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Collective Property Rights in Human Biological Materials in Kenya

*By: Paul Ogendi**

1. Introduction

This article reflects on property rights in relation to human biological materials obtained from research participants participating in genomic research. Property rights are crucial in genomic research because they can help avoid exploitation or abuse of such precious material by researchers. Furthermore, the property rights model preferred by a country may restrict or expand access to such materials for research and innovation. The concept of distributive justice is particularly instructive in choosing an appropriate model for property rights in human biological materials. Jefferson notes in this regard that ‘various alternative paradigms for ownership ... have attempted to balance competing interests between exclusion and access; private and public; altruism and ownership; and individual and community’.¹ Exclusion and access are emphasised in this article.

It is important to clarify that property rights can be conceptualised differently – including individually or collectively/communally. The former approach is mostly emphasised in Western jurisdictions and the latter in developing countries, including in Africa. Individual property rights therefore conform to the Western notion of property rights and Feldman aptly observes that ‘modern property law scholars think of property as a bundle of rights with four key attributes: use, possession, exclusion and disposition’.² Individual

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¹ David J. Jefferson 'Biosociality, Reimagined: A Global Distributive Justice Framework for Ownership of Human Genetic Material' (2015) 14 Chi-Kent J Intell Prop 357, 358.

² Robin Feldman ‘Whose body is it anyway? Human cells and the strange effects of property & intellectual property law’ (2011) 63:6, 1377 Stanford Law Review 8.

property rights therefore are premised on exclusion among other things, and may not achieve as much in terms of distributive justice.

Individual property rights in human biological materials are contested for various reasons. Feldman observes that the law is relatively clear on ownership of ‘concrete items, such as automobiles, jewelry, or a plot of land, to more abstract concepts such as our labor, our writings, our innovations, and even our commercial image’.³ However, regarding human biological material, Feldman further observes that ‘we are fast approaching the point at which just about anyone can have property rights in your cells, except you’.⁴ He believes that ‘[t]he logical person for initial ownership of cells is the person from whose body the cells originated. For public policy reasons, society may want to restrict people from using, selling or disposing of those cells in certain ways’.⁵ The lack of enthusiasm in this area is mainly external and some of the reasons include cultural, religious or humanistic reasons. Accordingly, Martinez states: ‘[i]f we say these things are property, then we run the risk of sanctioning a free market in them, an outcome which for religious, cultural or humanistic reasons we may find unacceptable.’⁶

The other side of the property rights debate in the human biological materials discourse does not focus on the individual but the collective. In this

³ Robin Feldman ‘Whose body is it anyway? Human cells and the strange effects of property & intellectual property law’ (2011) 63:6, 1377 *Stanford Law Review* 1.

⁴ Robin Feldman ‘Whose body is it anyway? Human cells and the strange effects of property & intellectual property law’ (2011) 63:6, 1377 *Stanford Law Review* 1. Interestingly, Feldman makes a very interesting observation with regard to the human body: ‘Whatever else I might own in this world, however, it would seem intuitively obvious that I own the cells of my body. Where else could the notion of ownership begin, other than with the components of the tangible corpus that all would recognize as “me”?’ In another interesting example, Feldman observes as follows: ‘From a more graphic perspective, suppose a man severs his finger while sawing wood in his backyard. One would expect that person to have the right to ask that the finger be re-attached, as opposed to any other potential uses or modes of disposition, including use for research. The person’s priority right to those cells cannot possibly be connected to rights of privacy, nondisclosure, or informed consent. The man would claim the finger, not because it contains information that should be kept private or because he did not properly obtain his own consent before slicing off his finger. He would claim the finger because it is his. See *Ibid*, 9-10.’

⁵ Feldman above, 10.

⁶ Martinez J. ‘A Cognitive Science Approach to Teaching Property Rights in Body Parts’ (Social Science Research Network 1992) SSRN Scholarly Paper 1593768, 295-296 <<https://papers.ssrn.com/abstract=1593768>> accessed 13 May 2022.

paradigm, the key concern is not exclusion but access. As contended by Jefferson:

[i]n order to begin to realize distributive justice in the context of biotechnological development, we must question the Western notion that the rights associated with property ownership are vested primarily in private individuals. Instead, we might imagine that for certain forms of property, models of ownership which locate rights in groups or collectives would be more appropriate.⁷

I therefore argue for a collective approach to property rights in human biological material. This model is particularly attractive for the genomic research landscape because it does not prevent the recognition of property rights over genomic data generated by private companies or the registration of innovations. The main positive point of this approach is that it ensures that human biological material is publicly owned by the state on behalf of the collective and can be used for public interest projects. It is not privatised in favour of any particular entity and is therefore not difficult to access. For a continent or a country that is yet to develop sufficient capacity for genomic research, especially in the private sector, publicly owned human biological material makes more sense and secures the future of the sector. Local companies and researchers will in future be able to tap into the available human biological material resources to do their research and innovation – without having to collect new material or purchase it from private entities who may even opt to make it unavailable by using trade secrets. In natural resources law, this approach is actually preferred and has been emphasised in many instruments in order to protect developing countries.⁸

2. The general trend in Kenyan laws in relation to property rights in human beings

⁷ David J. Jefferson 'Biosociality, Reimagined: A Global Distributive Justice Framework for Ownership of Human Genetic Material' (2015) 14 Chi-Kent J Intell Prop 357, 374.

⁸ See, generally, the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization in the Convention on Biological Diversity, 2011. The preamble states: '[r]eaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention'.

Although this section is not directly relevant to understanding the topic of property rights in human biological material, it is nevertheless important in assessing the general trend in Kenyan laws. This analysis will then inform the central thesis of this article, which is that Kenya may be more amenable to recognising collective property rights than individual property rights, since individuals have historically, by law, been denied the opportunity to trade in their body parts, organs and tissues. This section explores the broad subjects of property rights in: slavery and slave-like practices; dead bodies; and body parts, organs and tissues.

