said to have acquired a property right in the excised biological material and the products subsequently derived from using the specimen because they worked to extract the specimen from the source and they worked to create the products using their skills, expertise, time and resources.[43] Such a supposition seems to have been embraced by Justice George in the Californian Court of Appeal decision in *Moore v Regents of the University of*

[35] See D Dickenson, *Body Shopping: Converting Body Parts to Profit* (Oxford: Oneworld, 2008) 30.
[36] Ibid
[37] Ibid
[38] Ibid
[39] Ibid.
[40] Ibid.
[41] Locke (n 19) 209. Also, see D Dickenson, *Property, Women and Politics* (Cambridge: Polity, 1997) 78.
[42] Dickenson (n 35) 30.
[43] Ibid, 31.

California.[44] In dissenting from the Court of Appeal's decision that had found in Moore's favour for the conversion claim, Justice George opined that Moore's spleen was like mere raw material and it had evolved into something of value only through the unusual scientific expertise of the defendants, 'like unformed clay or stone transformed by the hands of a master sculptor into a valuable work of art'.[45] However, while a property based argument in respect of biological material may at first glance not be sustained upon a Lockean interpretation on the basis that the source had not done any work or labour, it is possible to suggest on closer analysis that doctors, surgeons and other medical personnel who extract non-reproductive biological from the source's body are acting as agents for the source when they extract biological material from the source's body since they can generally only extract such material from the source's body upon receiving consent/authorisation from the source of biological material. Consequently, whatever work that they undertake during the extraction process is done on behalf of the source or expressed differently, as a representative for the source and therefore, property interest actually vests in the source. The foregoing view seems to find support in the judgement in the Australian case of *Jocelyn Edwards; Re the estate of the late Mark Edwards.*[46] Although dealing with matters relating specifically to the question of property interest in sperm and espousing a slightly different reasoning to the foregoing view, Justice Hulme's reasoning is persuasive of the proposition that doctors and technicians act as agents of sources of biological material where he states:

> A second theoretical possibility was suggested by Mr Kirk and that was that the property lay in the doctors and technicians who lawfully exercised the "work or skill", such as was the case with Dr Donahoe in *Doodeward v Spence*. However, the better view is that the doctors who removed the sperm and the doctor and technicians who then preserved and stored it did not do so for their own purposes but performed these functions on behalf of Ms Edwards. In effect,

[44] *Moore v Regents of the University of California* [1988] 202 Cal. Rptr. 494.
[45] Ibid [505].
[46] *Jocelyn Edwards; Re the estate of the late Mark Edwards* [2011] NSWSC 478.

they were acting as her agents and so did not acquire any proprietary rights for their own sake.[47]

While there is no consensus among advocates for the reified perspective that the theory is applicable to the human body,[48] it is nevertheless arguable that biological material in the sense being discussed here (in other words, biological material that take physical form such as excised tissue and solid organs) could be considered as property under the reified view because they have a physical presence that qualifies them as 'things' under the reified perspective.[49] Support for this view is provided in the application of the reified perspective in several judicial decisions dealing with human biological material from dead and living persons.[50] For example, in the Australian case of *Roche v Douglas*[51], the plaintiff applied for a DNA analysis of a diseased tissue sample.[52] For the plaintiff's application to succeed, it had to be established that the diseased body tissue qualified as property.[53] The court, per Master Sanderson, noted that most British and Australian decisions concerning dead bodies were inapplicable because they did not take account of recent biomedical technology, such as DNA techniques.[54] The court found that in addition to the procedural benefits of identifying a property right in the deceased's tissue (that is, saving in time, cost and quantum evidence), 'it defies reason to not regard tissue samples as property. Such samples have a real physical presence. They exist and will

[47] Ibid [88] (Hulme J).
[48] For example, some advocates for the reified theory in the eighteenth, nineteenth and twentieth century did not think that the theory was applicable to the human body. Such writers include Strahan who stated:
"Physical objects alone are, then are subjects of ownership. But all physical objects cannot be owned. For example, there cannot by English Law be any property in a human body, living or dead, though the executors of a dead testator are entitled to possession of his body for the purpose of burial…" Strahan (n 20) 4. Also, see Austin (n 25) 7.
[49] Nwabueze 'Legal Paradigms of human tissues' (n 24).
[50] Although outside the remit of the present discussion, the courts have also resorted to the reified theory of property in disputes regarding reproductive samples, specifically, sperm. The cases of *Yearworth v. North Bristol NHS Trust* [2009] EWCA Civ 37 and *Hecht v. Superior Court* [1993] 20 Cal.Rptr. 2d .275 (Ct. App) illustrates such application of the reified theory.
[51] *Roche v Douglas* (2000) WASC 146.
[52] Ibid.
[53] Ibid.
[54] Ibid.

continue to exist until some step is taken to effect destruction. There is no purpose served in ignoring physical reality.'[55]

The Californian Court of Appeal also found the reified perspective to be of some practical utility in its decision in *Moore v Regents of the University of California*, where the court upheld Moore's conversion claim. The Court of Appeal applying the reified perspective, held:

> Plaintiff's spleen, which contained certain cells, was something over which the plaintiff enjoyed the unrestricted right to use, control and disposition. The rights of dominion over one's own body, and the interests one has therein, are recognised in many cases. These rights are so akin to property interests that it would be a subterfuge to call them something else.[56]

The Californian Supreme Court later held for policy reasons that Moore did not establish his claim for conversion. The reasoning of the Californian Supreme Court is outlined in detail in chapter 3.

A key challenge of applying the reified perspective to the human body or excised biological material is the theory's characterisation of property interests based on the exercise of unrestricted use, control, and disposition.[57] If the recognition of property in a person's biological material is dependent on the exercise of control and dominion, society could slip back to early civilization where a person could acquire

[55] Ibid.
[56] *Moore v Regents of the University of California* (n 44) [505].
[57] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 72; Also , see PA Martin and ML Lagod, 'Biotechnology and the Commercial Use of Human Cells: Toward An Organic View of Life and Technology' (1989) *5 Santa* Clara Computer & High Tech. L. J. 211, 238-41.

human property by sheer force, control, dominion or subjugation.[58] The Court of Appeal in the case of *Moore* seemed to be mindful of this potential risk by restricting property right in the body to one in which every person has a property interest in only his body and where no one could have property in the body of another person.[59] However, this apparent limitation placed by the court could lead to a suggestion that the reified concept of property is contradictory[60] because if exercising control and dominion over a thing is a sufficient basis for acquiring property, the fact that parents who have control over their children are not considered to own such children and the fact that a person under the control and dominion of another person (for instance, an incompetent adult under the control and dominion of his minder or guardian) is not considered to be the property of that person, seem to undermine the merits of the theory.[61] However, this need not be an inherent limitation of this particular theory; rather, it is a general feature of any theory to the extent that they only apply in so far as the public interest allows.

None of this is to suggest that a person should have property in his entire living body. Rather it is suggested that the fact that a person is deemed not to have property in his living body does not automatically prevent him from acquiring a property right in his excised biological material. Grubb seemed to support this contention when he states:

> Not only does no one else own my body, neither do I. Legal conceptions of "property" do not extend to ownership of another or self-ownership. This is

[58] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 72.
[59] Ibid. Also, see Court of Appeal's reasoning in *Moore v Regents of the University of California* (n 44) [494]: 'We have approached this issue with caution. The evolution of civilization from slavery to freedom, from regarding people as chattels to recognition of the individual dignity of each person, necessitates prudence in attributing the qualities of property to human tissue. There is, however, a dramatic difference between having property rights in one's body and being the property of another. To our knowledge, no public policy has ever been articulated, nor is there any statutory authority, against a property interest in one's own body.'
[60] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 72. Also, see J Nedelsky, 'Property in Potential Life? A Relational Approach to Choosing Legal Categories' (1993) 6 Can. J. L. & Juris 343, 362.
[61] Ibid.

> not to say a person cannot assert property interests in parts or tissue that were part of his body or that property interests cannot be claimed over a dead body or its parts.[62]

It might be better, for instance, to consider a person as having an inchoate right of property in material issuing from his body.[63] Alternatively, property rights could be considered as being only contingently connected to persons but not intrinsic aspects of them.[64] Thus, a human subject must be separate from an object in order for that object to be capable of qualifying as property. Applying this construct to excised biological material, it could be argued that excised biological material (excised tissue and body parts) can qualify as things because once they are removed from the body, they can be considered to constitute contingent possessions.[65]

Bundle of Rights theory of Property

Lawyers in Anglo-American Jurisdictions have generally preferred to understand property as consisting of certain relations, usually legal relations, among persons or other entities with respect to things.[66] A metaphorical way of stating this understanding is that property is a 'bundle of rights'.[67] Therefore, having property in one's car is not so much the car as a physical thing but the various rights that the proprietor is able to exercise in respect of the car without interference from others, which includes the rights to exclusively use, sell, and dispose of the car by way of a gift or sale.[68] The greatest accumulation of these rights 'which are common to, and

[62] A Grubb, 'I, Me, Mine': Bodies, Parts and Property' (1998) 2 Med L. Intl 299.
[63] B Dickens, 'The Control of Living Body Material' [1977] Uni. Of Tor. L. Jour. 142, 183.
[64] JE Penner, *The Idea of Property in Law* (Oxford: Clarendon Press, 2nd ed, 1997) 111.
[65] Ibid, 122.
[66] JE Penner, 'The "Bundle of Rights" Picture of Property' (1996) 43 UCLA L. Rev. 711, 712. For a useful criticism of the bundle of rights theory, see 711-820. Also see TW Merrill and HE Smith, What Happened to Property in law and Economics?' [2001] 111 Yale L.J. 357.
[67] See DC Jackson, *Principles of Property Law* (Sydney: The Law Book Co Ltd., 1967) 10.
[68] Nwabueze 'Legal Paradigms of human tissues' (n 24).

recognised by most mature systems of law' is described as ownership.[69] These rights are legal interests insofar as the legal system provides rules and procedures to safeguard the holder's interests against interference by others.[70] Each individual right in the bundle of rights is capable of qualifying as property. So a person does not need to be able to exercise all the possible rights in respect of a particular object in order to be potentially recognised as having property in the object. For example, if the proprietor of a motorcycle is prohibited from destroying his vehicle although he could dispose of it by way of a gift to a friend, he may still be considered to have property in his motorcycle.[71] Justice Mosk, dissenting in *Moore* seems to suggest a similar view when he states:

> Although the statute may limit so many of the incidents normally attached to the concept of property, with regard to body tissue…at the time of the excision, he [Moore] at least had the right to do with his own tissue whatever the defendant did with it…The majority cite no case holding that an individual's right to develop and exploit the commercial potential of his own tissue is not a right of sufficient worth or dignity to be deemed a protectable property interest. In the absence of such authority – or of legislation to the same effect – the right falls within the traditionally broad concept of property law.[72]

While some of the criticisms of the bundle of rights perspective of property (discussed below) may be somewhat overblown, a normative understanding of property as simply a bundle of rights is not considered in this discussion to represent fully the normative characterisation of property because it does not provide a clear

[69] RN Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (2013) J Med Ethics 1, 3 [Published Online First: January 31 2013 doi: 10.1136/medethics-2012-100815]; SNC Obi, *The Ibo Law of Property* (London: Butterworths, 1963) 43.
[70] Wall (n 3) 785.
[71] Nwabueze 'Legal Paradigms of human tissues' (n 24).
[72] *Moore v Regents of the University of California* [1990] (Moore SC) 793 P 2d 479 (Cal SC) [509-510] (Mosk J dissenting).

distinction between property and non-property rights.[73] In other words, defining property as a 'bundle of rights' is only a partial response to the question: 'what is property?' Such a normative understanding of property could be considered as the first strand of the enquiry but it is necessary to engage with a second strand of enquiry which revolves around the specific nature and character of each stick within the bundle of rights that distinguishes property rights from non-property rights. Such consideration, together with the bundle of rights perspective is accepted in this discourse as representative of the characterisation of property.[74] Expressed differently, a 'bundle of rights-plus' perspective is favoured here over the traditional 'bundle of rights' view. In line with the language of 'entitlements' that is invoked here, the discussion proceeds on the basis that 'property' or a 'property right' is first and foremost a 'collection of ownership entitlements'[75] and that collection of entitlements together with the line of reasoning that examines the nature of property rights is adopted as the accepted characterisation of property.

With regard to the specific nature of property rights, it has been suggested that for a right to be accorded the legal protection of property, it must be identifiable, transferable, devisable and valuable. The source of this principle is usually identified as Lord Wilberforce's dictum in *National Provincial Bank Ltd. v Ainsworth*[76]. This principle seems to suggest that not every stick in the bundle of rights would necessarily qualify as property. It is not necessary at this point to explore Lord Wilberforce's dictum in detail. His dictum will be discussed in the latter section of this chapter. However, at this juncture, an outline of the application of the bundle of rights theory will be provided in order to illustrate its utility. The controversies

[73] Wall (n 3) 801-802. See also, Penner, 'The "Bundle of Rights" Picture of Property' (n 66) 711-820. Also see CA Arnold, 'The Reconstitution of Property: Property as a Web of Interests' (2002) 26 Harv. Envi. L. Rev. 281, 331.
[74] Ibid.
[75] Ibid, 784; Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 77.
[76] *National Provincial Bank Ltd v Ainsworth* [1965] AC 1175 [1175]; Lord Wilberforce declared [1247-8]: that before a right could be admitted into the category of property, 'it must be definable, identifiable by third parties, capable in its nature of assumption by third parties, and have some degree of permanence or stability.

surrounding the bundle of rights perspective will also be examined in order to highlight the difficulties associated with the theory.

The prevalence of the bundle of rights understanding of property[77] is illustrated in its application as the standard starting point for an inquiry into the nature of property in several judicial decisions and academic commentary.[78] For instance, in the US Supreme Court case of *Scranton v Wheeler*,[79] Justice Shiras observed: 'The term "property" standing alone is a *nomen generalissum* extending to every species of valuable right and interest including things real and personal, easements, franchises, and other incorporeal hereditaments.'[80]

The practical utility of a conception of property as rights is also evident in the Supreme Court of California case of *Moore*[81], where Justice Mosk stated:

> 'The concepts of property and ownership in our law are extremely broad. A leading decision of this court approved the following definition: 'The term "property" is sufficiently comprehensive to include every species of estate, real and personal, and everything which one person can own and transfer to another. It extends to every species of right and interest capable of being enjoyed as such upon which it is practicable to place a monetary value.' Being broad, the concept of property is also abstract: rather than directly referring to a material object such as a parcel of land or the tractor that cultivates it, the concept of property is often said to refer to a "bundle of rights" that may be

[77] See Becker (n 14) 11-21; J Christman, *The Myth of Property: Toward An Egalitarian Theory of Ownership* (OUP 1994) 3-20; Munzer (n 7) 22-36; Waldron (n 14) 47-53 and 59-60; RA Epstein, *Takings: Private Property and the Power of Eminent Domain* (Harvard University Press, 1985) 35-104; For a description of the prevalence of the bundle of rights understanding of property in American legal philosophy, see JL Schroeder, 'Chix Nix Bundle –O- Stix: A Feminist Critique of the Disaggregation of Property' (1994) 93 Mich. L. Rev. 239, 239-41.
[78] Penner, 'The "Bundle of Rights" Picture of Property' (n 66) 712.
[79] *Scranton v Wheeler* [1990] 179 U.S. 141 (Shiras J).
[80] Ibid, 170.
[81] *Moore* (n 72) (Mosk J dissenting).

> exercised with respect to that object – principally, the right to possess the property, to use the property, to exclude others from the property and to dispose of the property by sale or gift… But the same bundle of rights does not attach to all forms of property.[82]

Interesting variations of the bundle of rights metaphor include those suggested by Lawson & Rudden[83] and Bell[84]. Lawson and Rudden, postulate that the law of property provides an owner with 'a bag of tools,'[85] while Bell refer to property rights as 'legal building bricks which can be used and put together in different ways.'[86]

The traditional formulation of the bundle of rights hypothesis is based on Hohfeld's discussion of rights and Honore's outline of the incidents of ownership.[87] Hohfeld's analysis exemplifies the fragmentation of property as abstract rights. He asserts that any right in *rem* should be considered to be a myriad of personal rights between individuals.[88] Therefore, ownership of an object should not be perceived as a legal relation between the owner and the object, rather it should be regarded as a sequence of rights that the owner has against other persons, each of whom has a correlative duty not to interfere with the owner's enjoyment of the object, by causing damage, stealing or any other form of interference.[89] Under Hohfeld's formulation, any standard right in an object should be treated as a bundle of rights

[82] Ibid 509-510.
[83] FH Lawson and B Rudden, *The Law of Property* (2nd edn, OU, 1982).
[84] AP Bell, Modern Law of Personal Property in England and Ireland (Butterworths Ireland, 1989).
[85] Lawson and Rudden (n 83).
[86] Bell (n 84).
[87] Honoré (n 1).
[88] WN Hohfeld, 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning' (1911) 23 Yale L.J. 16; Hohfeld, WN Hohfeld, 'Fundamental Legal Conceptions as Applied in Judicial Reasoning' (1917) 26 Yale L.J. 710.
[89] Ibid.

that the owner holds against many others[90] and a property right consists of a bundle of various kinds of rights; liberties, claim-rights, powers and immunities.[91]

Honoré's outline of the incidents of ownership complements Hohfeld's framework. Honoré identifies eleven incidents of a full liberal concept of ownership and provides an in-depth account of each incident. The important point to note about Honoré's framework is that, as well as elaborating on the kind of rights we have when we own, his framework is also informative on further incidents, or features of ownership, including duties and liabilities, which together represents a complete picture of the sticks within the bundle of rights theory, albeit, that the theory itself is considered in this discussion to present only a partial account of the constitutive elements of property because it does not clearly distinguish between property rights and non-property rights.[92] Accordingly, the bundle of rights concept of property could be suggested to refer not only to rights but a legal fusion of various normative relations.[93]

While some scholars appear to treat ownership and property as synonymous, such an assumption is not made here. For instance, Goold[94] invokes Honoré's eleven incidents of ownership, identified them as 'The Eleven Incidents of Property' and subsequently concluded after demonstrating that excised biological material conforms with Honoré's incidents of ownership; that excised biological material can be accorded property status. Similarly, Bjorkman and Hansson state that ownership and property are synonymous concepts.[95] Honoré's standard incidents of ownership

[90] WN Hohfeld, Fundamental Legal Conceptions as Applied in Judicial Reasoning and Other Legal Essays 67 (WW Cook ed, New Haven, 1923) 96.
[91] Ibid.
[92] Penner, 'The "Bundle of Rights" Picture of Property' (n 66) 713.
[93] Ibid.
[94] I Goold, 'Sounds Suspiciously Like Property Treatment: Does Human Tissue Fit Within The Common Law Concept of Property?' [2005] 7 U Tech Sydney Law Rev 62. For a detailed discussion of the misconception between ownership and property, see Wall (n 3) 801-802 and 804.
[95] B Bjorkman & SO Hansson, Bodily Rights and Property Rights. J Med Ethics 2006; 32: 209.

is as the title suggests, an exposition of ownership, not of property.[96] While Honoré's exposition on ownership provides a useful illustration of the sticks contained within the bundle of property, 'property, [however], also includes less powerful collections of incidents that do not rise to the level of ownership.'[97] Munzer, for instance, has suggested that these 'less powerful collections of incidents' which include bailments, easements and franchises are tantamount to *limited property*. [98] In the words of one commentator:

> The idea of property should be understood as an amalgam of Hohfeldian jural correlatives and opposites, Honoré's standard incidents of ownership, other less powerful interests not specified by Honoré and a catalogue of tangibles and intangibles. In essence, this means that although the idea of property is indeterminate at the margins, its meaning transcends the realm of ownership.[99]

There are those commentators like Becker, Waldron, and Munzer, who opine that the bundle of rights analysis proposed by Hohfeld and Honoré sufficiently explains the actual nature of property and that the bundle of rights analysis should be treated as being proven for all intents and purposes.[100] Munzer, for instance, suggests that the focus should now be on assessing the justifications of property in order to identify the limits of treating various objects as property, while Becker and Waldron consider that academic commentary should focus on examining the general justifications of property rights.[101] In Becker's opinion, 'the bundle of rights analysis of property can serve as a "dominant paradigm" under the aegis of which working lawyers and academic theorists may attend to the problems in the law of property.'[102]

[96] Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (n 69) 4.
[97] Munzer (n 7) 23.
[98] Ibid. Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (n 69) 4.
[99] Nwabueze (ibid), discussing Munzer (n 7).
[100] Becker (n 14); Munzer (n 7); Waldron (n 14).
[101] Ibid. Penner 'The "Bundle of Rights" Picture of Property' (n 66) 713.
[102] LC Becker, 'Too Much Property' (1992) 21 Phil. & Pub Aff. 196, 198-99.

While the reified theory as espoused by Blackstone[103] provides a clear distinction between a thing and rights exercised with respect to a thing that qualify as property, the bundle of rights perspective of property could be criticised for not representing a logical or methodological approach upon which to distinguish between property and non-property rights.[104] The theory, however, has a potential to consume non-property rights such as those underpinned, for instance, by privacy and consent frameworks and some human rights; and bring them under the umbrella of property. This view is reflected in commentaries made by Grey, Penner and Arnold. Grey suggests that the fragmentation of property as a bundle of rights has made it an ineffective tool for moral and political analysis.[105] In a similar vein, Penner opines that the bundle of rights construct is 'a slogan without any internal coherence or logical structure necessary for analysis of real life problems.' [106] He observes, for instance, that the bundle of rights perspective does not provide an explanation as to 'what rights are necessary or sufficient to treat something as property.'[107] This line of thinking was reiterated in Arnold's analysis of the bundle of rights theory where he states: 'it is true that the bundle of rights concept itself tends to disintegrate in its image of property as a bundle of abstract legal rights that have no characteristics to distinguish them from other rights or human relationships generally.'[108]

In the context of excised biological material, the legal uncertainty surrounding the bundle of rights theory would result in difficulties in determining whether personal rights invoked to protect an individual's self determination such as a right of bodily integrity[109] constitute property rights. The inadequacies of both the bundle of rights

[103] See Blackstone (n 27).
[104] See Penner, 'The "Bundle of Rights" Picture of Property' (n 66) 711-820. Also see Arnold (n 73).
[105] TC Grey, 'The Disintegration of Property', in JR Pennock and JW Chapman eds, NOMOS XXII: *Property* (New York: New York University Press, 1980).
[106] Penner 'The "Bundle of Rights" Picture of Property' (n 66) as surmised by Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 28.
[107] Penner (ibid).
[108] Arnold (n 73).
[109] A right of bodily integrity includes a right not to be physically harmed against one's will and a right not to have body tissue and body parts removed without consent of the individual concerned – See

and the reified paradigms of property are succinctly explained by Nwabueze in his discussion of the limitations of the bundle of rights construct where he aptly observes:

> In an attempt to free property from the narrowness of the Blackstonian thinghood conception, the bundle of rights perspective has seemingly introduced a limitless flexibility. If we must make a distinction between property rights and non-property rights, then we need to establish some distinguishing criteria. But upon what basis do we make property rights unique or ascertain the uniqueness of property rights? Even when we accept that a right, such as rights relating to dead bodies, and body parts should be treated as a property right on the basis of the bundle of rights conception of property, should there be any limit to the exercise of such rights?[110]

Kohler, however, opines that the current criticism of the bundle of rights theory in respect of its complexity and analytical relevance is usually exaggerated.[111] Although, accepting that an overly broad classification of property would create theoretical difficulties, he postulates that it is incorrect to suggest that the bundle of rights concept of property has reached that point.[112] He proposes that property rights could be distinguished from non-property rights by invoking a methodology that is 'intuitive, pragmatic and policy-based.'[113] He then goes on to conclude: 'faced with such a pragmatic approach to property, there really is no point in offering a characterisation, which seeks to transcend that reality. Property is no more than a normative set of relations, which might be attached to whatever society deems it necessary or beneficial to make the subject of property.'[114]

McFall v Shrimp [1978] 10 Pa. D. & C. 3d 90, where the court applying the law of consent held that a person's bone marrow could not be removed without his consent.

[110] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 33.

[111] P Kohler, 'The Death of Ownership and Demise of Property' (2000) 53 Current Legal Problems 237.

[112] Ibid, 241.

[113] *Ibid*, 242-3.

[114] Ibid.

While the bundle of rights paradigm of property is of significant utility in providing a flexible framework that allows valuable interests to be protected by treating them as property rights,[115] the definition of property simply as a 'bundle of rights' is an insufficient account of property because it fails to acknowledge the elements that make property rights unique. However, despite the difficulties associated with the bundle of rights perspective, the theory nevertheless offers a construct that is better equipped to address the objectives advanced in this discussion than the reified theory because the focus of the present discussion revolves around the classification of specific ownership entitlements regarding biological material as property interests, rather than the classification of biological material as property. In essence, the argument is not being advanced here that excised biological material is property nor is it suggested that excised biological material should be treated as property. Also, unlike advocates for the reified perspective, the arguments in this discussion over the allocation of property interest in favour of sources is not based upon the exercise of control or dominion over biological material, nor is it based on the alteration or modification of biological material from its naturally occurring state. Rather, the present discussion relates to the interactions and legal relations between sources and researchers in cases where biological material is transferred for research uses, as opposed to the biological material in itself.

The Bundle of Rights theory of Property (Controversies) – Key issues

Generally, under the bundle of rights theory, property consists of legal relations between a person and a thing, between persons with respect to things, and between persons without reference to things.[116] Although advocates for the bundle of rights theory agree that property consists of certain legal relations, they disagree as to the nature and scope of these relations. The key issues that have generated controversy include the person-object relation of property and the relation claimed to exist

[115] See Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 33.
[116] Ibid, 8.

between persons without reference to things. In essence, there are those, most notably in Western jurisdictions, who argue that property rights cannot create legal relations between a person and an object because things do not constitute right bearing entities and there are others who recognise that property rights create relations between a person and a thing or between persons with respect to things but they reject the view that allege that property rights can create a legal relationship between persons without reference to things.

The Person-Object relation of Property

The debate relating to the person-object relation of property stems from the restrictive definition of right bearing entities in Western legal thought. The definition commonly invoked is that of Munzer,[117] which restricts right bearing entities to those entities that can hold interests and make choices.[118] The implication of this limitation is that only living human beings, non-human persons and certain animals can be considered to be right bearing entities since only members of these groups fall within Munzer's category.[119] However, such a restrictive definition is unable to take account of the unusual relationships that individuals have with things that are reflective of their personalities.[120] Furthermore, although Munzer's definition of right bearing entities may be suited to Western legal thought, it is unable to embrace the stance taken in non-Western jurisdictions where inanimate entities such as dead bodies of ancestors and sacred forests are deemed to be capable of having relations with living human beings.[121] As Honoré aptly observes in his discussion of the person-object relation of property:

[117] Munzer (n 7) 42.
[118] Ibid.
[119] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 8.
[120] Radin, *Reinterpreting Property* (n 9).
[121] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 8.

> There can obviously be relations between persons and things, not merely between persons and persons. To argue that legal relations can only subsist between persons is either arbitrarily to restrict the definition of "legal relations" or obscurely to reflect the truism that legal claims can only be enforced by proceedings brought against persons.[122]

These limitations arguably support a case for a more inclusive conceptualisation of property that better reflects the range of relations that exist both in Western and non-Western jurisdictions.[123]

While the controversies surrounding the person-object relation of property and the legal relation alleged to exist between persons without reference to things, are not directly concerned with the objectives advanced in the present discussion, they have, nevertheless, been highlighted here to draw attention to the difficulties that flow from the legal definition of property as a set of relations or a bundle of rights.

Legal relations without reference to things

The view among some advocates for the bundle of rights theory that alleges that property rights create legal relations that exist between persons without reference to things, is sometimes referred as the 'thingless conception of property'. In explaining the thingless conception of property, Weinrib states: 'The realization that property consists only of legal relations between people makes it clear that there is no need for any tangible object to serve as the object of those relations.'[124] Arguably, dephysicalizing property to a thingless concept provides it with some flexibility which allows for judicial and analytical creativity and creates a crucial

[122] AM Honoré, 'Rights of Exclusion and Immunities Against Divesting' (1960) 34 Tulane Law Rev. 453, 463.
[123] See Radin, *Reinterpreting Property* (n 9); Arnold (n 73).
[124] AS Weinrib, 'Information and Property' (1988) 38 U.T.L.J. 117, 120.

opportunity for rights and interests on the fringes of property law, such as dead bodies, body parts and traditional knowledge, to be categorised as property.[125] This would therefore create a state of affairs where the outer limits of property would remain largely undefined and property protection can be accorded to every valuable interest according to the socio-economic needs and objectives of any legal system.[126] This potentially makes a thingless conception of property more expansive and of a higher practical utility than a definition with reference to things.[127]

However, this relation of property is rejected by academics such as Cohen[128] and Mackinnon[129]. Although, accepting the bundle of rights conception of property as a set of legal relations, these scholars insist that such legal relations must exist with reference to things. Arnold, in highlighting the controversy, postulates:

> The central premise of the bundle of rights conception of property is that property is a set of legal relationships among people, and therefore most emphatically is neither ownership of things nor relationships between owners and things. Some scholars insist that the definition of property has nothing to do with things and everything to do with social relationships. Other scholars, unable to move entirely away from the idea that there must be some object of the rights in the bundle, state that property is about legal relationships among people with respect to things. Nonetheless, these scholars give little attention to the thingness of property. Some scholars have attempted to bridge the inattentions to objects of property rights and the bare acknowledgement of property rights in things by asserting that the rights in the bundle involve relationships among people with respect to valuable resources. However, the definition gives little useful guidance about which resources are objects of

[125] Nwabueze *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 9 and 11.
[126] Ibid.
[127] Ibid.
[128] M Cohen, 'Property and Sovereignty' (1927) 13 *Cornell L.Q.* 8, 12.
[129] KAB Mackinnon, 'Giving It All Away? Thomas Reid's Retreat from a Natural Rights Justification of Private Property' (1993) 2 Can. J.L. & Juris. 367, 372.

> property, and the primary, almost exclusive, attention falls on market and power relationships among people. Overall, the bundle of rights conception is, at its core, anti-thingness.[130]

Can entitlements relating to human biological material be admitted into the legal category of Property?

Like the reified theory of property, it is arguable that the bundle of rights perspective is potentially applicable to rights exercisable over biological material. It could be suggested that the protection given to users of excised tissue (against sources of tissue), those who have turned human tissues into useful biomedical inventions,[131] possessory right over cadavers,[132] cultured human cells,[133] and stored human biological samples,[134] exemplifies the bundle of rights theory.[135]

Though the illustrated difficulties regarding the applicability of the existing concepts of property to the living human body and excised biological material might suggest that the present enquiry into a person's property interest in his excised biological material requires a more precise definition of property, possession, ownership and associated legal concepts than seem to exist,[136] the existing concepts do, however, offer utility to the present discussion in that they are potentially applicable to issues relating to excised biological material. The reified theory of property could be argued to offer the greatest protection to a deserving claimant with respect to biological

[130] Arnold (n 73) 285-6. Also see P Eleftheriadis, 'The Analysis of Property Rights' (1996) 16 Oxford Journal of Legal Studies 31 (Eleftheriadis defends Hohfeld's definition of property as a set of legal relations between persons).
[131] *Moore SC* (n 72); *Greenberg v. Miami Children's Hospital Res. Inst.* [2003] 264 F. Supp. 2d 1064.
[132] *William v William* [1882] 20 WLR.659 (Ch.D).
[133] *US v Arora* [1994] 860 F. Supp. 1091 (D.Md.)
[134] *Washington University v Catalona* [2006] 437 F. Supp.2d 985 (Dist. Ct. Missouri)
[135] Nwabueze, 'Legal Paradigms of human tissues' (n 24).
[136] Dickens (n 63) 144. Similarly, Nwabueze in his analysis of the applicability of the bundle of rights and reified theories of property to the human body commented: 'The extent to which the dominant paradigms accommodate issues relating to human body is unclear' Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 99.

material that have a physical manifestation[137] because it does not suffer from the difficulties relating to legal certainty that are associated with the bundle of rights perspective. This makes the reified perspective arguably of a higher practical utility in this discussion than the bundle of rights theory because the biological material that is discussed here (solid organs and tissue) also have physical form. However, in spite of this advantage, the bundle of rights explanation of property is adopted because the flexibility of the bundle of rights theory is more suited to the objectives advanced here. While the reified perspective focuses on physical objects, the focus of the present discussion is not on physical objects, it is not on excised human biological material in itself. Furthermore, while excised human biological is potentially capable of qualifying as property under the reified perspective, a position is not taken in this discussion regarding whether excised human biological material is property. Rather, the focus is on the various interactions in respect of excised human biological material. In order to advance source interests, the focus is on the status of specific ownership entitlements.

One of the reasons why the law refuses to recognise source income entitlement and admit it into the legal category of property is out of concern that a private property model will lead to a market in body parts. Supporters of this view argue that the inevitable result of a private property model is a 'free for all' market in biological material, which will not just have negative implications for socially useful medical and scientific research, but is also ethically and morally objectionable, since it will treat the human body like the basest of commercial commodities. However, applying the bundle of rights perspective, it is argued that if property is understood as a bundle of rights then a limited property right can be recognised in respect of excised biological material, which includes management and income entitlements. Such recognition will allow sources to claim legal remedies for unauthorised use of their biological material and would also enable them to claim compensation for their contribution to research. Like property interests in other forms of property,

[137] K Yelpala, 'Owning the Secret of Life: Biotechnology and Property Rights Revisited' (2000) 32 McGeorge l. Rev. 111, 154.

legislation can then limit the scope of the proposed interest by prohibiting sale in biological material, thus preventing a free for all market in human biological material.[138] In essence, as a result of the flexibility and malleability of the bundle of rights conception of property, not all the entitlements usually contained within the bundle of rights attributable to most forms of property will be granted to individuals and protection for the recognised entitlements can be devised and implemented in a way that will achieve the intended aim without resulting in the perceived potential negative consequences.

In consideration of the criticisms levelled at the bundle of rights theory of property regarding its inability to assist with the characteristics that distinguishes property rights from other rights, it is useful at this juncture to examine the line of enquiry that considers the nature of property rights. It is envisaged that this enquiry together with the bundle of rights conception of property will provide a logical premise upon which to determine whether entitlements relating to biological material are capable of admission into the category of property and whether they qualify as property rights.

The nature of property rights – Do entitlements relating to biological material meet the prerequisites of a property right?

As mentioned above, Lord Wilberforce in *Ainsworth*[139] outlined the recognised criterion that a right must meet before it can be admitted into the legal category of property. The case considered whether a wife deserted by her husband could remain in the matrimonial home that was mortgaged by her husband to a bank.[140] The woman argued that the fact that she was the mortgagor's wife accorded her an

[138] For a discussion of a limited property construct in respect of dead bodies and cadavers, see Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 72 and 91-99.
[139] *Ainsworth* (n 76).
[140] Ibid, 1176.

interest in the matrimonial home despite the fact that her husband legally owned the property.[141] She argued that her acquired interest in the matrimonial home was enough to override the bank's legal mortgage.[142] The question for the court was whether the interest claimed by the wife constituted a legally protectable property interest.

Lord Wilberforce postulates:

> Before a right or an interest can be admitted into the category of property, or of a right affecting property, it must be definable, identifiable by third parties, capable in its nature of assumption by third parties, and have some degree of permanence or stability. The wife's right has none of these qualities, it is characterised by the reverse of them.[143]

Lord Wilberforce's exposition seems to suggest that not every right in the bundle of rights metaphor would be accorded property status. Therefore, the possessory right that could be exercised over a corpse for burial purposes which is recognised by the common law[144] would not qualify as a property right because whilst it gives the next of kin an exclusive right to possess the dead body for burial, the person is unable to make personal use of the corpse or dispose of it by way of sale to third parties. Thus, the possessory right over the dead body does not meet the requirements set out by Lord Wilberforce in *Ainsworth*.[145] Lord Wilberforce's exposition has been found to be of practical utility by courts in other jurisdictions and it has also found scholarly support.[146] For instance, in *First Victoria National Bank v United States*,[147] Justice Goldberg, of the United States Court of Appeals, Fifth Circuit opined:

[141] Ibid.
[142] Ibid.
[143] Ibid 1247-8; But see the *Matrimonial Homes Act* 1967, UK, C. 75.
[144] See *R v Stewart* [1840] 113 E.R. 1007.
[145] Nwabueze, 'Legal Paradigms of human tissues' (n 24).
[146] Jackson (n 67), cited in Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 78.
[147] *First Victoria National Bank v United States* [1980] 620 F. 2d 1096.

> An interest labelled 'property' normally may possess certain characteristics: it can be transferred to others; it can be devised and inherited; it can descend to heirs at law; it can be levied upon to satisfy a judgment; it comes under the jurisdiction of a bankruptcy court in a bankruptcy proceeding; it will be protected against invasion by the courts; it cannot be taken without due process of law.[148]

Similarly, Jackson suggests:

> The distinction between proprietary and personal interests may be said to rest either on whether or not the holder is given the ability: (i) to 'deal with' the interest by transferring it to another, or (ii) to recover the interest should he lose it, or (iii) to bring an action with respect to the interest against a person or persons other than the grantor.[149]

The Supreme Court of Colorado also found the exposition in *Ainsworth* to be of some practical utility in *Culpepper v Pearl Street Building Inc*.[150] The question for the court in that case was whether a couple could establish that they had a property interest in their son's corpse.[151] Their son had been mistakenly cremated by the defendant and the plaintiff brought proceedings which included a claim for conversion against the defendant.[152] The court held that a corpse is not property because it is not commercially transferable and has no monetary value.[153]

A strict application of the *Ainsworth* criterion to biological material suggests that entitlements relating to biological material do not satisfy the requirement outlined in *Ainsworth*. For example, they are not commercially transferable and are inherently

[148] Ibid 1103-4
[149] Jackson (n 67) 16.
[150] *Culpepper v Pearl Street Building Inc* [1994] 877 P.2d 877.
[151] Ibid, 880.
[152] Ibid, 879.
[153] Ibid, 880.

non-commodifiable.[154] Consequently, it could be argued that such entitlements are not proprietary in nature and cannot be accepted into the category of property using the bundle of rights perspective.

However, it has been suggested that it is more likely that Lord Wilberforce was referring to full legal ownership rather than property rights and therefore, that the *Ainsworth* exposition does not represent an immutable standard upon which to determine whether a right falls within the category of property.[155] This interpretation of Lord Wilberforce's dictum seems plausible because a single stick in the bundle of rights metaphor is unlikely to meet the Ainsworth criterion. However, the interest of a person who has full legal ownership will fulfil the Ainsworth requirements because entitlements such as possessory, usage and alienability entitlements will normally be included in the ownership bundle and the person's ownership interest will be definable and capable of assumption by third parties.

Support for the above view is illustrated in cases where the courts have admitted individual ownership entitlements into the category of property even though those entitlements do not meet the Ainsworth criteria. For instance, Justice Goldberg in *First Victoria National Bank,*[156] although acknowledging the *Ainsworth* principle, went on to concede:

> An interest may qualify as 'property' for some purposes even though it lacks some of these attributes [it can be transferred to others; it can be devised and inherited; it can descend to heirs at law; it can be levied upon to satisfy a judgment; it comes under the jurisdiction of a bankruptcy court in a bankruptcy proceeding; it will be protected against invasion by the courts; it

[154] Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 83.
[155] Nwabueze, 'Legal Paradigms of human tissues' (n 24). Also, see Ibid, 84.
[156] *First Victoria National Bank* (n 147) 114.

> cannot be taken without due process of law]. For example, an individual can have a 'property' right in his job…so that he cannot be fired without appropriate procedural safeguards; yet the job is not assignable, transferable, descendible, or devisable. The 'right to publicity' is transferable during life…but may not be devisable.[157]

The supposition that Lord Wilberforce's dictum was more likely to be referring to full legal ownership is also supported by academic commentary that advocates for property protection of some interests, albeit that those interests do not meet the *Ainsworth* criteria. For example, Radin suggests: 'we must cease thinking that market alienability is inherent in the concept of property.'[158] Similarly, Waldron in discussing the difference between a 'concept' and a 'conception' of property opines that alienability was not part of the concept of property and consequently, might not be recognized by a particular legal system's conception of property.[159] Additionally, if it is accepted that the principle espoused in *Ainsworth* was 'cast in the mould of common law during a period that had not witnessed the tremendous biotechnological advances of today and that the common law may not have caught up with the realities of today,'[160] then it could be argued that entitlements relating to biological material are capable of being accepted into the category of property under the bundle of rights perspective, even though they do not meet the *Ainsworth* criteria. The Court of Appeal seem to recognise this limitation in *Yearworth and Others v North Bristol NHS Trust* when the court acknowledged that 'developments in medical science require a re-analysis of the common law's treatment of and

[157] Ibid, 1104.
[158] M Radin, 'Property and Personhood' (1982) 34 *Stan. L. Rev*. 957, 1903.
[159] Waldron (n 14) 340. Also, see CI Harris, 'Whiteness As Property' (1993) 106 *Harv. L. Rev*. 1709, 1734.
[160] *Onyeanusi v Pan Am* [1992] 952 F. 2d 788 at 792. Also see Nwabueze, Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information (n 7) 82.

approach to the [the question of property] in parts or products of a living human body.'[161]

To better understand the argument for the adoption of a more flexible criterion for property than the *Ainsworth* criterion in the context of excised biological material, Nwabueze's statement is quite informative:

> …though human body parts may be considered intrinsically non-commodifiable, biomedical technology has jeopardised their safety such that substantial legal protection, analogous to the protection given to property, is now desirable. For the law to serve society as an instrument of social engineering, it must respond meaningfully to changing socio-economic dynamics. The law has shown this adaptability and flexibility in the past by acknowledging a property interest in one's job or personality.[162]

He further states:

> At present, the main source of wealth for biotech companies is knowledge. Raw materials for biomedical research include cells and tissue samples. Biomedical research has contributed to health and social well-being. To maintain social value, the law should provide sufficient and balanced protection to the raw material and products of biomedical research. The law has already allowed patent protection to biological products, previously thought to be unpatentable.[163]

[161] *Yearworth* (n 50) 45.
[162] Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 83. Also, see DH Herman and YS Sor, 'Property Rights In One's Job: The Case For Limiting Employment-At-Will' (1982) 24 Ariz. L. Rev. 763; *Moore SC* (n 72) 507.
[163] Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 84. Also, See *Diamond v Chakrabarty* [1980] 447 U.S. 303; Yelpala (n 137) 154; *U.S. v. Arora* (n 133).

The respective contributions of Wall and Nwabueze in developing the foregoing argument regarding the inclusion of non-traditional forms of property under the property classification deserve mention at this point of the discussion. They have both made excellent attempts at proposing an analytical framework for categorising excised biological material and entitlements regarding excised biological material as property. Though, it should be noted that while the ultimate goal of Wall's framework is to determine the normative characterisation of particular entitlements as property, Nwabueze considers this question as part of his pursuit of an integrated framework for identifying an appropriate remedy for interference with a body part in a given case. Both analytical frameworks offer utility to the present discussion in its search to identify a suitable framework for the analysis of the main question advanced in this chapter, namely: do source ownership entitlements qualify as property interests under a normative understanding of property?

Wall's framework is developed upon a premise which considers the recognition of a property right as first and foremost recognition of a collection of "ownership entitlements" in a resource.[164] He asserts that 'recognition of property rights does not necessarily follow from recognition of ownership entitlements' and the decision as to whether an ownership entitlement qualifies as a property right will depend upon both an application of justificatory techniques and trespassory rules.[165] The justificatory level of his analysis seeks to establish whether recognition of a particular entitlement expresses the rights that an individual has *as a person* or if it produces a desirable state of affairs. This is based upon the notion that 'property rights can be generally seen as either expressive or instrumental; as either expressing through property rights the rights that a person has *as a person* or using property rights *as a means to* produce a desirable state of affairs.'[166] Whether the entitlement is subsequently admitted into the category of property and classified as a property right then depends upon whether property rules are the most effective

[164] Wall (n 3) 784.
[165] Ibid, 786.
[166] Ibid, 793.

rules for protecting that particular entitlement or whether the entitlement is better protected by other legal rules such as liability or inalienability rules.

Wall asserts that while there is a necessary connection between income rights and property law, there is, however, no such connection between property law and other ownership entitlements.[167] The difficulty with this assertion is illustrated by reference to historic and established forms of property such as a proprietor's ownership interest in the context of home ownership. The consequence of Wall's framework is that the ownership interest of the home owner in such instances will not qualify as a property right if for instance, the house is subject to a compulsory purchase order and the government pays the home owner a 'statutorily determined, non-market based compensation.'[168] Expressed differently, the fact that liability rules are invoked to offer a remedy for the compulsory acquisition of the land indicates that the homeowner has no property right in respect of the land even though he is recognised in law as the owner. [169] Two conclusions can thus be drawn from Wall's exposition:

> …[F]irst, the application of liability rules to a resource precludes the potential characterisation of that resource as property; second, for ownership interests to amount to property, those interests must be protected by way of property rules (rather than liability rules or rules of inalienability). However, both conclusions are at odds with the way [full ownership is regarded in popular and legal discourse] as being a good example of the existence of a property right in a resource.[170]

[167] Ibid, 784 and 804.
[168] Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (n 69) 3.
[169] Ibid.
[170] Ibid.

Nwabueze, on the other hand, suggests:

> …[O]nce an entitlement within the ownership spectrum is protected by a legal system, howsoever that protection is achieved, whether through the application of property rules, liability rules or rules of inalienability, then that entitlement qualifies as property.[171]

While the simplicity of Nwabueze's supposition for the normative characterisation of property would allow it to offer significant utility to the courts in a given case, it would appear that in the context of entitlements relating to biological material, such normative characterisation does not necessarily translate into legal reality. This is likely unique to this type of entitlements because of the extensive moral, ethical and philosophical objections to the application of property law to such interactions and the focus of the courts on predominantly policy reasons, rather than considerations involving established legal principles, in rejecting the proprietary status of such entitlements.

Essentially, while the enquiry suggested by Nwabueze might result in normative characterisation of a particular entitlement as property and such an entitlement will be a legal interest in so far as it is protected by the legal system, it is questionable whether the normative characterisation of the entitlement as a property right is reflected in Law. In other words, is it a legal property right?[172] For instance, source management entitlement is an entitlement within the ownership spectrum and is protected by law under the HTA 2004. In this connection and applying Nwabueze's normative characterisation of property, such an entitlement would qualify as a

[171] Ibid.