2.1 Slavery and slavery-like practices

In the past, owning a human being was allowed by law, especially in Western countries. The slaves were taken from other countries including Africa to work on farms and were subjected to all forms of human exploitation because their status as ‘things’ meant that they had no rights – the same as a cow or a table. In the post-slavery period, however, it is now firmly established ‘that there are no longer any property rights over another living human being’.⁹ This means that no human being can own another person as his or her property. Efforts to change ownership of another human being have been driven internationally with the adoption of the 1926 *Slavery Convention*.¹⁰ Article 1(1) of the *Slavery Convention* defines slavery as ‘the status or condition of a person over whom any or all of the powers attaching to the right of ownership are exercised’. Sub-article 2 defines slave trade:

The slave trade includes all acts involved in the capture, acquisition or disposal of a person with intent to reduce him to slavery; all acts involved in the acquisition of a slave with a view of selling or exchanging him; all acts of disposal by sale or exchange of a slave acquired with a view to being sold or exchanged, and, in general, every act of trade or transport in slaves.

⁹ Gerald Dworkin & Ian Kennedy 'Human Tissue: Rights in the Body and its Parts' (1993) 1 *Med L Rev* 291, 293.

¹⁰ 'Convention to Suppress the Slave Trade and Slavery' Signed on 25 September 1926, Geneva,

Entered into Force on 9 March 1927, in accordance with Article 12, <<https://lawphil.net/international/treaties/patcsg.html>> accessed 27 May 2022.

Slavery allowed for property rights in human beings. Kenya has neither ratified nor acceded to the Convention.¹¹ This may be because Kenya did not practise slavery and may instead have been a victim of slavery. Over the years, other ‘slavery-like practices’ such as apartheid have also been outlawed by international law. The 1974 *International Convention on the Suppression and Punishment of the Crime of Apartheid*¹² is instructive in this regard. Kenya signed the Convention on 2 October 1974 but has not yet ratified or acceded to it.¹³ Apartheid manifested mainly in South Africa and not in Kenya. This may be why Kenya has not yet acceded to the Convention. Furthermore, at the start of the 21st century, the law of human exploitation expanded beyond slavery and apartheid to include, inter alia, anti-trafficking conventions and the Rome Statute of the International Criminal Court (which also criminalises enslavement).¹⁴ The Convention for the Suppression of the Traffic in Persons and of the Exploitation of the Prostitution of Others was adopted by the UN General Assembly in 1949, but Kenya has not signed it.¹⁵ Kenya has however acceded to the *United Nations Convention Against Transnational Organized Crime* and its *Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children* on 16 June 2004 and 5 January 2005 respectively.

From the above analysis, the international law has taken leadership in outlawing ownership or the exploitation of another human being. Even though Kenya has not acceded to some of the instruments, some of the norms espoused in those instruments have achieved a status of customary

¹¹ ‘United Nations Treaty Collection’

<https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XVIII-3&chapter=18&clang=_en> accessed 20 July 2022.

¹² G.A. res. 3068 (XXVIII), 28 U.N. GAOR Supp. (No. 30) at 75, U.N. Doc. A/9030 (1974), 1015 U.N.T.S. 243, entered into force 18 July 1976.

¹³ ‘United Nations Treaty Collection’

<https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-7&chapter=4&clang=_en> accessed 20 July 2022.

¹⁴ Jean Allain ‘The international legal regime of slavery and human exploitation and its obfuscation by the term of art: “Slavery-like practice”’ (2012) *Cahiers de la recherche sur les droits fondamentaux* 27

¹⁵ ‘University of Minnesota Human Rights Library’

<<http://hrlibrary.umn.edu/research/ratification-kenya.html>> accessed 20 July 2022.

international law, and they are therefore binding on Kenya. It therefore does not matter whether Kenya is a party or not.

2.2 Property rights in dead bodies

In this section, the common law ‘no property rule’ is discussed because it applies in Kenya, and Kenyan laws are also canvassed.

2.2.1 English common law ‘no property’ rule

Perhaps a more relevant analysis when it comes to property rights in human biological material can be found in the property rights in dead bodies. This is because the development of property rights over human biological materials ‘evolved primarily from laws governing the disposition of corpses, organs, and replenishable tissues’.¹⁶ Given colonisation, the law in Kenya is not remote from that in England. In fact, common law is applicable in Kenya pursuant to section 3 of the *Judicature Act*.¹⁷ The historical or common law position in England is that dead bodies are incapable of property ownership.¹⁸ This is the ‘no-property’ rule as mentioned in the 1979 English case of *Exelby v. Handyside*.¹⁹ According to Skegg, the common law ‘no-property rule’ does not preclude recognition of some quasi-property rights in England including permanent possession of parts of corpses, in accordance with the Human Tissue Act 1961 (s. 1) or the Anatomy Act 1984 (s. 6).²⁰ The right to possession of a dead human body is also manifest when a spouse or next of kin is granted, by law, the right to take possession of a dead body

¹⁶ Marylon Ballantyne, Note, *One Man’s Trash is Another Man’s Treasure: Increasing Patient Autonomy Through Limited Self-Intellectual Property Rights*, as quoted in Megan L. Townsley ‘Is There Anybody out There – A Call for a New Body of Law to Protect Individual Ownership Interests in Tissue Samples Used in Medical Research’ (2015) 54 Washburn LJ 683, 700.

¹⁷ Cap 8 Laws of Kenya.

¹⁸ Gerald Dworkin & Ian Kennedy ‘Human Tissue: Rights in the Body and Its Parts’ (1993) 1 Med L Rev 291, 294.

¹⁹ (1749) 2 East PC 652 (CCP).

²⁰ Skegg PDG ‘Medical Uses of Corpses and the “No Property” Rule’ (1992) 32 Medicine, Science and the Law 311

<<https://doi.org/10.1177/002580249203200405>> accessed 27 May 2022.

for burial.²¹ The courts have however not clearly defined the property rights available in a dead body when faced with contentious cases.²² Consequently, the general obligations under common law are that those in possession of a dead body should dispose of it decently.²³

Consequently, in England, it is apparent that the common law position does not allow for property rights in dead bodies. However, one can acquire quasi-property rights in accordance with the applicable legislation. The Kenyan position therefore follows the common law approach – assuming there is no legislation to the contrary. As will be seen later, Kenya also has its own legislation in this area.

2.2.2 Kenyan laws and jurisprudence on dead bodies

The Kenyan law appears to recognise some form of restricted property rights over dead bodies. The restriction is usually in favour of public health. For starters, the *Public Health Act*²⁴ makes it unlawful to exhume dead bodies without permission. Section 146 thus provides that:

it shall not be lawful to exhume anybody or the remains of anybody which may have been interred in any authorised cemetery or in any other cemetery, burial ground or other place without permit granted in manner hereinafter provided.

What is more, even the right to possess a body for burial is not absolute. The court may decide who exercises that right and in some cases it has decided against the wife of a deceased person. In *Virginia Edith Wamboi Otieno v Joash Ochieng Ougo & Omolo Siranga*.²⁵ the courts, relying on customary

²¹ 'Rights and Obligations as to Human Remains and Burial | Stimmel Law' <<https://www.stimmel-law.com/en/articles/rights-and-obligations-human-remains-and-burial>> accessed 27 May 2022.

²² Skegg PDG 'Medical Uses of Corpses and the "No Property" Rule' (1992) 32 *Medicine, Science and the Law* 311 <<https://doi.org/10.1177/002580249203200405>> accessed 27 May 2022.

²³ Gerald Dworkin & Ian Kennedy 'Human Tissue: Rights in the Body and its Parts' (1993) 1 *Med L Rev* 291, 294.

²⁴ Cap 242.

²⁵ Civil case No. 4873 of 1986 *Wamboi Otieno v Joash Ochieng Ougo & another* (1987) eKLR.

law, found ‘that the question with regard to the place a deceased person is to be buried is a matter for the family of the deceased who, if need be, may involve other members of their clan’. The general trend is that there are no property rights in dead bodies and the state through the courts can decide who can have possession of the body for burial purposes. During the Covid-19 period, the state exercised a greater degree of control of the time and manner in which dead bodies were to be buried, and sometimes the regulations conflicted with cultural norms. A public health consideration is therefore paramount – and not property rights.

The courts have also made it clear that having possession of a dead body is not relevant in terms of inheritance. In *Anne Nyathira v Samuel Mungai Mucheru & 3 Others*,²⁶ the courts found that being in possession of a dead body is not an advantage in terms of inheritance. The Kenyan Court of Appeal observed as follows in this regard: ‘Parties were all in agreement, and the judge was emphatic that there is no property in a dead body and burying a deceased person does not give any party any priority or advantage as regards inheritance rights of a deceased estate’.²⁷

Nevertheless, recent High Court jurisprudence appears to suggest that there may be restricted property rights over dead bodies. Accordingly, the court in *Joan Akoth Ajuang & Another v. Michael Owuor Osido the Chief of Ukwala Location & 3 Others; Law Society of Keya & Another* observed as follows:²⁸ The right to possession of a dead human body for the purpose of burial is, under ordinary circumstances, in the spouse or other relatives of the deceased ... However, an unrestricted *property right* does not exist in a dead body. The matter of the disposition of the dead is so involved in the public interest, including the public’s health safety, and welfare, that it is subject to control by law instead of being subject entirely to the desires, whim, or caprice of individuals. (my emphasis)

²⁶ Civil Appeal No. 68 of 2015 *Anne Nyathira v Samuel Mungai Mucheru & 3 Others* [2016] eKLR.

²⁷ As above, paras 22-23.

²⁸ [2020]eKLR, para. 175.

If the above is anything to go by, Kenya therefore recognises a restricted form of property rights over dead bodies and this right is usually recognised in favour of the wife and close relatives.

2.3 Property rights in tissues and body parts

The Kenyan law appears to allow for the donation of tissues and body parts for various purposes. Under the *Human Tissues Act*,²⁹ it is possible to make a request for your body to be used for therapeutic purposes or for medical education or research. Section 2 thus states:

[i]f any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a *request* that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person *lawfully in possession* of his body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorize the removal from the body of any part or, as the case may be, the specified part, for use in accordance with the request. (my emphasis)

Furthermore, under the *Health Act* section 81(1)(a), one can now make a will to ‘*donate* his or her body or any specified tissue thereof to be used after his or her death’. (my emphasis) Section 81(1)(b) requires that the person who makes a donation in this manner must nominate an institution or person contemplated under the Act. Section 81(2) provides that:

In the absence of a donation under subsection (1)(a) or of a contrary direction given by a person whilst alive and upon death the person’s body remains unclaimed under any other law, the spouse or spouses, elder child, parent, guardian, eldest brother or sister of that person, in the specific order mentioned, may, after that person’s death, donate the body or any specific tissue of that person to an institution or a person contemplated in this subsection.

²⁹ Cap 252.

The purpose of donation is stated under section 82 as follows: training of students in health sciences; health research; advancement of health sciences; therapeutic purposes, including the use of tissue in any living person; or the production of a therapeutic, diagnostic or prophylactic substance. Under section 83, '[a] donor may, prior to the transplantation of the relevant organ into the donee, revoke a donation in the same way in which it was made or, in the case of a donation by way of a will or other document, also by the intentional destruction of that will or document'.