[172] Though adopting a reified perspective of property, Hardcastle, nevertheless, made a similar observation where he observed: '…it is uncertain whether leading common law jurisdictions recognise property rights in biological materials…In England, for example, neither existing legislation nor the common law currently recognises a source's property rights to separated biological materials…English Law has not determined whether a living person can claim property rights to separated biological materials.' (R Hardcastle, *Law and the Human Body: Property Rights, Ownership and control* (Hart; 2007) 12-13).

property right. However, while this may be the case, it is not so clear that source management entitlement is recognised as a property right by the legal system. In cases where sources of biological material have sought to claim property remedies, specifically, conversion, for which a finding of either an ownership interest or some other form of property interest is necessary, the courts (US) have categorically stated that such entitlements are not property interests. For instance, in the US case of *Moore*, the court refused Mr Moore's cause of action for conversion because it considered that his residuary interest in respect of his excised biological material does not amount to a legally protectable property right. The UK courts have yet to confirm their approach in respect of an individual's property right in respect of excised non-reproductive biological material.

While the UK case of *Yearworth* acknowledged that source ownership entitlements qualify as property interests, that judgement considered specifically the legal status of ownership entitlements relating to semen, which raise separate policy and to some extent separate legal issues from excised non-reproductive biological material (for example, the opportunity to experience parenthood or loss of this opportunity as in the case of *Yearworth* due to the defendant's action), issues that might have compelled the court to grant the claimants a remedy in cases involving semen but which are not necessarily present in cases involving non-reproductive biological material (discussed in more detail in the next chapter). Thus, while the judgement could logically be applied to non-reproductive biological material, it would not be prudent to do so since the court did not suggest that the judgement had a wider application beyond the context of semen and there have been no other UK cases to confirm the court's approach. Subsequent cases in Australia (for example, *Kate Jane Bazley v Wesley Monash IVF Pty Ltd [*2010][173]) have also been raised in the context of semen and have not confirmed a wider application beyond excised reproductive biological material. Furthermore, with the exception of biological material which has

[173] *Kate Jane Bazley v Wesley Monash IVF Pty Ltd* QSC 4 118 (considered the legal status of entitlements to sperm of a deceased man, deposited before his death. Although dealing with the sperm removed from a deceased person, see *Jocelyn Edwards* (n 46).

been the subject of human skill,[174] statute (HTA 2004) is also silent on the proprietary status of source ownership entitlements.

While it is arguable that the remedial framework does not determine the normative characterisation of an entitlement as property because both liability rules and inalienability rules have been invoked to offer remedies in respect of historic and established forms of property, a person must nevertheless have a legally recognised property right in order to claim property remedies such as conversion for interference with his or her ownership entitlement. A property right is ineffective if the legal system does not recognise it as such and thus without the power to enforce it as a property right.[175] The power to enforce property rights with legal backing is what gives them the status of rights. In view of the uncertainty in law as to whether entitlements relating to excised biological material qualify as legal property interests, it would appear necessary to issue a judicial or statutory pronouncement conferring property status in respect of such entitlements. Historic and established forms of property are ordinarily accepted as having such 'property' status because they are recognised either by statute or at common law as having property status. The certainty and clarity, however, offered by a statutory pronouncement is favoured here over a judicial pronouncement since the making of a judicial pronouncement on a particular issue is inherently limited by its dependence upon the right case being brought before the courts. A statutory pronouncement, on the other hand, is not so limited because Parliament can legislate as and when it considers it necessary to do so, providing due process is followed.

[174] Human Tissue Act (n 4) section 32 (9).

[175] These sentiments are expressed by Calabresi and Melamed, though it should be noted that Calabresi and Melamed discussed entitlements generally and their exposition is arguably not a property-dependent criterion. See G Calabresi and AD Melamed, 'Property Rules, Liability Rules and Inalienability Rules: One View of the Cathedral' (1972) 85 Harvard Law Review 1089, 1090-1091; Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (n 69) 3, discussing Calabresi and Melamed and deploying their exposition as a 'property non-dependent criterion.'

In view of the foregoing discussion, it is intended that the proposed statutory framework would incorporate a pronouncement to the effect that sources have a limited property interest in respect of their excised biological material which consist of management and income entitlements. The proposed statutory framework is discussed at great length in chapter 5. However, at this point, it should simply be noted that this discussion proceeds on the basis that entitlements relating to biological material potentially qualify as property interests within the normative understanding of property espoused by the bundle of rights theory of property, but that such characterisation is not currently recognised or enforced by law.

While it is acknowledged that there is a need for a more comprehensive normative understanding of property beyond simply that property is a 'bundle of rights', Wall's dependence on trespassory rules as determining the legal status of ownership entitlements or specifically, his apparent suggestion that an ownership entitlement must be protected by property rules to qualify as a property right, is not accepted here. Though Nwabueze's normative characterisation of property is favoured over Wall's approach, a slightly different approach based upon Kohler's suggestion is nevertheless taken in this discussion.

Kohler's proposition is based on the notion that property rights could be distinguished from non-property rights by invoking a methodology that is 'intuitive, pragmatic and policy-based'.[176] He then goes on to suggest that: 'faced with such a pragmatic approach to property, there really is no point in offering a characterisation, which seeks to transcend that reality.'[177] According to Kohler, 'property is no more than a normative set of relations, which might be attached to whatever society deems it necessary or beneficial to make the subject of property.'[178] Applying this proposition to entitlements relating to biological material,

[176] Kohler (n 111) 242-3.
[177] Ibid.
[178] Ibid.

both source management and source income entitlements may qualify as property interests as follows:

1. 'Intuitive'

They are entitlements within the ownership spectrum and are akin to property interests in respect of other historic and established forms of property.

2. 'Pragmatic and policy based' (Is it 'necessary' or 'beneficial' to make such entitlements the subject of property?)

It is both necessary and beneficial to make such entitlements the subject of property. The state is responsible for promoting the good health of its citizens and that responsibility includes supporting and facilitating environments in which the good health of its citizens may flourish.[179]One way in which the state fulfils this responsibility is by supporting and facilitating environments in which biotechnological research may flourish because the therapeutic potential of such research is helpful in advancing public health.[180] However, it is also important to bear the following in mind:

> Society's interests in good healthcare are not exhausted by promoting efficiency in the advancement of medical technology. Important as that goal remains to many, its single minded pursuit can obscure other important considerations. These include the promotion of justice, respect and trust among physicians, researchers and the public, and the encouragement of continuing tissue contributions that is likely to result from maintaining those values.[181]

[179] Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (Nuffield Council on Bioethics, 11 October 2011) 193 para 7.16.
[180] Ibid.
[181] C Harrison, 'Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue' (2002) 28 Am. J.L. & Med. 77, 104.

The 'raw material' contributed by sources of biological material towards biotechnological research is crucial to success in such research and the continued supply of biological material by the public is essential for survival of most health related biotechnological research. Recognising a property right in favour of sources of biological material offers a significant addition to the armoury of protection that seeks to safeguard and promote source interests. It enables sources to maintain a claim for property remedies such as conversion:

> [A] proprietary approach confers on a claimant the advantage of continuing control that is tellingly lacking in non-property frameworks underpinned, for instance, by consent, negligence, privacy and unjust enrichment rules. In some circumstances, such as an unauthorised blood test performed on a blood sample obtained with consent, the continuing control provided by property law might be the only chance a claimant has to obtain a remedy.[182]

Thus, the property framework safeguards a person's interest in controlling what happens to his excised biological material and provides a legal basis for a remedy in a way that other non-property approaches do not when inappropriate actions are taken regarding excised biological material.[183] By allowing sources to retain legally recognised interests in respect of their biological material, public confidence in research is promoted which in turn encourages prospective sources to supply their biological material for research, thereby maintaining the availability of biological material for research.

[182] Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (n 69) 1.
[183] LB Andrews, 'My Body, My Property' (1986) 28 Hastings Cent Rep 28.

Unlike the current liability based consensual framework for safeguarding source management entitlement, a property-based framework potentially offers a wider range of remedies for sources and a more substantial award of damages.[184] The higher amount of damages available under property-based remedies means that they are more likely to serve a powerful deterrence effect in discouraging researchers and other medical personnel from interfering with source ownership entitlements. For instance, the amount of damages available under liability based remedies such as remedies for lack of informed consent and breach of fiduciary duty are quite small as compared to damages for property-based remedies like conversion.[185] Also, while liability based criminal sanctions such as those contained within the current framework under the HTA 2004, have a role to play in a source's armoury of protection, criminal sanctions are insufficient on their own because while they do serve a deterrence effect in discouraging would-be offenders from engaging in offending actions that will negatively impact upon a potential victim, their primary objective is to vindicate the states' interests (in crime reduction, in maintaining public order and as the instigator of prosecutions) and not that of the victim ('in this context, the source of biological material). They do not, for instance, compensate the victim for distress, loss, or suffering resulting from the offending action. Even the 'victim surcharge' imposed upon conclusion of some criminal prosecutions is paid to the court as an instrument of the state rather than the victim.

Vesting sources of biological material with property interests, comprising for instance, management entitlement, strengthens a source's 'claim to maintain control over the disposition of that which is exclusively his or hers.'[186] This in turn helps to safeguard a source's autonomy and self-determination and ensures compliance with notions of human dignity. 'Both the consent and compensation

[184] See Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (n 69) 1. DM Gitter, 'Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material' (2004) 61 Wash. & Lee L. Rev. 257, 305.
[185] Ibid.
[186] MT Danforth, 'Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits' (1988) 6 Yale L. & Pol'y Rev. 179, 201.

requirements [that will necessarily be incorporated into any construct that seeks to protect source property interests], are at their base efforts to treat the [source of biological material] as fully autonomous – as able to control what is done with his or her body and to partake in any financial benefits derived from it.'[187]

From an ethical and moral standpoint, such source interests should receive robust protection in order to aid the psychological health of individual members of the public and the state has a duty to maintain public health: Source management entitlement, for instance, belongs to the category of ownership entitlements that are 'most intimately related to the autonomy and liberty of the [person].'[188] Andrews and Nelkin, for instance, suggest: 'to be psychologically healthy, people need to experience both self-agency, which is the ability to control what is done with their bodies, and self-coherence, which is the ability to maintain non-fragmented whole bodies.'[189] They assert that 'taking or using tissue, without the individual's knowledge or consent can compromise psychological development and emotional well-being.'[190]

To surmise the foregoing analysis, source management and income entitlements are capable of admission into the category of property because they are entitlements within the ownership spectrum and are akin to property interests in respect of other historic and established forms of property, and also because it is both necessary and beneficial to make such entitlements the subject of property. However, assuming these entitlements are subsequently characterised as legal property interests, does it also follow that they are protected by property rules, or should the policy framework for protecting these entitlements be underpinned by liability and/or inalienability rules?

[187] Ibid, 202.
[188] J Christman, Self-ownership, Equality and the Structure of Property Rights' (1991) 19 Political Theory 28, 34.
[189] LB Andrews and D Nelkin 'Whose Body Is It Anyway? Disputes Over Body Tissue in a Biotechnological Age' (1988) 351 Lancet 53, 54.
[190] Ibid.

Property, Liability and Inalienability rules

The current legal approach regarding source income and management entitlements and the policy frameworks that have been proposed as an alternative to it can be distinguished according to the legal rules that underpin them. An understanding of the nature of these rules and the differences between them is useful in order to better appreciate the case for the legal recognition of source income entitlement. In particular, it helps to appreciate the reason why the appropriate question for policy makers is one of balance, specifically, achieving a balance between the interests of sources and the concerns of those opposed to the legal recognition of source income entitlement, rather than simple inclusion or exclusion of source income entitlement.

The legal rules that will be explored in this part of the discussion consist of property rules, liability rules and inalienability rules. When a state is presented with the conflicting interests of two or more people or two or more groups of people with regard to who should be deemed the holder of an entitlement in a given resource, the state has to make a decision on which party to allocate the entitlement and the state is also obliged to determine the manner in which the entitlement should be protected.[191] The three above-mentioned legal rules are commonly invoked by the state for this purpose.[192] From an economic-oriented perspective, these rules can be distinguished from each other by the manner in which the entitlements that they protect are transferred, if the entitlements can be transferred at all, and the remedies available when there has been interference with the entitlement.[193]

For the purpose of this discussion, only property rules and liability rules will be examined in detail. However, it should be noted that the current system within the *HTA* 2004[194] which regulates the donation of biological material is an example of a system formulated on a type of inalienability rule, namely, a market-inalienability

[191] Calabresi and Melamed (n 175) 1090 -1092.
[192] Ibid. Also see, CM Rose, 'The Shadow of the Cathedral' (1997) 106 Yale L.J. 2175.
[193] Ibid.
[194] *Human Tissue Act* 2004 (n 4).

rule.[195] The system is formulated on a 'market-inalienability' rule and not on a 'pure inalienability' rule because it allows gift transfers but forbids transfers for sale. [196]Though, the HTA 2004 only explicitly bans sale in the context of transplant and is silent as to sale of biological material intended for research, [197] an 'informal' market inalienability system seems to operate in practice in the research context because the sale of biological material is discouraged while gift transfers are promoted by various organisations within the medical and scientific community.[198] However, under a pure inalienability rule, the transfer of an entitlement (either in a gift or sale transaction) is forbidden.

Where someone who wishes to acquire an entitlement from its holder buys it from the holder of the entitlement in a voluntary transaction, in which both the buyer and seller reach an agreement as to the value of the entitlement, then the entitlement is considered to be protected by a property rule.[199] Where an entitlement is protected by a property rule, both parties involved in the transaction are permitted to ascertain and bring to the 'bargaining table', their individual perspective in relation to the value of the entitlement and the seller is given a veto if the offer put forward by the buyer is not enough.[200] The state's duty in this regard is simply to determine who should be allocated the entitlement at the outset, but the state does not decide the value of the entitlement.[201] On the other hand, an entitlement is protected by a liability rule when someone can acquire the entitlement from the entitlement-holder or destroy it if he is willing to pay an objectively determined value for it.[202] Unlike property rules, liability rules involve an additional stage of state intervention because the state not only determines who should hold the entitlement in the beginning but also permits the

[195] See generally MJ Radin, Contested Commodities (Harvard University Press, 1996).
[196] Ibid.
[197] See generally, *Human Tissue Act* 2004 (n 4).
[198] See Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 179); Harrison (n 181) 94.
[199] Calabresi and Melamed (n 175) 1092.
[200] Ibid.
[201] Ibid.
[202] Ibid.

transfer or destruction of the entitlement on the basis of a value that it decides, rather than allowing the parties involved to make such decisions.[203]

Property, Liability rules and entitlements in human biological material

In determining the manner in which entitlements regarding human biological material ought to be protected and notwithstanding the legal characterisation of such entitlements as property interests, a property rule should not be accepted as being the only available legal rule to effect protection. Such deliberations should also consider the potential utility of liability rules in light of the specific objectives that are advanced and the desired social, economic and legal state of affairs. Whilst a property framework may be capable of protecting ownership entitlements, some ownership entitlements might be better protected by liability rules.[204] For instance, liability rules arguably better protect management and use entitlements because unlike property rules, liability rules protect these entitlements without commodifying the human body.[205] Additionally, liability rules are potentially preferable to property rules because they are able to take consideration of relevant ethical issues such as an individual's entitlement to control the actions of professionals and their organisation, considerations which are not necessarily reflected by a property approach.[206] Furthermore, because the state determines the conditions and value for transfer or destruction of an entitlement under liability rules, the interests of all stakeholders are likely to be better represented under such rules because the state can solicit expert advice and hear representations from all interested parties and also consider other relevant justice, moral, ethical and practical issues before deciding on the appropriate conditions and value for transfer or destruction of a particular entitlement. Thus, liability rules can facilitate a 'socially or politically determined remed[y]' for a difficulty

[203] Ibid.
[204] Wall (n 3) 804.
[205] Ibid.
[206] LI Palmer, 'Should Liability Play a Role in Social Control of Bio banks? (2005) 33 JL Med Ethics 70, cited in RN Nwabueze, 'Donated Organs, Property Rights and the Remedial Quagmire' (2008) 16 Med L Rev 201, 202.

that has proven insurmountable when left to private parties to resolve[207] and 'they can serve to shift an interaction that is ethically problematic in a private context, such as the medical bedside or the research environment, to a public forum.'[208]

Bearing in mind the need for an ethically and morally sensitive approach to the protection of ownership entitlements in excised biological material as a result of the moral value attached to the human body and biological material separated from it, a liability based policy construct, as opposed to a construct grounded in property rules, might be preferable because it could '[enable] the acquisition and study of [biological material] to go forward without the delays, commodifying tendencies and other disadvantages of up-front negotiations,'[209] which is a feature of property rules. For example, under a standard property framework, the cost of establishing the value of an initial entitlement through the negotiation process could potentially be so great that transfer of the entitlement may not take place, although the transfer will be beneficial to all parties involved in the enterprise. The seller for instance, may overestimate the value of the entitlement or the buyer could underestimate the value of the entitlement. In such cases, liability rules could be beneficial when a market model could be too expensive to operate or when markets fail.[210] Under a liability framework, a collective determination of the value would be made available and the benefit of this feature is that it will bring the beneficial transfer to fruition more quickly and there will be no need for the seller and buyer to waste time and resources negotiating the value of the entitlement. In the context of biological material, extended negotiations over the price of a tissue sample could potentially destroy the integrity of the tissue and if there is no agreement as to price between the tissue source and researchers then the tissue may not be used and the proposed research may not go ahead.[211] However, if there is a statutorily determined amount that is

[207] Rose (n 192) 2198; Harrison (n 181) 94.
[208] Harrison (ibid).
[209] Ibid, 94 and 99.
[210] Calabresi and Melamed (n 175) 1110.
[211] J Boyle, 'To Pay or Not to Pay, That is the Question: Finding an intermediary solution along the Moore Spectrum' (2002) 7 Journal of Medicine & Law 55, 55-56. For disadvantages of Market Models, see Calabresi and Melamed (n 175) 1106.

stipulated for the tissue, the transfer of the tissue could occur more quickly and the tissue could be used in the relevant research. In essence, in terms of economic efficiency, a liability rule is more economically efficient than a property rule. Also a liability rule has the added advantage of facilitating fair and equitable distribution of resources, which will be difficult to accomplish under a property rule, which usually gives the entitlement to the highest bidder.[212] With regard to interactions involving human biological material, this would mean that both commercial and non-commercial researchers would have access to biological material.

However, the empowerment that a property framework potentially gives to a source in controlling what happens to his or her biological material and the more wide ranging remedies that it offers in comparison to the remedial consequences that flow from liability rules,[213] might support the choice of a property rule over a liability rule because it would mean that sources have wider choices and potentially a greater prospect for recourse in the event that their entitlements are infringed. This is desirable because it would help to promote justice for sources. A sense of justice being served for sources is arguably important in maintaining the supply of biological material for research because it would likely influence the decision of members of the public in choosing whether or not to make their biological material available for research uses.

In consideration of the foregoing analysis, a framework comprising both liability and property rules is proposed in this discussion for protecting both management and income entitlements because the respective individual benefit of each principle addresses the shortcomings of the other,[214] thus, an aggregation of both principles

[212] Calabresi and Melamed (ibid) 1110.
[213] Gitter (n 184) 305-310. Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7). M Pawlowski, 'Property in Body Parts and Products of the Human Body' (2009) Liverpool L Rev 35, 36. K Mason and G Laurie, 'Consent or Property? Dealing with Body Parts in the Shadow of Bristol and Alder Hey' (2001) 64 MLR 710. Andrews (n 183).
[214] Calabresi and Melamed (n 175) 1106.

will represent a more robust safeguard for protection and a stronger option than if one principle was chosen over the other.

It should be emphasised at this juncture that the proposed framework will represent a property construct only to the extent that it would offer a property based remedial framework for interference with source management and income entitlements. Essentially, it would recognise both source management and income entitlement as legal property interests in order to enable sources to claim property remedies where there has been interference with either entitlement. The transfer of both entitlements would not be governed by property rules. In other words, both entitlements would not be transferable under a sale transaction, so someone who wishes to acquire the entitlements from the source cannot simply buy them from the source in a voluntary transaction, in which both the buyer and seller reach an agreement as to the value of the entitlements. In fact, a market-inalienability rule will be invoked for this purpose and sale transactions will be explicitly prohibited under the framework. Interactions between the source and recipient will mainly be governed by liability rules. The property rule becomes effective at the stage where there has been interference with either/or both source management and income entitlement.

While there is an argument that income rights can only be protected by property rules,[215] such an assumption is not made in this discussion. Rather, it is suggested that both property rules and liability rules are appropriate in enforcing income entitlement. However, a distinction is made between 'income right' as espoused by the former school of thought and 'income entitlement' as advanced in this discussion. According to Wall, 'the distinctive characteristic of income rights is [that] the economic value of the right is conceptually connected to the external metric of resource distribution and private negotiation.'[216] In other words, the features of income right that form the subject of Wall's discussion are based on a standard property model involving a

[215] Wall (n 3) 788-789, 798-801.
[216] Ibid, 800.

market transaction between a buyer and a seller. He argues that it is this feature that makes property rules suitable and liability rules unsuitable in protecting income rights because property rules incorporate a market mechanism that takes account of these factors but liability rules do not. [217] He observes that the cost of acquiring an interest under a framework formulated on a property rule is 'determined by the price for the good set by the external structure of socio-economic conditions'.[218] But the cost of acquiring an interest under a liability construct is determined by the liability rules themselves.[219] By Wall's reasoning, 'unlike property rules, liability rules are unable to govern the exercise of income rights because liability rules do not have the external metric to measure the value of the benefit exchanged…Instead, liability rules use an internal remedial metric for determining the cost of acquiring the interests [such as a statutorily pre-determined schedule for compensation].'[220] However, in contrast to the characteristics of income rights as espoused by Wall, the value of income entitlement envisaged in this discussion will not represent the market value of excised biological material because the proposed framework will not seek to give sources of biological material the market value of their biological specimen and such an argument is not made here. Rather, the present discussion advocates for financial recognition for sources of biological material that acknowledges their critical contribution towards scientific advancement and is of an amount that is sufficient enough to incentivise further donation towards biotechnological research enterprise. In contrast to income rights based on a standard property model and as featured in Wall's discussion, the value of income entitlement as proposed in this discussion is not established through private negotiations between the source of biological material and a recipient researcher. While it is arguably determined by market factors to a limited extent because it will reflect considerations of the average profits made in research using biological material, it is quintessentially a predetermined value that will be set by policymakers and will not be determined in a market transaction. This distinguishing feature therefore qualifies it for enforcement under a liability rule.

[217] Ibid.
[218] Ibid.
[219] Ibid.
[220] Ibid.

Returning to the distinction mentioned earlier in this discussion between the concepts of property and ownership, it could be suggested that the relationship that a person has with his body has some of the characteristics associated with legal ownership. These include possession, exclusive use, the ability to modify, immunity from forced appropriation and the ability to determine what happens to excised biological material removed from his body and the ability to transfer such biological specimen in a gift transaction to recipient hospitals, tissue banks and researchers for research and other uses. Nevertheless, the relationship does not amount to legal ownership because the law does not enforce majority of the key characteristics associated with legal ownership in favour of individuals. For instance, a person cannot legally sell his body, organs, or excised tissue or transfer such biological material by way of a contract for monetary consideration and the law prevents him from harming himself. However, it is arguable that while these limitations may preclude a finding of an ownership interest in respect of the body, the residual interests are capable of qualifying as property interests[221] and therefore, individuals could potentially have limited property interests in respect of their bodies and bodily material.[222] Munzer, for instance, suggested that if a list containing the interests that a person is legally recognised as having in his body is placed against the list of incidents involved in other established forms of property, then individuals might potentially have limited property rights in their bodies. He went on to state that:

> Too many of the incidents are lacking to say that persons own their bodies. Restrictions on transfer and the absence of a liberty to consume or destroy, for example, indicate that persons do not own their bodies in the way that they own automobiles or desks. Still, since the catalog lists a great many things that the law permits or enables people to do with their bodies, it will be a mistake to say that they have no property rights in them at all… It is unhelpful to say that no body rights are property rights…The incidents involved in body rights - namely, to use, manage and so on – are parallel to the incidents involved in

[221] See P Matthews, 'Whose Body? People As Property' (1983) 36 *Current Problems* 193.
[222] Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (n 7) 72 and 91-99.

> garden-variety property rights. And even if some sticks in the bundle of body rights seem quite different from what one might think of as property rights, it hardly follows that they all are.[223]

The term 'ownership' in this discussion refers to 'the greatest possible collection of ownership entitlements which a mature system of law recognises, comprising of a number of rights, incidents and liabilities.'[224] It is not advocated here that individuals should have an 'ownership interest' in respect of their excised biological material, rather, it is advanced that they should have some ownership entitlements in respect of their excised biological material, specifically, management and income entitlements and these entitlements should be recognised as limited property interests.

Conclusion

Based on the above analysis, it is arguable from a reified perspective of property that excised biological material could qualify as property because it has a physical presence that qualifies it as 'things' under the reified theory.[225] However, since the focus of this discussion is particularly with the normative characterisation of source ownership entitlements as property interests rather than categorisation of biological material as property, it is necessary to consider the main question posed in this chapter, namely, 'do source management and income entitlement qualify as property interests under a normative understanding of property?' An examination of this question based upon the bundle of rights perspective of property and the *Ainsworth* criterion as the accepted characterisation of property, would indicate that these entitlements and generally, source ownership entitlements do not qualify as property interests. However, if consideration is given to the various criticisms of the *Ainsworth* criterion; particularly the line of enquiry that suggests that the Ainsworth

[223] Munzer (n 7) 43-45.
[224] AM Honoré (n 1) 112-128 and AM Honoré,'Property and Ownership' Marginal Comments' in T Endicott, J Getzler and E Peel (eds), *Properties of Law: Essays in Honour of Jim Harris* (Oxford, OUP, 2006) 31-35.
[225] Nwabueze, 'Legal Paradigms of human tissues' (n 24) 90.

criterion relates to 'full legal ownership' rather than 'property' and the line of enquiry that advocate for an 'intuitive, pragmatic and policy-based approach in distinguishing property rights from non-property rights, then the bundle of rights metaphor plus Kohler's exposition could represent a sound premise upon which to admit entitlements relating to excised biological material as property interests. However, while these entitlements might qualify as property interests under a normative understanding of property, it is another question whether they are enforced by law as legal property interests. This line of enquiry will be explored in the next chapter.

CHAPTER 3 LEGAL CHARACTERISATION: ARE SOURCE OWNERSHIP ENTITLEMENTS ENFORCED AS PROPERTY INTERESTS UNDER THE LAW?

The legal status of human biological material – Case Law

Outline

The courts have generally considered questions in relation to the status of ownership entitlements regarding excised biological material from a predominantly property based approach. The law has either approached the question from a reified perspective of property where it considers whether excised biological material constitute property (or whether a person has acquired a property right to the biological material in question); or from a 'bundle of rights' perspective of property where it seeks to determine whether the source of biological material has ownership entitlements in biological material at the time of excision or retain ownership entitlements in biological material following removal, that are akin to the collection of entitlements contained within a property right. [1]

However, where the court adopts a bundle of rights approach, it usually fails to conduct any substantive analysis of the particular nature of property rights; the type of entitlements or number of entitlements contained within a property right; and the reasons why an entitlement or a collection of entitlements regarding biological material constitute or do not constitute a property right.[2] In cases involving biological material removed from living persons, the courts generally acknowledge the existence of ownership entitlements in favour of individual sources of biological material but fail to admit these entitlements into the legal category of property, based on public policy reasons rather than a rationale based on established legal principles that considers for instance, whether the recognised ownership entitlements reflect the accepted characterisation of property.[3] For instance, in the

[1] *Moore v Regents of the University of California* [1990] (Moore SC) 793 P 2d 479 (Cal SC) [492].
[2] JE Penner, 'The "Bundle of Rights" Picture of Property' (1996) 43 UCLA L. Rev. 711, 718-9.
[3] See *Moore* SC (n 1) [490] and [492].

case of *Moore*[4] the court observed that the relevant statute eliminates so many of the rights that are normally attached to property but then went on to conclude that the residual interest does not amount to property, without any explanation as to why the residual interest fails to correspond with the characterisation of property.[5] The court's decisions have varied, depending on the public policy objectives of the particular legal system and the facts of the case before the court. However, while some of the public policy reasons relied upon by the court do reflect legitimate concerns, these concerns are usually not insurmountable and can generally be addressed by suitably crafted policy framework without having to exclude source ownership entitlements from the legal category of property.

The debate regarding whether entitlements in respect of biological material constitute a property right has garnered momentum since the Supreme Court of California's decision in the case of *Moore v Regents of the University of California*[6], which will be explored during the course of this chapter.[7] On the one hand, society considers that the human body is the 'single most venerated and protected subject in any civilised society and should not be treated with the basest of commercial commodity.'[8] On the other hand, medical researchers and their employers and biotechnology firms regard the human body as primarily an object of scientific investigation[9] and they consider biological material separated from it as valuable commodities to be studied and exploited for the furtherance of public health and profit. The difficulty in achieving a satisfactory balance between these two conflicting notions seem to have manifested into uncertainty in the legal framework of leading common law jurisdictions such as the United Kingdom (UK), the United States of America (USA) and Australia. In these jurisdictions, there remains a degree of uncertainty as to whether ownership entitlements regarding non-reproductive

[4] Ibid [499]-[502] (Broussard J, concurring and dissenting) and Ibid [509]-[510] (Mosk J, dissenting).
[5] Ibid [492].
[6] Ibid [494].
[7] J Wall, 'The Legal Status of Body Parts: A Framework' (2011) 31 OJLS 783, 783.
[8] *Moore SC* (n 1) [498].
[9] A Plomer, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* (Cavendish Publishing, 2005) 94.

biological material removed from living persons, could be admitted into the category of property and thus qualify as a property right ('property right' hereafter).[10] Furthermore, the courts have generally used the concepts of 'legal ownership' and 'property' synonymously[11] and in some cases, it has elided both terms and elected to use the language of 'ownership' for convenience.[12] However, as indicated in the previous chapter, ownership and property are separate concepts.

Although there have been cases where the courts decisions seem to indicate that a property right can be created in excised human biological material in limited circumstances[13], these cases do not represent a coherent body of jurisprudence in which to determine with certainty whether a property right can be claimed in a human body and biological material separated from it.[14] In the words of Grubb, 'there is no clarity on the central questions: first, does excised [biological material] fall within the property regime at all? Second, if it does, who is entitled to claim "property interests" in it? Is it the source or the remover?'[15] Furthermore, even in cases where a property right is recognised in the body in limited circumstances, this is usually done to the exclusion of the one person who is central to the entire enterprise, namely, the individual from whom the material is taken.[16] This observation seems to be reflected in the decision of the Supreme Court of California in the case of *Moore* where the court denied the claimant a property right in excised biological material removed from his body, the result of which was that the recipient researcher was able to retain the proceeds of research using the claimant's excised biological material. The court then observed during the course of its judgement that 'we do not purport to hold that excised cells can never be property for any purpose

[10] R Hardcastle, *Law and the Human Body: Property Rights, Ownership and control* (Hart; 2007) 12-13, 79.
[11] *Moore* SC (n 1) [492].
[12] *Yearworth and Others v North Bristol NHS Trust* [2009] EWCA Civ 37 [25].
[13] See *R v Kelly (1999) QB 621 (CA).*
[14] Hardcastle (n 10) 63.
[15] A Grubb, 'I, Me, Mine: Bodies, Parts and Property' (1998) 3 Medical Law International 299, 305.
[16] G Laurie, *Genetic Privacy* (Cambridge, CUP, 2002) 304.

whatsoever'.[17] The court's decision seems to support the inference that a property right may be granted in respect of all but the originator of biological material.

In leading common law jurisdictions, once biological material is excised from the living body, the common law generally proceeds on the assumption either that it has been abandoned by its original 'owner', or that it is and was always res nullius (an object belonging to no one).[18] Prior to the emergence of the modern biotechnology industry, it would have been presumed that the biological material was removed because it was diseased and consequently, of no value to its source. In such instances, a description of biological material as 'waste' will be appropriate, as asserted by Golde's lawyers in the case of *Moore* and accepted by the Californian Supreme Court in that case. However, with the commencement of modern biotechnology, the dynamic is significantly altered.[19] For example, in the above case, Moore's excised spleen was removed because it was over twenty times the normal weight. Ordinarily, it would have been considered to be waste because it has no use or value. However, due to the advent of biotechnology, researchers were able to create a valuable cell line from his spleen (at the time the matter went to court, the commercial value of the cell line was estimated as US $3 billion over a six-year period)[20]. Now, commercial researchers and biotechnology companies are able to make significant profits from research using biological material. As a result, excised biological material has become a valuable commodity and can no longer be conceivably described as waste in these circumstances.[21]

In order to provide a contextual framework for the legal position in respect of entitlements regarding excised biological material, it is necessary to take a closer look at the rationale behind the legal approach. Although the primary concern is

[17] *Moore* SC (n 1) [493].
[18] J McHale, 'Waste, ownership and bodily products' (2000) 8 Health Care Analysis 2, 123-135.
[19] D Dickenson, *Body Shopping – Converting Body Parts to Profit* (Oneworld, 2008) 26.
[20] Ibid, 26.
[21] Ibid.

with biological material separated from living persons, case law dealing with dead bodies and biological material separated from them has been outlined in the first instance. This is a useful starting point because the common law regarding excised biological material from living persons has developed against the backdrop of judicial decisions relating to dead bodies and even the limited cases that have considered material separated from living persons have usually considered the law relating to dead bodies as their starting point.[22]

Human biological material from the Dead

The accepted common law position regarding property rights in dead bodies and biological material separated from dead bodies is enshrined in the questionable 'no property' rule, which states that 'there is no property right in a dead body or parts of it as it has no use or value.'[23] Matthews, however, in his reified perspective-focused analysis of the no property rule, argued that a corpse could be classified as a physical object and therefore it could be admitted into the category of property and afforded the legal protection accorded to property.[24]

The no property rule has been heavily criticised in academic commentary and judicial opinions, both in terms of the principle that it espouses and its origins.[25] The rule is arguably out of touch with every day practice because the accepted language in practice that individuals donate (make a 'gift') of their biological material or 'abandon it' arguably presumes some property orientated concept for the individual

[22] See *Yearworth* (n 12).
[23] *Doodeward v Spence* [1908] 6 CLR 406 Aust HC; *Williams v Williams* [1882] 20 ChD 659.
[24] P Matthews, 'Whose Body? People As Property' (1983) 36 Current Problems 193.
[25] For a suggestion that the rule is likely to be the product of a misconception of the earliest cases dealing with grave robbing, which were primarily concerned with jurisdictional relationship between the ecclesiastical and civil courts, see RN Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (Ashgate Publishing, 2007) vii and 37. Also see PDG Skegg, 'Human Corpses, Medical Specimens and the Law of Property' (1975) 4 Anglo-American L Rev 412; PDG Skegg, 'The "No Property" Rule and Rights Relating to Dead Bodies' (1997) Tort L Rev 222; M PawLowski, Property in Body parts and Products of the Human Body' (2009) Liverpool L Rev 35, 36.

of 'ownership, possession, or at least implied transference'[26] and similarly, the language employed by relatives such as those involved in the Bristol and Alder Hey scandals[27] who claim that the body parts of their deceased children were stolen from them presupposes that they had some form of ownership entitlements in their children's body parts which qualifies as property interests since only property can be stolen.[28] The no property rule also appears to be bounded by unclear legal precedents.[29] For instance, in *Dobson v North Tyneside H.A.*[30], the court ruled that mere preservation of pathological or anatomical specimens by fixing would not constitute the specified change required to bring the specimens within the exception to the no property rule but in *Doodeward v Spence*[31], it was accepted that mere preservation of a foetus would bring the preserved foetus within the exception.[32] Nevertheless, despite extensive criticisms of the 'no property' rule, the rule is engrained in the law and has been accepted to reflect the legal position for decades. Rose LJ made this observation in *R v Kelly*[33] where his Lordship stated:

> We accept that, however questionable the historical origins of the ['no property'] principle, it has now been the common law for 150 years at least that neither a corpse nor parts of a corpse are in themselves and without more, capable of being property protected by themselves…If that principle is now to be changed, in our view, it must be by Parliament…[34]

[26] D Price, 'From Cosmos and Damian to Van Velzen: The Human Tissue saga Continues' (2003) 11 Med. L. Rev. 5, 26.
[27] See generally K Liddell, A Hall, 'Beyond Bristol and Alder Hey: the future regulation of human tissue' (2005) 13 Medical Law Review 170.
[28] M Brazier, 'Organ retention and return: problems of consent' (2002) 29 J.M.E 30, 32.
[29] See generally *AB and others v Leeds Teaching Hospital NHS Trust and another* (2004) E.W.H.C. 644 (QB); *R v Kelly* (n 13); *Dobson v North Tyneside H.A.* (1996) 4 All ER 474; *Doodeward v. Spence* (n 23).
[30] Ibid.
[31] *Doodeward v Spence* (ibid).
[32] Price (n 26) 136-7 discussing *Dobson* (n 29) and *Doodeward v Spence* (ibid).
[33] *R v Kelly* (n 13).
[34] Ibid, [630]-[31].

Parliament had the opportunity to address the criticisms surrounding the no property rule by reforming or clarifying the rule during the introduction of the *Human Tissue Act* 2004 but failed to take the opportunity.[35]

A substantial body of literature has been written about the difficulties associated with the no property rule and so more could be said on it,[36] but it is not necessary to outline that debate in great detail to achieve the objectives of this discussion. The debate is simply highlighted here to make the reader aware of the issues surrounding the legal principles that are invoked in determining the legal status of the body and biological material excised from the body.

However, in spite of the no property rule, the common law offered some protection in respect of buried and unburied bodies in unconsecrated grounds. Under the common law, it was a misdemeanour to prevent the burial of a corpse[37] and for that purpose the common law recognized a duty on executors, administrators and occupiers of buildings to bury a deceased person.[38]

In *Dobson v North Tyneside Health Authority*[39] and *R v Kelly*[40], the English Court of Appeal introduced an exception to the 'no-property' rule. The effect of this exception was that an application of scientific skill and labour on a corpse or a part of the corpse transforms it into an object of property capable of being owned or stolen. This exception is commonly known as the 'work or skill' exception. It was

[35] Liddell and Hall (n 27) 186-7.
[36] For further discussion of the difficulties with the no property rule, see R Taylor, 'Human Property: Threat or Saviour' (2002) 9(4) Murdoch University Electronic Journal of Law – <http://www.murdoch.edu.au/elaw/indices/issue/v9n4.html> accessed 19 June 2014. Matthews (n 35). RN Nwabueze, 'Death of the "No Property" Rule for Sperm Samples' (2010) 21 King's Law Journal 561; Brazier (n 28); Price (n 26).
[37] *R v Hunter* [1974] QB 95; Also see A Samuels, 'Whose Body is it anyway?' (1999) 39 Med. Sci. Law 285-286.
[38] *R v Stewart* (1840) 113 E.R. 1007.
[39] *Dobson* (n 29).
[40] *R v Kelly* (n 13).

initially devised in the Australian case of *Doodeward v Spence*[41]. The scope and nature of the property right created by the work or skill exception has itself been the subject of considerable discussion. The discussion is considered in some detail below and so we need not be detained by it at this point. It should simply be noted that like the 'no property' rule, the 'work or skill' exception to the no property rule is also plagued with significant problems, which seems to strengthen the observations made by critics that the rule should be abolished, modified or clarified.

The issue for consideration in *Doodeward* was the allocation of a right to possession in respect of a still-born two-headed foetus. Griffith CJ in delivering the leading judgment of the High Court of Australia observed that a human body or a portion of a human body is capable at law of becoming the subject of property.[42] Although, reluctant to provide an exhaustive enumeration of the circumstances under which such a right may be acquired, his Honour observed that when a person has by lawful exercise of work and skill so dealt with a human body or part of a human body in his lawful possession and the corpse has acquired some attributes differentiating it from a mere corpse awaiting burial, the person that carried out the work acquires a right to retain possession of the corpse.[43]

Griffith CJ also observed that for this exception to apply the initial possession of the dead body or part of it must be lawful,[44] and such possession must not be injurious to public welfare.[45] However, although the exception appeared to be a step in the right direction, in light of the extensive criticisms levelled at the 'no property' rule, Griffith CJ failed to provide an explanation as to why (as a matter of legal principle)

[41] *Doodeward* (n 23).
[42] Ibid [414].
[43] Ibid [414].
[44] Ibid [406]-[407].
[45] Ibid [413].

such work and skill creates a property right in the altered corpse or biological material from the corpse. [46]

The cases of *Dobson*[47]and *Kelly*[48] allowed the English Courts to examine the 'no property' rule in a modern context. In *Dobson*, the brain of a deceased woman had been removed during a post-mortem investigation and fixed in paraffin, pending further possible investigations, which were not carried out. The brain was sent to a hospital for storage but it later transpired that the brain had eventually been disposed. The claimants, who were relatives of the dead woman, brought an action against the defendants in relation to their entitlement to the brain. The claimants were unsuccessful on several grounds[49] but the relevance of this case lies in the section of the leading judgment of the Court of Appeal that highlights the English court's changing attitude towards the legal status of corpses and biological material removed from them. Peter Gibson LJ in delivering the leading judgment, and with whom Thorpe and Butler-Sloss LJJ agreed, considered that there were two qualifications to the 'no property' rule, namely, that executors, administrators and others charged by law with interring the body of a deceased person have a right to the custody and possession of it until it is properly buried, and also that biological material separated from a dead body may attain property status following the application of human skill.[50] On the facts, Peter Gibson LJ found that 'although a body or part of a body which had undergone a process or other application of human skill, such as stuffing or embalming, might constitute property, the lawful removal

[46] Hardcastle (n 10) 29.
[47] *Dobson* (n 29). See also the case of Cyril Mark Isaacs and the Isaac's Report which concerned the retention of a deceased man's brain for intended use in research without his family's knowledge, following a post mortem examination < The National Archives (Department of Health), 'The Death of Cyril Mark Isaacs':
<http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/browsable/DH_4881515> accessed 19 June 2014;
Department of Health, 'Isaacs Report-The Investigation of events that followed the death of Cyril Mark Isaacs': <http://www.tsoshop.co.uk/bookstore.asp?Action=Book&ProductId=011322611X> accessed 19 June 2014.
[48] *R v Kelly* (n 13).
[49] *Dobson* (n 29) [596]–[601].
[50] Ibid.

and preservation of a brain in the course of a post mortem examination did not transform it into an item to which the plaintiffs had a right of possession.'[51]

In the case of *Kelly*, Kelly (an artist) had persuaded Lindsay (a technician employed by the Royal College of Surgeons) to remove 40 human body parts from the College, all of which had been preserved or fixed by college staff involving hours and, in some cases, weeks of skilled work.[52] Kelly made use of the body parts in his work as an artist and used some of the parts to make casts which were exhibited in an art gallery.[53] Kelly and Lindsay were subsequently charged with theft under section 1 of the *Theft Act* 1968 and convicted.[54] They later appealed their conviction arguing that the body parts did not constitute property and so could not be stolen and that the Royal College of Surgeons was not in lawful possession of the body parts, therefore the body parts did not belong to the College.[55] Their appeal was dismissed.[56] Rose LJ delivered the judgment of the Court of Appeal (Ognall and Sullivan LJJ agreeing) and considered that despite the questionable origins of the 'no property' principle, only Parliament could change the law because of its entrenched nature. His Lordship held that since *R v Sharpe*[57], it has been express or implicit in all the subsequent authorities and writings that a corpse or part of it cannot be stolen. Rose LJ found, nevertheless that parts of a corpse are capable of becoming property within section 4 of the *Theft Act* if they have acquired different attributes through the application of skill such as dissection or preservation techniques for exhibition or teaching purposes.[58] His Lordship also cited the decision in *Doodeward* in support and observed that the Court of Appeal did not dissent from that decision in the case of *Dobson.* Rose LJ also seem to suggest another potential property creating exception to the no property rule when he held that in the future, untransformed body parts

[51] Ibid.
[52] *R v Kelly* (n 13).
[53] Ibid.
[54] Ibid.
[55] Ibid.
[56] Ibid.
[57] *R v Sharpe* 169 All ER 959.
[58] *R v Kelly* (n 13).

may be property if they have a use beyond their mere existence.[59] The importance of *Kelly* lies in the fact that it is the first case in which an English court has held that parts of a dead body may be 'property' under the common law.[60]

The work or skill exception was also considered in the case of *Re Organ Retention*[61]. The circumstances surrounding this case will not be outlined in great detail. Although the case is quite interesting since it encapsulates the scandal that triggered the introduction of the *Human Tissue Act* 2004[62](primary legislation considered in the present discussion), the case is only mentioned here with regard to its application of the work or skill exception. Consequently, the facts will only be discussed in terms of its relevance as it relates to the work or skill principle.

The case of *Re Organ* commenced following enquiries at the Bristol Royal Infirmary and Alder Hey Hospital, which brought to light long-term medical practice of the retention of biological material from children who were deceased without their parents' knowledge.[63] Proceedings were initiated by aggrieved parents, who claimed among other causes of action that the defendants had committed the tort of wrongful interference. Gage J found that the claimant did not state a cause of action for the tort of wrongful interference.[64]

The analysis undertaken in this section will be restricted to the claim relating to the tort of wrongful interference because it is in considering that claim that his Honour examined the issue of property rights in biological material and the work or skill exception. With regard to the tort of wrongful interference, the defendant asserted that they had acquired a property right to the excised biological material in question

[59] Ibid.
[60] A Grubb, 'Theft of Body Parts: Property And Dead Bodies' (1998) 6 Med Law Rev 247.
[61] *Re Organ Retention Group Litigation* [2004] EWHC 644; [2005] (QB) 506.
[62] *Human Tissue Act* 2004, 2004 Chapter 30 .
[63] *Re Organ Retention Group Litigation* (n 61).
[64] Ibid [259].

because firstly, they acquired the biological material lawfully since they had authorisation under statute and common law to remove biological material from deceased persons as part of post-mortem procedures; and secondly, the work that they had carried out on the biological material and the skill applied in carrying out that work fell within the work or skill exception espoused in *Kelly* and thus a property interest had been created in the excised biological material in question and this property interest was allocated to them as the applier of the work and skill. The relevant aspects of the defendants' contention include the nature of the interest created through the application of work and skill,[65] the degree of work or skill required in order for the work or skill exception to be applicable[66] and to whom should the property right in the altered biological material be allocated following the application of work or skill.[67]

With regard to the first strand of the defendants' argument, the defendants submitted that it was not necessary for the court to consider whether the possessory rights granted to them by statute and at common law amounted to an ownership interest and that a right to possession of property was sufficient for the legal action.[68] In advancing this view, they contended that the possessor must at least have a right to permanent possession of the property, and that the right of possession may differ little in substance from the right of an owner.[69] This contention was accepted by Gage J.