Lastly, removing body parts is criminalised in Kenya. Section 13 of the *Anatomy Act*³⁰ makes it illegal to remove body parts from a dead body as follows:

Any person who-

- (a) Takes or removes from a dead body any part of the body before the body is received into an approved school of anatomy; or
- (b) Takes or removes from an approved school of anatomy, except for cremation or burial, any part of a dead body; or
- (c) Receives part of a dead body which has been taken or removed in contravention of this section,

Shall be guilty of an offence and liable to a fine not exceeding three thousand shillings or to imprisonment for a term not exceeding three months or to both such fine and such imprisonment.

Provided that this section shall not apply to a licensee who has been authorized in writing by the Director of Medical Services to take or remove, or to receive, a part of a dead body for educational, scientific or research purposes.

2.4 Donation of blood, tissues or gametes

Under Kenyan law, apart from organs harvested from a deceased person, the other thing a living human being can donate is blood, tissues or gametes. The Health Act under s 85(1) contemplates that Parliament would put in place an Act to create a body known as the Kenya National Blood Transfusion

³⁰ Cap 249.

Services. Under subsection (3) '[t]he Service shall be charged with the mandate of developing a comprehensive and coordinated national blood service based on voluntary *non remunerated* blood donations so as to guarantee availability of adequate and safe blood'. From this section, the use of the words 'voluntary non remunerated' exposes the general position of the law, which does not favour recognition of property rights in blood.

In Kenya, the law also bans the sale or purchase of body parts including tissues and gametes. Kenya's Health Act No. 21 of 2017 provides:³¹

No person shall remove tissue or gametes from a human being for transplantation in another human being or carry out the transplantation of such tissue or gametes except in a duly authorized health facility for that purpose.

Even though not expressly stated, one cannot sell a tissue or gamete. The Health Act further provides that '[a]ny person who contravenes the provisions of this section fails to comply herewith or who charges a fee for a human organ commits an offence'.³² It is clear therefore that such tissues and gametes should be donated freely and cannot be sold or purchased in Kenya. The penalty for contravening this section has been set to a fine not exceeding ten million shillings or to imprisonment for a period not exceeding ten years, or to both a fine and imprisonment.³³

The general position of the law in Kenya is supported by 'a broad consensus in international regulatory documents'.³⁴ In this regard, the *World Health*

³¹ See s 80(1).

³² See s 80(4)(a).

³³ See s 80(4)(b).

³⁴ Hurst SA 'To Ban or Not to Ban: The Ethics of Selling Body Parts' in Jean-Daniel Rainhorn and Samira El Boudamoussi (eds) *New Cannibal Markets: Globalization and Commodification of the Human Body* (Éditions de la Maison des sciences de l'homme 2017) <<http://books.openedition.org/editionsmsmh/10744>> accessed 26 May 2022.

*Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation*³⁵ guiding principle 5 provides as follows:³⁶

[c]ells, tissue and organs should only be donated freely, without any monetary payment or other rewards of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

From the above excerpt, one is allowed to make donations but should not receive payment in monetary terms or be rewarded with something having monetary value. However, reimbursement for ‘reasonable and verifiable’ expenses is permissible.

The commentary on Guiding Principle 5 is interesting because it reveals the philosophy behind the prohibition on sale or purchase of human organs. The commentary states:

[p]ayment for cells, tissues and organs is likely to take unfair advantage of the poorest and most vulnerable groups, undermine altruistic donation, and leads to profiteering and human trafficking. Such payment conveys the idea that some person *lack dignity*, that they are mere objects to be used by others. (emphasis mine)

³⁵ WHO/HTP/EHT/CPR/2010.01,

<https://apps.who.int/iris/bitstream/handle/10665/341814/WHO-HTP-EHT-CPR-2010.01-eng.pdf?sequence=1>. The Guiding Principle 5 is meant to ‘provide an orderly, ethical and acceptable framework for acquisition and transplantation of human cells, tissues and organs for therapeutic purposes’.

³⁶ Catherine M. Valerio Barrad ‘Genetic Information and Property Theory’ (1992-1993) 87 *Nw U L Rev* 1037, 1053.

From the commentary, there are disadvantages associated with the sale of human organs, including the fact that it ‘conveys the idea that some person lacks dignity’.

3. Property rights models

The models discussed here are categorised into non-market and market models for ease of reference. Generally speaking, the non-market models tend to emphasise collective property rights while the market models emphasise individual property rights as theorised in Western countries.

3.1 Non market models

Under this category, there are several models, including free access, common heritage, state ownership, and open access.

3.1.1 Common heritage

In the 1960s, the concept of common heritage became popular internationally. Accordingly, this concept has been used by developing states in efforts to shape international law relating to common areas (there are four ‘global commons’ managed by the international community: Antarctica; the high seas and seabed beyond areas of national jurisdiction; the atmosphere; and outer space). While developed in relation to common areas, the common heritage of mankind approach can be adapted to common resources.³⁷

In relation to genetic resources (which arguably includes human biological materials), the common heritage model would mean that: resources would not be subject to appropriation and would be managed in line with universal interests; any economic (or other) benefits arising from their exploitation would be shared internationally; their use would be limited to exclusively peaceful purposes; and scientific research using genetic resources would be conducted for the benefit of all.³⁸

³⁷ Rhodes Catherine ‘Potential International Approaches to Ownership/Control of Human Genetic Resources’ (2016) 24 *Health Care Analysis* 260 <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987399/>> accessed 19 July 2022.

³⁸ *Ibid.*

Common heritage as a concept emanated from the doctrine of *res communis* which means that resources that are obtained from common heritage territories should not be possessed, monopolised or owned by individuals, communities or states.³⁹ Rather, the use of such common resources should be subjected to the interests and rights of all mankind. This concept deals with common resources such as celestial bodies, the sea and subsoil obtained from common heritage. There is nothing precluding the application of the same concept to human biological material.

Equitable sharing of resources entails equal distribution of resources and global policies that cultivate a homogenous state of affairs in relation to common heritage resources. Developing countries have envisaged this benefit sharing as a means of providing solutions to the disparities between developing and developed states. Hence, it has been advocated that the benefit sharing of the common heritage of humankind should be extended beyond the sharing of tangible resources to other possible goods.⁴⁰ In relation to genetic resources, therefore, this means that such resources would be managed in accordance with universal interests and they would not be subject to appropriation. Additionally, any scientific research using genetic materials would be conducted for the benefit of all and would be shared internationally.⁴¹

The ethical appeal of benefit sharing in the common heritage of humankind is targeted at achieving equality among all states with regard to resource distribution. The founder of the concept of the common heritage of humankind, Arvid Pardo,⁴² clearly indicates this equality in a statement that: the common heritage of humankind challenges the structural differences between rich and poor countries and revolutionizes international relations towards equality among countries.⁴³

³⁹ Dauda B., Dierickx K. Benefit sharing: An exploration on the contextual discourse of a changing concept (2013) 14 *BMC Med Ethics* 36.
< <https://doi.org/10.1186/1472-6939-14-36> > accessed on 21 July 2022.

⁴⁰ Basler K *The concept of the common heritage of mankind in International Law*. The Hague: Martinus Nijhoff Publishers; 1998:96–97.

⁴¹ *Ibid*

⁴² Holmila E Common heritage of mankind in the Law of the Sea (2005) 1 *Acta Societatis Martensis* 187-205.

⁴³ *Ibid*.

3.1.2 Free access

In this model, '[w]here a free access approach is applied to genetic resources, anyone is free to access them, to use them as they choose, and to subsequently claim proprietary rights over them (excluding others from access/use if they choose to do so).'⁴⁴ This model was generally preferred internationally before it was replaced by the state sovereignty model in the early 1990s.⁴⁵ This approach is a default position in the event where no rules have been established and usually it still operates for certain genetic resources located in marine genetic resources in seabeds or high seas beyond state jurisdiction. The wealth of material and the ease with which genetic resources can be found, probed, and analysed is astounding. Equally remarkable is that most of these genetic resources are available to everyone for free.⁴⁶

However, free access to these genetic resources is a boon to science, but it has some risks. For example, among the genome sequences freely available on the internet are those for more than 100 pathogens, including for the organisms that cause anthrax, botulism, smallpox, Ebola hemorrhagic fever, and plague. It is possible that a government, a terrorist organisation, or even an individual could use data from these repositories to create novel pathogens that could be used as weapons.⁴⁷ Moreover, free access is controversial since it tends to favour those with expertise and particular knowledge, and financial and technological means to access and exploit resources. As a result, the benefit of genetic research is concentrated in only a few individuals, states and groups – regardless of where the genetic resources are sourced.⁴⁸

⁴⁴ Rhodes Catherine 'Potential International Approaches to Ownership/Control of Human Genetic Resources' (2016) 24 *Health Care Analysis* 260 <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987399/>> accessed 19 July 2022.

⁴⁵ *Ibid.*

⁴⁶ The Lancet. Keep genome data freely accessible (2004) *Lancet* 1;364(9440):1099-100. <[https://doi:10.1016/S0140-6736\(04\)17112-2](https://doi:10.1016/S0140-6736(04)17112-2). PMID:15451200; PMCID: PMC7134670> accessed 21 July 2022.

⁴⁷ *Ibid.*

⁴⁸ National Research Council (US) Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation; Merrill SA, Mazza AM, editors.

It is worth noting that free access to all human biological material generated by genetic research projects should and even must be made freely available.⁴⁹ This will ensure that the redistribution of genetic data remains free of royalties, and that research and development will be encouraged to maximise its benefit to society.

3.1.3 State ownership

According to Jefferson, this approach is popular in countries with large government-funded biobanks such as is in Europe and a number of other industrialised countries/regions including Austria, Estonia, France, United Kingdom, Germany, Iceland, Latvia, Norway, Singapore, Sweden, and Quebec (Canada).⁵⁰ In this model, the ownership of biobanks may even be in the hands of the private sector but the right to the human biological material is publicly owned by the state and in this regard this model differs from the Moore Model.⁵¹ In China, the newly released draft Detailed Rules for the Implementation of the Regulation on the Management of Human Genetic Resources appears to have integrated this approach in the management of its human genetic resources.⁵² According to Rhodes, 'State sovereign rights have been applied to genetic resources by the international community since the early 1990s, and are now the dominant international approach to genetic resources ownership/control.'⁵³

Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health. Washington (DC): National Academies Press (US); 2006. 1, Introduction <<https://www.ncbi.nlm.nih.gov/books/NBK19858/>> accessed 21 July 2022.

⁴⁹ Ibid.

⁵⁰ David J. Jefferson 'Biosociality, Reimagined: A Global Distributive Justice Framework for Ownership of Human Genetic Material' (2015) 14 *Chi-Kent J Intell Prop* 357, 366.

⁵¹ Ibid.

⁵² 'Human genetic resources in China: New Draft Regulation' *China Briefing* 4 May 2022, <https://www.china-briefing.com/news/human-genetic-resources-in-china-regulation-new-draft-rules/>. The first regulations on human genetic resources in China were the *Interim Measures for the Management of Human Genetic Resources* in 1998, followed by the draft *Regulations on the Management of Human Genetic Resources* in 2005.