With regard to the second aspect of the defendants' argument, the defendants asserted that the application of skill through the pathological processes of selection, preservation and dissection of the biological material and the creation of tissue

[65] Ibid, discussed in Hardcastle (n 10) 35-36.
[66] Ibid.
[67] Ibid.
[68] Re Organ Retention (ibid) [128]-[129].
[69] Ibid, [137].

blocks was sufficient to invoke the work or skill exception.[70] In his discussion of the work or skill exception, Gage J noted that the work or skill exception had long been an established principle in English Law.[71] He considered that part of a body may acquire the character of property where that part has been the subject of skill such as dissection or preservation techniques.[72] Gage J concluded that the work and skill carried out in this case which involved dissecting and fixing an organ from a child's body and the production of blocks and slides using the excised organ was sufficient to fall within the exception.[73]

Regarding the third strand of the defendants' argument, Gage J invoked the opinion espoused in *Clerk and Lindsell on Torts*[74] that the property right vests in the person who modifies the biological material because they are the first possessor,[75] to indicate that the property right is allocated to the person that applied work or skill to the biological material.[76] However, he then appeared to imply that property rights might be vested in parents by suggesting that a parent may be entitled to claim the tort of conversion if, at the time that he consented to a post-mortem on his child, he specifically asked for the return of any excised organ from the child's body.[77] However, there is still some uncertainty as to the precise interpretation of this section of Gage J's judgement.[78]

Like the 'no property rule', the 'work or skill' exception is also problematic. For instance, the degree of 'skill' that has to be applied in order for the person applying the skill to acquire a possessory right (like *Doodeward*) or a property right in the

[70] Ibid, [148].
[71] Ibid.
[72] Ibid.
[73] Ibid.
[74] A Tettenborn, 'Wrongful Interference with Goods' in AM Dugdale (ed), Clerk and Lindsell on Torts (19th edition, London, Sweet & Maxwell, 2006) 1024.
[75] *Re Organ Retention* (n 61) [156]. Hardcastle (n 10) 37-38.
[76] Hardcastle (ibid).
[77] *Re Organ Retention* (n 61) [161]. Hardcastle (ibid).
[78] Hardcastle (ibid).

biological material (as in *Kelly*), is unclear.[79] Recently, the exception was criticised by the Court of Appeal in the case of *Yearworth and Others v North Bristol NHS Trust*[80], where the Court observed that the exception was not entirely logical.[81] Additionally, the nature and scope of the exception has not been clearly defined, specifically, the legal principle that underpins the exception.[82] Five questions remain unanswered. [83] These include: (1) is it necessary for there to be an intention to create a novel item, or is it sufficient that work or skill of some description is carried out on excised biological material?[84] (2) must there be an exercise of skill in addition to work being carried out or will work alone suffice?[85] (3) does the common law work or skill exception simply confer a right to possession on the applier of work or skill or does it vest in such persons, the same category of property right that the law recognises with respect to normal chattels?[86] (4) to whom is the property right vested?[87] (5) is the common law work or skill exception restricted to biological material excised from corpses, or is it also applicable to biological material separated from living persons?[88]

With regard to the first question, the tenor of the court decisions in *Dobson* and *Kelly* would appear to suggest that an intention to create a novel item is necessary.[89] For instance, the court in Kelly required that the body part should be altered for a special purpose.[90] But the court decisions in *Doodeward* and *Re organ Retention* do not support such a suggestion.[91]

[79] The Bristol Royal Infirmary Inquiry, *Interim Report: Removal and retention of human material* (The Bristol Royal Infirmary Inquiry, 2001) Annex B, Part III, 125.
[80] *Yearworth* (n 12).
[81] Ibid, [45]. For further analysis of the work or skill exception, see Hardcastle (n 10) 28-40 and 129-130.
[82] Hardcastle (ibid) 39.
[83] Ibid.
[84] Ibid.
[85] Ibid.
[86] Ibid.
[87] Ibid.
[88] Ibid, 39-40.
[89] Ibid, 129.
[90] Grubb (n 60) 250, cited in Hardcastle (ibid) 39.
[91] Hardcastle (ibid) 129.

Regarding the second question, in Re Organ Retention, Gage J referred to skill by itself and then to 'work and skill'.[92] However, if the exercise of skill is required in addition to the carrying out of work, it is unclear what degree of skill is required because in *Kelly*, Rose LJ referred to dissection and preservation techniques,[93] but such formulations do not afford a standard capable of universal application.[94] Whereas, in *Dobson*, Peter Gibson LJ suggested that fixing a body part in paraffin would not be sufficient to invoke the exception.[95]

In respect of the third question, *Clerk and Lindsell on Torts* suggest that excised biological material could be considered the subject of property rights in the ordinary way,'[96] but *Doodeward* seems to suggest otherwise as Griffith CJ in *Doodeward* referred only to 'a right to retain possession of [the body]'[97] and 'a permanent right to possession,'[98] which indicates that the applier of work or skill is simply granted possessory rights and not the category of property rights that the law recognises in ordinary chattels. Furthermore, the court's judgement in *Re Organ Retention* talked of proprietary and possessory rights[99] but *Kelly* failed to address this question.

In addressing the fourth question, there are several possibilities.[100] With regard to biological material excised from a living person, a property interest could be granted to the originator or source of the material; in the case of material removed from a corpse, a property interest could be vested in the family of the deceased, the individual who alters the biological material, or the employer of the individual who alters the biological material.[101] If the opinion espoused in *Clerk and Lindsell on Torts*

[92] *Re Organ Retention* (n 61) [257]; Hardcastle (ibid).
[93] *R v Kelly* (n 13) [631].
[94] Hardcastle (n 10) 39.
[95] *Dobson* (n 29) [601]. Hardcastle (ibid).
[96] Tettenborn (n 74) 1024, cited in Hardcastle (n 10) 39.
[97] *Doodeward* (n 23) [414]. Hardcastle (ibid).
[98] Ibid.
[99] *Re Organ Retention* (n 61) [161].
[100] Hardcastle (n 10) 39.
[101] Ibid.

was accepted where it was suggested that the property right would vest in the person who alters the body parts on the basis that they are the first possessor,[102] and the ruling in *Kelly* where the court held that property rights should be allocated to the person (or the employer) who performed the work or skill, it could be inferred that the property right might be allocated to the applier of work or skill or their employer.[103] In *Re Organ Retention*, even though the statement in Clerk and Lindsell on Torts[104] was approved, Gage J appeared to imply that in certain circumstances property rights could be acquired by (or transferred to) a family member,[105] thus indicating that it is no way settled that the property rights in the altered biological material is vested in the applier of work or skill.[106]

With regard to the fifth and final question, in *Kelly*, Rose LJ simply referred to 'human body parts',[107] and in Re Organ Retention, Gage J also suggested that 'part of a body may acquire the character of property.'[108] However, because both these comments were made in the context of biological material excised from corpses, it would be unwise to assume that the exception extends to living person, albeit, that in principle, there is no reason why the common law exception should be confined to biological material removed from dead bodies.[109] Furthermore, the Court of Appeal's forceful criticism of the work or skill exception in *Yearworth* and their refusal to base their reasoning on the work or skill exception or extend the scope of the exception to sperm removed from living persons[110] seems to indicate that the work or skill exception is restricted to biological material removed from dead bodies and that it cannot be applied to biological material excised from living persons.

[102] Tettenborn (n 74) 1024, cited in Hardcastle (ibid).
[103] Ibid.
[104] *Re Organ Retention* (n 61) 156; discussed in Hardcastle (ibid).
[105] Ibid.
[106] Ibid.
[107] *R v Kelly* (n 13) [631]. Hardcastle (ibid) 40.
[108] *Re Organ Retention* (n 61); Hardcastle (ibid).
[109] Hardcastle (ibid).
[110] *Yearworth* (n 12) [45].

The apparent inconsistencies in the application of the work or skill exception and the uncertainty illustrated by the questions raised in respect of the principle demonstrate that the legal principle, upon which the work or skill exception is formulated, has not been adequately identified or articulated.[111] The development of the work or skill principle depends on recognition of a clear and concise underlying principle and without such a principle; the work or skill exception cannot develop in a coherent manner.[112]

A number of possible underlying principles for the work or skill exception could be distinguished. These principles will not be considered in great detail. For the objectives advanced here, it is sufficient to simply note that legal scholars have suggested that the exception represents an invocation of the 'first possession' principle.[113] The 'first possession principle' or 'first occupancy' justification of private property suggests that the first person to occupy some previously unoccupied resource should be its owner.[114] By this reasoning, once biological material is excised from the body, it is not owned by anyone until taken into possession by someone and the first person to take possession of the excised biological material is entitled to property rights in it. However, the specification doctrine provides a more logical explanation of the work or skill exception than the first possession principle.[115] Although as Hardcastle notes, the work or skill exception is arguably a 'misguided application of the specification doctrine because often the work performed [to invoke the work or skill exception] is for preservation purposes and does not result in creation of a new thing'[116] but the specification doctrine, a derivative of the Roman

[111] Hardcastle (n 10) 40.
[112] Ibid.
[113] Tettenborn (n 74) cited in Hardcastle (ibid); Grubb (n 60) 312; Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (Nuffield Council on Bioethics London, 1995) para [9.11]. For a detailed discussion of the 'first possession principle', see Hardcastle (n 10) 130-131.
[114] AJ Simmons, 'Original Acquisition Justifications of Private Property' in EF Paul, FD Miller and J Paul, (eds), *Property Rights* (Cambridge, CUP, 1994) 63. Also see Hardcastle (n 10) 130-131.
[115] For a comprehensive analysis of the specification doctrine, see Hardcastle (ibid) 130-143.
[116] Ibid, 142.

law principle of *specificatio*, applies when new things are produced or brought into existence.[117]

The difficulties with the work or skill exception is compounded by the fact that the exception has been given statutory force through the HTA 2004[118] and this is exacerbated by the possibility that the codification in the HTA 2004 may be broader than the common law formulation of the exception.[119] The court in *Kelly*, for instance, referred to body parts acquiring different attributes by virtue of the application of skill.[120] However, section 32(9) (c) of the HTA 2004 instead refers to 'material, which is the subject of property because of an application of human skill'.[121] Section 32(9) (c) of the HTA 2004 does not refer to the additional requirements mentioned in the relevant case law such as the acquisition of different attributes or the creation of a new item.[122] Under the statutory formulation, the simple application of human skill would appear to suffice.[123]

Human biological material from the Living

The recognised common law position regarding the legal status of the living body and biological material separated from it seem to be that an individual does not have a property right in his body or separated biological material from his body.[124] The common law, however, appears to compensate for this rule by devising an elaborate set of rules to protect the body and bodily autonomy[125] and to allow individuals to authorise the removal of their biological material for certain specified purposes, namely, medical or scientific purposes (management entitlement). The

[117] B Nicholas, *An Introduction to Roman Law* (Oxford University Press, Revised edn, 1975) 136.
[118] *Human Tissue Act* 2004 (n 62) s 32(9)(c). See Hardcastle (n 10) 129.
[119] Ibid.
[120] *R v Kelly* (n 13) 631. Hardcastle (ibid).
[121] *Human Tissue Act* 2004 (n 62) s 32(9)(c). Hardcastle (ibid).
[122] Hardcastle (ibid).
[123] Ibid.
[124] *Moore* SC (n 1) [492].
[125] *Yearworth* (n 12) 30.

recipients in turn (that is, hospitals and medical researchers) have a right to possess and use the donated body or bodily material in accordance with the authorisation given by the donor. This management entitlement is not generally regarded as a legal property right, rather it is granted to an individual under consensual frameworks contained within the *Human Tissue Act* 2004.

There is currently no common law authority in England or Australia that directly analyses whether an individual can claim a property right in non-reproductive biological material removed from his or her body.[126] However, the recent case of *Yearworth and Others v North Bristol NHS Trust*[127] is worth mentioning. Although the case specifically considers the issue of property in excised reproductive biological material, namely, semen, which falls outside the scope of this discussion, a brief outline of the case is useful because it has been suggested that the decision in the case indicates a possible change of judicial attitude regarding the question of individual property rights in excised non-reproductive biological material.[128]

In *Yearworth*, the English Court of Appeal ruled that a group of men who had produced samples of their semen for storage had property rights in their stored semen because the men had two categories of ownership entitlements which were safeguarded by the *Human Fertilisation and Embryology Act* 1990[129]. These entitlements include management[130] and use entitlements[131] in their semen. The men had been diagnosed with cancer and due to the potentially damaging effect of chemotherapy on their sperm; they were advised before undergoing chemotherapy to produce samples of their semen for storage, which they could then use at a later date. The court observed that it would not be prudent to base the common law in

[126] For cases that indirectly explore the question of individual property right in respect of excised biological material, see *DPP v Smith* [2006] EWHC 94, *R v Rothery* [1976] Crim LR 691 (CA).
[127] Ibid.
[128] See M Quigley, 'Property: The Future of Human Tissue? (2009) 17 Medical Law Review 457, 461-462.
[129] *Human Fertilisation and Embryology Act* 1990 c.37.
[130] Yearworth (n 12) [45(f)].
[131] Ibid.

respect of property in excised biological material from a living person on the 'work or skill' principle, which was devised as an exception to the 'no property' principle, itself of exceptional character, relating to the ownership of a human corpse.[132] The court rejected the 'work or skill' principle as an adequate basis for granting property rights in excised biological material and observed that the distinction contained within the principle between tissue that have become subject of property rights and those that have not, was 'not entirely logical'.[133] The court further considered that 'developments in medical science require a re-analysis of the common law's treatment of and approach to the [question of property] in parts or products from the body of the living'.[134] Whilst, it is arguable that the principle upon which the court's judgement was formed is potentially applicable to biological material, other than gametes, such as human tissue and solid organs, such an inference must be drawn with caution because this was not made clear in the court's judgement.[135]

Quigley observes:

> …it is not altogether clear what the implications of the judgement are for wider considerations involving the use of human tissue. The reasoning employed by the Court could logically be extended to apply to bodily tissues other than gametes and indeed whole organs and body parts, but it remains to be seen whether members of the judiciary will follow suit if relevant cases come before them. It could be that gametes are seen as a special type of tissue which compelled their Lordships to try and seek adequate remedy for the men.[136]

Developing the above view, it is possible that their Lordships in *Yearworth* considered gametes and the facts surrounding this case so unique as to compel them to grant a remedy to the plaintiffs. Their Lordships could have felt compelled to grant a remedy because of the potential long term consequences that the hospital's

[132] Ibid.
[133] Ibid.
[134] Ibid.
[135] Quigley (n 128).
[136] Ibid.

mistake could have upon the men. In particular, the possibility that the men may never father a biological child because at the time that their frozen sperm was irreversibly damaged due to the failure of the hospital system, they had already undergone chemotherapy and, consequently, they had no way of replacing the damaged sperm with sperm unaffected by chemotherapy. The hospital's mistake in this regard therefore potentially infringes the men's human rights, specifically, the men's right to start a biological family of their own/right to parenthood. This can be contrasted with excised non-reproductive biological material where researchers generally use diseased tissue leftover after treatment or regenerative tissue,[137] and consequently, the source of the biological material in those instances is unlikely to suffer the potential long term detriment that the claimants in *Yearworth* are likely to suffer.

There is an absence of subsequent English case law to confirm whether the courts will apply the approach taken in *Yearworth* to cases involving biological material, other than gametes. The Australian case of *Kate Jane Bazley v Wesley Monash IVF Pty Ltd,*[138] which was decided after *Yearworth* was also raised in the context of semen and did not confirm a wider application beyond excised reproductive biological material. Consequently, the established position set out in the US case of *Moore*[139], which triggered this enduring debate[140] will be taken to reflect the common law's position.

[137] TP Dillon, 'Source Compensation for Tissue and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits' (1989) 64 Notre Dame L. Rev 628, 639; Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (Nuffield Council on Bioethics (11 October 2011) 36-38; DM Gitter, 'Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material' (2004) 61 Wash. & Lee L. Rev. 257, 299, 313.

[138] *Kate Jane Bazley v Wesley Monash IVF Pty Ltd* [2010] QSC 4 118 (considered the legal status of entitlements to sperm of a deceased man, deposited before his death. Although dealing with the sperm removed from a deceased person, see *Jocelyn Edwards: Re the Estate of the Late Mark Edwards* [2011] NSWSC 478.

[139] *Moore SC* (n 1) [494].

[140] Wall (n 7) 783.

The judgement in *Moore* will be explored in great detail in this discussion because it was the first and remains the principal common law authority to address the question of whether or not a living person can claim property rights to biological material separated from his body.[141] In addition, the judgement in *Moore* sets out the relevant issues and schools of thought surrounding the debate that is explored in this discussion. Although the case of Moore is a US decision and the judgement is only binding in California because it was a decision of the Supreme Court of California, the issues discussed in the case are reflected across common law jurisdictions including the UK and the decision in the case has been quite influential in shaping policies and attitudes to sources of biological material and has been applied in subsequent cases. For instance, since *Moore*, individuals who supply biological material for research have been generally regarded as 'donors' and their supplied specimen have been largely treated as 'gifts' by the medical and scientific community.[142]

In *Moore*, the plaintiff, John Moore, sued five defendants stating thirteen grounds of action, including an action for breach of fiduciary duty and for the tort of conversion in respect of the appropriation of property rights in his spleen. The five defendants had some connection to the research that led to the development of the plaintiff's spleen into a patented and profitable cell line. Of the five defendants, the first defendant was Dr Golde, Moore's physician. Moore consented to the removal of his spleen for therapeutic purposes following advice from Dr Golde that the removal of the spleen was clinically necessary in Moore's treatment for leukaemia. However, Dr Golde later used it to develop a patented and profitable cell line, which falls outside the scope of the original consent given by Moore. At no stage did Golde seek Moore's consent or inform Moore of his intention to conduct further research on the spleen. Moore's spleen was valuable because it produced unusually large quantities

[141] Hardcastle (n 10) 69.
[142] See for instance *Washington University v Catalona* [2006] 437 F Supp 2d 985 (USDC Ed Mo 2006) (Catalona); 490 F 3d 667 (8th Cir 2007) (Catalona CA); Also, see Gitter (n 137) 262; C Harrison, 'Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue' (2002) 28 Am. J.L. & Med 77, 77-78.

of T-lymphocytes (white blood cells controlling the production of lymphokines, proteins which regulate the immune system). Isolating the genetic 'blueprints' from Moore's tissue would enable researchers to manufacture lymphokines for both research and therapeutic purposes and the cell line could produce unlimited quantities.[143] Moore's primary aim was to acquire a share of the profit derived from the cell line developed from his excised biological material.[144] He brought the conversion claim in an attempt to acquire a share of the profits from the cell line and, thus, claim back the content of his purported income entitlement.[145]

The Superior Court only considered the validity of the conversion claim. Demurrers were sustained by the Superior Court and Moore appealed to the Californian Court of Appeal. A majority of the Court of Appeal found in Moore's favour and held that Moore had property rights in his excised biological material sufficient to maintain the cause of action for conversion. The majority opined that policy considerations regarding the perceived potential threat to medical research were the major obstacle to the recognition of individual property right in the body. In finding in Moore's favour, the majority considered that 'if this science has become for profit, then we fail to see any justification for excluding the patient from participation in those profits.'[146]

However, the Californian Court of Appeal's decision was subsequently overridden by a majority of the Californian Supreme Court. The majority (Lucas CJ, Panelli, Eagleson, Kennard and Arabian JJ; Broussard and Mosk JJ dissenting) held that Moore had a cause of action for lack of informed consent because Golde failed to obtain Moore's informed consent to further procedures carried out after Moore's spleen was removed. The court considered that Moore was entitled to know about Golde's research and economic interests in the spleen when he [Moore] was making

[143] Dickenson (n 19) 24.
[144] See generally *Moore* (n 1); See also *Yearworth* (n 12) [39]; Wall (n 7) 794 n 63.
[145] Ibid.
[146] *Moore v Regents of the University of California* [1988] 202 Cal. Rptr. 494 [537].

his decision about whether to give or withhold consent to the extraction of his spleen. The court also found in favour of Moore for a breach of fiduciary duty. However, the court held that Moore did not have a cause of action in the tort of conversion. The court focused mainly on policy reasons in rejecting Moore's claim for conversion.

Before proceeding to outline their judgment, the majority first noted that no reported judicial decision supports Moore's claim, either directly or by close analogy because no court had previously used the tort of conversion in respect of human cells in medical research.[147] In light of that observation, the majority identified two questions for consideration: (1) did the tort of conversion give Moore a cause of action under existing law? (2) if not, would an extension of the tort of conversion be justified?

The majority opined that for Moore to succeed under existing law, he would need to have retained a property interest in his cells following their removal. The majority subsequently found that Moore had not retained a property interest in his cells following their removal because laws governing such things as biological material dealt with them as sui generis.[148] In addition, the majority pointed out that Californian statutory law (Health and Safety Code, section 7054.4) drastically limits a patient's control over excised cells by restricting how the cells may be used and requiring their eventual destruction. This limitation, the majority argued, eliminates so many of the rights ordinarily attached to property to the extent that the residual interest does not amount to property for purposes of conversion law.[149] In advancing their argument as to why Moore has no cause of action under existing law, the majority considered that the patented cell line and products derived from it cannot be Moore's property because the cell-line was both factually and legally distinct from

[147] *Moore SC* (n 1) [487].
[148] Ibid, [489].
[149] Ibid, [491].

the cells taken from Moore's body. In addition, they found that Moore's claim over the cell line was inconsistent with the patent, which constituted an authoritative determination that the cell line was the product of invention.[150] The majority's contention in this regard is questionable because the majority should have separated the question of rights as between the biological material and the cell-line and in so doing, clarify the different questions relating to each.[151] A cell-line is arguably a new item created from the original biological material and so any rights pertaining to the cell-line are not inhibited by a source's underlying property rights or non-proprietary rights to the original biological material.[152]

In addressing the second question, the majority provided three reasons as to why an extension of liability would be inappropriate: (1) a balancing of policy considerations counsels against extending the tort; (2) any such extension would be more appropriately achieved by legislative intervention, not judicial activism; and (3) the tort was not necessary to protect patients' rights.[153]

The tenor of the majority's judgment suggests that, of the three reasons outlined above, policy reasons were their primary concern.[154] In examining the relevant policy considerations, two main issues were outlined, which include, the protection of a competent patient's right to make autonomous medical decisions which is grounded in the established principles of fiduciary duty and informed consent and the threat of civil liability to researchers and hindrance to research. The majority acknowledged that although the first policy consideration would be promoted, albeit indirectly, by recognising a conversion cause of action; the second policy consideration weighed heavily against providing such a remedy because of the importance of human biological material in medical research and ultimately, the crucial role of research

[150] Ibid, [492].
[151] Hardcastle (n 10) 67 – 68.
[152] Ibid.
[153] *Moore SC* (n 1) [493].
[154] Ibid [494].

products in advancing public health. The majority asserted that the second policy consideration instead supports a judicially crafted limitation on a patient's right to sue anyone involved in medical research activities for conversion of his biological material.[155] In advancing their reasoning, they pointed out that the first policy consideration was adequately protected by the principles of fiduciary duty and informed consent and so it was not necessary to extend the law of conversion to this end.

Regarding the second policy reason, the majority considered that scientific research could be hindered both by restricting access to the necessary raw material and by destroying the economic incentive to conduct medical research.[156] They asserted: 'human cell lines are routinely copied and distributed to other researchers for experimental purposes, usually free of charge…This exchange of scientific material will surely be compromised if each cell becomes the potential matter of a law suit'.[157] However, the majority's argument is weakened by the obvious fact that the only reason why the defendant, Golde, patented the cell line is to prevent free and unfettered use of the cell line without payment under licence since that is the whole point of taking out a patent on an 'invention'.[158] On the one hand, they deny the plaintiff a remedy in conversion in order to protect medical research, however, their approach actually encourages greed in the biotechnology industry and makes researchers less likely to share samples because: why should a researcher share a sample that could potentially make him significant profits?[159] This could ultimately slow down biotechnological research because it encourages researchers to commodify tissues, immune from potential civil actions from sources of biological material.[160]

[155] Ibid [493].
[156] Ibid.
[157] Ibid.
[158] Dickenson (n 19) 32.
[159] L Andrews, interviewed in R Skloot, 'Taking the least of you' New York Times Magazine, (New York, 16 April 2006) 42: <http://www.sjsu.edu/philosophy/docs/Lotts_article_by_Skloot.pdf> accessed 19 June 2014.
[160] Ibid.

A different view might hold that the way forward is not to advance source private property rights, but rather, researchers' rights should be changed to the extent that property interest in respect of excised human biological material should vest only in the State. The State could permit researchers to use such material in research and award a monetary bonus to researchers who make medical discoveries and sources of biological material who facilitate such discoveries.[161] However, this view is arguably unrealistic because the promotion of private interests is firmly entrenched in biotechnological research and the long established patenting framework is designed to encourage and promote private, not public, interests. Also, biotechnological research is mostly conducted in the private/commercial sector which inherently promotes private interests.[162] Furthermore, some sources of biological material might object to such a system on the grounds that the government will be given too much control in such instances and will not necessarily exercise such control in their best interests and they might also consider it disrespectful on moral, cultural or religious grounds for their body or excised biological material to be treated as state property.[163]

The majority also considered that the economic incentive to conduct medical research would be destroyed; both as a result of the need to share profits with patients and uncertainty over title to biological material once the researcher took possession of them. However, the majority's concern in this regard does not appear to be an especially compelling consideration: even to the extent that it is a possibility, it is not inevitable and could be prevented. The remedy surely lies in an effective system of regulation that seeks to govern profit sharing arrangements and promote clarity during transactions that involve the transfer of title in excised biological material. For instance, if a person has a legally protectable property right in his or her excised biological material, he or she could transfer the right by way of a gift or in return for a share of profits from research enterprise. Since property rights

[161] J Boyle, 'To Pay or Not to Pay, That is the Question: Finding an intermediary solution along the Moore Spectrum' (2002) 7 Journal of Medicine & Law 55, 72.
[162] Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 137) para 67.
[163] Boyle (n 161).

have traditionally been regulated to achieve certain policy objectives, the source's ability to claim the content of his purported right to income in excised biological material could be regulated so that the percentage of profits to be paid by researchers to the source of biological material could be prescribed in statute. It could, for instance, be a fixed percentage or a flat amount that takes account of the average profits made in biotechnological research enterprise and is not so high as to destroy the economic incentive to conduct medical research, but sufficient enough to incentivise individuals to contribute their biological material for use in research enterprise. The offer of financial reward might actually increase the availability of material for use in research because it could act as an incentive for less selfless members of the public who are not particularly concerned about the common good of research to supply their biological material for use in research enterprise.

Although it is clear from the tenor of the majority's opinion that their principal concern was preventing hindrance to research from any further civil action like Moore's, one judge siding with the majority, Justice Arabian did express his fears about the implications that a marketplace in body parts could have upon human dignity. However, he went on to concede that a legislative response creating a licensing scheme that establishes a fixed rate of profit sharing between researcher and subject would avoid the moral and philosophical objections to a free market operation in biological material and address stated concerns by eliminating the inherently coercive effect of a waiver system and by compensating donors regardless of temporal circumstances.[164] Additionally, Justice Broussard, in dissenting from the majority's opinion aptly observed that concerns relating to the effect of a market place in body parts upon human dignity are less than compelling reasons to refuse the source of tissue property rights in tissue because refusing a source property right does not prevent the body from being commercialised but rather, it prevents the source of the tissue from benefiting from the economic value of the tissue and allows the recipient to retain and exploit the economic value of the tissue.[165]

[164] *Moore* SC (n 1) [498] (Arabian J).
[165] Ibid, [506].

Similarly, Herring asserts:

> However high minded the arguments against bodies being commercialised, they are out of touch with reality. Bodies are being commercialised whether we like it or not. In the western world, biotech scientists and their employers make large sums of money through research on parts of bodies. Why should they make all the gains from the body parts and not the people from whom the samples originated?[166]

Justice Mosk conveyed a persuasive dissent that significantly undermines the majority's opinion. His opinion will be outlined in great detail because it encapsulates the school of thought that rejects the majority's approach. Justice Mosk's argument derives its strength from its careful and comprehensive examination of the majority's assertions and concerns. It provides practical options that could be invoked to address and prevent the majority's concerns from being realised in practice. In so doing, Justice Mosk demonstrates that the majority's concerns are not inevitable where the originator of biological material is granted a legally protectable property interest that allows him to share in the proceeds of research.

In his dissent from the majority's opinion, Justice Mosk rejected both conclusions made by the majority, namely that Moore had no claim for conversion under existing law because he did not retain a property interest in cells following their removal from his body and that the law of conversion should not be extended to the context depicted by Moore's case.

[166] J Herring and PL Chau, 'My body, your body, our bodies' (2007) 15 Medical Law Review, 34-36.

In analysing the majority's assertion that Moore had no claim for conversion under existing law, Justice Mosk observed that past judicial decisions neither supports nor rejects Moore's claim.[167] Secondly, he observed that Californian statutory law as reflected in section 7054.4 of the Health and Safety Code restricts use of excised body parts and tissue to 'scientific use' and requires eventual destruction of such biological material. By his reasoning, the definition of 'scientific use' does not include commercial exploitation of Moore's excised cells and even if commercial exploitation is permitted, the section does not support the majority's conclusion that the statute eliminates so many of the rights attached to property, to the extent that what remains does not amount to 'property' for purposes of the law of conversion.[168] In developing this point, Justice Mosk pointed out that the concept of property under the common law is extremely broad and refers to a bundle of rights and also that the rights contained within the bundle of rights vary depending on the form of property.[169] Furthermore, he observed that the law limits or forbids the exercise of certain rights over certain forms of property for various policy reasons but while the limitation or prohibition diminishes the bundle of rights that would otherwise attach to the property, what remains is still deemed in law to be a legally protectable property interest.[170] By his reasoning, even if it is assumed that section 7054.4 restricts the use and disposition of Moore's excised tissue in the manner claimed by the majority, Moore nonetheless retained valuable rights in that tissue, which qualify for admission into the category of property.[171]

With regard to the majority's assertion that Moore had no claim for conversion under existing law because the patented cell line is factually and legally distinct from the cells taken from Moore's body, Justice Mosk considered that this assertion does not withstand critical scrutiny. He argued that it is irrelevant whether the cell line was factually distinct because the relevant issue for consideration was whether

[167] *Moore* SC (n 1) [508].
[168] Ibid.
[169] Ibid [509].
[170] Ibid, [510].
[171] Ibid, [510].

Moore's original excised tissue was property.[172] Furthermore, in contrast to the majority's opinion, he observed that the law of patents would not hinder Moore from asserting a property interest in his excised tissue and their products because the relevant question was the legal status of the excised tissue at the time it was removed from Moore's body.

In respect of the majority's conclusion that the law of conversion should not be extended to the context typified by the case of Moore, Justice Mosk observed that the majority's main policy concern was the potentially disabling civil liability for researchers.[173] He opined that with proper record keeping, a researcher can obtain the information that he needs precisely in order to avoid litigation.[174] He also considered that there has already been a drastic reduction in the formerly free access of researchers to new cell lines and other products since biological products of genetic engineering became patentable and since human cell line became amenable to patent production.[175] Consequently, it would be disingenuous for the majority to invoke the potential reduction of biological material as a reason to deny individual property right in excised biological material.[176] Essentially, there is already a reduction in the availability of material in spite of the rejection of individual property right, so acknowledging individual property right is unlikely to result in any significant further reduction in the availability of biological material for research. He also observed that the majority's single policy concern is outweighed by two policy considerations that are promoted by recognising that every individual has a legally protectable property interest in his or her own body and its products. In his view, these contrasting considerations include first, the fact that the dignity and sanctity with which society regards the human whole, body as well as mind and soul, are absent when research with human cells result in significant financial gain for researchers and no financial benefit for the source of biological material; and

[172] Ibid, [511].
[173] Ibid, [513].
[174] Ibid, [513].
[175] Ibid.
[176] Ibid.

secondly, the fact that preventing the source from sharing in the proceeds of research unjustly enriches the researcher, which is contrary to society's much valued rule of fundamental fairness in dealings between its members.[177] By his reasoning, the researcher is unjustly enriched because although both parties have made contributions to the enterprise, only the researcher's contribution is recognised.[178] The patient's input includes the contribution of tissue with unique attributes and without this contribution, the medical value of the bio-engineered cells would be negligible.[179] Similarly, without the researcher's contribution of knowledge and skill in developing the tissue, the commercial value of the patient's tissue would equally be negligible.[180]

With regard to the majority's assertion that the issues raised in Moore's case are adequately addressed by the traditional duties of fiduciary duty and informed consent, Justice Mosk found that these causes of action are unlikely to be successful in most cases.[181] Additionally, the principles of fiduciary duty and informed consent only address issues relating to the nature of a doctor's duty of care in treating his patient and thus, an issue regarding the use of biological material after treatment has been completed falls outside the scope of that duty.[182] To illustrate this point, in order to discharge a duty of care under the principle of informed consent, a doctor is only required to notify the patient of the nature and extent of risks attributed to a particular procedure but he is not required to notify the patient of the subsequent uses of any excised biological material.[183] Furthermore, the fiduciary duty requires a doctor to put his patient's interests above his own and offers a patient protection from a doctor who acts improperly but it does not offer the patient protection from researchers, or biotechnology firms who do not owe the patient a fiduciary duty.[184]

[177] Ibid.
[178] Ibid.
[179] Ibid.
[180] Ibid.
[181] Ibid.
[182] Hardcastle (n 10) 68.
[183] Ibid.
[184] L Andrews and D Nelkin, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (New York, Crown, 2001) 31.

In this connection, the doctrines of fiduciary duty and informed consent fail to protect a patient's right to share in the proceeds of the commercial exploitation of his or her biological material and potentially allow the true exploiters to escape liability and consequently, both doctrines are not an adequate substitute for the conversion claim.[185]

However, in the UK, although a patient might be unable to successfully claim civil remedies for breach of fiduciary duty and lack of informed consent for subsequent uses of biological material after treatment is finished, a doctor/researcher who uses a patient's tissue for commercially valuable research without previously disclosing such research and economic interests to the patient may be subject to regulatory action brought by the Human Tissue Authority.[186] This is because the Human Tissue Authority's code of practice on consent requires that researchers disclose commercial uses of biological material to the individual from whom the material was removed and the code of practice also requires researchers to disclose the range of activities and researchers that may be involved in using the biological material, including commercial establishments.[187]

Arguably, the source of tissue whose contribution made the biotechnological research enterprise possible should be justly compensated so as not to offend the public sense of justice and in so doing, potentially instigate a state of affairs that might reduce the supply of biological material for research.[188] This argument is examined in more detail in part II of chapter 4.

[185] *Moore SC* (n 1) [515] [Mosk J].
[186] *Human Tissue Act* 2004 (n 62) s28. Also, see Human Tissue Authority, *Code of Practice 9: Research* (Human Tissue Authority, 2009) para 9. <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm> accessed 19 June 2014.
[187] Human Tissue Authority, *Code of Practice 1: Consent* (Human Tissue Authority, 2009) para 149 <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?FaArea1=customwidgets.content_view_1&cit_id=667&cit_parent_cit_id=652> accessed 19 June 2014.
[188] TH Murray, cited in *Moore SC* (n 1) [510] (Mosk J dissenting].

The cases of *Greenberg v Miami Children's Hospital Research Institute*[189] and *Washington University v Catalona*[190] relied on the majority's opinion in *Moore*, although the reasoning in *Catalona* represents a slight distortion of the majority's opinion.

In *Greenberg*, parents of children who had been affected by Canavan disease brought proceedings against a researcher, Dr Matalon and the hospital that employed him. The respondents had developed and patented a test for the Canavan disease. The plaintiffs stated several causes of action, including the tort of conversion. The plaintiffs had approached the researcher to engage in a collaborative effort to identify the genes responsible for the Canavan disease so that a test could be developed that would detect carriers of the disease. The plaintiffs invested financially in the enterprise and they also invested their time and effort by locating other families with the disease and encouraging those families to provide biological material and financial resources. The enterprise was successful, the relevant gene was isolated and a test was developed. However, the researchers subsequently obtained a patent for the gene coding for the disease, the diagnostic screening methods and kits for carrier and antenatal testing without informing the family or requesting their consent. This patent empowered the researchers to charge a royalty fee every time the test was conducted. The families had not wanted a charge associated with the test and wanted it to be freely available to anyone who required the test.[191]

Like the majority in the case of *Moore*, Moreno J dismissed the conversion claim in the case of *Greenberg* because he considered that the plaintiff did not have property

[189] *Greenberg v Miami Children's Hospital Research Institute* [2003] 264 F Supp 2d 1064 (US DC Florida). Although Greenberg was commenced in the US District Court for the Northern District of Illinios, it was transferred to the US District Court for the Southern District of Florida on 8 July 2002 - Hardcastle (n 10) 71.
[190] *Washington University v Catalona* (n 142).
[191] *Greenberg* (n 189) [1066].

rights in the biological material or genetic information in question.[192] Moreno J found that a donor had no property right in biological material once he donates the material. Moreno J also held that once blood and tissue samples are voluntarily given to a third party, property rights in those material cease to exist.[193] However, presumably, for there to have been a transfer of a property right to a third party recipient, the right must surely have initially vested in the source of the material, and then on donation of the material, the property right is then transferred to the third party recipient.[194] Moreno J considered that another reason why the plaintiff did not have a property interest in the biological material in question is that the patented research was factually and legally distinct from the excised biological material.[195] Moreno J then went on to conclude that individuals cannot be recognised as having property rights in biological material because recognising such rights would threaten the survival of medical research as it would give donors a continuing right to possess the results of any research conducted by the recipient hospital.[196]

Unlike Mr Moore, the Greenbergs' claims alleging lack of informed consent and breach of fiduciary duty were unsuccessful because they were not patients of Dr Matalon in the clinical sense and consequently, there was no doctor-patient relationship between Dr Matalon and them.[197] The court however, upheld their cause of action for unjust enrichment and three years later, following the court's ruling,[198] the parties finally reached a confidential settlement which arguably still unfairly favours researchers.[199] While the court did acknowledge that the claimants had made a significant contribution to the research venture, sufficient for a claim of unjust enrichment[200] and in so doing, recognised that the respondent researchers

[192] Ibid, [1076].
[193] Ibid, [1075].
[194] Hardcastle (n 10) 72.
[195] *Greenberg* (n 189) [1073].
[196] Ibid, [1076].
[197] Ibid.
[198] Ibid.
[199] Dickenson (n 19) 36.
[200] *Greenberg* (n 189) [1073] (Moreno J): "The Complaint has alleged more than just a donor-donee relationship for the purposes of an unjust enrichment claim. Rather, the facts paint a picture of a continuing research collaboration that involved Plaintiffs also investing time and significant resources

should not be awarded all the spoils of the research enterprise,[201] it would still appear that most of the spoils from the research went to the researchers:[202] the settlement, though, exempting research doctors and scientists searching for a treatment for Canavan disease from having to pay royalties to the respondents and also exempting some licensed laboratories from having to pay royalties for patients undergoing the diagnostic test, required the claimants to agree not to contest the respondents' ownership of the Canavan gene patent.[203] Thus, with the exception of exempted laboratories, the respondents were able to continue to license and collect royalties for clinical testing.[204]

The claimants had invested time, money and effort in creating the tissue bank that that was essential to the respondents' research.[205] Indeed, the whole research venture was instigated by the claimants.[206] The respondent researcher, Dr Matalon did not have any particular expertise or interest in respect of the genetic basis for Canavan disease and he was also not already involved in researching the area at the time that he was approached by the claimants.[207] The respondent researcher's group had previously even made an unsuccessful application for funding from the National Institutes of Health, their application having been rejected because they did not have a demonstrable record in genetic research.[208] As one commentator observed: 'the only thing that was absolutely required in order to make the discovery was the participation of [the claimants]…the money and research skills were totally replaceable.'[209] Yet, the claimants were left without a firm right in the products of the research enterprise.[210]

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in the race to isolate the Canavan gene. Therefore, given the facts as alleged, the Court finds that Plaintiffs have sufficiently pled the requisite elements of an unjust enrichment claim."

[201] Dickenson (n 19) 38.
[202] Ibid, 36.
[203] Ibid.
[204] Ibid.
[205] Ibid, 37.
[206] Ibid.
[207] Ibid.
[208] Ibid.
[209] J Merz, quoted in Dickenson (n 19) 37.
[210] Dickenson (ibid) 38.

Similarly in *Catalona*, Limbaugh J held that research participants were donors and their donation of biological material was an inter vivos gift.[211] He further stated that for there to be an inter vivos gift, the donor must have a present intention to make a gift, the donor must deliver the property to the donee and the donee must accept the donation and the donee's property interest takes effect immediately and absolutely.[212] Like *Moore* and *Greenberg*, Limbaugh J also referred to policy considerations in support of his decision, in particular, the perceived impact that recognition of individual property right could have upon access to biological material and the resulting negative impact upon the scientific community.[213] But as mentioned above, the gift approach implies recognition of a property interest in biological material.

The respondent, Dr Catalona, appealed to the United States Court of Appeals for the Eighth Circuit. The Eighth Circuit (Wollan, Riley and Shepherd JJ) reasoned that the main consideration was whether individuals who make an informed decision to contribute their biological material voluntarily to a particular research institution for the purpose of medical research retain a property interest regarding such biological material which allows them to direct or authorise the transfer of such material to a third party.[214] The court found that the research participants had retained no such rights and had gifted their biological material to the GU Biorepoistory and consequently, the rights that the participants retained were not of a proprietary nature. Dr Catalona appealed to the Supreme Court of the United States, requesting that the Supreme Court review the Eighth Circuit's decision. On 22nd of January 2008, the Supreme Court of the United States denied *certiorari* without comment.[215]

[211] *Washington University v Catalona* (n 142) [997].
[212] Ibid.
[213] Ibid, [1002].
[214] Ibid, [673].
[215] SW Bernstein, M Bernadette, BM Broccolo, S Jennifer and JS Geetter (McDermott, Will and Emery) Ownership of Biological Samples and Clinical Data II: U.S. Supreme Court Denies *Certiorari* in the *Catalona* Decision. 21 Feb 2008: <http://www.mwe.com/publications/uniEntity.aspx?xpST=PublicationDetail&pub=5651&PublicationTypes=0c37aff3-0fa4-487b-ae40-09ee0164a996> accessed 19 June 2014.

From exploring the various judicial decisions, three potential property creating events could be identified which might transform biological material into things that are capable of being the subject of property rights.[216] These include the act of detachment, the work or skill exception and the act of detachment coupled with an intention to treat the separated biological material as property,[217] though the work or skill exception appears to be the only recognised property-creating event in the English court. With regard to the principle of detachment, *Catalona* and to a lesser extent, *Greenberg*, imply that property rights in excised biological material are created on detachment and, subsequently, that those rights can be transferred from the originator of the material to a third party once they are donated for medical research.[218] The application of the work or skill principle is illustrated in the cases of *Doodeward* and that of *Kelly* (see above). In respect of the third principle, strong support for a 'detachment plus intention' principle can be inferred from Rose LJ's prediction in *Kelly,*[219] where his Lordship opined that English law might develop so that a body part need not acquire different attributes before being recognised as property.[220] Rose LJ observed that where excised body parts have a use beyond their mere existence, this fact may be sufficient to bring them within the law of property.[221] His Lordship illustrated the application of this view in practice by indicating that this may be the case where the excised organ is intended for use in organ transplantation, for the extraction of DNA or as an exhibit in a trial.[222]

The criticisms of the work or skill exception expressed by the Court of Appeal in the English case of *Yearworth* and the apparent willingness of the court to acknowledge that there can be property in parts or products of a living human body irrespective of whether anything has been done to it to alter its attributes[223] would seem to indicate that the English courts may be willing to recognise another property

[216] Hardcastle (n 10) 125.
[217] Ibid, 100.
[218] Ibid, 151.
[219] Ibid, 151.
[220] Ibid, 151.
[221] *R v Kelly* (n 13) [631].
[222] Ibid.
[223] *Yearworth* (n 12) [38], [45d].

creating effect as an alternative to the work or skill principle or as replacing the work or skill principle. However, as discussed above, there is still uncertainty regarding the scope of the application of the judgement in *Yearworth* to non-reproductive biological material.

While the application of the work or skill exception provides a mechanism for recognising property in excised human biological material, without a broader basis for recognising property, its effect is to prevent the source of such biological material from claiming a legally protectable property interest in the excised biological specimen.[224] In many cases where biological material is supplied for research, the recipient researcher or hospital is usually the party with the necessary expertise, resources and skill to conduct the kind of work and skill necessary to fall within the work or skill exception.[225] The decision in *Yearworth*, however, attempts to redress the balance and explicitly recognises individuals as having property rights in separated biological material from their bodies (or at least in their gametes).[226]

The legal status of human biological material – Legislation

Like the common law, legislators have left us in a state of uncertainty regarding individual property right in excised biological material. Where the common law has tempered the confusion in delivering the clear message that the source of biological material is the one person who is least likely to have property rights in biological material and has taken a somewhat muddled and incoherent approach in respect of the question of property in excised biological material, legislation has been noticeably silent on this issue and has left us with something of a lacuna in this area. While the most recent legislative development in the common law jurisdiction,

[224] Quigley (n 128).
[225] Ibid.
[226] Ibid.

namely, the *Human Tissue Act* 2004[227], incorporates the work or skill exception in its provisions and in so doing, recognises the work or skill exception as a valid property creating event, it does not offer any answers in respect of the question of whether sources of biological material have a property interest in biological material excised from their bodies.

An outline of the *Human Tissue Act 2004* (HTA 2004) will be useful at this point in order to illustrate an example of an implementable policy framework that incorporates some of the legal principles examined so far and to also highlight inadequacies in the current provisions which would need to be addressed by any alternative framework such as the one proposed in this discourse.