⁵³ Rhodes C 'Potential International Approaches to Ownership/Control of Human Genetic Resources' (2016) 24 *Health Care Analysis* 260

While not yet explicitly extended to human genetic resources, sovereign rights were extended to viral genetic resources in 2011 on quite spurious grounds,⁵⁴ and so while their extension to human genetic resources seems inappropriate, it is not implausible. Statements of state sovereignty over genetic resources in international law generally use words like states have the authority to determine access to genetic resources which rests with the national governments and is subject to national legislation.

The use of a sovereign rights approach does not necessarily preclude subsequent claims of intellectual property rights being made by the user – it will depend on the terms agreed between the user and provider state. Notably, access and benefit-sharing arrangements based on state sovereignty are generally made through use of standard material transfer agreements which form a contract between the provider and the user.⁵⁵ In the context of genetic resources, states hold a sovereign right over their genetic resources and can grant access to those that need to use such resources under a condition of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) of appropriate benefit sharing.⁵⁶

Recommendations for the content of these agreements are generally set out in the relevant treaty, and in model contracts which are usually provided by the relevant international organisation. Often, within provisions on access and benefit-sharing, there is provision on incorporation of respect for the rights of individuals, local and indigenous communities over genetic resources and associated knowledge, which they traditionally hold or have played a key role in developing. States are expected, for example, to ensure such groups are involved in consent processes and benefit-sharing negotiations.⁵⁷

<<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987399/>> accessed 19 July 2022.

⁵⁴ Rhodes C. Sovereign wrongs: Ethics in the governance of pathogenic genetic resources (2013) 3(103) *Ethics in Biology, Engineering and Medicine, An International Journal* 97-114.

⁵⁵ *Ibid.*

⁵⁶ Rhodes, n. 53.

⁵⁷ *Ibid.*

However, the duty to preserve and sustain resources does not imply that resources are a common heritage for all; rather, resources are the property of the states.⁵⁸ Additionally, by virtue that distributive justice entails how individuals and communities distribute benefits and burdens in a just or moral manner, most States give the reason that there is need to guarantee access to human biological materials for the sole purpose of biotechnology development in their countries. There is a widespread recognition that biotechnology development creates technological presuppositions of a new possibility of justice: the just distribution of both social (for example, income, wealth) and natural (for example, rationality, intelligence) common goods.⁵⁹ Through distributive justice, all individuals will have access to the outcomes of medicine development as a result of human genomics research. For this reason, the government is mandated to provide biotechnology development.

3.1.4 Open access

Open access models may retain the basic *Moore* framework; however, they also emphasise the importance of, at least, allowing for open, unrestricted access to data generated by research that has used donated DNA.⁶⁰ The broad sharing of data generated by genomic research through open access has maximised the utility of the data and public benefit through the creation of a culture of openness in genomic research.⁶¹ Initially, protecting participants' privacy when human genomic material was shared in open access, solely rested on 'de-identification' of the data by stripping them of all recognisable annotation before sharing.⁶² Currently, however, data sharing policies

⁵⁸ Ibid.

⁵⁹ Rawls J. A *Theory of Justice*. Oxford: Oxford University Press; 1971. <https://www.taylorfrancis.com/chapters/edit/10.4324/9780203495667-33/theory-justice-john-rawls>> accessed 19 July 2022.

⁶⁰ Rhodes C 'Potential International Approaches to Ownership/Control of Human Genetic Resources' (2016) 24 *Health Care Analysis* 260 <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987399/>> accessed 19 July 2022.

⁶¹ Pereira S, Gibbs RA, McGuire AL. Open access data sharing in genomic research (2014) *Genes (Basel)* 5(3):739-47. doi: 10.3390/genes5030739. PMID: 25178093; PMCID: PMC4198928.

⁶² Ibid.

require researchers to obtain approvals from their institutions before sharing genomic data through open access. Additionally, guidance is provided by institutions to ensure compliance and the adequacy of informed consent documents.

Understandably, each successive policy decision to further restrict access to genomic data has received some pushback, with critics arguing that each was an overreaction and would unnecessarily impede science.⁶³ Nonetheless, limiting access to increasing amounts of data continues to be the primary policy response to mounting privacy concerns. Arguments against restricted access and for more open data-sharing policies must balance the social and scientific benefits of unrestricted access to and the use of data, with adequate protection of the rights and interests of individuals who contribute biological specimens and information to research. The almost exclusive focus on restricting access to genomic data as a matter of policy, however, impedes research and fails to respect the autonomy of those who choose to share their information openly. It has been observed that data in controlled access databases are used less frequently than data in open access databases, and as Rodriguez et al⁶⁴ remind us, researchers and other custodians have an ethical responsibility not only to minimise the risk of harm to participants, but also to maximise the utility of generated data.

Regardless of mechanism, if genomic data are made publicly available, then the individuals from whom those data originate ought to be protected against the misuse of that information.⁶⁵ One way of providing some protection for these participants could be the use of ‘click-through’ data use agreements. In this model, the person accessing the data would have to read and agree to a list of conditions of use of the data, including agreeing to not attempt to identify the individuals from whom the data were sourced. However, while this may require those accessing the data to recognise that attempting identification would be a violation of the use of the data, such click-through

⁶³ Ibid.

⁶⁴ Rodriguez L.L., Brooks, L.D., Greenberg J.H., Green, E.D. The complexities of genomic identifiability (2013) 339 *Science* 275–276.

⁶⁵ Ibid.

data-use agreements are not enforceable and, as such, may not provide adequate protection.⁶⁶

3.2 Free market models

Free market models can be discussed under two subcategories: market inalienability and hybrid market models. The two are discussed separately below.

3.2.1 Market inalienability

In this section, I discuss inalienability rules, personhood property and market inalienability concepts.

3.2.1.1 Inalienability rules

Generally, the proponents of inalienability rules and market inalienability try to provide clarity on why human body parts and/or human biological material may be excluded from being traded freely in markets like other commodities. The idea of inalienability rules was first introduced by Calabresi and Melamed who offered a framework of property rules, liability rules, and inalienability rules.⁶⁷ Calabresi and Melamed contended that the state had the responsibility to decide whom to entitle, how to protect the entitlement, and whether selling or trading the entitlement is allowed.⁶⁸ In doing so, property rules, liability rules and inalienability rules may be applicable.⁶⁹ First, property rules, give rise to the least amount of state intervention since ‘someone who wishes to remove the entitlement from its holder must *buy* it from him in a *voluntary transaction* in which the value of the entitlement is agreed upon by the *seller*’ (my emphasis). Property rules

⁶⁶ Gilbert N. Researchers criticize genetic data restrictions <<http://www.nature.com/news/2008/080904/full/news.2008.1083.html>> accessed 21 July 2022.

⁶⁷ Guido Calabresi & A. Douglas Melamed ‘Property Rules, Liability Rules, and Inalienability: One View of the Cathedral’ (1972) 85 Harv L Rev 1089.

⁶⁸ *Ibid*, 1049.

⁶⁹ *Ibid*, 1093. The authors for example note that in some goods these entitlements may be mixed: ‘Taney’s house may be protected by a property rule in situations where Marshall wishes to purchase it, by a liability rule where the government decides to take it by eminent domain, and by a rule of inalienability in situations where Taney is drunk or incompetent.’

therefore sanction the parties themselves to enter into voluntary transaction and to agree on the value of an entitlement without the interference of third parties, as is the case in commodities capable of being freely traded in markets.

Secondly, liability rules require some level of state intervention in that ‘[w]henever someone may destroy the initial entitlement if he is willing to pay an objectively determined value for it ... This value may be what it is thought the original owner of the entitlement would have sold it for.’ Therefore, under liability rules, ‘not only are entitlements protected, but their transfer or destruction is allowed on the basis of a value determined by some organ of the state rather than by the parties themselves.’ In liability rules, free trade is not sanctioned because the value of an entitlement is not decided between the parties themselves – but by a third party.

Lastly, inalienability rules require the greatest intervention by the state in that ‘[a]n entitlement is inalienable to the extent that its transfer is not permitted between a willing buyer and a willing seller’.⁷⁰ Under inalienability rules, ‘[t]he state intervenes not only to determine who is initially entitled and to determine the compensation that must be paid if the entitlement is taken or destroyed, but also to forbid its sale under some or all circumstances.’⁷¹ Unlike the first two rules, it appears that inalienability rules are more intrusive in that the parties’ freedom is strictly curtailed. To sum up on the rules, Calabresi and Melamed state:⁷²

Whenever society chooses an initial entitlement it must also determine whether to protect the entitlement by property rules, by liability rules, or by rules of inalienability. In our framework, much of what is generally called private property can be viewed as an entitlement which is protected by a property rule. No one can take the entitlement to private property from the holder unless the holder sells it willingly and at the price at which he subjectively values the property. Yet a nuisance with sufficient public utility to avoid injunction has, in effect, the right to take property with

⁷⁰ Ibid, 1092.

⁷¹ Ibid, 1092-1093.

⁷² Ibid, 1105-1106.

compensation. In such a circumstance the entitlement to the property is protected only by what we call a liability rule: an external, objective standard of value is used to facilitate the transfer of the entitlement from the holder to the nuisance. Finally, in some instances we will not allow the sale of the property at all, that is, we will occasionally make the entitlement inalienable.

It appears from the above that inalienability rules may prevent transactions in certain things in that no subjective or objective standard of value may be set for its transfer. Accordingly, inalienability rules often arise as a result of certain external costs, which may ‘not lend themselves to collective measurement which is acceptable and nonarbitrary’.⁷³

3.2.1.2 Property and personhood

Calabresi and Melamed’s work influenced many other property rights scholars at various levels. In relation to inalienability rules, Radin relied on this framework to develop a market inalienability framework. Before delving into this concept of market inalienability, Radin’s work on property and personhood appears to have set the stage for its development. Accordingly, the author contended that ‘to achieve proper self-development – to be a person – an individual needs some control over resources in the external environment’ and that ‘the necessary assurances of control take the form of property rights’.⁷⁴ The author categorised property as personal and fungible – the former allows a thing to be bound up with a person in some constitutive sense, and the latter allows property to be held purely instrumentally.⁷⁵ Since

⁷³ Ibid, 1111-1112. The example provided by the authors illustrates the point made regarding moralism as an external cost: ‘If Taney is allowed to sell himself into slavery, or to take undue risks of becoming penniless, or to sell a kidney, Marshall may be harmed, simply because Marshall is a sensitive man who is made unhappy by seeing slaves, paupers, or persons who die because they have sold a kidney. Again Marshall could pay Taney not to sell his freedom to Chase the slave owner; but again, because Marshall is not one but many individuals, freeloader and information costs make such transactions practically impossible. Again, it might seem that the state could intervene by objectively valuing the external cost to Marshall and requiring Chase to pay that cost. But since the external cost to Marshall does not lend itself to an acceptable objective measurement, such liability rules are not appropriate.’

⁷⁴ Margaret Jane Radin 'Property and Personhood' (1982) 34 *Stan L Rev* 957.