The HTA 2004 provides a legislative framework for several activities relating to the removal, storage and use of human biological material[228] taken from living and dead bodies. The Act also establish a regulatory body, namely, the Human Tissue Authority (HT Authority) to regulate activities within the remit of the Act, including developing codes of practice,[229] in order to provide practical guidance to professionals carrying out activities which are covered by the Act.[230] The Act makes a list of activities lawful if done with appropriate consent.[231] Under the Act, consent must be obtained for the removal, storage and use of human biological material for

[227] *Human Tissue Act* 2004 (n 62); *Human Tissue (Scotland) Act* 2006, 2006 asp 4.
[228] The HTA 2004 only applies to 'relevant material'. 'Relevant material' is defined in the Act as material, other than gametes, which consists of or includes human cells. It does not include embryos outside the human body, or hair and nail from the body of a living person. *Human Tissue Act* 2004 (ibid) s53.
[229] The Human Tissue Authority has developed nine codes of practice dealing with activities such as research, anatomical examination, etc. For further details of the codes of practice, see Human Tissue Authority, 'Codes of practice': <http://www.hta.gov.uk/policiesandcodesofpractice/codesofpractice.cfm> accessed 19 June 2014. The codes of practice were approved by Parliament in 2009 and were brought into force by HT Authority's Directions 002/2009. For details of the directions, see Human Tissue Authority, 'HTA Legal Directions': <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm> accessed 19 June 2014.
[230] Human Tissue Act 2004 (n 62) s13-15.
[231] Ibid, s1.

certain scheduled purposes,[232] which include research in connection with disorders or the functioning of the human body.[233] Also, biological material intended for research purposes include those supplied by individuals purely for research and those originally intended for diagnostic purposes but subsequently considered for use or storage for research; albeit, that the HTA does not apply to biological material stored or used solely for diagnostic purposes.[234]

The consent provisions of the Act do not apply to imported biological material[235] but the HT Authority encourages users of biological material to set up mechanisms to provide assurance that the biological material has been obtained with valid consent.[236] Under the HTA 2004, consent is also not required if the following conditions are met: biological material is from a living person;[237] the researcher is not in possession and not likely to come into possession of information that identifies the person from whom it has come;[238] and the biological material is used for a specific research project that has been approved by a recognised ethics committee.[239] Also, some activities permissible under the Act can only be carried out under the authority of a licence granted under the Act by the HT Authority.[240] Failure to comply with the provisions of the Act triggers criminal liability[241] but failure to comply with the codes of practice and related documents developed by the HT Authority is not a criminal offence under the Act; although, the HT Authority may take any breach into account in its decision to issue a licence under the Act or take other appropriate regulatory action.[242]

[232] Ibid, s1 (sch1).
[233] Ibid, s1 (sch1) (part 1) (6).
[234] See Human Tissue Authority, *Code of Practice 9: Research* (n 186) paras 25-29 and 34.
[235] *Human Tissue Act* 2004 (n 62) s1(4b) s1(6)(a) (b).
[236] Human Tissue Authority, *Code of Practice 9* (n 186) para 40.
[237] *Human Tissue Act* 2004 (n 62) s1 (7).
[238] Ibid, s1(9).
[239] Ibid, s 1(9).
[240] Ibid, s 16.
[241] Ibid, ss5, 32 and 33.
[242] Ibid, s28; Also, see Human Tissue Authority, *Code of Practice 9* (n 186) para 9.

In its guidance of what constitutes valid consent in the context of research, the HT Authority stipulates that individuals who donate biological material should be asked whether they are giving generic consent (including for instance, use in any future research project) or specific consent (that is, for a particular research project)[243] and they should also be informed of the range of activities and researchers that may be involved in using their donated sample and whether these include commercial establishments.[244] The HT Authority also suggests that sources of biological material should be informed of whether their donated specimen will or could be used for research involving the commercial sector.[245]

The HTA 2004 appears to provide sources of biological material with management entitlements in their biological material to the extent that they can determine how and by whom their biological material is used.[246] Furthermore, the Act could be categorised as a consensual framework based on a liability construct to the extent that failure to obtain consent from the source of biological material in circumstances where consent is required (that is, interfering with the source management entitlement) triggers statutory liability under the HTA, where the wrongdoer may be criminally liable for interfering with the source's entitlement.[247] The Act creates criminal penalties which penalise the wrongdoer for interference with source management entitlement.

While the Act does not prevent sources from resorting to claim civil remedies for emotional distress and harm they might have suffered as a result of interference, the Act does not facilitate a source's ability to claim such remedies. Specifically, with regard to a source's ability to claim property based remedies which would potentially offer a source a more substantial award of damages and wider choice for

[243] Human Tissue Authority, *Code of Practice 1: Consent* (n 187) para 148.
[244] Ibid, para 149.
[245] Ibid.
[246] Wall (n 7) 788.
[247] Ibid, 798.

redress than non-property remedies, the Act leaves the question of individual property right in excised biological material, a fundamental element of such claims, unanswered. Rather than simply fortifying the view that the common law treats excised biological material from a living human body as property if they have been subject to an application of human skill,[248] Parliament should have gone further to make a definitive pronouncement about individual property right and in so doing, clarify the acknowledged uncertainty that persists in legal discourse regarding the matter. The criminal sanctions contained within the Act, while they might have some value in discouraging would-be offenders from interfering with source interests, quintessentially serve to further the state's interests (rather than the victim/source of biological material) in enforcement, crime reduction, maintaining public order and the state's function as the instigator of public prosecutions.

An argument could be made that the HTA 2004 is grounded upon the recognition of property rights in spite of the fact that it does not generally invoke the language of 'property' in relation to the interests of sources of biological material.[249] This is because the entitlements recognised by the Act in favour of sources, namely, management entitlements, are akin to property interests. However, while this is a possibility, it is not conclusive that these interests are property interests because they are not classified as such under the Act. Furthermore, it is notable that the Court of Appeal in *Yearworth*, in its analysis of the *Human Tissue Act*, did not confirm that the provisions of the Act were capable of such an interpretation.[250]

[248] *Human Tissue Act* 2004 (n 62) s32(9). See *Yearworth* (n 12) [38].
[249] The Act only mentioned 'property' once, in relation to the prohibition on commercialization of transplantable material in *Human Tissue Act* 2004 (n 62) s32(9). s32 (9) exempts from the prohibition on commercialization, biological material which is the subject of 'property' because of an application of human skill. This statutory exemption is a reflection of the exception to the 'no property rule' devised in *R v Kelly* (n 13). See Nwabueze (n 25) 48. For a discussion of the Act, see generally D Price, 'Human Tissue Act 2004' (2005) 68 Modern Law Review 798.
[250] *Yearworth* (12) [38].

Conclusion

What is clear from the above analysis is that 'the law tempers the consequent confusion in delivering one clear message: the one person who is least likely to have a property right in [excised biological material] is the person from whom [the biological specimen] was taken'[251] or by whom it was given.

The decision in cases that have approached the question relating to the legal status of biological material from a reified perspective seem to suggest that excised biological material can acquire the character of property in limited circumstances. However, those decisions are limited in their scope and application because they relate to biological material removed from dead bodies and there has been uncertainty as to whether they are capable of general application to biological material removed from living persons. Even if these decisions are applicable to biological material removed from living persons, the accepted property creating event in those cases, namely the work or skill exception, unjustly favours recipients of human biological material and does nothing for sources of biological material.

Although the English case of *Yearworth* seems to redress the balance in favour of sources of biological material by rejecting the work or skill exception as the accepted property creating event in respect of biological material, the judgement specifically deals with sperm and, consequently, the decision is limited in its scope and application to non-reproductive biological material. Although the reasoning in *Yearworth* can logically be argued to apply to biological material, other than gametes, it would not be prudent to do so because the court in *Yearworth* did not confirm that such a general application can be made and there have been no subsequent English Authority to confirm the court's approach. Subsequent Australian cases that have considered the question of individual property interest in

[251] JK Mason and GT Laurie, 'Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey' (2001) 64 Modern Law Review 710, 719.

excised biological material have also considered the question in the context of gametes.

Judicial decisions that have found the bundle of rights approach to be of practical utility, such as the case of *Moore*; seem to have failed to recognise that 'ownership' and 'property' are two separate concepts. For instance, in *Moore*, the Supreme Court of California found that the relevant statute eliminates so many of the rights/entitlements normally attached to property to the extent that the residual interest does not amount to property. This finding of the court failed to acknowledge that property can be described as a 'bundle of rights'[252] or even a collection of 'ownership entitlements,'[253] therefore, any individual right or entitlement could qualify as a property right if it corresponds with the accepted characterisation of property. It is clear from the case of *Moore* and subsequent decisions that the courts have focused on policy reasons in refusing to admit source ownership entitlements, especially source income entitlement, into the category property; rather than substantive reasons formulated on established legal principles. However, it will become apparent in the next chapter that the policy reasons invoked by the court no longer withstand critical scrutiny. Although persuasive, they are not particularly compelling considerations to justify the exclusion of source ownership entitlements from enforcement under the legal category of property.

[252] DC Jackson, *Principles of Property Law* (Sydney: The Law Book Co Ltd., 1967) 10.
[253] Wall (n 7) 784.

CHAPTER 4 (Part I) SHOULD SOURCE OWNERSHIP ENTITLEMENTS BE PROTECTED? SHOULD SUCH PROTECTION INCLUDE A LEGAL CHARACTERISATION OF SOURCE OWNERSHIP ENTITLEMENTS AS PROPERTY INTERESTS?

The case for legal recognition – Source management entitlement

As well as the HTA 2004, source management entitlement is also arguably protected by the common law principle of bodily integrity[1] in that the principle of bodily integrity protects a person from being physically harmed against his or her will- the removal of biological material from a person's body without consent amounts to physical harm.[2] Where biological material is removed from a person's body without consent and his or her right to bodily integrity is thus undermined, the individual in such cases will have recourse to a claim for a remedy for the tort of battery and the state in such instances could prosecute the offender for the crime of battery. However, the protection accorded to source management entitlement under the principle of bodily integrity is much more limited than the protection contained within the HTA 2004, because while the HTA 2004 regulates the initial removal of biological material and subsequent uses, the principle of bodily integrity is only relevant to the initial removal of biological material from the source's body-it cannot be invoked to deal with subsequent uses of biological material because no physical harm is inflicted as a result of such usage. The focus of this discourse, however, is on the interests of sources who consented to the initial removal of biological material from their body and the interests of such sources in determining what happens to their biological material after it is removed from the body-in other words, those activities that are not covered by the principle of bodily integrity.

Since the law already recognises a need to protect source management entitlement by regulating the entitlement under the *Human Tissue Act* 2004, it is not necessary to outline in detail the justification for protecting a source's management entitlement because there appears to be a settled view among those involved in the debate regarding protection of

[1] *Collins v Wilcock* (1984) 1 WLR 1172 [1177].

[2] See RA Miller, *The Limits of Bodily Integrity - Abortion, Adultery, and Rape Legislation in Comparative Perspective* (Ashgate Publishing, 2007); H Fenwick, K Kerrigan and R Glancy, *Q&A Civil Liberties and Human Rights* (5th Edn, Routledge, 2011) 108.

source ownership entitlements that there is a need for increased protection for source management entitlement. Even commentators such as the Nuffield Council on Bioethics who have expressed strong opposition against legal recognition of other ownership entitlements, in particular, source income entitlement,[3] seem to concede that there is a need to introduce measures in the form of compensation for unauthorised use or misuse of biological material in order to ensure source management entitlement is fully safeguarded.[4] Furthermore, the main concerns of those opposed to legal recognition of source ownership entitlements and protection of those entitlements under a property framework, relate in actual fact to the perceived potential consequences of recognising source income entitlement, specifically, the impact of commodification and commercialisation on the dignity of the human body and the undesirable state of affairs that it could create in respect of research and those most vulnerable in society.[5] Consequently, all that is necessary is a brief outline of further limitations of the current system, in addition to those highlighted in the previous discussion of the HTA 2004 in Chapter 3, and the need to fully safeguard source management entitlement by characterising it as a legally protectable property right.

The current system is limited to the extent that it does not offer an effective mechanism to seek redress for all sources of biological material in the event that there has been interference with their management entitlement. Furthermore, where it does offer an option to seek redress to sources, it is potentially not sufficiently robust enough to address the various potential instances of interference with source management entitlement. For

[3] See Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (Nuffield Council on Bioethics, 11 October 2011) [para 68] and [para 7.18]. Nuffield Council on Bioethics, Human tissue: Ethical and Legal issues (Nuffield Council on Bioethics, April 1995) [para 6.35] and [para 13.24].

[4] See Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (ibid) 17. Also, see TP Dillon, 'Source Compensation for Tissue and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits' (1989) 64 Notre Dame L. Rev. 628, 632-633: 'Society have generally recognised a need to offer robust protection to rights connected to autonomy and personhood than rights relating to income.'

[5] B Williams, 'Concepts of Personhood and the Commodification of the Body' cited in RN Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information* (Ashgate Publishing, 2007) 91: 'The strongest argument against the recognition of a property right in the human body is the slippery slope argument that it would cause devaluation, objectification and commodification of life.' Also, see *Moore v Regents of the University of California* [1988] 202 Cal. Rptr. 494 [508].

example, while *Moore-type* [6]sources (where the researcher also happens to be the source's doctor in the clinical sense) will likely have a realistic prospect of claiming civil remedies in the event that researchers misuse or used their biological material without consent, other sources do not have such prospects. This is because while informed consent is required in research involving human subject and informed consent is also required under the HTA 2004 before left over tissue is used for medical research, the relationship between the source of biological material and the recipient researcher (even if the researcher happens to be a doctor) is not a clinical relationship because the source of biological material is not the researcher's patient.[7]

Though in the case of *Greenberg,*[8] sources of biological material who did not have a clinical (doctor-patient) relationship with the defendant researcher successfully claimed a remedy for unjust enrichment; the facts of *Greenberg* makes it an exceptional case because the sources in *Greenberg* did not simply contribute biological material to the research enterprise like the average tissue source. Rather, sources involved in the *Greenberg* case also initiated the research, contributed financial resources, and significant time and effort in locating and encouraging other potential sources to provide biological material and financial resources. In finding in favour of the plaintiffs in respect of their cause of action for unjust enrichment, the court recognized a 'continuing research collaboration that involved the plaintiffs also investing time and significant resources in the race to isolate the Canavan gene'.[9] However, generally, sources simply supply their biological material for research and cease to have further involvement with the research enterprise. They usually do not have the extensive involvement that the plaintiffs in *Greenberg* had and their involvement is unlikely to be considered significant enough to constitute 'continuing research collaboration' as in *Greenberg*. This view is also shared by other commentators, for instance, Gitter cast doubts

[6] *Moore v Regents of the University of California* [1990] (Moore SC) 793 P 2d 479 (Cal SC) [492].
[7] A Alpers and B Lo, 'Commodification and Commercialisation in Human Embryo Research: The Absence of National Standards Sets the United States Apart from Other Western Nations' (1995) 6 Stan. L. & Pol'y Rev 39, 43.
[8] *Greenberg v Miami Children's Hospital Research Institute* [2003] 264 F Supp 2d 1064 (US DC Florida).
[9] Ibid [1072]-[1073].

upon the universal application of the ruling in *Greenberg*, where she described the ruling as being 'too ad hoc to be relied upon for future research participants'. [10]

In a *Moore-type* case, where the researcher happens to be the source's doctor, the entitlement of the source to claim judicial remedies stems from the fiduciary duty and the duty of informed consent owed by doctors to patients. However, the remedies for breach of fiduciary duty and lack of informed consent are potentially limited in their scope and application because they generally relate to the scope and nature of a doctor's duty of care in treating the patient and do not address the use of biological material after the patient has completed his treatment.[11] A doctor is required under the doctrine of informed consent to notify his patient of the nature and extent of risks associated with a particular procedure but the doctrine does not place the doctor under an obligation to inform the patient of subsequent uses of excised biological material from the patient's body.[12] The courts in *Moore,* however, seemed prepared to take a broader view regarding the scope of these remedies in that the court held that a researcher-doctor has a duty to notify the patient of subsequent commercial uses of the patient's biological material. Furthermore, while this question has not been determined by the English courts, the fact that the codes of practice to the HTA 2004[13] stipulate that sources should be given appropriate information regarding the range of activities and researchers that may be involved in the use of their samples including if the samples could be used for research involving the commercial sector,[14] shows a preparedness, at least on the part of policy makers to encourage researchers to inform sources of subsequent uses of excised biological material. The word 'encourage' is used here to denote that the provision falls short of an obligation or duty upon researchers because the codes of

[10] DM Gitter, 'Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material' (2004) 61 Wash. & Lee L. Rev. 257, 338.
[11] R Hardcastle, *Law and the Human Body: Property Rights, Ownership and control* (Hart; 2007) 68.
[12] Ibid.
[13] Human Tissue Authority, *Code of Practice 1: Consent* (Human Tissue Authority, 2009) para 149 <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm> accessed 19 June 2014.
[14] Ibid

practice operate as guidelines[15] and this is reflected in the severity of non-compliance in that while a failure to comply with the main provisions of the HTA 2004 is a criminal offence, failure to comply with the codes of practice is not a criminal offence under the HTA 2004. Although, the Human Tissue Authority may take any breach into account in its decision to issue a licence under the Act or take other appropriate regulatory action[16] and the threat of such measures may have some deterrent value to the extent that researchers will not wish to jeopardise their research or even their career, the potentially far-reaching consequences of having a criminal conviction is likely to serve a more effective deterrent in discouraging breach of a particular provision than the threat of regulatory action.

Justice Broussard in *Moore* provides another useful illustration of the limitations of the current framework. Although his reasoning was discussed in the context of the United States, the principles are applicable across common law jurisdictions, including the UK. Justice Broussard notes:

> If a patient donated his removed cells to a medical centre, reserving the right to approve or disprove the research projects for which the cells would be used, and if another medical centre or a drug manufacturer stole the cells after removal and used them in an unauthorized manner for its own economic gain, no breach-of-fiduciary cause of action would be available and a conversion action would be necessary to vindicate the patient's rights. [Although, the offender may be criminally liable under the HTA 2004 if the situation occurred in the UK].[17]

[15] Human Tissue Authority, 'Codes of practice': <http://www.hta.gov.uk/policiesandcodesofpractice/codesofpractice.cfm> accessed 19 June 2014.
[16] *Human Tissue Act* 2004, 2004 Chapter 30, s28; Also, see Human Tissue Authority, *Code of Practice 9: Research* (Human Tissue Authority, 2009) para 9. <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm?FaArea1=customwidgets.content_view_1&cit_id=763&cit_parent_cit_id=757> accessed 19 June 2014.
[17] *Moore* SC (n 6) [504] (Broussard J dissenting in part).

However, if source management entitlement is characterised as a legal property right then in the event that there is an interference with the entitlement, for example, where the person's tissue is left over after surgery or diagnostic tests and subsequently used or stored without consent of the source for medical research, the affected individual will be entitled to claim property based remedies that are currently unavailable[18] because the entitlement will constitute a property right and entitled to property protection. The advantages of property based remedies as compared to remedies that flow from the current liability based consensual framework have already been discussed in previous chapters so it is not necessary to re-engage in that analysis at this point.

Another argument in favour of increased protection for source management entitlement relates to the connection of such entitlement with a person's health. For instance, Andrews and Nelkin argue that 'to be psychologically healthy, people need to experience both self-agency, which is the ability to control what is done with their bodies, and self-coherence, which is the ability to maintain non-fragmented whole bodies.'[19] They assert that 'taking or using tissue, without the individual's knowledge or consent can compromise psychological development and emotional well-being.'[20] Furthermore, because source management entitlement relates to a person's ability to determine how and by whom his or her biological material is used, it arguably belongs to the category of ownership entitlements that are 'most intimately related to the autonomy and liberty of the [person],'[21] and as such should be protected from interference by others.

[18] RN Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (2013) J Med Ethics 1, 1 [Published Online First: January 31 2013 doi: 10.1136/medethics-2012-100815]. See also, Gitter (n 10) 305; J Wall, 'The Legal Status of Body Parts: A Framework' (2011) 31 OJLS 783, 802: "Nwabueze, Powloski and Mason and Laurie all provide arguments that suggest that the wide range of remedies that property rules are able to provide will be more effective at protecting ownership entitlements than the remedial consequences that follow from a breach of liability rules."

[19] LB Andrews and D Nelkin 'Whose Body Is It Anyway? Disputes Over Body Tissue in a Biotechnological Age' (1988) 351 Lancet 53, 54.

[20] Ibid.

[21] J Christman, Self-ownership, Equality and the Structure of Property Rights' (1991) 19 Political Theory 28, 34.

The case for legal recognition – Source income entitlement

Justification for legal recognition of source income entitlement

The fact that there is no specific legal provision prohibiting commercial dealings in relation to the supply of excised biological material for research would suggest that such actions are permissible under the law. However, because the law does not actually enforce interests in commercial dealings by incorporating legal provisions to regulate such interactions and by extension, a source's ability to exercise or claim the content of his or her purported income entitlement at the time that biological material is supplied for research uses, the matter is left to researchers and sources to resolve. The norm within the medical and scientific community is largely that a source of excised non-reproductive biological material should not be offered monetary consideration in exchange for his or her biological material, either in form of a direct payment, a reward or a share in profits generated from products that are developed using the material. This position has been encouraged by ethical bodies such as the Nuffield Council on Bioethics in recent and past reports.[22]

While it is possible for sources to enter into contracts with researchers to transfer entitlements in excised biological material in return for monetary consideration, researchers are placed in a significantly advantageous position over sources in respect of the negotiations that would undoubtedly have to take place to enter into such agreements. This is because many sources would usually not have knowledge as to the commercial value of their excised biological material or have access to the funds and scientific expertise to exploit the commercial potential of biological material. For instance, many patients who go into hospitals to undergo operations to remove cancerous tumours would arguably not be thinking about the potential commercial value of their tumour samples. Certainly, such considerations did not cross Mr Moore's mind, or else he would have negotiated for his

[22] See Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) para 68 and 7.18; Nuffield Council on Bioethics, Human tissue: Ethical and Legal issues (n 3) para 6.35 and 13.24.

economic interests at the outset and would not have sought to do so retrospectively through his civil action for the tort of conversion. The potential availability of a contractual mechanism for sources is illustrated in the collaboration between the US based patient advocacy group known as Pseudoxanthoma Elasticum (PXE) International and a group of researchers interested in studying PXE. PXE International (represents individuals suffering from the genetic disorder known as PXE) negotiated with researchers for control over the licensing of tests derived from the research enterprise and for a share in the profits derived from any gene patent, from diagnostic tests and marketable products; in exchange for contributing to the research effort by encouraging participation, establishing a tissue repository and raising funds.[23] While this may represent a possible avenue for sources to claim the content of their purported income entitlement, it should be noted that the legal validity of this agreement has not been tested in court because none of the parties have challenged it in court so there is no judicial pronouncement to confirm that such an agreement is legally enforceable.[24] Furthermore, it is unlikely that there will be any definitive judicial pronouncement clarifying the legal enforceability of such contracts in the immediate future because neither party has expressed a desire to raise the issue in court.[25]

Another illustration of a possible avenue for sources who wish to claim the content of their purported income entitlement in excised biological material is provided by the case of Ted Slavin. Slavin was a haemophiliac, whose only access to treatment in the mid-1950s was an infusion of clotting factors from donated blood, which was not screened for diseases. Slavin was consequently exposed to the hepatitis B virus on numerous occasions.[26] He eventually received a diagnosis in the 1970s when a blood test found significantly high concentrations of valuable hepatitis B antibodies in his blood.[27] However, what is unusual and noticeably

[23] Gitter (n 10) 263, 262-264, 315-325.
[24] Ibid; D Nicol, 'Property in Human Tissue and the Right of Commercialisation: The Interface between Tangible and Intellectual Property' (2004) 30 Monash University Law Review 139, 158.
[25] Ibid.
[26] R Skloot, 'Taking the least of you' New York Times Magazine, (New York, 16 April 2006) 42: <http://www.sjsu.edu/philosophy/docs/Lotts_article_by_Skloot.pdf> accessed 19 June 2014.
[27] Ibid.

different about Slavin's case in comparison to *Moore* and to some extent *Greenberg* is that Slavin's doctor told him about the valuable antibodies in his body.[28] From this information, Slavin realised the potential commercial value of his antibodies, especially because a continuous supply of antibodies like Slavin's were required both for the hepatitis B test (a multibillion dollar product) and to aid development of the first hepatitis B vaccine.[29] Slavin began selling his samples to any recipient who requested for it and later embarked upon a collaborative venture with a group of researchers where he volunteered to supply his antibodies without charge while those researchers sought to find a cure for hepatitis B.[30] The research on Slavin's samples aided discovery of the link between hepatitis B and liver cancer that led to the creation of the first hepatitis B vaccine, which has saved many lives.[31] Alongside this venture, Slavin expanded his antibody business to include other individuals who possessed unique biological material in their bodies. He set up a company (Essential Biologicals) which later embarked upon a merger to become part of a huge biological-product corporation.[32]

It is evident from the cases of *Moore, Greenberg*, Slavin and PXE International that the current law unwittingly allows compensation claims on an arbitrary basis by those few individual sources or patient groups who are knowledgeable about the potential commercial value of their biological material and have the means to negotiate for such value before the biological material is transferred for use in research.[33] This situation is arguably unjust and need to be remedied by the legislature because it leads to injustices for the vast majority of sources of biological material who might not have such knowledge or be in a position to access the resources (costs of experts and legal representatives) needed to protect their interests.

[28] Ibid.
[29] Ibid.
[30] Ibid.
[31] Ibid.
[32] Ibid.
[33] C Harrison, 'Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue' (2002) 28 Am. J.L. & Med. 77, 93.

As source income entitlement is not currently enforced by the law, it is necessary to examine generally the arguments for and against its recognition under the law, irrespective of the policy framework chosen to enforce it.

There are various justificatory techniques that could be invoked to support the view that individuals should be granted some legally enforced entitlements in relation to their bodies and excised biological material, or that they should be granted those entitlements under a particular legal framework like property. Arguments could be based upon individual liberty,[34] the maximization of utility,[35] the moral development of the person,[36] or their personality,[37] human nature,[38] the investment of work or skill,[39] economic efficiency,[40] or the distributional outcomes.[41] These justificatory techniques could be divided into two main categories.[42] The first is the category that perceives 'property as pre social, a natural right expressing the rights of persons which is prior to the state and the law, this being the view of Hugo Grotius, Samuel von Pufendorf, John Locke, Immanuel Kant and Georg W.F. Hegel'.[43] The second category is the category that views 'property as social, a positive right created instrumentally by community, state, or law to secure other goals, [this being] the theory of Thomas Hobbes, David Hume, Adam Smith, Jeremy Bentham, Emile Durkheim, and Max Webber.'[44] In other words, one can perceive property rights as generally being either expressive or instrumental as either employing property rights to express the rights

[34] R Nozick, *Anarchy, State and Utopia* (Basic Books 1974); A Carter, *The Philosophical Foundations of Property Rights* (Harvester Wheatsheaf, 1989) 38-51; Wall (n 18) 792.
[35] J Bentham, *The Theory of Legislation* (first published 1802, CK Ogden ed, K Paul, Trench, Trubner and Co 1931); Carter (ibid) 51-64.
[36] TH Green, Lectures on the Principles of Political Obligation (first published 1895, Longmans Green & Co 1941); Carter (ibid) 101-13.
[37] GW Hegel, *Philosophy of Right* (Oxford University Press 1967); J Waldron, *The Right to Private Property* (Clarendon Press, 1988).
[38] D Hume, *Dialogues Concerning Natural Religion* (Hafner Publishing, 1948) 39-41.
[39] J Locke, *Second Treatise of Government,* (CB Macpherson ed, first published 1690, Indianapolis: Hackett Publishing Co. 1980) 19.
[40] H Demsetz, 'Toward a Theory of Property Rights' (1967) Am Econ Rev 347; G Calabresi and AD Melamed, 'Property Rules, Liability Rules and Inalienability Rules: One View of the Cathedral' (1972) 85 Harvard Law Review 1089, 1093-98.
[41] Calabresi and Melamed (n 40) 1098-1102.
[42] J Getzler, 'Theories of Property and Economic Development' (1996) 26 J Interdiscpli Hist 639, 641.
[43] Ibid.
[44] Ibid.

that a person has as a person (expressive justification) or invoking property rights as a means to produce a desirable state of affairs (instrumental justification).[45] These mechanisms invoked to justify the recognition of property rights are not mutually exclusive, they are just alternative justificatory methods that consider different factors.[46]

Ownership entitlements could be separated into four different rights categories[47] according to the different functions in which they perform and the different societal interests that they serve.[48] These categories, which incorporate Honoré's outline of ownership entitlements, will offer utility to the present discussion in its considerations over which justificatory technique to invoke in support of the case for the legal recognition of source income entitlement. In other words, the discussion of these categories will help to determine whether the expressive or instrumental justificatory technique is appropriate as a mechanism to justify the legal recognition of source income entitlement.[49] The categories include: control rights, income rights, derivative rights and structural necessities.[50] Control rights and income rights comprise the primary focus of this discussion because the two entitlements which are of interest in the present discussion (that is, management and income entitlements), fall within those two categories. For instance, management entitlement falls within the category of control rights and income entitlement belong to the category of income rights. Nevertheless, a brief outline of all four categories will be provided to give a complete picture. 'Control rights' relate to the use of things and comprise entitlements such as possession, use, management and capital entitlements.[51] The function of control rights is to facilitate a state of affairs where the rights-holder is the 'final arbiter over what is to be done with a thing, unless this is contracted away'.[52] 'Income

[45] Wall (n 18) 793.
[46] Ibid.
[47] Christman, Self-ownership, Equality and the Structure of Property Rights' (n 21) 29.
[48] J Christman, 'Distributive Justice and the Complex Structure of Ownership' (1994) 23 Philosophy and Public Affairs 225, 226.
[49] Wall (n 18) 792-795.
[50] Christman, Self-ownership, Equality and the Structure of Property Rights' (n 21) 29.
[51] Ibid.
[52] Ibid.

rights' on the other hand, relate to the allocation of social wealth[53] and make it possible for the rights-holder to derive a benefit in exchange for giving up one or more control rights.[54] For example, where a person sells his blood sample, he or she gives up his possession, use and management entitlements in the blood in exchange for income.[55] 'Derivative rights' represent the logical extensions of control rights and consist of security and transmissibility entitlements and right to the absence of term.[56] The final category, 'structural necessities', comprise the rights and duties that are essential to bring the structure of ownership in line with rights and duties from other areas of law and consist of the duty to prevent harm, liability to execution and the incident of residuary.[57]

Instrumental justification and source income entitlement

Recognition of both control and income rights can be justified by adopting the instrumental justificatory technique because the instrumental justificatory technique looks to whether recognition of a particular entitlement will produce a desirable state of affairs and recognising both categories of rights could create a future state of affairs which is morally and economically desirable.[58] Granting the source of biological material control rights in his or her excised biological material may result in a situation where individuals are more willing to provide their biological material for research, which will in turn lead to a state of affairs where researchers can readily access biological material to conduct more extensive research and develop knowledge which could lead to social benefits in aiding the health of the population and economic benefits to the economy.[59] The recognition of income rights in favour of sources of biological material might also lead to a ready availability of biological material for use in research because individuals will potentially be encouraged by the offer or the prospect of financial gain to transfer the entitlements that they have in their

[53] Wall (n 18) 790.
[54] Christman, Self-ownership, Equality and the Structure of Property Rights' (n 21) 29.
[55] Wall (n 18) 790.
[56] Christman, Self-ownership, Equality and the Structure of Property Rights' (n 21) 29.
[57] Ibid.
[58] Wall (n 18) 793.
[59] Ibid.

biological material for use in research. These arguments are explored in more detail during the course of this chapter.

Expressive justification and source income entitlement

Unlike the instrumental justificatory technique, the expressive justificatory technique arguably does not provide a sound normative basis on which to justify legal protection for income rights because the value of income rights is dependent on the 'social and economic contingencies of the market sector.'[60] For example, the value of a pint of blood is established by agreement between the buyer and seller.[61] In arriving at the value for the blood sample, consideration would usually be given to market conditions such as the scarcity of that particular type of blood and whether there is a demand in the market for it.[62] The expressive justification, on the other hand, attempts to provide a normative basis on which to justify entitlements by taking into account factors relating to the attributes and characteristics of the person, such as their welfare, autonomy or personhood.[63]

Examples of arguments rooted in the expressive justification include libertarian views that contend that individuals should be entitled to dispose of their excised biological material by whatever methods they desire since the biological material belongs to the person and consequently they should be able to do what they want with it.[64] Other expressive arguments include the line of commentaries that suggest that recognising an individual's property right, specifically control rights, in excised biological material, advances, expresses or naturally extends the rights and interests that he or she has in the body.[65] Advocates for this view include Boulier, stating that if society perceives a person's body as his or her

[60] Ibid, 794.
[61] Ibid, 790-791.
[62] Ibid.
[63] Ibid, 794.
[64] S Wilkinson and E Garrard, 'Bodily Integrity and the Sale of Human Organs' (1996) 22 J Med Ethics 334; see also K Reddy, 'Organ Donation for Consideration: An Indian Point of View' in W Land and J Dossetor (eds) Organ Replacement Therapy: Ethics, Justice, Commerce (Springler-Verlag, 1991). Wall (ibid) 795-796.
[65] Wall (ibid) 795.

property, logic and justice necessitates the recognition of property rights in biological material removed from the body.[66] Similarly, Hardcastle asserts that recognising property rights in excised biological material is a natural extension of the right to bodily integrity.[67] However, while these arguments may appear convincing, their validity is potentially limited to the justification of control rights in excised biological material.[68] They are less than compelling if invoked to justify the recognition of income rights because of a discrepancy between the constitutive elements of income rights and the factors taken into account by the expressive justification.[69]

The considerations taken into account by the expressive justification (namely, a person's autonomy and liberty) arguably makes it the preferred technique for justifying the protection of control rights since 'control rights comprise the set of ownership entitlements most intimately related to the autonomy and liberty of the [person].'[70] In essence, and particularly with something as personal as biological material removed from one's body, 'the ability of a person to possess, use, manage and alienate objects-to have some control of the world around them-is fundamental to [that] person's satisfaction, their autonomous life or the expression of their personhood.'[71] However, such considerations are not dependent upon and are consequently independent of the social considerations of market incidents and wealth distribution that determines the value of income rights.[72]

The result of this is a discrepancy between the constitutive elements of income rights and the factors taken into account by the expressive justification.[73] For instance, whereas the

[66] W Boulier, 'Sperm, Spleen and Other Valuables: The Need to Recognise Property Rights in Human Body Parts' (1994) 23 Hofstra L Rev 693, 693.
[67] Hardcastle (n 11) 147.
[68] Wall (n 18) 794,796.
[69] Ibid.
[70] Christman, Self-ownership, Equality and the Structure of Property Rights' (n 21) 34.
[71] Wall (n 18).
[72] Ibid, 794.
[73] Ibid.

constitutive elements of income rights are 'distribution determined,'[74] the attributes and characteristics of the person, which are core elements of an expressive analysis, are 'distribution blind'.[75] Put concisely, income rights cannot be justified by reliance upon the expressive justification because the welfare, autonomy or personal development of the individual is blind to the considerations which determine the value of income rights, namely, the distribution of resources in society.[76]

While it is possible to argue that the ability to exercise income rights can be justified under the expressive justification, for example, it could be suggested that as a matter of autonomy and self-determination, an individual who wishes to sell his biological material should be allowed to do so.[77] However, it would be inconsistent to suggest that in order to promote the individual's autonomy or self-determination, he should be granted an entitlement to the proceeds of commercialisation (that is, the content of his income right) or that there is a connection between the substance and content of his income right and his personhood.[78] In the context of the supply of biological material for research, an entitlement of a source of biological material to the proceeds of commercialisation of research using his or her biological specimen could be more convincingly based upon justice arguments, in that others such as researchers and biotechnology companies are permitted to exercise such an entitlement.

Although there is merit in the argument that an individual is entitled to have an income right in biological material removed from his body, Wall suggests, for instance, that this argument cannot be based upon the rights of the person *as a person*. [79] He goes on to observe that:

[74] Christman, Self-ownership, Equality and the Structure of Property Rights' (n 21) 30-31.
[75] JW Harris, *Property and Justice* (Clarendon Press, 1996) 125-130. See also Wall (n 18) 794.
[76] Wall (ibid) 794.
[77] Ibid.
[78] Ibid.
[79] Ibid, 794-795.

> To claim a right to income is to claim the ability to obtain a monetary benefit in exchange for the biological material. It is difficult to see how being able to obtain this monetary benefit can follow from the rights-holder's personhood. Instrumental arguments may be employed to justify an individual's income rights, perhaps even in addition to expressive arguments that attempt to justify control rights.[80] However, unlike justification for legal recognition of income rights where the expressive theory is inappropriate and advocates for income rights are limited to the instrumental justificatory technique, both the expressive and instrumental technique can provide a sound normative to oppose the recognition of income rights.[81]

An argument is advanced in this discussion for the legal recognition of source income entitlement in excised biological material for the reasons discussed in the above analysis of the instrumental justificatory technique and based on the analysis that will be conducted during the course of this chapter.

The present discussion proceeds on the basis that the instrumental justificatory technique is more appropriate as a justificatory premise on which to justify the legal enforcement of income rights than the expressive justificatory technique. Consequently, in seeking to justify the legal enforcement of income entitlement, the focus of the discussion will be on the social and economic consequences of recognising source income entitlement, rather than pre-social/natural rights arguments. However, since both the expressive and instrumental justificatory techniques are suitable in opposing the recognition of income rights, the analysis of the case against the legal recognition of income entitlement will consider arguments from both a pre-social/natural rights perspective, as well as, social and economic arguments.

[80] Ibid.
[81] Ibid, 796.

Since the objections of those opposed to legal recognition of source income entitlement seem to underpin the current approach, the analysis of those arguments will first be conducted before proceeding to state the case for the legal recognition of source income entitlement.

Opponents of source income entitlement – Instrumental justification (Theoretical arguments)

As reflected in the reasoning of the Californian Court of Appeal in *Moore* and the Supreme Court in the same case[82], and in subsequent cases such as *Greenberg*[83], *Catalona*[84] and *Yearworth*[85], the main instrumental consideration against the legal recognition of ownership entitlements in excised biological material, particularly, income entitlement, and the admission of such entitlements into the legal category of property is the potential hindrance that such recognition could pose to the progression of medical and scientific research.[86] In view of this, a detailed analysis will be conducted in the course of this chapter of the potential impact that recognition of source income entitlement could have upon the progression of medical and scientific research, in an attempt to demonstrate that the concerns of opponents of source income entitlement no longer withstand critical scrutiny as their concerns are framework specific and are unlikely to be realised with the appropriate pro-compensation policy framework. Also many of their concerns relate only to a framework formulated upon strict property rules where income entitlement is exercised in accordance with market considerations. For instance, where an upfront purchase price is paid in direct exchange for excised biological material or where a negotiated share in profits derived from commercialisation of the product of the research enterprise, is agreed in exchange for use of excised biological material. It is advocated in this discussion that considerations should be given instead to other compensation frameworks such as hybrid

[82] *Moore CA* (n 5) [508].
[83] *Greenberg* (n 8).
[84] *Washington University v Catalona* [2006] 437 F Supp 2d 985 (USDC Ed Mo 2006) (Catalona); 490 F 3d 667 (8th Cir 2007) (Catalona CA).
[85] *Yearworth and Others v North Bristol NHS Trust* [2009] EWCA Civ 37.
[86] See also, Hardcastle (n 11) 68.

models that invoke liability rules[87] or a combination of liability and property rules[88], which represent an intermediate solution between the current market-inalienability model and a standard property model,[89] and promote a fairer outcome for sources of biological material, while encouraging a progressive environment for research to flourish. These alternative frameworks will be explored in the next chapter.

Additionally, arguments put forward by opponents of source income entitlement do not represent compelling reasons for rejecting legal recognition of source income entitlement because of the fact that other contributors involved in research enterprise receive a material benefit or have the opportunity to derive a material benefit from the enterprise in exchange for their contribution. In essence, researchers and biotechnology companies who invest their skills, expertise, time and money in research acquire a share of profits made from marketing the research product, whilst, suppliers of chemical agents are paid for the material that they supply, so why should sources of biological material who contribute the crucial raw material to the enterprise, be hindered from partaking in the economic benefit from the enterprise?[90] Furthermore, without the source's contribution, there would be no 'pay day' for other contributors involved in the enterprise. Without the source, the research enterprise cannot proceed and nobody would be paid.

Unlike previous discussion of the debate surrounding legal recognition of source income entitlement which has focused mainly on theoretical arguments, this chapter will include arguments supported by empirical research in advocating for legal recognition of source income entitlement, in addition to theoretical arguments. It should also be noted regarding the structure of the next segment of the discussion that the opponents' arguments are set

[87] Harrison (n 33) 93-100.
[88] See Gitter (n 10) 338-341 - Although Gitter's model is identified as a property/liability framework, it invokes predominantly property rules and therefore suffers from many of the difficulties associated with a standard property based framework. Gitter's model is discussed in more detail in chapter 5.
[89] See Harrison (n 33); J Boyle, 'To Pay or Not to Pay, That is the Question: Finding an intermediary solution along the Moore Spectrum' (2002) 7 Journal of Medicine & Law 55, 74-77; Gitter (ibid) 338-341.
[90] See *Moore SC* (n 6) [510] (Mosk J dissenting).

out in detail to begin with before an analysis of those arguments is conducted in order to avoid repetition of the same criticisms because much of the opponents' arguments are affected by the same or similar weaknesses.

Hindering progression of medical (biotechnological) research - Outline

Opponents of source income entitlement allege that granting sources an entitlement to monetary compensation could threaten the survival of biotechnological research by significantly reducing the economic incentive to conduct such research.[91] They also argue that it will reduce the volume of biological material available, presumably, because there will be a need for a source and researcher to negotiate a mutually satisfactory compensation arrangement before biological material is transferred and some of these negotiations may be unsuccessful where a source and researcher are unable to agree and since tissue has a finite survival time once removed from the body, the biological sample may be destroyed while negotiations take place.[92] Additionally, opponents assert that the offer or prospect of compensation could potentially lead to a distortion of research samples where sources misrepresent information relating to their medical history to researchers in an attempt to make them more valuable for research investigation.[93] They argue that that these factors combined, could ultimately have a detrimental impact on public health.

The irony of the opponents' argument, however, is encapsulated by Hoffmaster where he observes:

> Curiously...when commercialization works to the advantage of scientists, its negative impact on research is less emphasized. The possibility of obtaining patents has already begun to cast a shroud of secrecy around science and has decreased the extent to which research materials and results are freely shared among scientists. Nevertheless,

[91] See Ibid [494]; Harrison (n 33) 87.
[92] Boyle (n 89) 66-67.
[93] U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells – Special Report* (OTA-BA-337, 1987) 11; Dillon (n 4) 637.

allowing researchers to profit is regarded as a stimulant to science, whereas compensating sources for their materials is regarded as a depressant.[94]

Reduction in economic Incentive to conduct medical research

In support of the case against the legal recognition of source income entitlement, critics opposed to such recognition observe that biotechnological research is a costly, uncertain and financially risky enterprise and the recognition of source income entitlement threatens to compound those challenges.[95] For instance, 'it typically takes about 15 years to convert a promising new compound into a drug on the market[96]…on average, of every 1,000 experimental drug compounds in some form of pre-clinical testing, only one actually makes it to clinical trials.'[97] Added to this difficulty is the fact that 'only one in five of those drugs make it to market…of the drugs that get to market, only one in three bring in enough revenues to recover their costs.'[98]

Opponents of source income entitlement also point out that much health related research is conducted in the private sector[99] and although researchers and companies who are involved in the biotechnology industry may be so involved in that particular industry (that is, the health care industry) rather than other industries because they are motivated to help to alleviate the suffering caused by human illnesses and diseases and to save lives in addition

[94] B Hoffmaster, 'Between the Sacred and the Profane: Bodies, Property, and Patents in the Moore Case' (1992) 7 Intellectual Property Journal 115, 134.
[95] Dillon (n 4) 636-637. U.S. Congress, Office of Technology Assessment (n 92) 5. Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 194 para 7.18.
[96] Science, 'Drug Discovery and Biotechnology Trends: Recent Developments in Drug Discovery: Improvements in Efficiency': <http://www.sciencemag.org/site/products/ddbt_0207_Final.xhtml> accessed 19 June 2014. See also, EuropaBio, 'Why do they cost so much?': < http://www.europabio.org/why-do-they-cost-so-much> accessed 19 June 2014.
[97] Plunkett Research Ltd, 'The State of the Biotechnology Industry Today': <http://www.plunkettresearch.com/biotech-drugs-genetics-market-research/industry-and-business-data> accessed 19 June 2014.
[98] Ibid.
[99] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 193 para 7.17.

to making a profit, they must nevertheless make a profit in order to stay in business.[100] Thus, commercialisation of research products and the resulting profits from commercialisation provides the required incentive for such ventures to invest in developing new products.[101] Therefore, if the projected profit for a particular research endeavour is not significant enough to justify the investments made and the financial risks taken by commercial ventures then such ventures might not participate in research and without their financial backing, it may not be possible for some research projects to go ahead. Advocates for this school of thought go on to suggest that whilst the need to make profit can sometimes turn biotechnological research itself into a profit-making endeavour,[102] it does not negate the significant social utility of such research.[103] They assert that the state is responsible for promoting the good health of its citizens and that responsibility includes supporting and facilitating environments in which the good health of its citizens may flourish.[104] In their view, one way in which the state fulfils this responsibility is by supporting and facilitating environments in which biotechnological research may flourish because the therapeutic potential of biotechnological research aids public health.[105]

Opponents of source income entitlement also consider that the promotion of a donation-based system rather than a compensation-based system facilitates the progression of research because it ensures that money, which would otherwise have been spent in compensating sources, is available for research and development.[106] Accordingly, if the recent developments in biotechnological research are anything to go by, then more research could mean more lives being saved.[107] Although acknowledging that many

[100] Dillon (n 4) 639.
[101] Ibid. Nicol (n 24) 163-164.
[102] Nicol (ibid) 163.
[103] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 193 para 7.17. See also Dillon (n 4) 639.
[104] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (ibid) 193 para 7.16.
[105] Ibid.
[106] R Scott, *The Body As Property* (1981) cited in Dillon (n 4) 639.
[107] See EuropaBio, 'Biotechnology applications and benefits': <http://www.europabio.org/sites/default/files/new_poster_benefits_2013_light_1.pdf> accessed 19 June 2014; Economy Watch, 'Biotechnology in Medicine': <http://www.economywatch.com/business-technology/biotechnology/biotechnology-in-medicine.html> accessed 19 June 2014; Pharma Research, 'Over 900 Biotechnology Medicines in Development, Targeting More than 100 Diseases' (2011):

individuals may not directly benefit from donated blood or organs during their lifetime; nevertheless they observe that each person will most certainly benefit in some way from new medicines derived from research using donated tissue.[108] A quick glance at this argument suggests that it has some merit because after all, if the source of biological material would most certainly receive a non-financial therapeutic benefit from new medicines using donated tissue then it is reasonable that the source does what he or she can to facilitate such ventures and that includes contributing his or her biological material to such ventures without expecting financial consideration as such conduct would ultimately reduce the costs incurred in developing new medicines. However, on closer scrutiny, the argument appears to be weakened by the fact that the same logic works against other contributors to the research enterprise, but unlike sources of biological material, they are encouraged to acquire financial benefit through various regulatory and legislative mechanisms that safeguard their interests. For instance, researchers, owners/shareholders of biotechnology companies and suppliers of chemical agents would equally obtain a non-financial therapeutic benefit from new medicines, but yet, they derive financial gain from the enterprise. They are even encouraged by policy makers to invest and engage in such ventures through policies that emphasise the prospect of resulting financial gain.

Critics of source income entitlement assert that a pro-source compensation policy would likely exacerbate the difficulties already inherent in biotechnological research enterprise by increasing the economic and transaction costs (that is, costs of discovering exchange opportunities, payments to agents and middlemen, costs of negotiating exchange, and costs of monitoring and enforcement[109]) facing researchers and, in so doing, discourage investors from engaging in research enterprise and ultimately undermining public health. For instance, in the case of tissue donated to tissue banks, researchers would incur considerable transaction costs in locating and negotiating mutually satisfactory compensation

<http://www.phrma.org/media/releases/over-900-biotechnology-medicines-development-targeting-more-100-diseases> accessed 19 June 2014.

[108] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 193 para 7.17.

[109] Gitter (n 10) 279. See also S Pejovich, Economic Analysis of Institutions and Systems (Kluwer Academic Publishers, Dordrecht, 1995).

agreements with every source of biological material whose biological material may be used in a particular research enterprise.[110] Costs of negotiation are likely to be even more significant where researchers involve middlemen or agents to represent them in the negotiation process.[111] Also, the negotiation process is likely to be quite protracted and complex due to the fact that many biotechnological research projects use a collection of biological samples donated by several individuals worldwide.[112] The difficulty in this situation could become compounded in cases where researchers do not have the identifying information of sources because those sources chose to remain anonymous or where the researchers obtained the biological sample from another scientist or a tissue bank without the details of the sources of biological specimen.[113] Furthermore, opponents of source income entitlement fear that the negotiation process could become quite expensive and impossible where sources and researchers are unable to agree on a mutually satisfactory price in exchange for biological material.[114] Such a state of affairs could potentially be prohibitive to many private foundations and non-profit organisations who might be discouraged from making further financial donations towards biotechnological research because their funds are being used to compensate sources rather than in productive and socially useful research.[115]

Another potential source of increased costs is considered to be the extensive and expensive record keeping system that will potentially be required to maintain the identifying information of each biological sample used in a particular research enterprise so that where a source transfers his or her biological material in return for a share of profits rather than an upfront payment, then that person can be identified and his or her whereabouts located to execute the terms of the compensation agreement. The concern is that the record keeping process will be all the more complex and expensive because a particular sample from an individual may be used in several experiments and also because of the possibility that

[110] Gitter (ibid).
[111] Dillon (n 4) 634-635.
[112] Gitter (n 10), 279-280.
[113] Ibid, 280.
[114] Dillon (n 4) 635-636.
[115] Ibid, 641.

biological material from several individuals worldwide could have been utilised in developing the final product.[116] Furthermore, it is considered that there could be a further increase in transaction costs because research institutions could face significant monitoring and enforcement costs in making sure that their staff comply with compensation arrangements.[117] It has been argued that the transaction costs that could potentially be incurred in locating and negotiating compensation agreements is likely to be much more significant than the actual payments to individual sources and that payments to sources of biological material is unlikely to have a significant economic impact on the use of biological material.[118] Thus, the problem is arguably not because compensation could be paid to individuals but the difficulties and significant costs associated with implementing a compensation process.[119] With this reasoning, researchers may actually come across these difficulties before they can properly ascertain the profitability of the research enterprise and if the uncertainty involved in biotechnological research is factored into the list of considerations,[120] then researchers could be discouraged from engaging in such endeavours. These potential difficulties might arguably be more significant for non-commercial researchers who have no intention of commercialising the results of their research since they will not have the opportunity to recoup these potentially significant transaction costs from profits derived from commercialising the products, although it is likely that these costs will be included in their research grants.

In addition to the impact that an increase in financial and transaction costs could have upon investment in biotechnological research, critics of source income entitlement speculate that researchers and their sponsors are unlikely to deduct the increased transaction costs and

[116] U.S. Congress, Office of Technology Assessment (n 93) 17; However, these views were stated before the emergence of the computer age so record keeping should not represent a significant problem anymore because computer databases of sources could be created and there are various computer programs that simplify the process of record keeping.
[117] Gitter (n 10) 279.
[118] U.S. Congress, Office of Technology Assessment (n 93) 13.
[119] Ibid.
[120] Telephone interview with W Greenberg, Associate Professor, Department of Health Services Administration, The George Washington University, Washington D.C. (Mar. 8, 1989) cited in Dillon (n 4) 637 .

costs of compensation/payments made to sources from the profits made from the research enterprise.[121] Instead they suggest that the inevitable increase in financial and transaction costs involved in developing the product and the costs of payments made to sources would likely be recouped by increasing the price of the product of the research enterprise. On their view, this could potentially mean that treatment and drugs will be more expensive than they would have otherwise been, had sources not been compensated, particularly, if companies also recoup the transaction costs incurred in purchasing biological samples that do not yield successful products.[122] This could make treatment costs even more expensive because both transaction costs incurred in a successful project and costs incurred in other unsuccessful projects will be recouped from a particular successful project. The concern is that the increase in treatment costs could ultimately undermine public health since it would increase the health bill.[123] This may prove quite problematic for a country like the United Kingdom which currently has a restrained health budget, as reflected by the current budget deficit in the National Health Service and the cuts being made to the budget as a result of the recent economic recession.[124]

While it is arguable that recognising source income entitlement threatens to increase the economic and transaction costs incurred by researchers, the argument is weakened by its focus on a free market mechanism as a means of enforcing source income entitlement. Essentially, the negotiation process which has been argued could result in increased costs is a feature of a free market model formulated solely on property rules where market transactions represent the norm and individuals negotiate with researchers either for a price in return for their biological material, or a share of the proceeds of the commercialisation of research using their biological material. However, the potential

[121] Dillon (n 4) 639.
[122] Ibid, 637.
[123] See generally U.S. Congress, Office of Technology Assessment (n 93); Dillon (ibid) 634.
[124] See D Campbell, 'NHS hospitals suffer annual loss for first time in eight years - Combined deficit of £456.8m reported by 26 of 102 trusts, renewing fears about long-term financing of the NHS' (The Guardian, 20 March 2014). See R Smith, 'NHS will face £15bn budget shortfall due to effects of recession managers warn' (The Telegraph, 10 Jun 2009).

difficulties associated with the negotiation process would not occur if the negotiation process is removed. This would be the case with a compensation system formulated on liability rules as opposed to property rules, where the current donative principle is maintained at the initial phase where biological material is supplied, and in those instances where biological material proves to be of significant commercial value, an objective state run administrative or regulatory body, such as the Human Tissue Authority, could then determine the amount of compensation or the share of profits that the researchers should pay to the source of biological material proportionate to the value of the source's contribution.[125] The problem of increased economic and transactions costs would also be addressed if in line with the framework advocated in this discussion, Parliament pre-determines a statutorily fixed amount that a researchers pays a source of biological material after a marketable product is developed from the source's biological material. The benefit of both suggestions is that they would remove the need for sources of biological material and researchers to engage in an expensive negotiation process because the amount of compensation or price to be paid in exchange for the biological material would be determined by objective third parties. Furthermore, under the alternative frameworks, the value for compensation would either be calculated after the value of the research product is known, or alternatively, the value for compensation would be a value predetermined by the state which becomes due only when the value of the research product is known. This feature of liability rules also addresses other fears of opponents of source income entitlement (discussed below) regarding the impact that delays and bidding wars associated with negotiations, could have upon the integrity of biological material and the source of biological material. Furthermore, it addresses the limitation identified with the highest bidder scenario regarding the inefficient use of resources because the operation of a donative principle at the onset of the supply of biological material ensures that all potential developers of biological material will have equal access to the specimen.

[125] Harrison (n 33) 93-100.

Although a system formulated on liability rules as envisaged above would not remove the difficulties outlined by opponents of source income entitlement regarding the acquisition of an expensive and complex record keeping system for maintaining source identifying details and tracking the use of biological material, it is submitted that if consideration is given to the meticulous care and planning required in biotechnological research then such record keeping should not prove unduly burdensome for researchers.[126] Additionally, the fact that clinical and demographic data about the person from whom biological material was removed will usually have greater scientific and commercial value and systems already exist in the medical and scientific community to keep record of such data[127] would suggest that such record keeping system is already part of the biotechnological research infrastructure. Furthermore, in light of recent developments in modern technology, record keeping should not represent a separate problem in itself because the complex modern computer systems regularly used by organisations and establishments already include software packages and databases to simplify the process of record keeping.

[126] *Moore CA* (n 5) [508]; Gitter (n 10) 289.

[127] Harrison (n 33) 99. Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) para 1.14:

> Medical information associated with donated tissue adds significantly to the value of the tissue as a research resource: such information may be obtained either by maintaining a link with the donor's full health record, or by retaining a particular dataset of information about the person's medical history. In both cases, in the research setting, the information available will normally be linked with the sample through a code so that the researcher does not directly access identifying information such as names and addresses.(footnote omitted) Sometimes samples can be collected with some basic non-identifying data, which is then completely separated from the source data and straightforward linkage completely broken (although, in fact, with modern technology it may now be possible to match fragmented DNA in a sample to a specific donor).

Delays, destruction of biological material and reduction in availability of biological material

Another concern of those who object to the recognition of source income entitlement is that if sources are permitted to exploit their excised biological material for financial gain or sell their biological material, then sources will treat their biological material in the same way as sellers of other commodities by attempting to realize maximum profits from sale of biological material.[128] A seller might attempt to maximize his profits by selling to the prospective buyer who tenders the highest bid. Holding out for the highest bid could involve potentially time consuming negotiations with several prospective buyers, followed by a waiting period which is brought to an end when the offer put forward by prospective buyers peaks at its highest level.[129] Those against source income entitlement claim that if this were to happen in the context of the supply of biological material for research, such a process will increase delays, trigger a 'bidding war' (competitive bidding) and could potentially result in the inefficient use of biological material.[130] They fear that the bidding war that will be triggered by the highest bidder scenario could result in excessive delays that could lead to destruction of the molecular integrity of tissue in a particular case. This is due to the fact that tissues, once removed from the body have a finite survival time. Where a tissue sample has been cultured, the longer it is in culture, the less it is like the original sample and protracted negotiations could mean that valuable attributes of the tissue are lost.[131] Also, if negotiations extend then the source of the tissue sample could also die and the tissue may be lost because sources of tissue that have unique qualities such as Moore (the 'Mo' cell line)[132] and Lacks (the 'Hela' cell line)[133] are usually very sick (valuable tissues usually found in diseased body)[134] and since valuable tissue are rare and not found in every human body, it is possible that the tissue could be permanently lost and the researchers may have to abandon the project altogether.[135] Although advocates for this view acknowledge that researchers and sources will certainly consider the finite survival time of a particular sample

[128] Dillon (n 4) 634.
[129] Ibid.
[130] Ibid.
[131] U.S. Congress, Office of Technology Assessment (n 93) 32-33.
[132] *Moore* SC (n 6).
[133] D Dickenson, *Body Shopping: Converting Body Parts to Profit* (Oneworld, 2008) 22-23.
[134] Dillon (n 4) 639.
[135] Ibid, 634.

of biological material and the source, and will have factored such considerations into their negotiations, nevertheless, they assert that 'the probability that excessive delays will occur will be increased'[136] as a result of recognising source income entitlement in excised biological material. It has been argued that all these factors could ultimately prolong the suffering of those who are hoping for a treatment from a particular research project.[137]

Opponents of source income entitlement also seek to avoid a potential state of affairs where tissue is sold to the highest bidder because of a concern that the highest bidder may not always represent the most capable entity to fully exploit the therapeutic potential of the biological material to generate the best product.[138] Although supporters of this view acknowledge that a company that is unable to develop biological material into a therapeutic product can resell the sample to a more capable company once it discovers that it is unable to create the desired product; they consider that the discovery may come too late, in light of the finite survival time of excised tissue and the tissue sample could be destroyed.[139]

There is an emerging school of thought that rejects the recognition of source income entitlement but advocates that researchers should be required to contribute a share of profits, proportionate to sources' contributions, to public health infrastructures. They argue that a source's share of profits should be donated to public tissue banks for the maintenance of these banks. According to this view, sharing the profit on a wider scale instead of allocating shares to private sources will facilitate access to biological material and in so doing, promote socially useful biotechnological research.[140] Advocates for this school of thought suggest that rather than recognising source income entitlement, the law should fully safeguard source management entitlement by introducing remedies through legislation

[136] Ibid.
[137] Boyle (n 89) 67.
[138] Dillon (n 4) 634.
[139] Ibid, 635.
[140] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 194.

to compensate sources of biological material for unauthorised use of their biological material/interference with their management entitlement.[141] They suggest that sources of biological material are more concerned with having control over what happens to their excised biological material, than exploiting excised biological material for financial gain.[142] They further suggest that this concern shared by sources is adequately addressed by increased protection for source management entitlement and not by legal recognition of source income entitlement.[143]

Whilst the sentiment that encourages increased protection for source management entitlement is accepted and even shared in this discussion, it is not accepted here that such increased protection should be a substitute for the protection of source income entitlement. It is rather advanced that both entitlements should be fully safeguarded. Furthermore, while the notion of contributing sources' share of profits to public tissue banks in order to promote socially useful medical research might appear persuasive, it is not an especially compelling argument. The reason for this is simple: each contributor to the research enterprise (researchers, shareholders/owners of biotech companies, suppliers of chemical agents and sources) is a beneficiary of research products developed using biological material obtained from public tissue banks, since they would all presumably have used drugs and treatments derived from research; therefore, if the sources' share of profits is donated to public tissue banks then surely the same logic could be applied to the potentially larger share of profits that is acquired by researchers and their sponsors. But of course, this would be inconceivable both for researchers and their sponsors.

[141] Ibid.
[142] Ibid, 16 para 70.
[143] Ibid.

Distortion of Research Sample

Opponents of source income entitlement also fear that the promise of financial gain could encourage some sources of biological material to misrepresent the information that they provide to researchers in an attempt to make their excised biological material appear more valuable.[144] A source might, for instance, provide misleading or inaccurate answers to questions relating to his or her medical or personal history which might otherwise prevent them from meeting eligibility criteria for research.[145] Such conduct, it is argued, could distort the research results, reduce the quality of the results and potentially jeopardize the health of the individual source of biological material and other sources involved in the research project.[146] However, like other concerns raised by opponents of source income entitlement, this difficulty is not insurmountable. For instance, researchers could curtail such behaviour by first screening sources of biological material to determine whether they meet certain eligibility requirements such as whether their biological material could potentially be of value to the proposed research project before disclosing the possibility of compensation to the individual.[147] Also a system based on liability rules such as the framework envisaged in this discussion, where compensation is delayed until after a marketable product is developed from the biological material and the full commercial value of the biological material is realised, will remove the lure of immediate financial gain that could cause sources of biological material to mislead researchers. Incidences of source misrepresenting information could be further curtailed by the fact that it takes many years to develop a marketable product from excised biological material[148] and by the inherent difficulties and uncertainties present in biotechnology enterprise which make the development of a marketable product less than certain in a given enterprise.

[144] U.S. Congress, Office of Technology Assessment (n 93) 11; Dillon (n 4) 637.
[145] Ibid.
[146] Gitter (n 10) 282; U.S. Congress, Office of Technology Assessment (ibid) 106; Dillon (ibid).
[147] Gitter (ibid) 282-283; U.S. Congress, Office of Technology Assessment (ibid).
[148] W Greenberg (n 120); Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 16 para 68.

Opponents of source income entitlement – Erodes notions of altruism and communal values

The precise definition of altruism remains the subject of debate and whilst various definitions have emerged over the years for the term, no single definition is accepted as reflecting fully the meaning of the term.[149] Nevertheless, a distinction can be drawn between motivational and behavioural conceptions of the term.[150] Motivational definitions of altruism focus on the internal psychological states that form the basis of behaviours.[151] According to this perception, a particular action would be deemed altruistic if the person carrying out the action is doing it because he or she desires to contribute to the welfare of another.[152] Behavioural conceptions of altruism, on the other hand, are not concerned with the internal psychological states that trigger behaviours but rather look to the costs and benefits of the action to the individual carrying out the action.[153] For instance, the actions of a woman who does not have access to in vitro fertilisation (IVF) treatment and who subsequently agrees to participate in an egg sharing regime to make part of her eggs available for another woman's treatment or for research, in exchange for free or discounted IVF treatment, will be behaviourally altruistic because her action will benefit specific (if unknown) others, or future others through research that will potentially be useful in advancing public health, at great costs (time, discomfort and medical risks involved in egg extraction procedures)[154] to her. However, her action will not be motivationally altruistic because her contribution was motivated by the benefit that she would potentially receive (that is, a reduction in the price for her own fertility treatment) rather than by a desire to assist other women to conceive or experience motherhood.[155]

[149] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 139; See also DS Wilson 'On the Relationship Between Evolutionary and Psychological Definitions of Altruism and Selfishness' (1992) *Biology and Philosophy* 7: 61-68; See generally: E Sober and DS Wilson, *Unto others: Evolution and Psychology of Unselfish Behaviour* (Harvard University Press, 1998); CD Broad, 'Egoism as a Theory of Human Motives,' in Broad, *Broad's Critical Essays in Moral Philosophy*, (London: George Allen and Unwin, 1971).
[150] Ibid.
[151] Ibid.
[152] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 139.
[153] Ibid.
[154] Ibid, 183 para 6.74, 48 Box 1.8.
[155] Ibid, 140 para 5.28.

The current system for donation of biological material is founded upon a commitment to preserve and encourage motivationally altruistic actions.[156] In other words, 'a foundational commitment to a vision of society in which members are motivated to care for the health needs of others and where values such as generosity and compassion are encouraged and recognised.'[157]

Motivational conceptions of altruism are adopted here to reflect the meaning of altruism and so an altruistic action is defined as 'one that is motivated by concern for the welfare of the recipient of some beneficent behaviour, rather than by concern for the welfare of the person carrying out the action.'[158]

Opponents of source income entitlement assert that the recognition of source income entitlement could potentially have a detrimental impact upon the practice of altruistic donation by 'crowding out' altruism.[159] In the first instance, they advocate for the protection of altruism in its apparent status as an important virtue in society. Thus, the continued role of altruism in donation is encouraged 'as underpinning important communal values that express something very significant about the kind of society in which we wish to live.'[160] In this connection, 'an altruistic basis for donation helps underpin a communal, and collective, approach to the provision of bodily material needed by others for the preservation or improvement of their health.'[161] They further assert that the recognition of source income entitlement will likely 'place men in situations in which they have less freedom or little

[156] Ibid, 145.
[157] Ibid.
[158] Ibid, 139.
[159] RM Titmuss, The Gift Relationship: From Human Blood to Social Policy (Pantheon Books, 1971) 242; R Korobkin, 'Buying and Selling Human Tissues for Stem Cell Research' (2007) 49 Arizona Law Review 45, 58.
[160] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) viii, 132, para 6.75.
[161] Ibid.

freedom to make moral choices and to behave altruistically if they so will.'[162] Some argue that if sources of biological material are motivated by the prospect of pecuniary gain then this would turn the act of donation into a market transaction. On this view, such a change would undermine the value of donation because '[donation] would no longer stand for self-less motivation or sacrifice on the part of the donor, nor would it express a sense of shared obligation or solidarity to provide that which is essential for life or health.'[163] Such a state of affairs, it is suggested, would erode communal virtues and 'undermine a community wide commitment to [provide for others and replace it] with another banal instance of reward for services rendered.'[164]

Another strand of the pro-altruism argument suggested by opponents of source income entitlement is that recognition of source income entitlement could potentially lead to a reduction in the availability of biological material for research uses because prospective altruistic donors might come to view donation as an intrinsically commercial enterprise that undermines the dignity and inherent value of the human body rather than a 'charitable or humanitarian effort that they find enticing' and subsequently refuse to participate in such an enterprise.[165] Expressed slightly differently, 'commercialisation might reduce the psychic benefit of volunteerism, thus reducing the desirability of altruism and reducing the amount of it, or viewed from the opposite perspective, a 'no-compensation' rule might encourage altruism that otherwise would not exist'[166] because some individuals are motivated to donate their biological material only by the opportunity to be altruistic. Opponents further argue in this connection that the number of prospective sources that would be incentivised to supply their biological material by the prospect of financial reward/compensation will be

[162] Titmuss (n 159). Also, see generally E Anderson, 'The Ethical Limitations of the Market' (1990) 6 Economics and Philosophy 179.
[163] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 144. See also Anderson (ibid).
[164] Ibid.
[165] Korobkin 'Buying and Selling Human Tissues for Stem Cell Research' (n 159) 58-9.
[166] Ibid, 59.

less than the number of prospective sources that would be motivated to donate by only the opportunity to be altruistic.[167]

The first strand of the opponents' argument is not a compelling reason to reject source income entitlement because the mere fact that sources are lawfully able to (if they so wish) both exercise their income entitlement by entering into payment or profit sharing agreements with researchers or claim the content of their income entitlement by obtaining actual payments or share of profits derived from research, would not necessarily prevent altruistic donation. This is because altruistic sources who are motivated solely by a desire to contribute to the welfare of others or advance public health by facilitating biotechnological research and who do not wish to participate in compensation would be free to reject compensation. This group of sources might actually be further encouraged to participate in research if the mechanism for compensation incorporates an additional provision that encourages or compels researchers to contribute all rejected compensation from individual sources towards the maintenance of public tissue banks as such contribution would help to facilitate the progress of socially useful research, as opposed to the current system where researchers and their employers, and biotechnology companies get to keep all the proceeds of research ventures.

While some sources who might have been willing to provide uncompensated donations will likely accept payment if it is offered to them, all that simply demonstrates is that those individuals evidently find compensation more desirable than the 'good feeling' from

[167] Ibid, 58-9.

altruism and not that the availability of compensation has infringed the freedom of those who wish to be given the opportunity to supply biological material altruistically.[168]

Failure to recognise source income entitlement could potentially result in negative consequences for biotechnological research: some altruistic individuals who ordinarily would supply their biological material for biotechnological research may refuse to do so because all other contributors and investors in the research venture, apart from them, expect to make a profit. In addition, individuals who are not particularly altruistically inclined might refuse to undergo the inconvenience and potential risks (however minimal) associated with the removal of tissue from their bodies and the potential risk of being stigmatised for disease susceptibility without the legal enforcement of their entitlement to compensation, especially since researchers (in the case of commercial researchers) will hope to profit from the research.[169]

Experience shows that individuals who supply their biological material for research do so, not because of money, but because they wish to improve the health of others.[170] Some sources may participate in research because they desire to promote research on specific diseases which may affect their loved ones or even the sources themselves; and other sources may be altruistically motivated generally towards the health care system and out of concern for public welfare.[171] However, if the definition accepted for an altruistic action is 'one that is motivated by concern for the welfare of the recipient of some beneficent behaviour,' then it is arguable that altruism, on a strict application of the foregoing definition, is not a factor that significantly influences a source's decision to contribute

[168] Ibid, 59.
[169] See Ibid, 60; National Bioethics Advisory Commission, 1 Research involving Human Biological Materials: Ethical issues and policy guidance (August 1999) 50.
[170] Harrison (n 33) 92.
[171] Ibid.

biological material in the research context. At the time when biological material is transferred from the source to the recipient researcher, the welfare or 'well-being of immediate others is absent because it is unknown or too far into the future'[172] and 'while material donated for research will be used with the aim of improving health in the long term, the connection between the donation and that outcome is both extended and uncertain.'[173] Furthermore, 'while research results may benefit many in the long term, the very uncertain nature of such research means that such beneficiaries seem very remote.'[174] In this connection, the source's contribution for research cannot really be motivated out of concern for the welfare of the recipient of the biological material. 'Participants may certainly feel a sense of contributing to society for the common good but are less likely to envisage their actions as an act of altruism towards specific (if unknown) others.'[175] Interestingly, the immediate recipient of biological material in the research context seeks to profit from it and it is probably safe to assume that sources do not donate out of concern for commercial users of biological material or because they wish to assist such users in their profit endeavours.

The second strand of the opponents' argument necessitates an empirical inquiry to the extent that it would be necessary to investigate whether the 'availability of compensation would convince more potential altruists not to donate than it would persuade non-altruists to supply their [biological material].'[176] There is little empirical evidence available to assist in this enquiry.[177] However, findings from empirical studies that sought to examine the impact

[172] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 142.
[173] Ibid, 145.
[174] Ibid.
[175] Ibid.
[176] Korobkin 'Buying and Selling Human Tissues for Stem Cell Research' (n 159) 59.
[177] Ibid.

of incentive on donation of biological material do not support the opponents' concerns relating to the 'crowding out' of altruism.[178]

Some commentators are concerned that the recognition of source income entitlement in the research context will discourage altruism in other areas where it is normally practiced such as in the donation of organs for transplant to a human recipient.[179] However the significance of this concern is reduced by the fact that legislation under the HTA 2004 already generally bans the sale of biological material intended for transplant purposes and also empirical evidence does not support such a contention.[180] For instance, a review authorised by the Working Party which assisted the Nuffield Council of Bioethics in its deliberations towards the 2011 report on donation[181] found that there was little empirical evidence to support the contention that the availability of payment in the context of donated biological material might 'crowd-out' prospective altruistic donors.[182] Additionally, the operation of a legal market in blood intended for transfusion in the US has not deterred altruistic motivated individuals from donating blood for that purpose.[183] While there has been a noticeable decline in overall blood donations in the US since the market system was implemented,[184] such decline is not necessarily a consequence of the market system.[185]

[178] See Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 145 para 5.47, 166 para 6.19, appendix 1 and 2. N Lacetera, M Macis and R Slonim 'Will there be blood? incentives and substitution effects in pro-social behavior (2009) IZA Discussion Papers: No. 4567, 20.
[179] Gitter (n 10) 313.
[180] See Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 145 para 5.47, 166 para 6.19, appendix 1 and 2.
[181] Ibid.
[182] Ibid.
[183] Harrison (n 33) 93.
[184] Also see K Baum, 'Golden Eggs: Towards the Rational Regulation of Oocyte Donation' (2001) Brigham Young University Law Review 107, 138. For a contrasting view, see AR Schiff, 'Solomonic Decisions in Egg Donation: Unscrambling the Conundrum of Legal Maternity' (1995) 80 Iowa Law Review 265, 291 n 114.
[185] Gitter (n 10) 314.

As one commentator observes:

> The United States instituted a system of monetary compensation for blood in response to the inadequacy of an entirely donative system.[186] Thus, any shortage in the nation's blood supply may result simply from the American public's disinclination to behave altruistically[187] as opposed to the availability of payment for their blood or plasma.[188]

Rejecting source income entitlement does not necessarily promote communal virtues or distribute widely the product of biotechnology research.[189] Rather, the biological samples acquired from sources without compensation are used by researchers and biotechnology companies in developing commercial products which in some cases, the NHS may be unable to afford to make available to the public and which some individual members of the public may be unable to privately fund.[190] 'Our legal and economic systems are premised upon the notion that promise of reward for individual effort, not communitarian ideals, will stimulate [biotechnological] research and innovation that will redound to the benefit of society.'[191] Thus, the recognition of source income entitlement is simply keeping with these ideals.

As sources begin to acquire greater awareness of the tremendous commercial value and the resulting profits acquired by researchers and biotechnology firms from research involving human biological material, it will become increasingly important for sources to be seen to

[186] KJ Arrow, 'Gifts and Exchanges' (1972) 1 Philosophy and Public Affairs 343, 350.
[187] JD Mahoney, 'The Market for Human Tissue' (2000) 86 Virginia Law Review 163, 217.
[188] Ibid.
[189] Gitter (n 10) 313.
[190] Ibid.
[191] Ibid.

be treated equally with other contributors to the research enterprise and to be allowed the opportunity, if they so wish, to receive remuneration for their contribution in furthering biotechnological research. The preservation of altruism and the practice of altruistic donations should not necessarily rule out compensation in any form. In everyday normality, people are regularly paid for activities which others perform without compensation and altruistically motivated individuals are not necessarily deterred from performing activities for which others receive remuneration.[192] Examples can be seen in both the public and the private sector, from the police force to the fire service…'from hospices to political campaigns, volunteers perform services which are a source of paid employment for others.'[193]

The current system which emphasizes altruism on the part of the contributors of excised biological material but reinforces capitalist ideals among everyone else involved in biotechnological research enterprise[194] is flawed on grounds of justice (discussed in part II of this chapter). Additionally, the pro-altruism arguments that have been put forward by opponents of source income entitlement in support of it are less than compelling because the concerns that underpin those arguments are not insurmountable. While altruism is a good value to encourage in society, 'one way altruism smacks of exploitation and engenders mistrust, which actually undermines altruism…presuming that [sources] will be donors, but making them feel like dupes will kill the goose that lays the golden eggs.'[195]

[192] Harrison (n 33) 93.
[193] Ibid.
[194] Dickenson (n 133) 39.
[195] Ibid.

Sources may elevate financial concerns over health because of promise of financial gain

Another argument made by opponents of source income entitlement emphasises the negative impact that it could have upon the health of contributors and prospective contributors of human biological material to research and upon the integrity of researchers. Two versions of the argument can be distinguished. One version relates to the actions of unscrupulous researchers. In this connection, opponents argue that researchers might lure sources of biological material with promises of 'ultimately fictitious percentages of far-off royalties.'[196] They argue that individuals with limited education and limited financial means, in other words, the poor and economically disadvantaged in society, are especially vulnerable to such exploitation.[197] This view goes on to suggest that even those researchers who wish to deal fairly and honestly with sources might find themselves unable to do so because the prospective profits from a particular research enterprise will likely be too 'vague and speculative at the time that the [biological material] is obtained.'[198] Consequently, researchers would be unable to estimate accurately the potential commercial value of particular biological samples and may inadvertently provide misleading information to sources of biological material.[199]

The first point to note about this version of the opponents' argument is that it is framework specific. For instance, a framework that implements a statutory fixed rate of compensation will prevent the occurrence of this supposed difficulty. Where parliament introduces a pre-determined fixed rate of compensation into the 'statute book', researchers would need not bother themselves with seeking to estimate the commercial value of particular biological samples nor would the unscrupulous individuals among them have the opportunity to provide 'fictitious percentages of far-off royalties'[200] because the correct rate for

[196] BM Knoppers and C Laberge, 'DNA Banking/Collecting: A Canadian "Sample" of Consent Forms,' cited in Gitter (n 10) 311 n 209.
[197] Dillon (n 4) 637-38; Gitter (ibid) 311.
[198] Harrison (n 33) 92.
[199] Ibid.
[200] Knoppers and Laberge (n 196).

compensation will be clearly defined by statute which will be accessible for examining by all parties, including sources of biological material.

The foregoing envisaged difficulty might also be seen as a regulatory matter to the extent that proper monitoring and regulation of the transactions between researchers and sources by the relevant professional, ethical and regulatory bodies such as the Health and Care Professions Council and the Human Tissue Authority (HT Authority) would reduce the incidence of such behaviour. The HT Authority's Code of Practice for instance, requires recipients of human biological material intended for research purposes to provide information in respect of their commercial interests to sources of biological material,[201] therefore, a researcher who provides misleading or inaccurate information runs the risk of facing regulatory action and incurring penalties administered by the HT Authority[202] and it is likely that researchers would not wish to jeopardise their research and ultimately their career by taking such risks. Also, depending upon the factual circumstances in such cases, sources of biological material may be able to seek redress under the doctrines of fraudulent misrepresentation, negligent misrepresentation, duress, undue influence, unconscionability and the researchers may be liable under professional disciplinary laws.[203]

Furthermore, where sources are entitled to claim recourse to civil remedies in the event that a researcher provides the source with misleading or inaccurate information, the threat of civil litigation and resulting damages that the researcher will potentially be ordered to pay to the source will likely deter researchers from engaging in such unscrupulous behaviour. Alternatively, it could encourage researchers to provide clear information to

[201] Human Tissue Authority, *Code of Practice 1: Consent* (n 13) para 148.
[202] *Human Tissue Act* 2004 (n 16) s28; Also, see Human Tissue Authority, *Code of Practice 9: Research* (n 16) (para 9).
[203] Gitter (n 10) 312.

sources stipulating that estimates of projected profits and of the source's share of profits made at the time when a sample is obtained are provisional until, for instance, the 'stage of inevitability, the stage of applied research at which the development of a product that could have market value becomes inevitable.'[204]

The other version of the opponents' argument alleges that sources of biological material may harm themselves by taking unnecessary risks with their health in anticipation of financial gain.[205] According to this view, individuals might purchase certain drugs to mutate their bodies and with the evolution of cosmetic surgery and generally plastic surgery, they might even undergo certain procedures to mutate the body and body tissues in a way that would make them more valuable.[206] Furthermore, advocates for this view suggest that some people could potentially even postpone surgery or other medical procedures necessary to promote their health in a misguided attempt to preserve their supposed unique body tissues for possible future research uses.[207]Additionally, they allege that a system of payment in exchange for biological material will simply exploit the poor and economically disadvantaged and unduly incentivise them to undergo high risk procedures which they would normally have considered unacceptable, in the hope of acquiring pecuniary gain.[208]

The foregoing argument does not represent a compelling reason to reject source income entitlement if the following three points are considered: Firstly, it is currently common practice for researchers to induce research participation with financial remuneration.[209]

[204] RJ Levine, Research That Could Yield Marketable Products From Human Materials: The Problem of Informed Consent, (January - February 1986) 8 IRB: Review of Human Subjects Research 6, 6.
[205] Dillon (n 4) 637.
[206] Ibid.
[207] Ibid.
[208] Ibid, 638, Gitter (n 10) 311.
[209] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 3) 141-142; Gitter (ibid).

Individuals are offered financial reward in return for their participation in clinical trials and the recent Nuffield Council of Bioethics report confirmed that the primary motivation for participants taking part in such trials is the offer of financial reward rather than any desire to contribute to the common good.[210] Participants in clinical trials are thus 'encouraged to take unnecessary risks with their health in order to improve their financial situation.'[211] Consequently, if it is acceptable for researchers to induce research participation in this context with financial reward, then it is surely not far-fetched or intolerable to allow financial reward in the context of the supply of biological material for research. Secondly, biological material used for research is usually leftover or diseased biological material that has been removed for therapeutic purposes during the course of a patient's treatment[212]and so no additional surgical procedure is required to remove or transfer the biological specimen for use in research and in this regard, there would be no actual medical risks involved for the source in supplying the material for research. For instance, Mr Moore's spleen had to be removed as part of his treatment for leukaemia as opposed to removal specifically for research purposes. Also, biological material obtained for research purposes may also be tissue that is regenerative or not vital for the healthy functioning of the human body and can thus be removed without having a 'permanently deleterious effect upon the [individual], as opposed to organs necessary for human health.'[213]

The following two statements by advocates for source income entitlements highlight further weaknesses inherent in the second strand of the opponents' argument:

> …if the altruistic model is defensible on the basis that comparatively poor people should not be allowed to risk their health in order to make money, then that same principle should also rule out allowing such people to enter dangerous, albeit well

[210]Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (ibid).
[211] Ibid.
[212] Dillon (n 4) 634 and 639.
[213] Gitter (n 10) 313, 313 n 223, 299 n 164; 268 n 35.

> remunerated, professions, such as mining or service in the armed forces: since society tolerates the latter, it should tolerate the former. Moreover…while exploitation of people on low incomes is clearly regrettable, what is more regrettable are the socioeconomic circumstances that lead to impoverishment in the first place…given the widespread existence of impoverishment, the question to ask is whether there is evidence that in fact payment for [biological material] might be a well-informed choice for the individual in question.[214]

Mahoney notes:

> [P]reventing excessive risk-taking by banning payments, instead of through the regulation of collection procedures and required disclosure of relevant hazards, is a curious strategy. When a conclusion is reached that workers are exposing themselves to excessive risks, the usual response is to alter workplace conditions to reduce the risk, not to forbid payments for the work while suggesting that altruistically minded volunteers perform the work for free.[215]

The sentiments expressed in the foregoing statements are applicable to the context of the supply of biological material for research. Excessive risk-taking by the economically disadvantaged and generally by sources of biological material could be alleviated by an effective regulatory system and by a combination of provisions which could include the screening of participants for eligibility for research participation before disclosing details of projected profits from research, implementation of cooling off periods after initial source

[214] J Radcliffe-Richards, AS Daar, RD Guttmann, R Hoffenberg, I Kennedy, M Lock, RA Sells, N Tilney, 'The case for allowing kidney sales,' surmised in Nuffield Council on Bioethics (n 7) 142 -143. See generally, J Radcliffe-Richards, AS Daar, RD Guttmann, R Hoffenberg, I Kennedy, M Lock, RA Sells, N Tilney, 'The case for allowing kidney sales,' International Forum for Transplant Ethics (1998) 350 The Lancet 1950.
[215] Mahoney (n 187) 213.

consent to research and counselling services for prospective sources and actual sources of biological material to ensure they are fully informed as to the procedures necessary to effect transfer of their biological material for use in research.

Opponents of source income entitlement – Expressive justification

One of the main expressive arguments frequently made by opponents of source income entitlement highlights the possibility that such recognition might result in commodification of the human being or the moral person. This argument appears to stem from the view that individuals possess an attribute of human dignity, the preservation of which is contingently connected to the treatment of the human body because 'the body is inseparable from the person…'[216] Essentially, the body is an essential feature of being human because 'human beings exist in their bodies and respect for the body is indivisible from respect for the person.'[217] Supporters of this view assert that pricelessness is the distinguishing characteristic of dignity and thus, the dignity of the person could be significantly undermined should the body and by extension excised biological material from it, be treated like a commodity, an object that is directly exchanged for money (a price), because it may lead people to see themselves and others simply as vessels containing body parts with a market value rather than seeing themselves as persons with dignity.[218] As Kant observes, 'in the kingdom of ends everything has either a price or a *dignity*…If it has a price, something else can be put in its place as an equivalent; if it is exalted above all price and so admits of no *equivalent*, then it has a dignity.'[219] Kant goes on to suggest that human beings are not means-to-ends; rather, they should be treated as ends-in-themselves.[220]

[216] P Ramsey, cited in U.S. Congress, Office of Technology Assessment (n 93) 131.
[217] Ibid.
[218] For a discussion of this view, see SR Munzer, 'An uneasy Case against Property Rights in Body Parts' (1994) 11 Social Philosophy and Policy 259, 269, 286.
[219] I Kant, Groundwork of the Metaphysic of Morals (HJ Paton trans, Hutchinson & Co. 1972) 96
[220] A George, Marketing Humanity: Should we allow the sale of Human body parts? [2005] UTS L Rev 2; 2005 7 UTS Law Review 11, II (D).

Although the foregoing discussion summarises generally the anti-commodification argument espoused by opponents of source income entitlement, it should be noted that the precise meaning of commodification and to what extent it should be avoided in social institutions remains unclear.[221] In the words of Hansmann, 'it is difficult...to find a clear statement of precisely what is meant by commodification or why it is undesirable.'[222] Nevertheless, there appears to be two accepted interpretations of the term and the difference between the two interpretations goes some way in explaining the uncertainty.[223]

A narrow definition of the term restricts commodification or a commodity simply to something that can be legally bought or sold in a market.[224] Munzer, for instance, suggests that permitting sales in excised biological material makes excised biological material into 'commodities'.[225] He commenced his premise on the assumption that commodities are things that can be bought or sold in a market and while 'almost all monetized items are in fact commodities…some ways of assigning monetary values do not seem to involve or create commodities.'[226] By his reasoning, a free market system of compensating sources of biological material where biological material can be bought or sold will potentially commodify the human body but commodification could be avoided where compensation is not determined in a market transaction (property rule) but rather, under a liability rule.[227] For instance, the assessment of workers' compensation according to statutorily pre-determined schedules which could include 288 weeks compensation for a lost leg and 160 weeks compensation for a lost eye under the New York workers' compensation statute,[228] appear to 'monetize body parts but do not make them into commodities.'[229]

[221] Ibid.
[222] H Hansmann, 'The Economics and Ethics of Markets for Human Organs' (1989) 14 Journal of Health Politics, Policy and Law 57, 74.
[223] George (n 220).
[224] MJ Radin, 'Market-Inalienability' (1987) 100 Harvard Law Review 1849, 1849, 1852; Munzer (n 218) 259, 281.
[225] Munzer (ibid) 259.
[226] Ibid, 259, 280.
[227] Ibid, 280-281.
[228] Workers' Compensation Law, in *McKinney's Consolidated Laws of New York Annotated,* cited in Ibid, 281.
[229] Munzer (ibid) 281.

Though both systems involve 'monetization' of biological material, the way in which the value for compensation is determined differs. Under the free market system, the entitlement to compensation is protected by property rules to the extent that the value for compensation is determined through a market mechanism that involves private negotiations between the buyer and seller.[230] Whereas, under the liability rule, compensation is not determined through private negotiations but rather, it is objectively assessed by third parties (administrative body, tribunal, the State) on a collective, non-market basis.[231] Since the definition implies that commodification is commensurate with a market and a commodity is something that can be bought and sold in a market, the second system which operates a non-market mechanism arguably does not make biological material into commodities and does not entail commodification.[232]

The wider definition of commodification, on the other hand, involves objectification of the human body.[233] On this view, the mere assignment of monetary value to biological material removed from the human body constitute commodification of the human body[234] because the biological specimen is treated like 'something that is interchangeable for another identical object and that can therefore be replaced by an equivalent item to satisfy an obligation.' [235] In this connection, it is irrelevant whether such compensation is determined through private transactions under a property rule (free market system) or collectively determined by the state or instruments of the state under a liability rule. More importantly, opponents of source income entitlement fear such commodification will lead to commodification of the person since it will undermine '[the general public's] moral and religious sense of the significance of their bodies and thus, their dignity.'[236] So, rather than seeing themselves as persons with dignity, people will value themselves and the worth of others simply in monetary terms, that they are only worth as much or as little as the price paid or the financial reward given in

[230] Ibid, 280-281. See also Calabresi and Melamed (n 40) 1092.
[231] Ibid.
[232] Munzer (ibid) 281.
[233] George (n 220).
[234] Harrison (n 33) 90.
[235] George (n 220).
[236] Harrison (n 33) 89.

exchange for their excised biological material.[237] Justice Arabian encapsulates this sentiment in *Moore v Regents of the University of California* where he states:

> Plaintiff has asked us to recognize and enforce a right to sell one's own body tissue *for profit.* He entreats us to regard the human vessel-the single most venerated and protected subject in any civilized society-as equal with the basest commercial commodity. He urges us to commingle the sacred with the profane. He asks much.[238]

However, objections to source income entitlement based on the foregoing anti-commodification argument are out of touch with reality. By reason of their apparent basis on a presumption that the human body is not already commodified, such objections are difficult to sustain. While biological material removed from the human body may not be currently bought and sold in a market like other common goods, they are however being commercialized whether source income entitlement is legally recognised or not. The biotechnology revolution has resulted in unprecedented commercialization of human biological material and both researchers and shareholders in biotechnology firms routinely profit from such commercialization.[239] Scientists, universities, biotechnology firms, pharmaceutical companies, medical device makers, state governments, lawyers or health care providers can ethically and lawfully profit from biotechnology research using human biological material without vocal opposition.[240] Surely, if we assume that human biological material will generate profit in our society then fairness dictates that the source from whom the biological material is taken should partake in those profits.[241] This argument which is based on notions of justice is discussed in more detail in part II of this chapter.

[237] For a discussion of this argument, see Harrison (ibid); Gitter (n 10) 298-304.
[238] *Moore SC* (n 6) [498] (Arabian J).
[239] Gitter (n 10) 300.
[240] Korobkin, 'Buying and Selling Human Tissues for Stem Cell Research' (n 159) 46.
[241] Gitter (n 10) 302.

Furthermore, Individuals can ethically and lawfully 'rent' out their bodies for use in clinical trials, models and actors can readily exploit their natural endowments for profit by acquiring pecuniary gain for having particularly beautiful bodies and faces. Additionally, singers can profit from their vocal talents and even research scientists can obtain financial gain for their scientific genius.[242] Thus, there is already some commodification of the human body and by extension, the biological material in or removed from the human body. Thus, it is therefore not intolerable or far-fetched to suggest that individuals be accorded a legally enforced entitlement to acquire pecuniary gain from contributing valuable biological material to biotechnological research. The wider question, however, of whether people actually feel objectified or dehumanized by such interactions is a question to be explored in empirical study.[243]

The fact that human biological material is bought or sold in a market need not mean that it is reducible only to market prices or that its worth or value is represented solely by market prices. In other words, 'it is possible to place a price tag on something without that price being the only measure of its value.'[244] Shultz expresses the essential features of this view where she states:

> Many things that partake of the monetary economy also involve aspects of life that are deeply revered. We buy a wedding ring or a home but its personal worth is not equated with its price. Doctors deal with the creation, sustenance and termination of life. We do not expect the fees we pay them to capture all of their meaning and importance to us. Neither do we deny them the capacity to get monetary recognition for their work. Similarly, we appraise a couple's ability to sustain the costs of raising a child when we decide whether they are fit adoptive parents. We award child support

[242] Dickenson (n 133) 29; Harrison (n 33) 82; Gitter (n 10) 297.
[243] Harrison (ibid) 91.
[244] Gitter (n 10) 301.

> when a divorce occurs; we assess damages for the costs of raising a child born because of a negligent diagnostic test, or for an untimely death in a wrongful death action. We are not confused about whether these financial representations adequately sum the value of the lives or relationships in question. We simply say that money is one dimension of human interaction and valuing. The critical issue is not whether something involves monetary exchange as one of its aspects, but whether it is treated as reducible solely to its monetary features. Analogously, life insurance initially provoked condemnation but has come to enjoy broad social acceptance.[245]

Likewise, the simple fact that financial considerations are incorporated into transactions involving excised human biological material should not necessarily 'implicate the overall dignity of the person' from whose body the material was extracted.[246] It could, for instance, be suggested that personhood is not primarily dependent on the treatment of the human body because 'the body [is] merely a necessary condition for the pursuit of the truly important things about being human…its significance is only instrumental, not essential.'[247] Thus, 'to be a person, to have moral being, is to have the capacity for intelligent causal action' and by this reasoning, personhood therefore involves abilities such as 'self-awareness, curiosity and concern for others,' which generally have little association with the body, being associated with the body only through 'their dependence on the neo cortex.'[248]

In keeping with the abovementioned sentiments, it is arguable that the choice is not simply between inclusion and exclusion of commodification in social institutions-'commodification is not necessarily an all-or nothing matter.'[249] Many aspects of social enterprise are typified by a state of 'incomplete commodification' or expressed differently, by 'coexistent

[245] MM Shultz, 'Reproductive Technology and Intent-Based Parenthood: An Opportunity for Gender Neutrality' (1990) Wisconsin Law Review. 297, 336.
[246] Harrison (n 33) 89.
[247] J Fletcher, cited in U.S. Congress, Office of Technology Assessment (n 93) 132.
[248] Fletcher (ibid).
[249] Harrison (n 33) 89.

commodified and non commodified understandings.'[250] The employment setting provides a typical example of such an 'existing domain of incomplete commodification'.[251] In the employment setting, a person's labour is bought and sold but in order to acknowledge and protect non-market values such as employees' health and autonomy, such interactions are also regulated[252] through various legislative and regulatory instruments. These include the Employment Rights Act 1996[253], Working Time Regulations 1998[254], the Pensions Act 2004[255], the Health and Safety at Work Act 1974[256] and the more traditional 'collective bargaining' between trade unions and an organisation's executive/management team. The collective bargaining model is itself also regulated by the Trade Union and Labour Relations (Consolidation) Act 1992[257]. In this context, the wage or compensation for value which is paid to the employee and which represents the commodifying provision is thus balanced with other non-commodifying provisions which recognise the 'personhood' or 'community' of employees.[258]

More could be said in response to the anti-commodification argument and indeed the various arguments espoused by opponents of source income entitlement. However, at this juncture, it should simply be noted that the view taken in this discussion is that the opponents' arguments are not especially compelling reasons to reject the legal enforcement of source income entitlement: even to the extent that they raise legitimate concerns relating to the sanctity of the human body, potential exploitation of human sources of biological material, and progression of socially useful biotechnological research, the remedy surely lies in an effectively constructed policy framework that empowers sources to claim the content of their purported income entitlement while at the same time mitigates against concerns raised by opponents, rather than a simple inclusion or exclusion of source income

[250] MJ Radin, Contested Commodities (Harvard University Press, 1996) xiii.
[251] Harrison (n 33) 90.
[252] Ibid; Radin, Contested Commodities (n 250) 109-114.
[253] Employment Rights Act 1996 chapter 18.
[254] Working Time Regulations 1998, No 1833.
[255] Pensions Act 2004 chapter 35.
[256] Health and Safety at Work Act 1974 chapter 37.
[257] Trade Union and Labour Relations (Consolidation) Act 1992 chapter 52.
[258] Radin, Contested Commodities (n 250) 109-114; Harrison (n 33) 90.

entitlement. Such a framework is achievable under a liability rule or a hybrid system combining property and liability rules. The arguments in favour of source income entitlement will now be explored in the next section.

CHAPTER 4 (Part II) SHOULD SOURCE OWNERSHIP ENTITLEMENTS BE PROTECTED? SHOULD SUCH PROTECTION INCLUDE A LEGAL CHARACTERISATION OF SOURCE OWNERSHIP ENTITLEMENTS AS PROPERTY INTERESTS?

Proponents of source income entitlement – Instrumental justification (Theoretical arguments)

Promote Justice

Introduction

There are different conceptions of Justice,[1] however the focus of this discussion is on the notion of 'distributive justice' which is concerned with the fair distribution of benefits and burdens in society.[2] Distributive Justice is of relevance to this discussion because one of the considerations explored relates to the fair distribution of the economic benefits that flow from biotechnological research and how these benefits ought to be shared or distributed.[3] Whilst this discussion is not concerned with solving the thorny problem of weighting the exact share of profits that should be allocated to each party whose interest is represented in a biotechnological research enterprise, it does, however, seek to determine the principles that should guide such distribution and consequently, it is necessary to examine the concept of distributive justice.

Distributive Justice could be considered as a tool that facilitates the distribution of benefits and burdens among individuals who belong to a relevant group, the benefits and burdens being distributed in proportion to some criterion for distribution such as merit, needs equality and status.[4] It provides a moral and practical foundation for policy formation and

[1] Aristotle, *The Nichomachean Ethics*, trans. W. D. Ross, from *The Oxford Translation of Aristotle*, ed. W. D. Ross, vol. 9 (Oxford: The Clarendon Press, 1925); M Maiese, 'Principles of Justice and Fairness' *Beyond Intractability*. G Burgess and H Burgess (eds), Conflict Information Consortium, University of Colorado, Boulder. Posted: July 2003 <http://www.beyondintractability.org/bi-essay/principles-of-justice> accessed 19 June 2014.
[2] TK Paz, *Torts, Egalitarianism and Distributive Justice* (Ashgate Publishing, 2007) 5.
[3] See also, N Rescher, *Fairness: Theory & Practice of Distributive Justice* (Transaction Publishers, 2002).
[4] Paz (n 2).

analysis.[5] In the words of Rawls: 'Justice is the first [and most important] virtue of social institutions, as truth is of systems of thought'.[6] Principles of distributive justice '[provides the] moral guidance for the political processes and structures that affect the distribution of benefits and burdens in societies'[7] and helps to determine the appropriate distributive shares of the benefits and burdens in societies.[8] According to Rawls, 'each person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override' and justice does not permit sacrifices to be imposed on a few even if those sacrifices are outweighed by the larger sum of advantages enjoyed by many.[9] With this reasoning, it is therefore not in the interest of justice for a source's private interests in profits made from commercialising research using his or her biological material to be rejected simply because such an approach might promote the progression of socially useful research. Additionally, the school of thought that suggests that a source's share of profits from research should not be allocated to individual sources but rather that it should be shared on a wider scale as it is in the public interest to do so, would arguably not be in the interest of justice because it would mean that sources are essentially compelled to forfeit their entitlement to compensation, that sacrifices are imposed upon sources, in order to garner some benefit for the wider public.

The theory of relative deprivation highlights the importance of the effective operation of distributive justice principles in regulating interactions between persons in society with respect to rights, positions, powers, burdens and benefits.[10] In the context of

[5] J Konow, 'Distributive Justice' 1: <http://myweb.lmu.edu/jkonow/Distributive%20Justice.pdf> accessed 19 June 2014.
[6] J Rawls, *A Theory of Justice* (Revised Edition, Belknap Press: Harvard University Press, 1971) 3.
[7] J Lamont and C Favor, 'Distributive Justice' *The Stanford Encyclopedia of Philosophy* (Spring 2013 Edition), EN Zalta (ed) < http://plato.stanford.edu/archives/spr2013/entries/justice-distributive/> accessed 19 June 2014.
[8] Rawls (n 6) 4.
[9] Ibid.
[10] M Maiese, 'Distributive Justice' Beyond Intractability. G Burgess and H Burgess (eds), Conflict Information Consortium, University of Colorado, Boulder. Posted: June 2003 <http://www.beyondintractability.org/bi-essay/distributive-justice> accessed 19 June 2014. See also M Deutsch, 'Justice and Conflict' in *The Handbook of Conflict Resolution: Theory and Practice*, M Deutsch and PT Coleman eds, (San Francisco, Jossey-Bass Publishers, 2000) 43; WG Runciman, Relative deprivation and social justice : A study of attitudes to social inequality in twentieth-century England (University of California Press, 1966); I Walker, HJ Smith, Relative Deprivation: Specification, Development, and Integration (Cambridge University Press, 2001).

biotechnological research enterprise, an examination of the theory of relative deprivation would offer useful insight regarding the importance of upholding distributive justice principles in respect of the distribution of the economic benefits that flow from biotechnological research enterprise. According to the theory, individuals are likely to feel a sense of injustice where they perceive that a negative discrepancy exists between their outcomes and the outcomes received by others who are in similar situations and share similar characteristics with them.[11] Essentially, when individuals perceive that that they are at an unfair disadvantage in comparison to others or that they have not been allocated what they consider to be their entitlement or their 'fair share', their confidence in the institutions and systems that allow for such apparently unfair distribution and in society generally, will likely be undermined and they may desire to challenge such institutions and systems in order to improve their conditions.[12] This is particularly the case where a person's or a group's essential needs are not being met or if there are large discrepancies between the wealthy and those who enjoy little or no material wealth. [13] This phenomenon is evident in the recent civil unrest in Greece[14] and other European countries[15] and also the 'Arab Spring' uprisings[16] which started in 2010 and still continues at the time of writing (2014).[17]

Additionally, armed and civil resistance in Guatemala also seem to indicate a likely occurrence of social revolt in societies where resources are distributed unfairly. [18] 'Since the

[11] Ibid.
[12] Ibid.
[13] Ibid.
[14] N Kitsantonis and R Donadio 'Greek Parliament Passes Austerity Plan After Riots Rage': <http://www.nytimes.com/2012/02/13/world/europe/greeks-pessimistic-in-anti-austerity-protests.html?pagewanted=all&_r=0> accessed 19 June 2014; See also, BBC News Europe, 'Athens clashes as Greek police fire tear gas' <http://www.bbc.co.uk/news/world-europe-19724284> accessed 19 June 2014.
[15] B Gonzalez and A Khalip, 'Europe Austerity Protests: Strikes Sweep Southern Europe In Response To Cuts': <http://www.huffingtonpost.com/2012/11/14/europe-austerity-protests-strikes-greece-italy-france_n_2129091.html> accessed 19 June 2014; See also, BBC News Europe, 'Violent clashes as austerity protests grip EU cities': <http://www.bbc.co.uk/news/world-europe-20320993> accessed 19 June 2014.
[16] About.com, Middle East Issues, 'Arab Spring Uprisings': <http://middleeast.about.com/od/humanrightsdemocracy/tp/Arab-Spring-Uprisings.htm> accessed 19 June 2014; See also, BBC News World, 'Arab uprisings: Country by country – Egypt': <http://www.bbc.co.uk/news/world-12482291> accessed 19 June 2014.
[17] Maiese, 'Distributive Justice' (n 10).
[18] GP Murga, 'Promised the Earth: Agrarian Reform in the Guatemalan Socio-Economic Agreement' (1997):

colonial period, unfair land distribution and the prevailing agricultural economic system have been the prime causes of armed and civil resistance in Guatemala.'[19] While a selected few influential individuals have unrestricted access to communal lands that was taken from the Maya, the majority of the population in Guatemala live in poverty and only have access to farm lands that are too small to meet the basic needs of the average family. Such unfair land distribution infringes principles of distributive justice which includes equity, equality and need and thus, results in conflict.[20]

The foregoing discussion thus demonstrates that justice plays a crucial role in the very constitution of the fabric that holds society together and it would be accurate to state:

> The stability of a society—or any group, for that matter—depends upon the extent to which the members of that society feel that they are being treated justly. When some of society's members come to feel that they are subject to unequal treatment, the foundations have been laid for social unrest, disturbances, and strife. The members of a community depend on each other, and they will retain their social unity only to the extent that their institutions are just.[21]

By the above reasoning, the promotion of the interests of sources of human biological material is arguably important in maintaining the supply of biological material because it would likely form an incentive for those sources to contribute their biological material for use in research. Since the economic interests of others involved in biotechnological research

<http://www.c-r.org/sites/c-r.org/files/Accord%2002_7Promised%20the%20earth_1997_ENG.pdf> accessed 19 June 2014; Maiese (ibid).

[19] Murga (ibid).

[20] Maiese, 'Distributive Justice' (n 10).

[21] Rawls (n 6) cited in: M Velasquez, C Andre, T Shanks and MJ Meyer, 'Justice and Fairness' <http://www.scu.edu/ethics/practicing/decision/justice.html> accessed 19 June 2014. See also, Maiese, 'Distributive Justice' (ibid); Maiese, 'Principles of Justice and Fairness' (n 1).

enterprise are enforced, the economic interests of sources ought to be enforced, or else, sources might perceive that they are at an unfair disadvantage in comparison to other contributors involved in research enterprise and they might refuse to participate in research enterprise or make their biological material available for use in research.

Distributive justice and source income entitlement in the proceeds of commercialization of biological material

In the context of goods commonly produced through social and economic cooperation such as the proceeds of commercializing excised human biological material and products developed using human biological material (made possible by social and economic cooperation between sources of biological material; researchers, their sponsors and the universities that employ them; and biotechnology companies, pharmaceutical companies and medical device makers), what is Justice? As mentioned above, economic and commercial benefits ('the profits') from biotechnological enterprise are currently shared exclusively between the biotechnology industry and the researchers/universities that support that industry but the source from whom the raw material for the enterprise is extracted and without whom the enterprise will not go ahead, receives nothing. The question is: is this a fair distribution? Is this an effective operation of distributive justice? Commonsense morality would suggest not.

In *Moore*, Justice Mosk advanced the following forceful argument in favour of Mr Moore's and generally the income entitlement of individuals who contribute biological material to research:

> We are repeatedly told that the commercial products of the biotechnological revolution "hold the promise of tremendous profit." In the case at bar, for example, the complaint alleges that the market for the kinds of proteins produced by the Mo cell line was predicted to exceed $3 billion by 1990. These profits are currently shared exclusively between the biotechnology industry and the universities that support that industry… There is, however, a third party to the biotechnology enterprise--the patient who is the source of the blood or tissue from which all these profits are derived. While he may be a silent partner, his contribution to the venture is absolutely crucial…but for the cells of Moore's body taken by the defendants there would have been no Mo cell line at all. Yet defendants deny that Moore is entitled to any share whatever in the proceeds of this cell line. This is both inequitable and immoral…There are bountiful benefits, monetary and otherwise, to be derived from human biologics. To deny the person contributing the raw material a fair share of these ample benefits is both unfair and morally wrong…Biotechnology depends upon the contributions of both patients and researchers. If not for the patient's contribution of cells with unique attributes, the medical value of the bioengineered cells would be negligible. But for the physician's contribution of knowledge and skill in developing the cell product, the commercial value of the patient's cells would also be negligible. Failing to compensate the patient unjustly enriches the researcher because only the researcher's contribution is recognized.[22]

[22] *Moore v Regents of the University of California* [1990] (Moore SC) 793 P 2d 479 (Cal SC) [517] (Mosk J).

The above argument made by Mosk J seems to be established upon the belief that distributive justice demands that sources of biological material be compensated for their input towards biotechnological research enterprise.[23] Essentially, the researchers who investigate the therapeutic potential of human biological material receive salaries and even in some instances, acquire shares in the profits resulting from biotechnological research enterprise.[24] Policy makers who introduce laws that govern biotechnological research and regulators that supervise the activities of the biotechnology industry also receive salaries, as do the journalists and academics who study and write about the field.[25] Suppliers of chemical reagents and other equipment used in biotechnological research are paid for their supplies.[26] Biotechnology companies, pharmaceutical companies and medical device makers that invest capital in biotechnological research expect to reap profits from their investments as well.[27] Thus, on grounds of equity, the suppliers of the essential raw material (biological material) that are important in driving scientific innovation and making scientific discoveries also should receive compensation.[28]

There are those who suggest, however, that 'the biotechnology industry is entitled to reap all of the pecuniary rewards flowing from its inventive work, because its endeavours require significant investment of capital, labour and time and offer only a small likelihood of success.'[29] Advocates for this view argue that sources of biological material do not merit any share of the economic and commercial benefits that flow from biotechnological research because they do not work or do anything to create the biological material. On this view, sources merely contribute naturally occurring raw material which only evolves into something valuable through the inventiveness and effort of the researchers, 'like unformed

[23] R Korobkin, "No Compensation" or "Pro Compensation": Moore v. Regents and Default Rules for Human Tissue Donations (2007) 40 (1) Journal of Health Law 11.
[24] Ibid.
[25] Ibid.
[26] DM Gitter, 'Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material' (2004) 61 Wash. & Lee L. Rev. 257, 295.
[27] Korobkin, *"No Compensation" or "Pro Compensation"* (n 23).
[28] Ibid.
[29] Gitter (n 26) 294.

clay or stone transformed by the hands of a master sculptor into a valuable work of art'.[30] According to this view, it is the researcher's contribution that actually transforms biological material into marketable products.[31] While there is some merit in this argument, it is however important to note: 'Human [biological material], embodying both physiological properties and information often available from no other source, falls into a different category of value contributed.'[32] It is true that in most cases biological material has little or no value at the onset of supply when it is transferred from the source to the researcher and it is only when the researcher has invested his or her skill and labour in developing it that it becomes commercially valuable.[33] It is also true that in other cases each individual biological specimen may only be valuable as part of a collection when it is for instance, aggregated with specimen from other sources that share similar characteristics, but could have little or no value of itself.[34] Nevertheless, there are still instances as exemplified by the case of Moore and Lacks where sources supply rare tissue 'that clearly had unique [attributes] that gave it monetary value even without the input of further skill and labour from researchers.'[35]

It should also be noted that even where the source's biological material does not possess unique qualities and only furthers knowledge or becomes valuable when it forms part of a collection or when aggregated with other biological specimen with similar characteristics, each individual specimen that forms part of the collection is still a valuable member of the collective unit and without each individual sample, there would be no valuable collection. Human biological material is an essential tool for most health related biotechnological

[30] *Moore v Regents of the University of California* [1988] 202 Cal. Rptr. 494 [537] (George J dissenting). For a discussion of this argument, see D Dickenson, *Body Shopping: Converting Body Parts to Profit* (Oneworld, 2008) 31; Gitter (n 26) 294.
[31] Gitter (ibid).
[32] C Harrison, 'Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue' (2002) 28 Am. J.L. & Med. 77, 82.
[33] D Nicol, 'Property in Human Tissue and the Right of Commercialisation: The Interface between Tangible and Intellectual Property' (2004) 30 Monash University Law Review 139, 153, 158.
[34] Ibid. Harrison (n 32) 84.
[35] Nicol (n 33).

research[36] and researchers cannot simply acquire medical knowledge or develop valuable drugs, diagnostics and therapies out of 'thin air'. That researchers' contribution (labour, skill, inventiveness, capital) is apparently more valuable and thus more deserving of reward than the source's contribution (mere contribution of raw material with which researchers work),[37] is a question of 'proportionate allocation rather than simple inclusion or exclusion [of source compensation].'[38]

The argument that sources are not entitled to any share of profits or compensation from biotechnological research enterprise because they simply supply naturally occurring material which they had not worked to create is also not insurmountable. Source biological material used in biotechnological research is arguably analogous to natural resources.[39] In the example cited by the appellate court in *Moore*, '[if a farmer] pays an oil refinery company to remove from his land crude oil that is ruining his crop, the farmer who would be unable without the refinery's aid to turn the crude oil into a usable product, is still entitled to a share of the refinery's profits from his land's product.'[40] By this reasoning, the fact that sources like Mr Moore might consent to and might even be willing to pay for surgery to remove a potentially fatal diseased tissue from their body and would be unable to turn such tissue into a commercially valuable cell line without the input of a researcher should not be reason to prevent such individuals from partaking in the financial proceeds of the cell line and other products developed using the diseased tissue.[41]

[36] Ibid, 163.
[37] Harrison (n 32) 82.
[38] Ibid.
[39] Gitter (n 26) 295, n 149.
[40] *Moore CA* (n 30) 507 (quoting Rorie Sherman, 'The Selling of Body Parts' National Law Journal (7 Dec 1987) 1).
[41] TP Dillon, 'Source Compensation for Tissue and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits' (1989) 64 Notre Dame L. Rev. 628, 641.

While some commentators have sought to make a distinction in the above analogy which purports to justify the sharing of profits with the farmer but not a source of biological material on the basis that unrefined oil has some value but a diseased tissue is a liability to the source,[42] such an argument is unconvincing. This is because in the hypothetical case of the farmer, although the crude oil might have some value, it is still a liability to the farmer because it was ruining his crops, which is why he would pay to have the oil removed from his land. Furthermore, while diseased tissue like that of Moore and Lacks might be a liability to them in that it was slowing killing them, it also had unique attributes that gave it commercial value.[43] Human biological material is also analogous to the chemical reagents and other equipment used in research to the extent that like manufacturers of chemical reagents and other tools incurred capital expenditure in developing their reagents and tools, sources also incurred capital expenditure in the 'production' of their biological material:[44]

> The [source's] capital expenditure covers the great expense of a lifetime of care and nurture in the 'production' of [biological material] that are suitable for [research]…[45] The acts of feeding, washing, educating, exercising and just residing in a human body all contribute to the production [and promote the conditions required for the production of biological material that can be used in research. If the individual failed to provide nutrition to the human body, the body will starve and eventually die and there will be no biological material to be used for research in the first place].'[46]

Developing the above reasoning, Kevorkian suggests: 'What is glibly and mistakenly execrated as the [donor's] profit is really "at cost" reimbursement for substantial "capital

[42] Ibid.
[43] Nicol (n 33).
[44] A George, Marketing Humanity: Should we allow the sale of Human body parts? [2005] UTS L Rev 2; 2005 7 UTS Law Review 11, (IV (B) (2).
[45] Ibid.
[46] Ibid.

expenditure" of a uniquely biological kind over a long period of time. And that mistake is partly responsible for an unjust and harmful moral conclusion.'[47]

The legal enforcement of source income entitlement is arguably also a matter of equality in the sense that the law should recognize the source's right to do with his biological material what recipients can lawfully do with the biological material. Therefore, because researchers and companies can ethically and lawfully exploit excised biological material for its economic and commercial value and various legal provisions are in place to safeguard their interests in order to encourage innovation among them and provide an incentive for them to engage in research ventures, the same treatment should be directed at sources of biological material. Accordingly, there ought to be legal safeguards to enforce source economic interests in biological material removed from their bodies.[48]

There are those who however assert that: 'in an ideal world, equality would be furthered if individuals had no right to profit from their natural endowments-from the kind of "brute luck" that gave Moore a multi-million dollar spleen-but only from the "option luck" resulting from their voluntary choices.'[49] However, we do not live in an ideal world. Since current conditions allow participants in clinical trials, actors, models, singers and even scientists to legally exploit their natural endowments for profit,[50] this notion of equality cannot justify denying compensation to sources of biological material in the research context.[51]

[47] J Kevorkian, 'Marketing of Human Organs and Tissues is Justified and Necessary' (1989) 7 Medicine and Law 557, 560; George (ibid).
[48] M Dodson and R Williamson, 'Indigenous Peoples and the Morality of the Human Genome Project' (1999) 25 Journal of Medical Ethics 204, 207-208.
[49] Harrison (n 32) 82. See also E Rakowski, *Equal Justice* (Clarendon Press, 1991) 138, 173-74.
[50] Dickenson (n 30) 29, Harrison (ibid); Gitter (n 26) 297.
[51] Harrison (ibid).

Additionally, legal recognition of source income entitlement could be seen 'as one of reciprocity [to the extent that] the person from whose body the biological sample is taken should share in the rewards resulting from his or her contribution.'[52] Sources of tissue with unique qualities have done their bit to deliver advantages in the form of commercially valuable biological material to the biotechnology industry and while they might have benefited in the past from therapeutic products derived from research using biological material and while they can also expect to receive therapeutic benefit from future diagnostics and treatments developed from biotechnological research, if reciprocity is about mutuality then it is arguable that sources should also expect to benefit financially from the enterprise since they themselves delivered financial benefit to others engaged in the cooperative venture.

Although the social utility argument has been outlined in varying depth in previous chapters, it will be consolidated in this part of the discussion in order to provide a complete representation of the justice arguments.

Arguably, maintaining the economic incentive to drive innovation, conduct and invest in biotechnological research is in the best interests of society as a whole because of the valuable knowledge of the causes and consequences of diseases, and the therapeutic and diagnostic products generated from such research, which aid human health and help to alleviate the suffering caused by debilitating diseases and illnesses ranging from cancer to diabetes to infertility. Those who object to the legal recognition of source income entitlement have regularly advocated that such a measure is necessary to maintain the economic incentive in biotechnological research because placing researchers under an obligation to compensate sources for use of biological material will potentially undermine

[52] Ibid, 82.

the progress of research and might ultimately lead to a delay in the search for a cure for sufferers of diseases and high diagnostics and treatment costs. They advance that these potential state of affairs makes the legal recognition of source income entitlement contrary to the interests of society as a whole. However, since many of these concerns can be alleviated with the appropriate compensation construct, these concerns do not represent a compelling justification for rejecting source income entitlement. On the other hand, the single-minded pursuit of research interests as currently reflected in the current donative model, threatens to obscure important considerations that are crucial in helping to promote the progress of biotechnological research.[53] Such considerations include justice for sources of biological material and trust between researchers and the public.[54] Continuing contribution of biological material towards research enterprise arguably depends upon the maintenance of these values.[55] If the public (actual and prospective sources of biological material) come to distrust the medical and scientific community then they could simply choose not to participate in biotechnological research which could decrease the availability of biological material for use in research. This potential state of affairs is arguably not in the interests of society as a whole.

Additionally, because biological material supplied for research is in some instances initially removed in the clinical setting during the course of a patient's treatment and some researchers are also medical doctors, patients in the clinical setting may begin to suspect that their doctors are more interested in profiteering from their biological material than improving their health or dignity and they might then struggle to maintain therapeutic relationships.[56] This could undermine the doctor-patient relationship and might make a patient less likely to place confidence in his or her doctor and heed the doctor's medical advice, or it might even result in reluctance from patients to seek medical help in the first

[53] Ibid, 104.
[54] Ibid.
[55] Ibid.
[56] Harrison (n 32) 85.

place.[57] Such a state of affairs could ultimately undermine patient care. Legal recognition of source income entitlement would at the very least, promote the perception that sources are being treated equally as compared to other contributors to the research enterprise and like all contributors to research, they too can if they so wish, claim remuneration in recognition of their contribution or choose to direct such remuneration into further research.

Arguably, as well as ensuring the availability of competent and ethical doctors, the state's responsibility in safeguarding public health also requires it to ensure that the public have sufficient trust in doctors to seek medical care.[58] The current status quo raises serious public health concerns to the extent that it threatens to undermine doctor-patient relationship – the state arguably has a responsibility to prevent damage to the doctor-patient relationship and in this regard, to prevent potential damage to public health.[59]

The legal recognition of source income entitlement under the appropriate policy framework, however, is in the interests of society as a whole because it will both help to promote justice among researchers and sources of biological material, and maintain trust between the medical and scientific community and the public, which could potentially induce supply of biological material. The fact that surveys already show that the public perceive that the biotechnology industry is 'dominated by the profit motive rather than concern for their welfare'[60] seem to indicate that the industry and policy makers may need to tackle the issue of source compensation sooner rather than later.

[57] Gitter (n 26) 291, n 131.
[58] Ibid.
[59] Ibid.
[60] M Levitt and S Weldon, 'A well-placed trust? Public perceptions of the governance of DNA databases' (2005) 15 Critical Public Health 311.

The dominant principle of distributive justice and source income entitlement in the proceeds of commercialization of biological material

Since the various modes of distribution as reflected in the different categories of distributive justice principles advance different social goals,[61] it is necessary to seek to identify the dominant principle of distributive justice that ought to operate in the context of biotechnological research, one that should produce a more favourable state of affairs for sources of biological material than the current system and help to promote justice for them. Such enquiry necessitates an examination of the different social goals advanced by each principle of distributive justice.

Equity based principles of distributive justice foster the 'motivation to produce and to be rewarded for one's productivity.'[62] They are founded upon the goal of society to engage its members in efficient and effective production.[63] Equality based principles are rooted in the understanding that equal distribution makes individuals feel that they fully belong to society and this sense of full-fledged membership allows society to keep its members and thus preserve its survival as an institution.[64] The principles of need and social utility on the other hand ensures that the basic and essential needs of each member of society (need) or the collective needs of the society are met (social utility), which in turn, helps to sustain the well-being of its members and reduces the incidence of both criminal disturbance and political unrest.[65] However, due to the different social goals that each principle seeks to advance, they are often in tension with each other.[66] For this reason, one principle is usually considered to be the dominant criterion for distribution and the chosen principle for distribution will then result in the emergence of an economic system characterised by

[61] Maiese, 'Distributive Justice' (n 10). See also, RT Buttram, R Folger and BH Sheppard, 'Equity, Equality and Need: Three Faces of Social Justice' in in BB Bunker and M Deutsch (eds) *Conflict, Cooperation, and Justice: Essays Inspired by the Work of Morton Deutsch* (San Francisco: Jossey-Bass Inc, 1995) 263.
[62] Ibid.
[63] Ibid.
[64] Ibid.
[65] Ibid.
[66] Ibid.

equality, competition, or social welfare safety nets.[67] More economically developed nations are usually focused on a central criterion based upon equity principles as there is generally equality of opportunities to compete in such countries while less developed nations are more inclined towards a needs based system and a communitarian society such as the Amish community may be more inclined towards a system based upon social utility, though it should be noted that most societies usually incorporate elements of each distributive justice principle. [68]

The central distributive criterion in biotechnological research enterprise appears to be equity based principles of distributive Justice.[69] The current patenting provisions and other related legal and regulatory provisions reward innovation and productivity in biotechnology enterprise by protecting the interests of researchers and biotechnology companies in the proceeds generated from commercialising biological material.[70] Patent Law for instance, '[gives] the patent holder a period of time when they are free from competition in the marketplace'.[71] The combined impact of these provisions is to form an incentive for biotechnology firms and researchers to invest in the discovery of new drugs and diagnostics. Additionally, such provisions promote the input of productive contributions and foster productivity in the biotechnology industry. These outcomes are reflective of competitive markets which are characteristic of a mode of distribution based upon equity.[72] It is not advocated here that this mode of distribution should change. However, it is submitted that because an argument based on equity favours the compensation of sources of biological material for the valuable contribution that they make towards biotechnological research enterprise (as shown above), legal recognition of source income entitlement in relation to

[67] Ibid.
[68] Ibid.
[69] Gitter also supported such an observation (See Gitter (n 26) 313: 'Our legal and economic systems are premised upon the notion that the promise of reward for individual effort, not communitarian ideals, will stimulate [biotechnological] research and innovation that will redound to the benefit of society.')
[70] Nicol (33) 163.
[71] Ibid.
[72] Maiese, 'Distributive Justice' (n 10).

the proceeds of commercialisation of research using the source's biological material simply represents the proper application of an equity based principle of distributive Justice.

While philosophers like Rawls look to devising or analysing the outcome of a particular distribution in order to ascertain whether the distribution is just, there are those who allege that distributive justice is about the process not the outcome.[73] Nozick, for instance, opines that distributive justice requires simply the construction of rules relating to the acquisition and transfer of resources and benefits, which members of a society should be obliged to follow.[74] By his reasoning, the objective of distributive justice should not be inclined towards attaining any particular outcome of distribution but should rather be centred upon promoting a fair process of exchange.[75] On the other hand, there are others who consider both process and outcome to have a role to play in effecting distributive justice,[76] since a fair distributive outcome may have resulted from an unfair procedure and conversely, a fair procedure could result in an unfair distribution.[77] Those who subscribe to this school of thought observe that the processes of distribution must be fair in order for people to feel that they have received a fair outcome.[78] In this connection, distributive justice is thus linked to procedural justice.[79] In general terms, procedural justice in a liberal democracy 'requires that people have the ability, through their constitutional institutions or otherwise, to affect decision-making about the distribution of important social goods.'[80] Arguably from a procedural justice viewpoint, justice is not being served because source economic interests are not represented in the commercialisation process involving human biological material nor are their views considered in decisions relating to the allocation of the economic and commercial benefits that flow from biotechnological research. While ethical

[73] Ibid.
[74] See generally, R Nozick, *Anarchy, State and Utopia* (New York: Basic Books, 1974). See also, Maiese (ibid).
[75] Ibid.
[76] Maiese (ibid).
[77] Ibid.
[78] Ibid.
[79] Ibid.
[80] Harrison (n 32) 82. See also Human Genome Organisation (HUGO) Ethics Committee, 'Statement on Benefit Sharing' (2000) 10 Eubios Journal of Asian and International Bioethics 70, 70.

bodies such as the Nuffield Council of Bioethics have attempted to muster public deliberation on this matter in their 2010 public consultation[81] and reflect the results of such deliberation in their subsequent 2011 report,[82] more is required. The reason being that while the Nuffield Council of Bioethics' consultation is a step in the right direction, their consultation and subsequent report was more focused upon donation of biological material in the transplant context and issues relating to the supply of biological material for research seem to have been considered as a side issue. Consequently, the public deliberation that informed their report cannot be taken to fully reflect public opinion regarding the allocation of the economic and commercial benefits that flow from biotechnology research enterprise and generally in relation to other key issues raised in the context of the supply of biological material for research purposes. The proposed policy framework advanced in the next chapter will seek to promote justice for sources of biological material by incorporating a more effective application of equity based principles of distributive justice and procedural justice than the current system.

Proponents of source income entitlement – Instrumental justification (Empirical case)

It remains necessary to put the specific claims of both proponents and opponents of source income entitlement through the rigours of empirical investigation. However, the limited empirical evidence available from case studies in the context of living organ donation[83] and those involving controlled experiments and observational studies studying generally the impact of incentive on donation of biological material[84] seem to indicate that the offer of

[81] Nuffield Council on Bioethics, *Give and take? Human bodies in medicine and research* (Consultation Paper, Nuffield Council on Bioethics, April 2010).

[82] See generally, Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (Nuffield Council on Bioethics, 11 October 2011).

[83] AJ Ghods, 'Renal transplantation in Iran' (2002) 17 Nephrol Dial Transplant 222, 222–228. Also see AJ Ghods, 'Ethical issues and living unrelated donor kidney transplantation' (2009) 3 Iranian Journal of Kidney Diseases 183, 183-91; AJ Ghods and S Savaj, 'Iranian Model of Paid and Regulated Living-Unrelated Kidney Donation' (2006) 1 Clin J Am Soc Nephrol 1136, 1136 -1145*;* A Bagheri, 'Compensated kidney donation: an ethical review of the Iranian model' (2006) 16 Kennedy Institute of Ethics Journal*,* 269*,* 269-82.

[84] N Lacetera, M Macis and R Slonim 'Will there be blood? incentives and substitution effects in pro-social behavior (2009) *IZA Discussion Papers*: No. 4567, 20; L Götte and A Stutzer, 'Blood donations and incentives: evidence from a field experiment' (2008) IZA Discussion Papers, No. 3580

financial incentives does induce donation from some individuals. Also, findings from empirical studies[85] that sought to examine the impact of incentive on donation of biological material more generally also do not support the concerns of opponents of source income entitlement that altruistic donation could be crowded out by the offer of financial incentives.[86] Aggregated together, this would seem to support the case for the legal recognition of source income entitlement as it suggests that such recognition could create a desirable state of affairs in favour of research because it could promote the availability of biological material for research without inhibiting altruistic donations.

Empirical evidence from Iran which offers payment in the context of living organ donation seems to support the foregoing contention.[87] 'During the period (1967 – 1988), all transplants [in Iran] were from living related donors (LRD) and the number of transplants performed was much lower than national demand.'[88] As a result of an increasing waiting list for kidney transplant where demand exceeded supply, a government regulated and compensated[89] program for living unrelated kidney donation (LURD) was introduced in 1988.[90] The program is widely considered to be a regulated market for transplantable kidneys, although sources are paid a fixed amount (ten million Iranian Rials (approximately US$1,000)) which is described as a 'social or sacrificial' gift.[91] This is also in spite of the fact that the amount has not increased since the system was introduced in 1988,[92] and is

[85] See Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) para 5.47, para 6.19, appendix 1 and 2.
[86] Ibid. See also Lacetera, Macis and Slonim (n 84) 20.
[87] Ghods, 'Renal transplantation in Iran' (n 83). Also see Ghods, 'Ethical issues and living unrelated donor kidney transplantation' (n 83); Ghods and Savaj, 'Iranian Model of Paid and Regulated Living-Unrelated Kidney (n 83); Bagheri (n 83).
[88] Ghods: 'Renal transplantation in Iran' (ibid) 222.
[89] Ghods and Savaj, 'Iranian Model of Paid and Regulated Living-Unrelated Kidney (n 83) 1137; RWL Major, 'Paying Kidney donors: time to follow Iran?' (2008) 11 McGill Journal of Medicine 67, 67.
[90] Ghods, 'Renal transplantation in Iran' (n 83) 222.
[91] A Bagheri, cited in Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) 71 n 200.
[92] Ghods, 'Ethical issues and living unrelated donor kidney transplantation' (n 83) 189.

therefore not determined by market factors. However, the important point to note is that by the end of 1999, Iran's kidney transplant waiting list was successfully eliminated.[93]

It is possible to suggest that the quick and successful elimination of the waiting list in Iran was due to the lower prevalence of patients with end stage renal disease in developing countries such as Iran, as compared with developed countries, because many patients from villages and small towns in developing countries are unable to access appropriate health services and do not receive a diagnosis, and are therefore not referred for dialysis therapy, which then results in fewer numbers of transplant candidates.[94] However, this does not negate the fact that Iran once had a problem with kidney shortages for transplant and was able to eliminate this problem only once a regulated market was introduced. Additionally, the majority of kidneys used in the transplants culminating in the period of elimination were from kidneys that would have been collected from the market program. For instance, in the period 1984 -2000, over 76% of all kidney transplants were from LURDs.[95] This would therefore suggest that the regulated market and by extension, the offer of compensation created an increase in the availability of kidneys which otherwise would not have occurred. The circumstances in Iran stands in contrast to that in countries such as the United States and United Kingdom where such a financial reward system does not exist, where demand exceeds supply[96] and there are long waiting lists of people waiting for kidneys. For instance, as at 12 June 2014, there were 5618 patients on the transplant waiting list for a kidney in

[93] Ghods, 'Renal transplantation in Iran' (n 83) 222-223, See also Ghods and Savaj, 'Iranian Model of Paid and Regulated Living-Unrelated Kidney (n 83) 1137, Ghods, 'Ethical issues and living unrelated donor kidney transplantation' (ibid) 183; Major (n 89) 68.

[94] Ghods and Savaj, 'Iranian Model of Paid and Regulated Living-Unrelated Kidney (ibid) 1139.

[95] Ghods, 'Renal transplantation in Iran' (n 83) 223, 223 fig 2.

[96] Major (n 89) 68. See also FL Delmonico, MA McBride, 'Analysis of the wait list and deaths among candidates waiting for a kidney transplant' (2008) 86 Transplantation 1678, 1678-1683; Ghods, 'Ethical issues and living unrelated donor kidney transplantation' (n 83) 185 – 186.

the United Kingdom[97] and in the United States, there were 100, 874 patients on the waiting list for a kidney as at 13 June 2014.[98]

The risks to a living donor's health in the donation of a kidney for transplant purposes is arguably comparatively more significant than the potential risks to the health of individuals who supply biological material for research purposes. Biological material supplied for research purposes would usually comprise regenerative tissue, of which removal would not have a permanently deleterious effect on the health of the source.[99] In other cases, it might be diseased tissue which was removed in the course of a patient's treatment,[100] and so donation of such material for research would not involve further medical procedures to be conducted upon the patient. It is possible to suggest that if the offer of financial incentives can be associated with an increase in the supply of kidneys in Iran, then where sources are offered financial incentives in the comparatively 'less risky' research context, there might also be an increase in the supply of biological material.

Whilst the Iran model is not without its limitations and has highlighted some difficulties with a system that offers financial reward in exchange for the supply of biological material, those difficulties are not insurmountable. The Iranian model is plagued with problems of illegal payments and exploitation[101] which would seem to support the contention of those who advocate for a ban on financial rewards for biological material. However, such difficulties

[97] NHS Blood and Transplant, Organ Donation and Transplantation Activity figures for the UK as at 13 June 2014 (NHS Blood and Transplant, 13 June 2014): <http://www.organdonation.nhs.uk/statistics/downloads/weekly_stats.pdf> accessed 19 June 2014.
[98] US Department of Health and Human Services (OPTN data, 13 June 2014): <http://optn.transplant.hrsa.gov/latestData/rptData.asp> accessed 19 June 2014. <http://optn.transplant.hrsa.gov/latestData/step2.asp?> accessed 19 June 2014.
[99] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) 36-39 para 1.9, 1.10, 1.12 and 1.13-1.16; See also Gitter (n 26) 313, 299 n 164.
[100] Dillon (n 41) 634, 639; Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (ibid).
[101] Ghods, 'Ethical issues and living unrelated donor kidney transplantation' (n 83) 189-190; Major (n 89) 68.

can be resolved with appropriate legislation and robust enforcement measures. There could, for instance, be a ban which is reinforced by criminal sanctions preventing biotechnology companies from giving sources of biological material any amount outside the statutory prescribed compensation. Alternatively, such a system could stipulate that where a researcher considers that a source of biological material deserves to be paid a higher amount than the statutory compensation, the researcher could only do so if he or she provides satisfactory justification for the higher amount to the Human Tissue Authority and can only pay the higher amount to the source with the approval of the Authority. Legislation may also specify an upper limit in such instances which may not be exceeded in any case. An analogy can be drawn with the guidelines from the American Society for Reproductive Medicine (ASRM) which stipulates that payments for eggs for fertility treatment exceeding $5000 should be justified and those exceeding $10,000 are not appropriate.[102] However, since these provisions are only guidelines, it is common in the US for payments of $5000 to $10,000 to be made and in some cases; such payments could even reach as high as $50,000 where sources have particular physical, cultural or intellectual traits.[103] For instance, sources who are Ivy-League students or women of East Asian or Jewish descent.[104] On the other hand, the provision envisaged here will be a mandatory provision stipulated in legislation and so researchers and other recipients of tissue will be obliged to comply with it.

The model proposed has an added advantage over the Iranian model because the compensation under the proposed model is not paid in direct exchange for biological material, instead, it is a delayed compensation, payment of which is subject to some prescribed conditions being met, which removes the prospect of immediate payment and reduces a 'quick money' mentality where people might think they could acquire immediate gain from their excised biological material and may take risks that is not favourable to their health and which they would otherwise not have taken.

[102] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) 73.
[103] Ibid.
[104] Ibid.

The fact that studies involving controlled experiments and observational studies conducted in the US also indicate a higher rate of participation where financial incentive is offered when compared with instances where financial incentive is not offered seems to reinforce the view that the offer of financial incentives in the research context might induce individuals to contribute biological material and thus increase the availability of biological material. A US field experiment that analysed participation at four pairs of blood drives where one drive from each pair offered potential donors a gift card ($5 in two drives and $20 in the other two), while the paired controls offered no incentive, found that both turnout and the amount of blood collected at the drives offering the incentives were increased, with larger effects noted at the drives that offered the greater incentive.[105]

Based on the above study, it is reasonable to deduce that if an incentivising effect, increased participation and increased supply of biological material is observed in circumstances where low value incentives are offered, then a relatively significant compensation as envisaged here, in view of the huge amount of profits made in biotechnological research,[106] will potentially induce supply of biological material for research and have a positive impact on biotechnological research enterprise. The apparent surplus of kidney sellers in Iran[107] where kidney sellers are offered ten million Iranian Rials (approximately US$1,000);[108] and the 'ready availability of eggs for fertility treatment in the US'[109] where payments of $5000 to $10,000 are commonplace[110] seem to support such a contention.

[105] Lacetera, Macis and Slonim (n 84) 12-16, 20.
[106] Biotechnology companies worldwide boosted profit by 37 percent to a record $5.2 billion in 2012 (M Tirrell, 'Biotechnology Draws Record Profit as Research Money Slows': <http://www.bloomberg.com/news/2013-04-23/biotechnology-draws-record-profit-as-research-money-slows.html> accessed 19 June 2014).
[107] Ghods, 'Ethical issues and living unrelated donor kidney transplantation' (n 83) 189; Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) 167.
[108] Bagheri (n 83).
[109] AD Levine, 'The oversight and practice of oocyte donation in the United States, United Kingdom and Canada' (2011), cited in Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) 167 n 599.
[110] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (ibid) 73.

Support for a system that offers substantial financial incentive as opposed to low value/nominal incentive seems to be indicated in studies conducted in Sweden and Switzerland. One such study involving 262 students found that the offer of a small financial incentive ($7) neither positively nor negatively impacted upon whether prospective blood donors actually donated.[111] However, a Swiss study involving 10,000 previous blood donors showed a five per cent higher donation rate in those offered a free lottery ticket (estimated face value $4.30; speculative value incalculable) who had a low rate of past donations, over those receiving a free request to donate, and those being additionally offered a cholesterol test (estimated value $13).[112] On the other hand, observations from the 'street talk' project carried out by the New Economics Foundation in the UK would seem to indicate support for the first study (Sweden) by suggesting that the offer of financial incentives is likely to have neither a positive or negative impact on individuals' willingness to provide biological material. The project organisers invited 499 people from shopping streets and centres in the UK to give their opinions on the efficacy and ethics of various forms of incentives for donation.[113] It was discovered that 'a significant majority of participants considered direct payments of any size for all donation types to be unethical and opined that such payments would not influence their own decision to donate, although they viewed more positively a donation to charity in return for bodily donation.'[114]

It is, however, possible that the participants' response was attributable to the forms of donation that they were asked to consider which include 'joining the Organ Donor Register to donate organs after one's death and donating sperm or eggs to help a childless couple'.[115] Both forms of donation either involve facilitating life-saving or life-giving treatment to the recipients and thus improving the well-being of immediate others. In the case of organ donation, the donated organs are likely to be used in the treatment and thus

[111] C Mellström, and M Johanneson, 'Crowding out in blood donation: was Titmuss right?' (2008) 6 Journal of the European Economic Association 845, 845-63.
[112] Götte and Stutzer (n 84) 10-17.
[113] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) 167, Appendix 1.
[114] Ibid.
[115] Ibid.

in improving the health of immediate others. Similarly, donating sperm or eggs to help a childless couple also involves contributing to the welfare of immediate others, specifically, enabling the couple to have the opportunity to become parents and in so doing alleviating the potentially detrimental impact that childlessness can have upon their physical and mental health. With such donations, there is a close connection between the donation and the well-being of and the benefit to specific (if unknown) others and 'values such as generosity and compassion are encouraged [and will likely play a more significant role in motivating donation than in the research context].'[116] Also, societal expectation in such contexts is that a donor conform with the 'community-wide commitment to provide for others… and he or she should be moved to self-sacrifice by the health needs of others and his or her action should express a sense of shared obligation, of solidarity to provide that which is essential for life or health'.[117] In both contexts, financial reward may be considered to be capable of posing a high risk to communal values[118] and distorting the selfless and altruistic motivations of the donors and become the primary reason for acting rather than a genuine concern for the welfare of others.

The respondents' views may differ if the donation was for research purposes where 'while donated biological material will be used with the aim of improving health in the long term, the connection between the donation and that outcome is both extended and uncertain,'[119] 'the benefit to immediate others is absent'[120] and argument of solidarity exert less moral force. Furthermore, argument of altruism are likely to exert less moral force because the immediate beneficiary/user of the biological material in the case of commercial researchers, does not require it to improve his or her health but will be exploiting the donated biological material for its commercial and economic value. Thus, the respondents' views may be altered if they were told that the donation was going towards commercial research and the

[116] Ibid, 145.
[117] Ibid, 144.
[118] Ibid, 147.
[119] Ibid, 145
[120] Ibid.

recipient researcher and biotechnology company stand to make significant profits from the enterprise by selling or claiming royalties from products derived from the enterprise-products derived from material which the donors gave for free and which the recipients will indirectly sell back to the donors through sales of drugs and diagnostics to the National Health Service (which is supported by the public's tax and national insurance contributions) and private purchases of drugs and diagnostics from pharmacists and chemists.

It is also interesting to note that studies have shown a distinction between participants' intentions and their actual behaviour, in other words, 'what people say they will do in certain circumstances does not necessarily match what they actually do'.[121] For instance, Swiss studies asking people about their intentions have suggested that an offer of a free cholesterol test would be effective in recruiting additional donors.[122] However, studies measuring actual behaviour have failed to recruit additional donors by offering a free cholesterol test.[123] This discrepancy between intention and actual behaviour is illustrated in findings from observational and experimental studies that sought to measure the impact of incentive upon altruistic donations. These studies do not support the concern 'that altruistic donors are 'crowded out' by the availability of a (small) financial incentive,'[124] but findings from studies that only ask participants about their intentions seem to support concerns about the possibility of crowding out of altruistic donors by the availability of financial incentive.[125]

[121] Ibid, 167.
[122] SA Glynn, AE Williams, CC Nass, J Bethel, D Kessler, EP Scott, J Fridey, SH Kleinman, GB Schreiber, 'Attitudes toward blood donation incentives in the United States: implications for donor recruitment' (2003) 43 Transfusion 7, 7-16.
[123] L Goette, A Stutzer, G Yavuzcan, BM Frey, 'Free cholesterol testing as a motivation device in blood donations: evidence from field experiments' (2009) 49 Transfusion 524, 524, 527-530;
Götte and Stutzer (n 84) 10-17.
[124] See Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) 145 para 5.47, 166 para 6.19, appendix 1 and 2. See also Lacetera, Macis and Slonim (n 84) 20.
[125] L Goette, A Stutzer, BM Frey 'Prosocial motivation and blood donations: a survey of the empirical literature' (2010) 37 Transfusion Medicine and Hemotherapy 149, 149-153.

Findings from the above studies seem to suggest that even if some individuals and potential sources say they will be appalled by payment and would reject any form of payment offered to them in recognition of their contribution to research, this is not necessarily the case in practice. The reality, on the other hand, is that offers of financial incentive do induce participation and do provide a powerful incentive for some people to participate in a particular enterprise– the plethora and popularity in everyday normality of competitions offering financial incentives (for example, 'Deal or No Deal, Bingo, the 'National Lottery', the 'Health Lottery', 'Who wants to be a millionaire') and the high rate of participation in and success of long standing competitions such as the National Lottery would appear to support this contention.

However, in spite of the apparent support for the case for source compensation and by extension, the recognition of source income entitlement, certain limitations of the above case studies should be noted. Firstly, results from one culture and one set of circumstances or conditions may not necessarily translate to another so the findings and observations drawn from studies from Iran, US, Sweden and Switzerland may not necessarily reflect what would happen in the UK Jurisdiction. Secondly, results drawn from the context of organs intended for transplant purposes may not necessarily translate into the research context. Consequently the conclusions drawn from the above studies should be regarded as instructive but not determinative of what would happen if source income entitlement is legally recognised in the research context in the United Kingdom.

Conclusion

In summary, the law should reinforce the current criminal liability based mechanism for safeguarding source management entitlement with a clear and coherent mechanism to claim property based remedies which would actually serve to further source interests rather than simply promoting state interests. To facilitate a source's claim to such property based remedies, source management entitlement should be recognised as a legally protectable property right. Also, the law should recognise and enforce source income entitlement because the arguments that have been maintained for its rejection are less than compelling and such recognition will not only help to promote justice for individual sources whose contribution are crucial to success in biotechnological research enterprise, but it will also help to safeguard the survival of biotechnology research which will ultimately aid public health. As with source management entitlement, source income entitlement should also be enforced as a legally protectable property right and sources should be entitled to recourse to claim property based remedies in the event that there has been interference with their income entitlement.

Opponents' concern that recognition of source income entitlement will hinder research progression by increasing the economic and transaction costs associated with research is undermined by the fact that such a supposition is framework specific. While it is arguable that recognising source income entitlement threatens to increase the economic and transaction costs incurred by researchers, the negotiation process which has been argued could result in increased costs is a feature of a model formulated solely on property rules where market transactions represent the norm. The potential difficulties associated with the negotiation process would not occur if the negotiation process is removed. This would be the case with a compensation system formulated on liability rules as opposed to property rules, where the current donative principle is maintained at the initial phase of the supply of biological material and compensation is only paid in those instances where the biological material proves to be of significant commercial value. Furthermore, this would

also be the case where compensation is only paid after a marketable product is produced from research using the source's biological material, and the rate of compensation is either pre-determined by the legislator or determined by an objective state run administrative or regulatory body, such as the Human Tissue Authority.

A liability based framework will also address the opponents' fears in respect of the impact that delays and bidding wars associated with negotiations, could have upon the integrity of biological material and the source of biological material. Such a framework could also address the limitation identified with the highest bidder scenario regarding the inefficient use of resources because the donative principle maintained at the onset of the supply of biological material will ensure that all potential developers of biological material have equal access to the specimen. While a liability based system will not remove the difficulties outlined by opponents of source income entitlement regarding the acquisition of an expensive and complex record keeping system for maintaining source identifying details and tracking the use of biological material, it is suggested that if consideration is given to the meticulous care and planning required in biotechnological research then such record keeping should not prove unduly burdensome for researchers. [126] Furthermore, a system based on liability rules where compensation is delayed until after a marketable product is developed from the biological material and the full commercial value of the biological material is realised, will remove the lure of immediate financial gain that could cause sources of biological material to mislead researchers as to their personal and medical history. Incidence of source misrepresenting their medical information could be further curtailed under such liability based framework by the fact that it takes many years to develop a marketable product from excised biological material,[127] and by the inherent difficulties and uncertainties present in biotechnological research enterprise which make the development of a marketable product less than certain in a given enterprise.

[126] *Moore* CA (n 30) 508; Gitter (n 26) 289.

[127] Telephone interview with W Greenberg, Associate Professor, Department of Health Services Administration, The George Washington University, Washington D.C. (Mar. 8, 1989) cited in Dillon (n 41) 637; Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (n 82) para 68.

Likewise, opponents' contentions that the recognition of source income entitlement would discourage altruism and erode communal values is also less than compelling because altruistic sources would be free to reject compensation if they so wish and while it is inevitable that some sources who might have been willing to provide uncompensated donations will accept payment if it is offered to them, all that simply demonstrates is that those individuals evidently find compensation more desirable than the 'good feeling' from altruism and not that the availability of compensation has infringed the freedom of those who wish to be given the opportunity to supply biological material altruistically.[128]

Failure to recognise source income entitlement, however, could potentially impede the progress of biotechnological research because some altruistic individuals who ordinarily would supply their biological material for biotechnological research may refuse to do so because all other contributors and investors in the research venture, apart from them, expect to make a profit. In addition, individuals who are not particularly altruistically inclined might refuse to undergo the inconvenience and potential risks (however minimal) associated with the removal of tissue from their bodies and the potential risk of being stigmatised for disease susceptibility without the legal enforcement of their entitlement to compensation,[129] thus potentially decreasing the supply of biological material available for research. Furthermore, there is little empirical evidence to support the opponents' fear that the availability of compensation will 'crowd out' altruistic donations.

The suppositions of opponents of source income entitlement that economically disadvantaged sources, in particular, could be lured to take excessive and unnecessary risks with their health because of the prospect of financial gain is also not insurmountable

[128] R Korobkin, 'Buying and Selling Human Tissues for Stem Cell Research' (2007) 49 Arizona Law Review 45, 59.
[129] Ibid, 60; National Bioethics Advisory Commission, 1 Research involving Human Biological Materials: Ethical issues and policy guidance (August 1999) 50.

because such incidence could be curtailed by both effective regulation and soft paternalistic safeguards which include cooling-off periods (after initial donation) and counselling services.

The anti-commodification argument espoused by opponents of source income entitlement seems to be based on the presumption that transactions involving excised human biological material do not already incorporate financial considerations. For this reason, such an argument is undermined by the fact that biological material is already commercialised by the medical and scientific community and the biotechnology industry who regularly exploit such biological specimen for profit. Furthermore, the incorporation of financial considerations into transactions involving human biological material should not necessarily 'implicate the overall dignity of the person' from whom the material was extracted because arguably personhood is not solely dependent on how the human body/parts of the human body is treated.[130] Additionally, the long history of collective processes for valuing human body in both the English and the Anglo-American legal systems would seem to suggest that a '[system of compensation founded upon] a liability rule could be substantially less objectionable than a [market system] to those who would seek to avoid commodification in our social institutions,'[131] thus keeping with the recurring criticism and weakness of arguments espoused by opponents of source income entitlement, namely, that their arguments are framework specific and an appropriately construed policy framework could address their concerns and fears.

On the other hand, recognition of source income entitlement would help to promote justice among all contributors to research enterprise and aid the creation of a desirable state of affairs in favour of research to the extent that it would help to reinforce and maintain public

[130] Harrison (n 32) 89.
[131] Ibid, 91.

trust in biotechnological research. The availability of compensation could also potentially induce supply of biological material for research and thus promote research progression, which will aid public health and help to alleviate the crippling impact of diseases and illnesses upon humanity.

CHAPTER 5 HOW SHOULD AN IMPLEMENTABLE POLICY FRAMEWORK FOR THE PROTECTION OF SOURCE INCOME ENTITLEMENT AND SOURCE MANAGEMENT ENTITLEMENT BE CONSTRUED?

The Free Market Model

The debate regarding the recognition of source income entitlement has largely focused on a system founded upon property rules. Opponents of source income entitlement have argued that a free market model where a price for excised biological material is agreed between a willing buyer and a willing seller will inevitably result from a framework founded upon property rules. The free market model has thus been the only model that has been closely scrutinized as an alternative to the current status quo and the difficulties associated with a free market model accounts for most, if not all, of the concerns of opponents of source income entitlement (these concerns were outlined in detail in the previous chapter).

Opponents are right to be concerned about the potential state of affairs that could result from the introduction of a free market model in the context of the supply of biological material for research. Though a free market model has some advantages (for instance, it ensures that biological material goes to the highest bidder who will likely make most productive use of it since they were willing to pay valuable consideration to acquire it,[1] it gives sources of biological material the opportunity to bargain autonomously for valuable consideration in exchange for their biological material[2] and enables sources of biological material to make both economic and non-economic decisions to foster both the availability and affordability of diagnostic and therapeutic products for other members of the public[3]), these advantages are outweighed by the numerous ethical, moral and practical problems that could arise if such a scheme is implemented.[4] A free market model will likely threaten

[1] DM Gitter, 'Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material' (2004) 61 Wash. & Lee L. Rev. 257, 341, 345.
[2] Ibid, 270.
[3] Ibid, 345.
[4] C Harrison, 'Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue' (2002) 28 Am. J.L. & Med. 77, 85-93; J Boyle, 'To Pay or Not to Pay, That is the Question: Finding an intermediary solution along the Moore Spectrum' (2002) 7 Journal of Medicine & Law 55, 65-71.

the survival of socially useful biotechnological research, undermine communal values and create a strong incentive for sources of biological material, particularly the economically disadvantaged in society, to elevate financial concerns over their health in anticipation of immediate payment.[5] As these concerns have been discussed in detail in the previous chapter, it is not necessary to conduct a thorough analysis of a free market model in this discussion. It is simply adequate to state here that a free market model is far from ideal as an alternative to the current system.

The drawbacks of the free market model have led some commentators to consider alternative models that represent an intermediary course between a donative model and a property right model.

Harrison, for instance, proposes a hybrid donative/liability framework where the rule of donation is maintained at the time that biological material is transferred from the source to the recipient, and in cases where such biological material proves to be commercially valuable to research and development, an objective statutorily created administrative body or tribunal will adjudicate the rate of compensation that should be paid by the commercial user to the source.[6] Gitter also adds her voice to the debate by proposing a hybrid property rights/liability model which enable sources to exchange their property interests in biological material for valuable consideration and 'when necessary, to invoke an action for conversion

[5] For further discussion of the potential difficulties of a free market model, see Harrison (ibid) 85-93; Boyle (ibid) 65-71; MT Danforth, 'Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits' (1988) 6 Yale L. & Pol'y Rev. 179, 199.

[6] See Harrison (n 4) 93-104. Due to space constraints, a definitive treatise could not be provided on all existing proposals that have been advanced as alternative frameworks to the pure property/market model. The intention here was to highlight the proposals that bear the most relevance to the present discussion, as well as offer a large scope for analysis. For an insight into other frameworks, see Danforth (ibid) 198-201 (The work of Danforth, in particular, was very instructive on the licence mechanism that is incorporated as part of the proposed framework advanced in the present discussion); RE Gold, Body Parts: Property Rights and the Ownership of Human Biological Materials (Washington, D.C.: Georgetown University Press, 1996) 176-177; Boyle (n 4) 74-78.

where researchers withheld from them vital information that would have facilitated their ability to bargain for such [interests].'[7] An analysis of both models is conducted below to highlight the scale of the challenges facing the legislature and how those challenges could potentially be resolved. An outline of the proposed framework advanced in this discussion is then provided in order to offer another potential approach to a solution, but more importantly, to address those issues that are left unresolved by Harrison and Gitter's models and other existing proposals.[8]

While both Harrison's and Gitter's models specifically incorporate mechanisms inherent in the US jurisdiction, they do nevertheless have cross-jurisdictional appeal and can be applied in the United Kingdom, albeit with some modifications.

Alternative Models to the Free Market Model

The Harrison Donative/Liability Model

Harrison incorporates a combination of market inalienability and liability rules[9] in her model which could be classified as a hybrid donative/liability model. Although, dealing specifically with the supply of biological material in the United States (US), she did, however, suggest some modifications to the model that could make it capable of application to jurisdictions outside the US.[10] Her proposal retains the donative approach at the onset of tissue supply (subject to informed consent from the tissue contributor) and bans private sales of tissue from the individual source.[11] However, for those cases where tissue proves to be of exceptional commercial utility to research, Harrison suggests implementation of an

[7] Gitter (n 1) 345.
[8] See Danforth (n 5) 198-201; Gold (n 6) 176-177; Boyle (n 4) 74-78.
[9] Harrison (n 4) 96.
[10] Ibid, 93-104.
[11] Ibid, 96.

objective, non-market construct where a federal administrative tribunal is created by statute and charged with applying statutory standards to determine the appropriate amount of compensation to be awarded to the individual from whom the tissue originated.[12] Under this model, researchers (commercial and non-commercial) could freely use donated tissue without incurring costs or making payments to the tissue contributor. However, commercial users (commercial researchers, biotechnology companies, pharmaceutical companies and medical device manufacturers) would be required to compensate a tissue source once they decide to market the product that was developed from research using the tissue. Compensation will only become due to the tissue source if the commercial utility of the tissue met statutory eligibility criteria.[13] Harrison identifies triggers for payment as including patent applications, and applications to the Food and Drug Administration for drug approval.[14]

Harrison's model is analogous to other established models of publicly mediated compensation that address loss of body parts such as the Industrial Injuries Compensation Scheme (UK)[15]/workers' compensation systems (US),[16] and tort claims for personal injury where liability rules are drawn from statutes or the common law and applied by the courts and their juries (personal injury claims), or drawn from statutorily pre-determined schedules relating to specific injuries or losses and implemented by an administrative body created by statute (workers' compensation schemes).[17]

[12] Ibid.
[13] Ibid, 97.
[14] Ibid, 98.
[15] The main Acts and Regulations which regulate Industrial Injuries Benefits include the Social Security Act 1998 chapter 14, Social Security Contributions and Benefits Act 1992 chapter 4, Social Security Administration Act 1992 chapter 5, Social Security (Claims and Payments) Regulations 1987 No. 1968 (For a comprehensive guide to the scheme, see Gov.UK, 'Industrial Injuries Disablement Benefits: technical guidance': <http://www.dwp.gov.uk/publications/specialist-guides/technical-guidance/db1-a-guide-to-industrial-injuries/further-information/> accessed 19 June 2014) .
For a discussion of the scheme, see R Lewis, 'Employers' liability and workers' compensation: England and Wales' (2012) <http://orca.cf.ac.uk/26855/1/Lewis%202012.pdf> accessed 19 June 2014.
[16] Harrison (n 4) 94-95.
[17] Ibid.

A key advantage of such a model over a free market model is that source compensation is not paid at the onset of donation, but rather it is determined after commercial use of the source's tissue and more importantly, when the value of the product developed from research using the tissue is more clearly understood. This 'enables the acquisition of tissue to go forward without the delays, commodifying tendencies and other disadvantages of up-front negotiations,'[18] which is a prohibitive feature of a free market model.[19] The fact that compensation is delayed and payment of which is not inevitable upon donation of tissue, but contingent upon the commercial usefulness of the tissue being first demonstrated in research and development, makes payment of compensation less powerful an incentive to induce sources to take unnecessary risks with their health for immediate prospect of gain.[20] Added to this is the fact that payment of compensation to the source is determined by the outcome of research which itself is subject to the difficulties and uncertainties involved in biotechnology enterprise.[21] Such liability based model also relieves the perception that sources of biological material are 'selling' their body parts to the extent that unlike a free market model, it does not set a price on the body part itself but rather focuses on the profits derived from the product of research using biological material.[22]

Another point to note about Harrison's framework is that unlike the free market model, Harrison's model does not threaten to erode altruistic and communal values, but rather it reinforces these values by both maintaining a rule of donation at the onset of tissue acquisition and also making it possible for sources who are entitled to compensation to waive their rights to receive compensation if they so wish.[23] This in turn helps to promote research and reinforces fundamental values (altruism and communal values) that are considered to comprise part of the fabric of a civilised society. One other advantage of such

[18] Ibid, 99.
[19] See TP Dillon, 'Source Compensation for Tissue and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits' (1989) 64 Notre Dame L. Rev. 628, 633-636; Boyle (n 4) 55-56; G Calabresi and AD Melamed, 'Property Rules, Liability Rules and Inalienability Rules: One View of the Cathedral' (1972) 85 Harvard Law Review 1089, 1106.
[20] Harrison (n 4) 92.
[21] Ibid.
[22] Danforth (n 5) 200.
[23] Harrison (n 4) 99.

a proposal is that 'it would operate even-handedly after the fact of use, to impose an obligation based on the prospect of profits, regardless of who and where the original parties were. Its rules could be applied uniformly to… the full range of tissues collected in hospitals [and research establishments] anywhere in the world.'[24]

Harrison's model also safeguards the interests of tissue sources by removing any incentive for researchers to avoid their responsibility for paying eligible sources their share of compensation. It seeks to achieve this by compelling researchers to contribute the source's adjudicated compensation towards 'charitable purposes such as non-profit biomedical research or the provision of healthcare to the uninsured' in the event that the source cannot be located or where the source is located but he or she decides not to claim his or her compensation on religious or other grounds.[25] Such a provision could potentially prove effective in discouraging researchers and their sponsors from deliberately losing identifying information of the tissue source or from discouraging participants from exercising their entitlement to compensation.[26]

Though Harrison's model is focused on safeguarding source income entitlement,[27] specifically, the income entitlement of sources whose tissue prove to be commercially valuable to research and development, she also makes a suggestion that could potentially safeguard source management entitlement. She does this by premising her framework upon a requirement for tissue source consent for both removal of tissue and the use of excised tissue for research and commercial purposes.[28] She seeks to enforce this requirement by suggesting that tissue could be deemed inalienable if its originator did not give informed consent.[29] However, it should be noted that whilst this suggestion might safeguard source management entitlement to some extent by preventing use of tissue obtained without the

[24] Ibid.
[25] Ibid, 98.
[26] Ibid.
[27] Ibid, 96.
[28] Ibid.
[29] Ibid.

informed consent of the tissue source, its utility is limited because it does not adequately address the issues raised in such instances. For example, it is unlikely to prove effective where the misappropriated tissue has already been used in research and lack of tissue source consent is discovered at a phase in the research process where the tissue is no longer in its original state and has been significantly altered or converted into another product. Likewise, its effectiveness is questionable where the original tissue is still available but profits have already been generated from unauthorised research uses of such tissue. It does not make provisions for what would happen to those proceeds and neither does it include any provisions to compensate those sources for the emotional harm or distress that they might have suffered from unauthorised or misuse of their tissue.

While Harrison's model represents an effective intermediate solution between the donative model and the free market model and addresses some of the difficulties with both models, her model does have other drawbacks. For example, the proposal would incur certain costs, particularly, the 'social costs of the legislative and administrative process and the related private costs to the parties for their participation in proceedings' relating to the adjudication of compensation for the tissue source.[30] It is important to note, however, that the impact of such costs is reduced to some extent by the fact that the occurrence of such proceedings is restricted only to when specific statutory criteria are met and also by the fact that there is usually 'a long time lag between the research phase and the marketing phase and many products never actually make it to market'.[31] Furthermore, such costs are likely to be much less than the potential costs of negotiating a price for every contribution of biological material under a free market model.[32]

Harrison's proposal also does not provide for tissue sources like the Greenbergs, who donate non-unique tissue or relatively commercially insignificant tissue, in addition to,

[30] Ibid, 99.
[31] D Nicol, 'Property in Human Tissue and the Right of Commercialisation: The Interface between Tangible and Intellectual Property' (2004) 30 Monash University Law Review 139, 163-4; See also *Greenberg v Miami Children's Hospital Research Institute* [2003] 264 F Supp 2d 1064 (US DC Florida) [1074].
[32] Harrison (n 4) 99.

financial and non-financial contributions toward the research enterprise. Her framework does not address the primary need of those sources which comprise non-economic interests such as the right to control the commercialisation of the proceeds from research or specifically in the *Greenberg* context, the right to veto the commercialisation of research results in order to foster the availability and affordability of such results.[33]

Some commentators who note the significance of Harrison's model in safeguarding the interests of non-commercial researchers (that is, by allowing non-commercial researchers to use tissue without having to pay the source for such uses) have nevertheless suggested that the model in itself commodifies tissue.[34] Harrison, however, seems to indicate that commodification concerns could potentially be addressed by a system of collective rather than individual compensation. In other words, rather than making direct payments to individual tissue contributors, compensation could be aggregated instead for the benefit of a family, patient group and political community.[35] However, the very fact that excised human biological material is already commercialised undermines such concerns to the extent that there is already some form of commodification of such material and such commodification seems to be ethically and legally permitted and consequently, it is not far-fetched or intolerable to allow source compensation. For instance, excised human biological material that is the subject of property because of the application of human skill can lawfully and ethically be exchanged for reward under the HTA 2004,[36] and researchers can legally commercialise the results of research using human biological material and they can legally and ethically exploit its economic and commercial value.

[33] Gitter (n 1) 343; D Dickenson, *Body Shopping: Converting Body Parts to Profit* (Oneworld, 2008) 34-37.
[34] Nicol (n 31) 162.
[35] Harrison (n 4) 103.
[36] *Human Tissue Act* 2004, 2004 Chapter 30, section 32(1), (8) and (9). The Act excludes excised biological material which is the subject of property from the prohibition on commercial dealings, thus, indirectly permitting commercial dealings in respect of such biological material.

Whilst a framework based on a system of collective compensation does have its merits, payment of collective compensation should not preclude payment of individual compensation where appropriate, under the pretext of avoiding commodification. 'Commodification is not necessarily an all-or-nothing matter.'[37] As noted in chapter 4, many aspects of social enterprise are typified by a state of 'incomplete commodification' or in other words, 'coexistent commodified and non-commodified understandings.'[38] A suitable compensation framework can incorporate both systems of individual as well as collective compensation. Where a single tissue turns out to be commercially useful to research and development then it is reasonable for the individual tissue contributor to be compensated. Equally, where a collection of tissue from one family, patient group or political community proves to be commercially valuable to research and development then compensation should be paid to the family, patient group or political community as one collective unit. Our society is founded upon both communitarian and individualistic concepts. In the United Kingdom, a collective National Health System exists but private practices and hospitals also function alongside the collective healthcare system and individuals have the choice of seeking treatment from private healthcare providers if they so wish. Furthermore, since current conditions permit individuals including participants involved in clinical trials, actors, models and even researchers, to readily exploit their natural endowments for profits,[39] it is difficult to sustain an argument for the exclusion of individual compensation in the research context.

Gitter Property Rights/Liability Model

Gitter, on the other hand, advocates for Congress to implement a statutory hybrid property rights/liability model.[40] Under Gitter's model, individuals will be recognized as having property rights in their excised tissue which would include the right to exchange the tissue for valuable consideration and negotiate mutually satisfactory agreements with researchers

[37] Harrison (n 4) 90.
[38] MJ Radin, *Contested Commodities* (Harvard University Press, 1996) xiii.
[39] Dickenson (n 33) 29; Harrison (n 4) 82; Gitter (n 1) 297.
[40] Gitter (ibid) 339.

fully informed as to all the risks involved in the research and the researchers' commercial interests;[41] or to waive such rights if they choose instead to make a gratuitous donation.[42] Gitter suggests that an individual tissue contributor should be permitted to maintain an action for conversion of his or her tissue against any researcher who uses tissue without first seeking the tissue contributor's informed consent,[43] or where the tissue contributor entered into an agreement with a researcher regarding his or her tissue that is voidable under the doctrines of fraud, duress, undue influence or mutual mistake.[44] Under Gitter's model, an aggrieved tissue source whose tissue was used for research without his or her informed consent would be entitled to compensation only if the tissue was used for commercial purposes, and such claims would be further limited to where the researcher earned a profit from commercialising the results of research using the tissue, as tissue contributors would for all intents and purposes be functioning as investors who stand to lose the value of their investment.[45] A recurrent theme in Gitter's proposal is that tissue contributors should be legally entitled to invoke a property rule in those instances where they negotiated in advance for their rights to tissue[46] and in the event that they did not negotiate in advance for their rights to tissue, they should be empowered to pursue a civil claim in conversion, where researchers withheld from them vital information that would have facilitated their ability to bargain for such rights.[47]

Such a model has some obvious advantages: the promise of pecuniary gain will potentially have an incentivising effect on the willingness of individuals to supply tissue for research, in particular, those members of the population that are not altruistically inclined,[48] and it could encourage individuals to become more alert to potentially scientifically significant phenomena within themselves and inform researchers of their observations which could

[41] Ibid, 340.
[42] Ibid, 339.
[43] Ibid, 340.
[44] Ibid, 339.
[45] Ibid, 340.
[46] Ibid, 345.
[47] Ibid.
[48] Ibid, 341, 345.

then potentially lead to the instigation of valuable research.[49] The model also equitably compensates tissue sources for their contribution[50]and 'enable them to make decisions that will foster the availability and affordability of diagnostic and therapeutic products to other consumers.'[51] Furthermore, the feature of the model which allows tissue contributors to bargain with researchers will help to ensure that 'tissue ends up in the hands of the highest bidder who is likely to be the researcher who will use it most productively, as evidenced by their willingness to pay valuable consideration for it.'[52] Also, the threat of litigation from a conversion action will serve a deterrent to those researchers who may contemplate using tissue without first seeking informed consent from the tissue source.[53] It should be noted, however, that due to the provision incorporated within Gitter's model that restricts entitlement to conversion action only to cases where the researcher earned a profit from commercializing a given tissue sample, the threat of conversion action will only serve a deterrent to those researchers who wish to commercialize tissue. Therefore, there would be no general remedy for a tissue source whose tissue was used in research without his or her informed consent, where the source's tissue was used in a failed commercial enterprise and the researcher did not earn a profit, or where it was used in non-commercial research.

Also, the likelihood that tissue will end up with the highest bidder under Gitter's model might not necessarily be an actual benefit for research because it could lead to unequal access to tissue between commercial and non-commercial researchers and potentially exclude non-commercial researchers from the bargaining process and from making a contribution to the wider biotechnological research endeavour. While non-commercial researchers will likely include the transaction costs of tissue in their grant applications, they are unlikely to have access to the size of funding that commercial researchers would have at their disposal because they predominantly rely on government funding and public generosity either directly or through charitable research foundations. On the other hand, it is possible that the highest bidder feature of Gitter's model might represent a difficulty for

[49] Ibid, 341.
[50] Ibid.
[51] Ibid, 341, 345.
[52] Ibid.
[53] Ibid, 341.

non-commercial researchers only if the tissue source decides to exchange the tissue for valuable consideration. Since Gitter's model enables sources to make gratuitous donations if they do not wish to exercise their right to bargain for valuable consideration in exchange for tissue, access to tissue will be maintained for all researchers in those instances where tissue contributors make gratuitous donations. Nevertheless, a more effective approach is exemplified by Harrison's model which allows a source to be equitably compensated for his or her crucial contribution in furthering research progress, and at the same time, helps to maintain equal access to tissue for all researchers.

In spite of the advantages of Gitter's model, it has a crucial limitation in that it is quintessentially a free market model that functions through property rules and thus, it suffers from many of the difficulties associated with a free market model. For instance, the opportunity accorded to sources to bargain with researchers and negotiate for valuable consideration in exchange for their biological material might significantly hinder research for the reasons previously outlined, namely, the research might not go forward due to delays, commodifying tendencies and other difficulties that could potentially result from upfront negotiations.[54]

Like the free market model, another criticism of Gitter's model is that it grants all sources an entitlement to negotiate for valuable consideration in exchange for their tissue. The limitation of this feature is that it could prove quite problematic for researchers by significantly increasing transaction costs because researchers will be obliged to negotiate a payment agreement with every individual source of biological material.[55] This would compound the bargaining issues already outlined, particularly, because research usually involves collections of biological material obtained from multiple sources, the collections may have considerable value but each individual biological specimen may be worth very

[54] Harrison (n 4) 99.
[55] Ibid, 87.

little of itself.[56] A more effective approach will be to restrict the payment of compensation to sources who possess biological material that have unique properties like Mr Moore, and those sources like the Greenberg who contribute non-unique tissue but have made additional contribution in form of either financial or non-financial contribution such as identifying and encouraging potential donors to participate in the research project and creating a database of potential sources. The criteria for determining whether the biological material is unique might be that the source's biological material 'clearly had unique features that gave it monetary value even without the input of further skill and labour from the researcher'.[57]

The proposed approach could also promote sources' non-economic interests by permitting sources (whether or not they possess tissue with unique qualities) to negotiate for non-economic interests with researchers.[58]

[56] Nicol (n 31) 153.
[57] Ibid.
[58] Gitter (n 23) 343.

Proposed Liability/Property framework

Introduction

Though Harrison and Gitter's models each represent an excellent and effective compromise to the status quo, and Harrison's model in particular, addresses many objections raised against a free market model for compensating sources of biological material, they are nevertheless far from complete solutions as demonstrated by some of the limitations outlined above and can still be developed further to offer not necessarily a complete solution but a more effective one. The proposal outlined below is intended not as a complete or perfect solution but rather as a more effective compromise to the current system. It is proposed that supplementary provisions should be introduced to the *Human Tissue Act* 2004 which incorporates an additional mechanism to safeguard source management entitlement and a new compensation construct for enforcing source income entitlement.

Statutory pronouncement – Source limited property right

The provisions could contain a pronouncement that sources have a limited property right in respect of their excised biological material, which comprise of both management entitlement and income entitlement. Both entitlements should only be exercised in accordance with the current provisions in the HTA 2004 and the supplementary provisions proposed below. Specifically, source management entitlement should only be exercised under the consensual framework contained within the HTA 2004 and for the purpose of claiming both property-based judicial remedies and liability-based extra-judicial remedies in cases where there has been interference with the entitlement. Similarly, source income entitlement should only be exercised in accordance with the liability based compensation construct contained within the proposed supplementary provisions and for the purpose of claiming both property-based judicial remedies and liability-based extra-judicial remedies in cases where the entitlement has been infringed. To ensure clarity, the proposed

supplementary provisions to the HTA 2004 should only affect future (after proposed provisions come into force) transfers or supply of excised biological material and should not affect existing collections.

The need for a legislative rather than a judicial remedy

The occasional litigation brought by individual sources of biological material is unlikely to create a 'coherent and predictable policy' to accommodate the wide ranging circumstances in which biological material is collected, distributed and used in biotechnology[59]and the complicated uncertainties and difficulties inherent in biotechnological research enterprise. Parliament, rather than the courts, may be best suited to undertake the foregoing task[60] because unlike the courts, Parliament has the capacity and resources to amass empirical evidence, request the advice of experts and hold public consultations, inquiries and hearings, at which all stakeholders and interested parties can present evidence and discuss their views.[61] In this connection, a legislative measure is potentially the most effective in accommodating the justice concerns as well as the ethical and practical challenges relating to the compensation of sources of biological material for their contribution towards biotechnological research enterprise.[62]

Framework Rationale

The framework proposed here should seek to ensure that dealings with human biological material accord with the following three principles:[63] First, the removal of human biological material should be consensual and conducted only in circumstances that promote the

[59] Harrison (n 4) 83.
[60] Ibid. See also JE Krier and SJ Schwab, 'Property Rules and Liability Rules: The Cathedral in Another Light' (1995) 70 New York University Law Review 440, 477.
[61] *Foley v Interactive Data Corp* (1988) 765 P.2d 373 [397]; *Moore v Regents of the University of California* [1990] (Moore SC) 793 P 2d 479 (Cal SC) [496]. Harrison (n 8) 83.
[62] Harrison (ibid).
[63] Ibid, 96.

individual source's dignity and bodily integrity.[64] Second, the use of excised biological material for research and also for commercial purposes should be consensual.[65] Third, the economic and non-economic benefits derived from using excised biological material in research should be shared with sources of biological material (Individuals, families and the wider political community) in a manner that adequately balances the host of ethical, moral, philosophical and practical issues associated with the debate relating to source ownership entitlements, specifically, the pros and cons of the donative model and the private property model.[66] The requirement for informed consent, the criminal sanctions within the HTA 2004 and the judicial and extra-judicial remedies that would be contained in the proposed supplementary provisions should address the first two objectives.[67] The third objective would be accommodated by the compensation construct advanced below, which incorporates a combination of liability and property rules that facilitate the payment of compensation in certain instances to sources of biological material for their involvement in furthering socially useful biotechnological research.[68]

Such an intermediate solution is not intended here as a definitive treatise that resolves all the concerns expressed so far in respect of either the donative model or the free market system.[69] However, the proposal would help to alleviate many of those concerns and does represent a strong alternative to both the donative and free market model.[70]

Transfer of biological material (Licence mechanism and cooling-off period)

While cases like *Greenberg*[71] and *Catalona,*[72]and the current attitude in practice in the medical and scientific community promote the view of the transfer of biological material

[64] Ibid.
[65] Ibid.
[66] Ibid.
[67] Ibid.
[68] Ibid.
[69] Ibid, 78.
[70] Ibid.
[71] *Greenberg v Miami Children's Hospital Research Institute* [2003] 264 F Supp 2d 1064 (US DC Florida).

from sources to researchers as gifts, there is a need to reconsider this approach in order to better promote source interests. It is proposed that the transfer of biological material from source to recipient towards research enterprise could instead operate as a revocable and assignable licence[73] to exploit the therapeutic and/or economic value of biological material (depending on whether the material is supplied through a collecting organisation for use in commercial and non-commercial research, supplied for non-commercial research uses only or supplied directly to a commercial research facility for use in commercial research. The relevance of this will become clearer during the course of this chapter).

The proposed supplementary provisions to the HTA 2004 could incorporate a licence mechanism where a licence is created whenever a source gives informed consent to research uses of his or her excised biological material. In the patent context, a licence is typically issued by a patent holder for the benefit of a corporation on the condition that the licensee (the corporation) pays a set fee and a percentage of the royalties to the licensor (the patent holder).[74] As such transactions do not involve transfer of property interests; the licensor retains his or her property interest in the patent.[75] Analogously, the source of biological material retains his (statutorily created) property right in respect of biological material that he supplies to the researcher on the condition that he receives the statutory fixed rate of compensation in accordance with prescribed statutory provisions in the event that the biological material proves significantly useful in the development of a marketable product. The licence provisions could be governed by the HTA 2004 as supplemented by the proposed provisions and in accordance with the informed consent given by the source. The informed consent form signed by the source could take effect as the document recording permission from the source to the researcher to use the source's biological material for research (licence document).

[72] *Washington University v Catalona* [2006] 437 F Supp 2d 985 (USDC Ed Mo 2006) (Catalona); 490 F 3d 667 (8th Cir 2007) (Catalona CA).
[73] Licence could be defined as: a 'formal or official permission to do something' (Oxford Dictionaries: <http://oxforddictionaries.com/definition/english/licence> accessed 19 June 2014).
[74] Danforth (n 5) 199 n 88.
[75] Ibid.

In order to safeguard source interests, following the initial transfer of biological material from the source to the recipient, the source could be given a statutorily pre-determined cooling-off period during which he or she can revoke the licence by withdrawing the original consent given. Researchers could be prohibited from using the biological material until after the cooling-off period. The length of the statutory cooling-off period could take account of expert information from the biotechnology industry regarding the finite survival time of human tissue[76] and the possibility that delays in using the tissue could destroy the value of the cultured samples[77] because 'the longer a tissue sample is in culture, the less it is like the original specimen'.[78] Where a source withdraws his or her consent during the cooling-off period and in so doing, the licence to use the source's biological material for research, he or she could request that the biological sample be destroyed. However, in order to ensure maximum utility of biological material and help to promote research progress, the source could alternatively be given the option to transfer his biological material for use in another research project. To prevent numerous withdrawals and transfers which could potentially be catastrophic for biotechnology research, a source could be permitted only one opportunity after withdrawal from the first project to transfer his or her biological material to another project. Where the source withdraws consent from a second research venture during the cooling-off period, a default rule could be triggered for subsequent destruction of the source's biological specimen. On expiry of the cooling-off period, the source's entitlement to withdraw consent to the use of his or biological material in research could become restricted to only instances where the researcher uses the biological material beyond the scope of the consent given by the source. An example could include where the source stipulated that his or her material should only be used for non-commercial research and the biological material was then subsequently used for commercial research in contravention of the source's instruction. The source, in these circumstances, will be entitled to withdraw his consent, thereby revoking the licence that allowed the researcher to use the source's biological material without incurring liability in law.

[76] Dillon (n 19) 634.
[77] U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells – Special Report* (OTA-BA-337, 1987) 32-33.
[78] Ibid.

However, in view of the public good of biotechnological research, revocation of the licence could be promoted as the last resort. The process for dealing with the source's grievances could adopt similar principles and procedures to the handling of grievances in the work place in employment law and the handling of breaches of contractual provisions under contract law. There could be a requirement in such instances for the source and researcher to enter into informal consultations with each other with the aim of reaching an alternative cause of action to revocation of the licence. So for instance, the researcher could sign an undertaking to discontinue the offending action and comply with the source's original instructions, or the source could be persuaded to extend the scope of the original consent to accommodate the offending action and new research activities intended by the researcher. If the source still wishes to revoke the licence, the source could be given the option to notify the Human Tissue Authority of his or her grievance. The Human Tissue Authority could then act as an arbitrator between the source and the researcher in trying to resolve the source's grievance. However, should the source subsequently decide to revoke the licence, the researcher will be required to discontinue use of, and destroy the source's biological material and research results and products that have been developed using the source's biological material. The researcher should also be required to provide written evidence of the destruction to the source.[79] In addition to revoking the licence and requiring destruction of the biological samples, the source could seek a judicial or extra-judicial remedy for the initial offending action (infringement of source's property right) that triggered the process (see below). While the severity of the potential economic impact of this provision for researchers might mean that it appears unrealistic, this is unlikely to be the case. Such provisions are common place in material transfer agreements between researchers in the medical and scientific community,[80] thus, incorporating it in the proposed framework does not place an unfamiliar or intolerable burden upon researchers. Furthermore, the various opportunities under the proposal for consultations to resolve grievances should reduce the frequency of such occurrences.

[79] For a similar provision in material transfer agreements that are already commonplace between researchers in the medical and scientific community, see Leland Stanford Junior University, Sample licence agreement: <http://otl.stanford.edu/documents/98059.pdf> 3, accessed 19 June 2014.
[80] Ibid.

The licence mechanism is incorporated in order to allow a source of biological material to retain his or her property interest regarding biological material and consequently, his or her eligibility to claim property-based remedies in cases where researchers use biological material in contravention of the consent given by the source, while also allowing researchers to use biological material for research. The limitation on the source's entitlement to withdraw his or her consent after the proposed statutory cooling-off period is necessary to promote certainty in research, specifically, to ensure researchers can freely use biological material without having to make contingencies for the possibility that the source might revoke the licence at any time and without just cause. Such contingencies might include the researcher refraining from making full investment and commitment to research enterprise which could potentially inhibit research progress. While the licence is ultimately revocable, the occurrence of such revocation after the cooling-off period is largely dependent on the researcher's actions. If researchers wish to avoid this course of action, they simply need to comply with the source's original instructions/licence terms.

Nevertheless, the threat of revocation is necessary to protect sources from unscrupulous researchers because it would likely discourage researchers from undertaking inappropriate and unauthorised actions with the source's biological material. The requirement to destroy the samples rather than re-delivery to the source has been incorporated for practical reasons because once biological material is used in research, re-delivery may not be desirable because the biological sample might be a bio-hazard[81] or it might no longer exist.

The assignable feature of the licence is incorporated to allow for flexibility in collaborative efforts between researchers and other parties involved in biotechnology enterprise, in particular, commercial companies who are usually involved in taking the research products to the market. The licence should also not affect any patent granted in respect of the product from research enterprise because a patent will create a distinct legal right in respect of the product of the research enterprise but the licence governs the use of the original biological material.[82] In other words, a source can, for instance, direct that his

[81] Nicol (n 31) 150.

[82] See Ibid, 152, *Moore v Regents of the University of California* [1990] (Moore SC) 793 P 2d 479 (Cal SC) [511].

biological material be used only in research relating to a specific disease and can seek civil action where this instruction is contravened but the source cannot generally control the licensing and setting of royalty fees in respect of products generated from research or seek a civil remedy where he or she disagrees with such decisions.

In addition to the cooling-off period incorporated under the proposed framework, the supplementary provisions could also include soft paternalistic safeguards[83] to ensure that sources are well informed of the relevant procedures that they might need to undertake to make their biological material available for use in research, how and by whom their biological material will be used in research and generally, the processes involved in biotechnological research enterprise. Such safeguards could include optional counselling and educational classes[84] which would be made available for sources who wish to access them. Such services should be managed by the HT Authority. It is preferable that such services are managed by the HT Authority rather than researchers and commercial users of biological material because unlike the HT Authority which is first and foremost a representative for the state and of the public interests,[85] researchers and commercial users of biological material will have vested private interests in research and may inadvertently or deliberately mislead prospective sources of biological material. The availability of such services should be made known to a prospective source by the recipient before the source signs the consent forms transferring his or her biological material for use in research. The provision of such services will likely be useful in reducing the incidence of sources that are either uninformed[86] or misinformed about the research process.

[83] W Barnett II, M Saliba and D Walker, 'A Free Market in Kidneys: Efficient and Equitable' (2001) 3 The Independent Review 373, 382; A George, Marketing Humanity: Should we allow the sale of Human body parts? [2005] UTS L Rev 2; 2005 7 UTS Law Review 11, IV (c).
[84] Ibid.
[85] The HT Authority also represents the interests of those it regulates, i.e. researchers and other users of biological material. (See Human Tissue Authority, 'Our regulatory work': <http://www.hta.gov.uk/> accessed 19 June 2014.
[86] Barnett II, Saliba and Walker (n 83); George (n 83).

Management entitlement

Under the proposed framework, the current consensual framework contained within the HTA 2004 should be retained in its entirety and should continue to regulate the exercise of source management entitlement. In other words, it will continue to regulate issues relating to the transfer of biological material from sources to recipient researchers and govern matters relating to the ability of sources to determine how and by whom their biological material is used. However, supplementary provisions could be incorporated into the current provisions to reinforce the protection that it offers to sources.

Currently, the HTA 2004 defines 'appropriate consent' in terms of whose consent is needed to carry out relevant activities under the Act but it does not generally stipulate when and how consent should be sought or what information recipients of biological material should provide to sources from whom biological material is extracted.[87] The Act does not, for instance, specify that recipients of biological material should provide information on intended or potential commercial uses of biological material to sources of biological material when seeking consent for use of such material in research. The requirement to inform sources of commercial uses is rather contained within the Human Tissue Authority's Code of Practice.[88] However, as discussed in previous chapters, while it is expected that organisations will comply with the guidance in the various codes of practice, non-compliance with a code of practice is not in itself a criminal offence under the HTA 2004. While the Human Tissue Authority ('HT Authority') may, however, take appropriate regulatory action for non-compliance with a code of practice and may consider such non-compliance in its decisions to issue licences under the Act, the threat of regulatory action arguably serves a less powerful deterrence effect than the threat of criminal liability. The resulting impact is that researchers may simply choose to face the risk of regulatory action rather than inform sources of potential commercial uses of biological material. This is not

[87] See Human Tissue Authority, *Code of Practice 1: Consent* (Human Tissue Authority, 2009) Para 13 <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm?FaArea1=customwidgets.content_view_1&cit_id=655&cit_parent_cit_id=652> accessed 19 June 2014. <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm> accessed 19 June 2014.

[88] Ibid, para 149.

necessarily a significant concern for those sources who are content for their biological material to be used in commercial research, but, it may mean that the interests of other sources who might have moral, cultural, religious, or other objections[89] to the commercialisation of their biological material are not adequately protected. The proposed supplementary provisions could therefore incorporate into the Act, the current provision contained within paragraph 149, Code of Practice 1,[90] which require that researchers inform sources if their biological material 'will or could be used for research involving the commercial sector [and also] the range of activities and researchers which may be involved, and whether these include commercial establishments.'[91] Failure to provide such information to sources could then constitute a criminal offence in addition to the possibility of regulatory action by the HT Authority.

The current guidance in the Human Tissue Authority's code of practice on consent allows sources to give either generic or specific consent.[92] However, under the proposed framework, a source's choice in terms of whether to supply his or her biological material to commercial or non-commercial research uses, could be limited as follows: in order to maintain the availability of biological material for non-commercial research within the proposed compensation system and reduce the incidence of sources being unduly influenced in their decision making by the prospect of future payment of compensation, sources could be given the option either to supply biological material for general research uses (that is, both commercial and non-commercial research); or to supply for non-commercial research uses only. They should not be permitted to restrict their contribution solely to commercial research with the hope for instance, of increasing their chances of a compensation pay-out. In reality, the objective of the preceding provision is probably limited in its scope to instances where sources supply their biological material to tissue banks, hospitals and other establishments that make biological material available to both

[89] R Hardcastle, *Law and the Human Body: Property Rights, Ownership and control* (Hart; 2007) 2.
[90] Human Tissue Authority, Code of Practice 1: Consent (Human Tissue Authority, 2009) para 149 <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm> accessed 19 June 2014.
[91] Ibid.
[92] Ibid, para 35.

commercial and non-commercial researchers. The rationale behind the provision will be ineffective where sources supply their biological material directly to commercial research establishments. This potential limitation, however, might be addressed if an overarching tissue bank is established which supplies biological material to all researchers in the UK rather than the current status quo where multiple tissue banks operate to supply biological material to researchers. However, the creation of one overarching tissue bank might be difficult to achieve because of the need for widespread cooperation among numerous stakeholders with conflicting interests. Specifically, the operations of both 'for-profit' and 'non-profit' tissue banks and storage facilities are firmly entrenched in the UK system and the interests and goals of both types of institutions are fundamentally dissimilar, therefore, it would be difficult (although, not impossible) to achieve the consensus required to merge them together to function as one overarching institution.

Presently, with the exception of anatomical examination and the public display of dead bodies or body parts where consent must be in writing,[93] the HTA 2004 does not specify the format in which consent should be given or recorded.[94] Though it should be noted that the HT Authority does specify in its code of practice that where consent is obtained but it is not in writing, detail of when the consent was obtained and the purposes for which the consent was given should be clearly documented in the patient's records, the laboratory records or both.[95] Consequently, it would seem that either verbal or written consent from the source of biological material would suffice for research uses of such material to proceed. However, in view of the enhanced representation of source interests within the proposed framework and the somewhat complex measures recommended to safeguard those interests, it might be necessary for the supplementary provisions to stipulate that consent for all research uses of biological material should be in writing, so as to promote clarity, certainty and consistency. As with consent for anatomical examination and public display of bodies or body parts, the HT Authority could also devise model consent forms which could include both prescriptive key provisions which must be included in all consent forms and also non-

[93] Human Tissue Act (n 36), section 3(3) & 2(4).
[94] Human Tissue Authority, Codes of Practice 1 Consent (n 90) para 56.
[95] Ibid, para 58.

prescriptive provisions that could be adapted to the needs of individual research establishment, provided they comply with the HTA 2004, the proposed supplementary provisions and the HT Authority's codes of practice.

Save for where sources make financial investment in research (discussed below), the source management entitlement should only be exercised as outlined in the foregoing discussion and for the purpose of claiming judicial and extra judicial remedies. However, it should not include the power to control either the intellectual property in respect of products developed from biological material or decisions involved in the commercialisation process (that is, patenting, setting of royalty fees, terms for licensing agreements, drug prices) because sources are unlikely to be expert on such issues and giving them such power may unduly slow down biotechnology research. However, if a source makes such views known on his or her consent form, the researcher/commercial user may choose at their discretion to take such views into consideration.

Remedies

Source interests could be better served under the proposed framework because it would help to address some of the perceived inadequacies of the current criminal sanctions[96] in protecting source interests. The proposed property status accorded to source management entitlement will enable a source of biological material to seek civil claims for property based remedies which could include a cause of action for conversion where there has been an interference with his or her management entitlement. However, to prevent a proliferation of conversion actions which could potentially stifle the progress of biotechnology research, it is necessary to place a restriction on what sources can claim for. One way to do this would be to provide an exhaustive list of categories of potential offending actions that would

[96] Human Tissue Act 2004 (n 36), Part 1, section 7; Human Tissue Authority, Codes of Practice 1 Consent (n 90) paras 117-119.

constitute an interference with source management entitlement and for which an aggrieved source could seek a remedy. Such actions could include:

a. Where researchers do not inform a source of biological material that his or her biological material could be used for commercial purposes and the biological material is then used for commercial purposes. This feature is important in order to help to protect those sources who might have moral, religious, philosophical or other objections to the commercialisation of separated biological material.[97] Placing researchers under an obligation to provide this information to potential sources and enforcing such a provision will safeguard the interests of this group of sources in making an informed decision about whether to transfer their biological material to commercial researchers or choose instead to make their biological material available for use in non-commercial research.

b. Where a source's biological material is left over after surgery, diagnostic tests or clinical audit and used or stored without consent of the source, for research.

c. Where biological material is donated for a specific research project and it is then used for another research project without the consent of the source.

However, even with the enhanced status of source management entitlement as a property interest under the proposed supplementary provisions, some sources will potentially encounter significant difficulties in establishing a cause of action for property remedies like conversion, specifically, in respect of the requirement to establish an entitlement to damages.[98] The general rule where there has been a conversion is that damages should be

[97] Hardcastle (n 89) 2.
[98] Nicol (n 31) 152-154, see generally 147 -154.

based on the full market value of the goods.[99] Compensation for the value of goods is generally determined with reference to the replacement cost of the goods to the claimant.[100] In many cases where biological material is supplied for research, the specimen has little or no commercial value at the time that it is transferred to the researcher.[101] The biological material only evolves into something of value when the researcher has employed skill and put in labour to transform it.[102] In other cases, each individual biological specimen may only be valuable as part of a collection when it is for instance, aggregated with specimen from other sources that share similar characteristics, but could have little or no value of itself.[103] Sources like Mr Moore who possess biological material with unique qualities will likely have a realistic prospect of success in establishing a cause of action for conversion because their unique biological material will potentially have distinctive features that makes it commercially valuable even without the input of further skill and labour from a researcher,[104] but sources with non-unique tissue may find that they are unable to overcome this potential obstacle. To ensure that the interests of the latter category of sources are adequately protected, it would be necessary to broaden the scope of remedies available to include extra-judicial measures. Such extra-judicial measures could articulate a similar set of policies to the Industrial Injuries Compensation Scheme[105] (UK) and the workers' compensation systems (US). This could take the form of a statutory pre-determined schedule corresponding to specific offending actions, which reflect generally the importance of protecting source management entitlement (that is, its connection to the autonomy and psychological well-being of an individual), the seriousness of specific offending actions and the general impact of such actions upon sources of biological material. Like the Industrial Injuries Compensation Scheme which is currently administered by the Department for Work and Pensions in the UK, the proposed framework could also be administered by an administrative body in the form of the Human Tissue Authority, as opposed to, judicial measures that are administered by the courts. However to avoid difficulties with arbitrariness, ensure consistency and reduce the potential administrative

[99] Ibid, 152.
[100] Ibid, 153.
[101] Ibid.
[102] Ibid.
[103] Ibid, Harrison (n 4) 84.
[104] Nicol (ibid) 153-154.
[105] Lewis (n 15).

costs associated with adjudicating a suitable amount of compensation for each individual claim for compensation, the legislator could introduce a blanket fixed amount for compensation. This fixed amount will be paid by the offending recipient of biological material to the source of biological material in all eligible cases where the HT Authority finds that there has been interference with a source's management entitlement. Under such a scheme, an aggrieved source could submit an application for a compensation claim to the HT Authority outlining his or her grievance and provide relevant documentation to support his or her claim. The HT Authority could then request that the alleged offender (recipient researcher) also submit written documentation in response to the source's claim. Based on the documentation provided by both parties, the HT Authority (the HT Authority's Executive Team) could then determine whether there has indeed been an interference with the source's management which falls within the list provided under the statutory framework.

Where the HT Authority finds that there has been an interference with the source's entitlement, the HT Authority could make an order requesting that the offending party pay the source the fixed statutory compensation within a specific time period plus an additional administrative penalty to the HT Authority to cover the administrative costs of adjudicating the source's case and making the order. Failure to comply with an order made by the HT Authority could constitute a criminal offence and additionally, the HT Authority could also take appropriate regulatory action against the non-complying party. In line with other extra-judicial mechanisms and judicial measures, any party that objects to the HT Authority's decision will have the right to appeal within a specific time period to an appeal panel consisting of members of the HT Authority's Board. Potential claims for compensation regarding interference with source management entitlement could be limited under the proposed framework to those cases where consent is currently required under the HTA 2004. In other words, cases involving use of non-identifiable tissue for research will not be eligible for compensation because the use of such tissue for research does not currently

require consent of the source and can be used if the researcher has received ethical approval by a recognised research ethics committee.[106]

Income entitlement

The proposed compensation construct to enforce source income entitlement could comprise a mechanism for compensating sources of biological material that places a researcher under an obligation to compensate a source in accordance with prescribed criteria in statute (HTA 2004 as supplemented by proposed provisions). Both private sales and contracts for private sale of human biological material could be prohibited and any contravention of this prohibition could constitute a criminal offence. This provision is incorporated here to prevent the emergence of a market in human biological material and avoid the practical, moral and ethical problems associated with it. The various criticisms levelled at Harrison's model and Gitter's model could be addressed by stipulating a fixed statutory compensation to be paid to a source of biological material and prohibiting additional payment to the statutory fixed compensation. Added to this, contributions made by different classes of sources could be distinguished by restricting the class of sources who are entitled to claim individual compensation. Also, the non-economic interests of sources of biological material could be recognised and promoted by enabling sources to negotiate with researchers at the onset of their contribution for such non-economic interests, and by allowing sources to foster the affordability, availability and accessibility of diagnostic and therapeutic products, and research data by permitting only sources who have made financial investments over a specific threshold to collaborate with researchers and lawfully enter into contractual agreements with researchers to negotiate for both economic and non-economic interests. In rare cases where the researcher feels strongly that a source should be entitled to a higher amount of compensation than the statutory limit, the researcher can pay the higher amount (the award), with the consent of the HT Authority. To obtain the HT Authority's consent, the researcher could be required to notify the HT

[106] Human Tissue Act 2004 (n 36) Part 1, section 7; Human Tissue Authority, Codes of Practice 1 Consent (n 90), paras 117-119.

Authority in writing of the proposed award and reasons why the researcher believes that the source should be entitled to the proposed award (this could, for instance, be due to the significance of the source's biological material to the enterprise or the significance of the source's additional non-financial contribution to the success of the enterprise). The HT Authority can decide at its discretion whether to approve the award. Their deliberations could include the wider ethical implications of such an action.

Presently, biological material used in biotechnology research in the UK is supplied largely from within the public sector (the National Health Service).[107] Where the commercial sector generates profit from such freely donated material then it is just that they should give something back in recognition of the value of the public's donation.[108] While some might argue that the commercial sector already gives something back by making available new medicines and treatments which members of the public rely, this argument is not compelling because commercial researchers, biotechnology companies, pharmaceutical companies and medical device makers do not make those products freely available to the public. Rather, the public pay for such products through their taxes and national insurance contributions and also when they privately purchase drugs and other therapeutic and diagnostic products from chemists and pharmacies. While the commercial sector must profit to stay in business and so it will be unrealistic to suggest that they make the products of research available free of charge to the public because the raw material that made the research possible was made available to researchers free of charge by the public, it is not intolerable or far-fetched to suggest that commercial users of biological material give an additional material benefit in some form to the public to reflect the value of the public's donation.

[107] Nuffield Council on Bioethics, Human Bodies: donation for medicine and research (Nuffield Council on Bioethics, 11 October 2011) 206.
[108] Ibid.

Case for delayed compensation

The transaction costs associated with negotiating a payment/compensation agreement with every individual source of biological material at the time when biological material is supplied by the source could be prohibitive and discourage investment in biotechnology research. This is because many biological samples would be supplied either in clinical settings where specific research uses of the sample might not yet have been conceived or in research ventures that are still at an early stage of development where researchers may be unable to ascertain the eventual commercial value of the biological material.[109] Furthermore, the uncertainties inherent in biotechnology enterprise means that many biological samples would never actually yield products that will make it to market.[110] It is for this reason that a system of 'delayed compensation' is favoured in this discussion. Under the proposed framework, researchers could use the material without 'up-front' cost but commercial users who seek to generate profit from the biological material would be required to compensate the source of biological material (individually or as a collective unit) after use in every successful research enterprise that leads to a marketable product, in accordance with prescribed statutory provisions outlined below. Whether compensation is paid to an individual source or to a collective unit (that is, collective compensation aggregated for a family unit or contributed towards the maintenance of non-profit tissue banks or other public research infrastructure, for the benefit of the wider political community) could depend upon whether statutory eligibility criteria are met.

Determination of compensation standards

Generally, under the proposed framework, a fixed rate of compensation could be paid to an eligible source only where a marketable product is realized from research using biological material extracted from the source, and only when the forecasted or actual profits for the product exceeds a minimum threshold.

[109] Harrison (n 4) 87.

[110] Nicol (n 31) 164; D Nicol and J Nielsen, 'Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry' (2003) Centre for Law and Genetics Occasional Paper No 6, 113 and see generally 6 – 249; Harrison (n 4) 87.

In order to accommodate both the private interests and public utility inherent in biotechnology research and help to maintain the economic viability of such research, sources should not be compensated simply because they have supplied their biological material for research. In other words, all sources who contribute biological material for research should not have an automatic entitlement to compensation. Rather, a source's entitlement to compensation could be determined on the basis of the relative scientific and commercial utility of the source's biological material to the research.[111] Such an approach that assigns differential rewards to contributions with varying utility accords with the general preference for an equity-based mode of distribution in private ventures and is analogous to the principle inherent in patent law in which scientific contributions that constitute inventorship and contributions that have a lesser role in patented invention are treated differently.[112] For instance, 'the patent law system recognises those individuals who meet the statutory definition of inventorship as being entitled to patent rights but generally recognizes no valuable legal rights in favour of other contributors, even though they also made contributions towards the enterprise in form of ideas or skills that aided the discovery.'[113] On a theory of equity and some conceptions of reciprocal justice and equality, and in view of the prospect of success in claiming property based remedies, contributions of sources like Moore and Lacks would seem to represent the strongest case for individual compensation because the biological material of such sources are crucial to a particular scientific discovery and resulting products, and without the biological material of these sources, the relevant scientific discovery would not have been made and the resulting products would not be developed.[114]

Contributions of other biological sample, which may be valuable only as part of a collection or which may only further scientific knowledge when combined with other samples with similar characteristics might more appropriately be[115] rewarded in a wider context through

[111] Harrison (ibid) 84.
[112] IH Doner, 'Patent Prosecution: Practice & Procedure before the US Patent Office' (Bna books, 2d ed, 1999) 123-33; Harrison (n 4) 84 n 41.
[113] Ibid.
[114] Harrison (ibid) 83.
[115] Ibid, 84.

collective compensation that is either paid out for the benefit of a family unit (where a valuable collection of biological material comprised material supplied by a single family unit) or the wider political community (where a valuable collection comprised of samples obtained from multiple sources from the wider political community). Collective compensation aggregated for the benefit of the wider political community could potentially strengthen notions of community by expressing an attitude of solidarity,[116] and 'enable greater anonymity of samples and thus reduce threats to privacy posed by the need to locate individual sample contributors for purposes of compensation.'[117] However, while it may be the preferred option for some commentators,[118] payment of collective compensation should not preclude payment of individual compensation in appropriate cases such as those of Lacks and Moore where the end product was exclusively derived from biological material that originated from the body of one person. Under the proposed framework, a system of both individual and collective compensation should be adopted.

During the consultation process leading to enactment of the proposed new provisions, consideration should be given to various examples from practice in determining appropriate standards for compensation.[119] One such standard could include the following: where the biological material used in a successful research venture (that is, research resulting in development of a marketable product) was originally obtained from one individual source (for example, the Mo cell line which was developed from biological material excised from the body of Moore and the HeLa cell line which was developed from biological sample removed from the body of Lacks), then a unit of compensation should be paid to the person from whose body the biological material was removed. Alternatively, it could be paid to the

[116] Ibid, 103; Gitter (n 1) 322.
[117] Ibid.
[118] See Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 107) 194; Nicol (n 31) 162.
[119] Another standard for compensation could be that the '[biological material] clearly had unique features that gave it monetary value even without the input of further skill and labour from [researchers]' (Nicol (ibid) 153). The legislator might then set a threshold figure which the commercial value of excised biological material (before use for research) must exceed in order to be deemed unique or significant enough to warrant compensation after commercial use. Another standard to determine eligibility for compensation 'might also be that a particular marketed product could not have been conceived, developed or made without use of the [biological material]' (Harrison (n 4) 97 n 112).

source's next of kin in instances where the source is deceased (unique tissue is usually found in a diseased body and individuals like Lacks and Moore who possess such material are usually really sick and may not live long enough to directly benefit from their contribution to research).[120] On the other hand, where the biological material used in a successful research venture was originally obtained from multiple members of a single family unit then compensation could be paid to the family as one single unit. However, where the biological material used in a successful research venture was originally obtained from multiple sources from the general public and wider political community then a unit of compensation could be paid as a contribution towards the maintenance of non-profit tissue banks and research foundations and in so doing, help to maintain the accessibility and availability of biological material for further research, which would ultimately benefit the wider public. For compensation purposes, a 'source' is an individual, a single family unit or a political community. Sources who make financial contributions (for instance, the Greenbergs) over a certain threshold to a research enterprise, in addition to supplying biological material, would be treated to all intents and purposes as other investors and collaborators in research enterprise. They could be permitted to enter into legally enforceable contractual agreements to negotiate for both economic interests (for example, a share in profits, licensing and royalty fees) and non-economic interests.

Non-economic interests could include the promotion of research on a particular disease or condition that may be of concern to the individual and the accessibility of research results to other researchers that may be conducting research in the same or related areas, availability and affordability of treatment, diagnostic and therapeutic products for a particular afflicted community to which the source or someone close to the source may belong, the allocation of researchers' resources to benefit particular patient groups or the general public.[121] The threshold amount that a source's financial contribution must exceed before the source acquires an entitlement to enter into contractual agreements with researchers could be based upon the average usually contributed by investors who make financial investment

[120] Dillon (n 19) 634, 639.
[121] Harrison (n 4) 93.

towards research enterprise. Sources who make other financial contributions at or below the threshold amount and generally, all sources who participate in research enterprise, could notify researchers of non-economic interests at the onset of their contribution. However, researchers will not be compelled under the framework to take such non-economic interests into account. Researchers could take such interests into account at their discretion.

Parliament could set in advance appropriate standards for compensation[122] on the basis of a public consultation exploring the relevant issues. Such standards could include the introduction of a fixed rate of compensation which should apply universally to all cases where compensation becomes due under the proposed provisions.[123] In determining the fixed rate for compensation, considerations could be based upon both theoretical and empirical evidence regarding the appropriate amount of compensation that would be high enough to encourage prospective sources (patients and the general public) to supply their biological material for use in biotechnological research, while low enough to allow commercial enterprise to make profit substantial enough to provide an economic incentive to embark upon biotechnological research and promote investment in such research.[124] Setting a statutory fixed rate of compensation will help to promote legal certainty and avoid problems of arbitrariness and uncertainty that could result from separately determining compensation in individual cases.[125] It would also avoid the administrative and transactional costs involved in individual adjudication of compensation, albeit that a one-off administrative and legislative costs would be incurred before enactment of the proposed provisions in determining the statutory standards for compensation. A minimum threshold for profits could also be incorporated as part of the criterion for compensation. In essence, the forecasted or actual profits from the product generated from a particular biotechnology enterprise should exceed the threshold in order for compensation to become due to eligible sources. Where the forecasted profits exceed the minimum threshold then compensation

[122] Danforth (n 5) 200.
[123] Ibid.
[124] Ibid
[125] Ibid.

could become due to the eligible source. Also, where the original forecast for profits is equal to, or below the threshold amount and the source was originally ineligible for compensation, but the actual profits subsequently generated exceeds the threshold, compensation could become due to the source. The threshold amount could be based upon representations from the biotechnology industry and empirical evidence relating to the average profits made in biotechnology research within a given period of time. For instance, it could be the average of profits made in the two decades prior to enactment of the proposed provisions and where possible, the projected profits for the two decades immediately after enactment of the provisions.

Payment of compensation

Once a marketable product is developed, the foregoing conditions met, the eligibility of source biological material and mode of compensation (individual or collective compensation) is determined, and identification details of source are identified, researchers could be required in the first instance to notify the HT Authority of the prospective case for compensation. Researchers should provide written documentation relating to the circumstances surrounding the source's eligibility for compensation and details of the source (that is, an individual, a family unit or non-profit tissue bank or research foundation). Data Protection and privacy issues will presumably need to be considered in supplying such information to the HT Authority. Where the HT Authority receives notification of potential source compensation, the Authority may at its discretion examine the circumstances and written documents provided in order to determine whether or not the statutory eligibility criteria have in fact been met and whether relevant statutory provisions have been complied with. In any event, the HT Authority should be required to keep a record of such notifications and the relevant supporting documents. With the exception of potentially rare cases where commercial users decide to award the source a higher rate of compensation than the fixed statutory rate and in which the HT Authority might be required to engage in extensive deliberations, the role of the HT Authority generally in this regard could be restricted simply to record keeping and monitoring. The major role of the HT Authority

under the framework could be in the enforcement of source management and income entitlement where there has been interference with either one or both entitlements. After notifying the HT Authority of a prospective case for compensation, the commercial user of biological material could be required to write to the source informing him or her of eligibility for compensation, the amount of compensation (that is, the fixed statutory rate of compensation or a higher rate of compensation where appropriate). In such instances, the commercial user should also be required to request that the source confirm his or her intention to claim the entitled compensation or alternatively, request the source's permission to donate the source's compensation to a research foundation or non-profit tissue bank of the source's choice where the source does not wish to personally claim the compensation due to him or her. Depending on whether the source wishes to claim his or her compensation or donate the compensation to a non-profit tissue bank or research foundation, the commercial user could be required to either arrange transfer of compensation to the source or a research establishment of the source's choice. Any waiver of the source's entitlement to personally benefit from compensation should be made in writing. The provision that allows source to direct their compensation towards a non-profit tissue bank or research foundation helps to promote autonomy by giving the source the opportunity to determine where the value of his or her contribution goes, as well as communal values.[126]

Where the source is deceased, the compensation could be paid to the source's next of kin. However, in circumstances where the source declines to participate in the process or cannot be traced, the researcher could be required to donate the compensation as a contribution for the benefit of the political community towards the maintenance of a UK non-profit tissue bank or research foundation (for example, UK Human Tissue Bank, Cancer Research UK, Wellcome Trust, British Heart Foundation). This requirement seeks to prevent commercial users from avoiding their responsibility to pay source compensation simply because they have inadvertently or deliberately lost the source's identifying information. It also addresses cases where information linking biological material to the organisation at

[126] Boyle (n 4) 75.

which it was collected is missing or lost because biological material was not supplied directly to the specific research enterprise and the individual identifying information had not been transferred with the biological material.[127] In the event that compensation is aggregated for the benefit of a political community, the commercial user should be required to inform the HT Authority as above mentioned and arrange for the compensation to be paid to a UK based non-profit tissue bank or research foundation of the commercial user's choice. Written records of all payment made to sources should be filed with the HT Authority for record keeping, transparency and monitoring purposes.

In cases involving research conducted using non-identifiable tissue (as defined in *Human Tissue Act* 2004, Part 1, section 7),[128] where the researcher received ethical approval from a recognised research ethics committee to use the material; or where sources requested anonymity at the time when biological material was supplied, or the biological material was anonymized for any other reason during the research process, the commercial user should still be placed under an obligation to pay source compensation and should donate the compensation as a contribution for the benefit of the political community towards the maintenance of a UK non-profit tissue bank or research foundation as above.

Tissue banks, patient groups and other establishments that collate large pools of biological samples can continue to charge researchers or commercial users for their collection services and related costs but any compensation resulting from use of the material themselves should be regulated under the proposed framework and paid to eligible sources.[129] Collecting organisations could also be permitted to negotiate for non-financial provisions.[130] This could include commitments in respect of the use of their samples in research that seek to address diseases and illnesses of special interest to their group.[131]

[127] Harrison (n 4) 98.
[128] See also Human Tissue Authority, Codes of Practice 1 Consent (n 90) paras 117-119.
[129] Harrison (n 4) 98.
[130] Ibid, 98 n 113.
[131] Ibid.

Review mechanisms

Statutory standards would have to be fit for purpose in keeping with the dynamic nature of biotechnology and the rapidly changing circumstances in biotechnological research by being 'clear in principle but flexible in application,'[132] and by incorporating review mechanisms for compensation standards and other relevant provisions contained within the proposed framework.

Remedies

To ensure expedient payment of compensation, an appropriate time limit could be imposed in which commercial users will be required to administer compensation to eligible sources. This could be a suitable time period from either when a commercial user of biological material first discovers that forecasted profits for the marketable product exceeds the statutory minimum threshold or in relevant cases where the actual profits generated from the product exceeds the minimum threshold (see above). In any event, failure by a commercial user to pay compensation to an eligible source within the stipulated time without reasonable excuse would constitute a criminal offence and an interference with source income entitlement. Furthermore, as with source management entitlement, an aggrieved source should be granted the option to seek both judicial and extra-judicial remedies in case of interference with source income entitlement. This could be, for instance, where a source discovers that a commercial user had developed a marketable product from his or her biological material and the relevant statutory conditions are met under the proposed framework but the commercial user failed to notify the source accordingly and refuses to pay the source the compensation due to him or her. The source could seek a judicial remedy in form of an action for the tort of conversion and/or extra-judicial remedies in form of an application to the HT Authority for an order requesting that the commercial user pays the original compensation. The process is the same as above mentioned for source management entitlement with the exception that in a case of interference with income entitlement, the HT Authority simply makes an order for the

[132] Ibid, 99.

original compensation that is actually due to the source, as opposed to, the form of compensation paid for interference with source management entitlement which is essentially for the loss, distress and suffering that could potentially have been caused to the source as a result of an unauthorised use or misuse of the source's biological material. However, as with source management entitlement, the order could also include payment of an additional administrative penalty to the HT Authority to cover the administrative costs of adjudicating the source's case and making the order. Failure to comply with an order made by the HT Authority could constitute a criminal offence and additionally, the HT Authority could also take appropriate regulatory action against the non-complying party. In line with other extra-judicial mechanisms and judicial measures, any party that object to the HT Authority decision will have the right to appeal within a specific time period to an appeal panel consisting of members of the HT Authority's Board.

So as not to overburden the HT Authority and to bring the scheme in line with judicial and extrajudicial compensation mechanisms generally and achieve a balance between paternalism and individual autonomy, the onus will be upon individual sources and family units to enforce their entitlements to compensation through the courts and the HT Authority. In other words, in cases where compensation (income entitlement) becomes due to an individual source or family unit but it has not been paid within the statutory stipulated time period, the HT Authority can, at its discretion and without an application from the source of biological material, investigate the case and issue an order where appropriate but the Authority is not obliged to do this. However, the Authority should be responsible for enforcing the interests of the wider political community for compensation purposes and should be required to ensure that commercial users pay compensation to research foundations or non-profit tissue banks where relevant. The HT Authority should also be responsible in this regard for instigating available actions under the proposed framework as a representative for the political community and by extension, the public interest.

Advantages and Limitations

As above mentioned, although described as a property/liability framework, Gitter's model is quintessentially a free market model and so it is fundamentally dissimilar to the framework advanced here. The proposed framework does, however, share some similarities with Harrison's hybrid donative/liability model in that it also represents an intermediary solution between the current donative model and the free market model. Like Harrison's model, it helps to promote altruistic donations and communal values by both maintaining a donative principle at the onset of supply when biological material is transferred from the source to the recipient and also by allowing sources to waive their entitlement to compensation if they so wish. A substantial measure of altruism will particularly be required and promoted in respect of non-commercial research as researchers involved in such research would not be required to pay source compensation because they, presumably, would not seek to commercialize products from such research.[133] Added to this, the proposal provides a mechanism that facilitates payment of compensation to sources who make significant contributions to research and whose contributions impacted upon the success of research enterprise. However, a key difference between the proposed framework and Harrison's model is that whilst Harrison's model does not explicitly recognise property right in favour of sources of biological material and primarily seeks to protect income entitlement, the framework proposed here does in fact vest sources of biological material with a limited property interest to include safeguards for not only source income entitlement, but also for source management entitlement.

By allowing a source to retain property interest in respect of his or her biological material through a licence mechanism after biological material has been transferred to the recipient, a source is thus empowered to maintain his or her entitlement to property based remedies. This helps to achieve justice on a source's behalf by both allowing a source to seek redress where there has been interference with his or her entitlements and helping to provide an effective deterrent in discouraging would-be offenders from interfering with source interests at the outset. Both the threat of civil action in the form of an action in conversion

[133] Ibid, 93.

and the addition of extra-judicial remedies to the armoury of existing protections (criminal sanctions) available to sources of biological material helps to create an even greater incentive for researchers to provide informed consent because the monetary awards that they would need to pay to the source either by order of the court in a civil action, or by order of the HT Authority under the liability scheme, could prove great enough to serve a powerful deterrence effect.[134] The limited property interest vested in sources under the proposed scheme, in particular, management entitlement, further strengthens a source's 'claim to maintain control over the disposition of that which is exclusively his or hers,'[135] thereby helping to safeguard a source's autonomy and self-determination and ensuring compliance with notions of human dignity. Added to this is the compensation requirement regarding source income entitlement which at its base, is also an effort to treat the source of biological material as fully autonomous – as able to decide for himself or herself whether to partake, either personally or otherwise, in the economic benefits derived from research using his or her biological material.[136] The proposal advanced achieves a balance between concern for source dignity and autonomy and concern for the advancement of biotechnological research through a rationalized policy that promotes the values and interests of sources of biological material and recognizes the importance and benefits of scientific and medical progress.[137]

The proposed framework would also allow sources of biological material to retain legally recognized interests regarding their excised biological material whilst also providing researchers with the flexibility to conduct research and commercialise the products of research enterprise where appropriate.[138] In allowing sources to retain legally recognised interests regarding biological material, public confidence in research will be promoted which in turn will help to encourage prospective sources to supply their biological material for research, thereby helping to maintain the availability of biological material for research and aiding discoveries that could advance public health. Among the advantages of the proposed

[134] Gitter (n 1) 341.
[135] Danforth (n 5) 201.
[136] Ibid, 202.
[137] Ibid.
[138] Boyle (n 4) 78.

framework would be its ability to maintain access to biological material for both commercial and non-commercial researchers and allow researchers to use biological material for research without upfront costs while requiring that commercial users pay compensation to eligible sources only if the enterprise becomes successful. The proposed framework will also generally avoid the delays and other potential difficulties associated with upfront negotiations by incorporating a mechanism for delayed compensation rather than upfront compensation at the onset of supply of biological material. The contractual option available to sources whose intention it is to invest financially in research would enable sources to form a continuous partnership with both researchers and the biotechnology industry which would in turn allow them to foster the availability and affordability of diagnostic and therapeutic products to the public.

Like Harrison's liability based model, the proposed framework also relieves the perception that sources of biological material are 'selling' their body parts (which some members of the public may consider morally objectionable) to the extent that unlike a free market model, it does not set a price on the body part itself but rather focuses on the profits derived from the product of research using the biological material.[139] It also places the focus on rewarding the source for making a crucial contribution to a successful research venture that will ultimately help to promote public health, as opposed to a market system which simply pays the source a price in exchange for biological material. The requirement that a statutory fixed rate of compensation is paid only where a marketable product is realised and if forecasted profits or actual profits exceeds a minimum threshold which in itself is based upon the average profits made in biotechnology enterprise, will help to maintain the affordability and profitability of biotechnology research and promote clarity in respect of the obligations of both researchers and commercial users of human biological material.

The current law unwittingly allows compensation claims on an arbitrary basis (since it does not explicitly ban reward for material supplied for research purposes) by those few

[139] Danforth (n 5) 200.

individual sources or patient groups who are knowledgeable about the potential commercial value of their biological material and have the means to negotiate for such value before the biological material is transferred for use in research, albeit that it is still questionable whether such agreements are enforceable in the law courts.[140] The proposed framework, in contrast, offers a coherent policy that addresses 'concerns about justice, commodification and the integrity of professional relationships between [sources of biological material] and the doctors and researchers who work with them.'[141] The proposed framework will also 'stand on more certain legal footing [than the current status quo] because it will be [clearly] defined by statute.'[142]

However, such a proposal would necessitate certain costs. These include the costs of the administrative and legislative process in determining statutory standards for compensation, in particular, the public and private costs of organising and making representations at the legislative hearings and public consultations that would be necessary to determine such standards. The impact of these potential costs is however reduced by the fact that it need only happen once, before enactment of the proposal, and it would certainly not entail costs anywhere near the same scale as the potential costs of negotiating with every prospective individual source under a market system. Also, it could be less than the potential costs of separately adjudicating individual cases for compensation under Harrison's model. While the process of adjudicating cases of interference with source ownership entitlement by the HT Authority could entail certain administrative costs to the public purse, the provision under the proposal for such costs to be recouped from the offending party through the incorporation of an administrative penalty into all orders issued by the HT Authority, will help to ensure that this process does not represent a significant impost on the HT Authority's budget and generally, the public purse.

[140] Harrison (n 4) 93.
[141] Ibid.
[142] Danforth (n 5) 200.

Some might argue that such a system would require investment in an extensive and expensive record keeping system to maintain the identifying information of each biological sample used in a particular research enterprise so that sources can be identified and their whereabouts located for compensation purposes.[143] Added to this is the potential monitoring and enforcement costs to research institutions in making sure that their staff comply with compensation requirements.[144] While there is merit in this argument, the fact that clinical and demographic data about the person from whom biological material was removed will have greater scientific and commercial value and systems already exist in the medical and scientific community to keep record of such data[145]would suggest that such record keeping system as potentially required under the proposed framework is already part of biotechnological research infrastructure. Furthermore, since biotechnological research already involves meticulous care, such record keeping would be unlikely to prove unduly burdensome for researchers.[146] Additionally, in light of recent developments in modern technology, record keeping should not represent a separate problem in itself because the complex modern computer systems regularly used by organisations and establishments already include software packages and databases to simplify the process of record keeping.

On the commodification issue, the proposed framework potentially still commodifies the human body. While it is true based upon a narrow construction of 'commodification' that the proposal does not entail commodification because it would explicitly ban the buying and

[143] Gitter (n 1) 279.
[144] Ibid.
[145] Harrison (n 4) 99. Nuffield Council on Bioethics, *Human Bodies: donation for medicine and research* (n 107) para 1.14:

> Medical information associated with donated tissue adds significantly to the value of the tissue as a research resource: such information may be obtained either by maintaining a link with the donor's full health record, or by retaining a particular dataset of information about the person's medical history. In both cases, in the research setting, the information available will normally be linked with the sample through a code so that the researcher does not directly access identifying information such as names and addresses.(footnote omitted) Sometimes samples can be collected with some basic non-identifying data, which is then completely separated from the source data and straightforward linkage completely broken (although, in fact, with modern technology it may now be possible to match fragmented DNA in a sample to a specific donor).

[146] *Moore v Regents of the University of California* [1988] 202 Cal. Rptr. 494 [508]; Gitter (n 1) 289.

selling of human biological material,[147] this is not the case if the wider definition were to be adopted. Since the wider definition of commodification involves objectification of the human body[148] and entails treating something (the human body) which is not a commodity as if it were a commodity just like other goods, [149]the mere fact that money is involved potentially commodifies the human body. This will likely remain the case in spite of the fact that a price is not placed upon biological material as in a market transaction, and payment of compensation is subject to some conditions and not inevitable upon supply of biological material. Essentially, the only reason why a source participating in such an enterprise would be compensated is because of his or her biological material. But for the existence and contribution of the source's biological material, the person would not be entitled to compensation under the scheme. The compensation is therefore ultimately for the biological material in itself – money is given in exchange for the biological material, thus making it a commodity. However, whether this potential difficulty represents a significant drawback of the system will depend upon the 'operative understanding of commodification and the weight assigned to avoiding it' by Parliament.[150]

Nevertheless, the contingent nature of money in transactions involving human biological material and the likely continued future involvement of money in biotechnological research for as long as such research is driven predominantly by the commercial sector with the main aim of generating profits for their shareholders, would seem to strengthen the case for adopting a narrow construction of commodification in the context of source ownership entitlement. Otherwise, it would represent a double standard and invoke the same justice concerns currently inherent in the current system.

Also, the anti-commodification argument is less than compelling because collective processes for valuing human biological material already exist within the English Legal system

[147] MJ Radin, 'Market-Inalienability' (1987) 100 Harvard Law Review 1849, 1859.
[148] George (n 83) II (D).
[149] Ibid.
[150] Harrison (n 4) 95.

for tort claims and in workers compensation systems like the Industrial Injury Compensation Scheme. The acceptance of these mechanisms in law and popular discourse (as evidenced by the various legal provisions dealing with it and the public invoking these provisions to seek redress) would support the supposition that compensation under a liability rule in the context of research uses of biological material could be substantially less objectionable than a pure property rule to those stakeholders and interested parties who seek to avoid commodification in social institutions.[151] In summary, the legislative solution proposed 'offers the opportunity to advance biotechnological innovation, enhance the public accountability of researchers, and foster citizen involvement in pressing public health decisions, while ensuring honourable and equitable treatment of [sources of biological material].'[152]

[151] Ibid, 91.
[152] Gitter (n 1) 345.

CONCLUSION

The main objective advanced in this discussion has been to seek to devise an implementable framework for regulating interactions in respect of human biological material supplied for research, with particular emphasis on safeguarding the management and income entitlements of individual sources of biological material. To assist with this objective, the following questions were explored:

1. Theoretical characterisation: Do source ownership entitlements qualify as property interests under a normative understanding of property?

2. Legal characterisation: Are source ownership entitlements enforced as property interests under the law?

3. Should source ownership entitlements be protected? Should such protection include a legal characterisation of source ownership entitlements as property interests?

4. How should an implementable policy framework for the protection of source income entitlement and source management entitlement be construed?

The analysis of the first question led to the conclusion that excised human biological material might qualify as property under a reified understanding of property because they have a physical presence that qualifies them as 'things' under the reified theory.[1] However, because the focus of the question revolved around the status of source ownership entitlements and not the categorisation of excised biological material as property, the bundle of rights understanding of property was found to be more instructive in this regard. The difficulties associated with the bundle of rights theory was outlined in chapter 2. The

[1] RN Nwabueze, 'Legal Paradigms of human tissues' in C Lenk, N Hoppe, K Beier and C Wiesemann, *Human Tissue Research: A European Perspective on the Ethical and Legal Challenges* (Oxford: Oxford University Press, 2011) 90.

main difficulty with the theory being its tendency to consume all other rights including some human rights and bring them under the umbrella of property, a difficulty which has led one commentator to suggest that the fragmentation of property as a bundle of rights has made it an ineffective tool for moral and political analysis[2] and another commentator to suggest that the bundle of rights construct is 'a slogan without any internal coherence or logical structure necessary for analysis of real life problems.'[3] In essence, the point being made is that a normative understanding of property as simply a 'bundle of rights' does not represent a substantive criteria upon which to differentiate property rights from non-property rights.

In view of the foregoing criticism of the bundle of rights theory, the discussion in chapter 2 considered not just the fragmentation of property as a bundle of rights but also the *Ainsworth* criterion[4] espoused by Lord Wilberforce regarding the specific nature of a property right, as potentially comprising the characterisation of property. Application of this characterisation to the context of source ownership entitlements indicated that such entitlements do not qualify as property interests. In spite of this, however, it was conceded that if consideration is given to the line of enquiry that suggests that the *Ainsworth* criterion does not represent an immutable standard upon which to determine whether a right qualifies as a property right, then source ownership entitlements could qualify as property interests. Similarly, source ownership entitlements might qualify as property interests if the line of enquiry is accepted that it is not necessary to offer a universal characterisation of property but rather that society should invoke an 'intuitive, pragmatic and policy-based'[5]approach in distinguishing property rights from non-property rights or expressed differently: '…property is no more than a normative set of relations, which might be attached to whatever society deems it necessary or beneficial to make the subject of

[2] TC Grey, 'The Disintegration of Property', in JR Pennock and JW Chapman eds, NOMOS XXII: *Property* (New York: New York University Press, 1980).
[3] JE Penner, surmised in RN Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information*. (Ashgate Publishing, 2007) 28.
[4] *National Provincial Bank Ltd v Ainsworth* [1965] AC 1175 [1247] – [1248].
[5] P Kohler, 'The Death of Ownership and Demise of Property' (2000) 53 Current Legal Problems 237, 242-243.

property'.[6] Such an approach might hold, for instance, that the particular source ownership entitlements advanced in this discussion (that is, source management and income entitlements) ought to be regarded as property interests because they are entitlements within the ownership spectrum and are akin to property interests in the bundle of rights attached to historic and established forms of property. Secondly, that the utility of the characterisation of the advocated entitlements as property interests better protect the interests of sources of biological material because of the more wide ranging remedies offered by a property approach in comparison to remedies underpinned by liability rules.[7] The significance of this is that a source will have wider choices and potentially a greater prospect for recourse in the event that there has been interference with his or her entitlement. Furthermore, such characterisation also better protect source interests as compared to non-property approaches in terms of the empowerment that it will potentially give to a source in controlling what happens to his or her excised biological material. Additionally, the substantial award of damages potentially offered under a property approach would also serve a powerful deterrence in discouraging would-be offenders from interfering with a source's interests. Such a state of affairs is desirable because it would help to promote justice for sources. A sense of justice being served for sources is arguably important in maintaining the supply of biological material for research because it could influence the decision of members of the public in choosing whether or not to make their biological material available for research uses.

While source management entitlement is protected by law under the *Human Tissue Act* 2004 and to some extent by the common law principle of bodily integrity, the law does not enforce a source's income entitlement. Furthermore, although both entitlements and generally, source ownership entitlements might qualify as property interests under a

[6] Ibid.

[7] DM Gitter, 'Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material' (2004) 61 Wash. & Lee L. Rev. 257, 305-310; Nwabueze (n 3); M Pawlowski, 'Property in Body Parts and Products of the Human Body' (2009) Liverpool L Rev 35, 36; K Mason and G Laurie, 'Consent or Property? Dealing with Body Parts in the Shadow of Bristol and Alder Hey' (2001) 64 MLR 710.

normative understanding of property as a bundle of rights, it is not so clear that they are recognised as property interests under the law. There is currently no English common law authority that considers the legal status of source ownership entitlements regarding excised non-reproductive biological material and the US cases that have considered this matter have categorically refused to recognise source ownership entitlements as legally protectable property interests.

The English case of *Yearworth*, though accepting source ownership entitlements as legal property interests, dealt specifically with sperm and is thus limited in its application to matters involving gametes. The court in *Yearworth*, while recognising a need for a change in the judiciary's approach in its treatment of excised human biological, did not, however, confirm that its judgement is applicable to biological material, other than sperm and there has been no subsequent English authority to confirm the court's approach. Subsequent Australian authorities[8] have also been raised in the context of sperm and have failed to confirm that a general application could be made to biological material, other than, sperm. Two things should be noted about the US cases that have rejected source property/individual property right regarding excised biological material: firstly, the courts have failed to recognise that ownership and property are two separate concepts and such misunderstanding has led them to mistakenly conclude that the existence of only a limited/reduced collection of ownership entitlements precludes a finding of property interests. In other words, they have failed to realise that property is a flexible concept and so an entitlement could potentially qualify as a property interest and a stick in the property bundle under a bundle of rights conception of property even if it does not constitute full ownership.[9] Secondly, in refusing to admit source ownership entitlements into the legal category of property, the court have focused on policy reasons rather than substantive reasons formulated upon established legal principles. These policy reasons have been

[8] *Kate Jane Bazley v Wesley Monash IVF Pty Ltd* QSC 4 118 (considered the legal status of entitlements to sperm of a deceased man, deposited before his death. Although dealing with the sperm removed from a deceased person, see Jocelyn Edwards: Re the Estate of the Late Mark Edwards [2011] NSWSC 478.

[9] RN Nwabueze 'Body Parts in Property Theory: An Integrated Framework' (2013) J Med Ethics 1, 3 [Published Online First: January 31 2013 doi: 10.1136/medethics-2012-100815].

shown in the present discussion to be less than compelling and no longer withstand critical scrutiny. Consequently, there is arguably no sound justification for refusing to admit source ownership entitlements, specifically source management and income entitlements, into the legal category of property.

The examination of the third question involved engaging in a general discussion as to why both source management and source income entitlements require legal protection, irrespective of the form that such protection may take. Though an argument was made for increased protection for source management entitlement, the crux of the discussion actually revolved around protecting source income entitlement because all parties whose opinions are represented in the debate seem to agree that there is a need for increased legal protection for source management entitlement. It was suggested that management entitlement be explicitly characterised as a legal property interest for strategic reasons, namely, to enable sources of biological material to claim property based remedies such as conversion, for which recognition of a legal property interest is essential. It was considered that the addition of these remedies to the armoury of protection available to sources will offer a more robust protection to sources than the current framework.

Although, in cases where there has been interference with a source's management entitlement, the offender will be criminally liable under the Human Tissue Act 2004, such criminal sanctions quintessentially serve to further the state's (not the victim/source of biological material) interests in enforcement, crime reduction, maintaining public order and state's function as the instigator of public prosecutions.

With regard to source income entitlement, it was advanced that the arguments invoked by opponents of source income entitlement in support of the current system no longer withstand critical analysis because their concerns are specific to a pure property/free

market model. The potential impact of their arguments and concerns are likely reduced and in some instances, even eliminated, with alternative models to the pure property approach, such as liability models or hybrid property/liability models. Such alternative models not only address the opponents' concerns but also achieve a fairer outcome for sources of biological material whilst also promoting biotechnological research and innovation. The foregoing observations were then relied upon in support of the case for legal enforcement of source income entitlement.

It was proposed that a hybrid liability/property framework would offer the most effective protective framework for both source management and source income entitlements. The proposed hybrid liability/property framework was premised upon a notion of balance between the interests of sources, researchers and commercial ventures involved in biotechnological research enterprise and the wider public interests of such enterprise. The framework vest sources of biological material with a limited property interest in their excised biological material and incorporate safeguards in respect of not only source income entitlement, but also for source management entitlement. By allowing a source to retain his or her statutorily created property interest in respect of biological material through a licence mechanism after the transfer of biological material to the recipient, it empowers a source to maintain an entitlement to property based remedies which will help to provide an effective deterrent in discouraging would-be offenders from interfering with the source's entitlement and it also allows a source to be compensated in instances where there has been interference with his or her entitlement. Both the threat of civil action which could include an action in conversion and the addition of extra-judicial remedies to the armoury of existing protections (criminal sanctions and limited access to remedies for lack of informed consent and breach of fiduciary duty) for sources of biological material will help to create an even greater incentive for researchers to provide informed consent. This is because the monetary award that they could potentially be required to pay to the source either by order

of the court in a civil action or by order of the HT Authority under the proposed liability scheme should prove great enough to serve a powerful deterrence effect.[10]

The limited property interest vested in sources under the proposed scheme, in particular, management entitlement, further strengthens a source's 'claim to maintain control over the disposition of that which is exclusively his or hers,'[11] thereby helping to safeguard a source's autonomy and self-determination and ensure compliance with notions of human dignity. The proposal advanced in this discussion achieves a balance between concern for source dignity, autonomy and justice, and concern for the advancement of biotechnology research through a rationalized policy that helps to promote the values and interests of sources of biological material while at the same time recognizing the importance and benefits of scientific and medical progress by limiting the scope of the values and interests that are promoted and enforced on behalf of sources.[12]

[10] Gitter (n 7) 341.
[11] MT Danforth, 'Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits' (1988) 6 Yale L. & Pol'y Rev. 179, 201.
[12] Ibid.

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