⁷⁵ Ibid, 960.

personal property is important – the author argues that broad liberty with respect to control should be afforded.⁷⁶ In applying the idea of personal property, the author noted that ‘on the embodiment theory of personhood, the body is quintessentially personal property because it is literally constitutive of one’s personhood’.⁷⁷ She however noted that the body may present some interesting paradoxes because some body parts can be fungible if they are removed from the body or separated. She posits:

In some cases, bodily parts can become fungible commodities, just as other personal property can become fungible with a change in its relationship with the owner: Blood can be withdrawn and used in a transfusion; hair can be cut off and used by a wigmaker; organs can be transplanted. On the other hand, bodily parts may be too "personal" to be property at all. We have an intuition that property necessarily refers to something in the outside world, separate from oneself. Though the general idea of property for personhood means that the boundary between person and thing cannot be a bright line, still the idea of property seems to require some perceptible boundary, at least insofar as property requires the notion of thing, and the notion of thing requires separation from self. This intuition makes it seem appropriate to call parts of the body property only after they have been removed from the system.

According to the above quotation, if a body part is removed from the body or is separated from its owner it may lose personhood status and become fungible as opposed to personal property because it acquires the status of a ‘thing’. This idea is not consistent with Radin’s initial position that one can have personal property over a thing, like a house or a ring. I do not believe the criteria should be removal or separation from a body, but perhaps the idea of something being bound with a person in some constitutive sense is more plausible. Notwithstanding the above concern, the idea of personal and fungible property is important, because it ‘depends partly on the subjective nature of the relationships between person and thing’.⁷⁸ This then

⁷⁶ Ibid.

⁷⁷ Ibid, 966.

⁷⁸ Ibid, 966. According to Radin, ‘[m]any relationships between persons and things will fall somewhere in the middle of this continuum. Perhaps the entrepreneur factory owner has ownership of a particular factory and its machines bound up with her being to some degree.’

presupposes an obligation on the state to apply inalienability rules to such entitlements. One such obligation is market inalienability, which is also a subject of Radin's work.

3.2.1.3 *Market inalienability*

Radin's work on market inalienability is relevant when one considers property rights and human biological material. Even though the discussion appears to focus on human body parts, the same can be applied to human biological material. Radin developed the 'non-salability' idea that was introduced by Calabresi and Melamed in their work discussed earlier in relation to state intervention under inalienability rules.⁷⁹ Accordingly, Radin introduces the idea of market inalienability as a species of inalienability rules. She posits: '[s]omething that is market inalienable is not to be sold, which in our economic system means it is not to be traded in the market'.⁸⁰

She in particular gives an example of blood and babies and notes that controversy persists about whether they can be bought and sold.⁸¹ According to Radin, market-inalienability precludes sales but not gifts and to this extent it places some things outside the market place (for selling) but not outside the realm of social intercourse (gifting).⁸² Therefore, '[u]nlike the inalienabilities attaching to welfare entitlements or political duties, market-inalienability does not render something inseparable from the person, but rather specifies that market trading may not be used as a social mechanism of separation.'⁸³ What the author seems to be alluding to is that there are some things that may not be traded in the market whatsoever, either through buying or selling, but they can be given freely through donations using other avenues. As also alluded to by Thorne, in the United States trade in elephant tusks and endangered species is banned altogether but the market 'in children, sexual favors, and human organs are characterized by a desire that supply flourish, but strictly on a donative, non-commercial basis'.⁸⁴ This

⁷⁹ Margaret Jane Radin 'Market-Inalienability' (1987) 100 Harv L Rev 1849.

⁸⁰ *Ibid*, 1850.

⁸¹ *Ibid*.

⁸² *Ibid*, 1853.

⁸³ *Ibid*, 1854.

⁸⁴ Emanuel D. Thorne 'When Private Parts Are Made Public Goods: The Economics of Market-Inalienability' (1998) 15 Yale J on Reg 150.

understanding is important, for instance when one considers altruistic donations. In this regard, Radin argues that '[m]arket-inalienability posits a nonmarket realm that appropriately coexists with a market realm, and this implicitly grants some legitimacy to market transactions, contrary to the noncommodifier's premise'.⁸⁵ Thorne also notes that market-inalienable goods are not capable of being sold in markets but they can donate such goods freely to any recipient of their choice.⁸⁶

Perhaps Thorne's work, apart from defending Radin's concept of market inalienability, is more important in terms of the idea of exhortation, which he observes is:

the non-price efforts used to secure market-inalienable goods and services. Exhortation includes efforts to inform and persuade all participants in the donative system who cannot be paid for what they supply. In the case of organs, exhortation includes efforts by procurement organizations to get next-of-kin to donate organs, and also efforts directed at physicians and hospital staff to identify, without remuneration, potential donors. In fact, exhortation is often used to secure what can be neither bought nor commanded, such as loyalty, friendship, devotion, and even love.⁸⁷

Thorne further notes that the motivation of donors in terms of responding to exhortation may include 'a sense of duty, responsibility, love, and other psychological rewards'.⁸⁸ Accordingly, Thorne argues that when one engages in exhortation, you are supplying information as a procurer, and the number of organs available in a situation where there is a market ban will depend on the level of effort expended on exhortation.⁸⁹ Thorne further notes that one can enlarge the supply of market-inalienable goods because fundamentally they are 'like common property, such that exhorting

⁸⁵ Margaret Jane Radin 'Market-Inalienability' (1987) 100 Harv L Rev 1875.

⁸⁶ Emanuel D. Thorne 'When Private Parts Are Made Public Goods: The Economics of Market-Inalienability' (1998) 15 Yale J on Reg 164.

⁸⁷ Emanuel D. Thorne 'When Private Parts Are Made Public Goods: The Economics of Market-Inalienability' (1998) 15 Yale J on Reg 157.

⁸⁸ *Ibid.*

⁸⁹ *Ibid.*, 159.

donations of market-inalienable goods is analogous to fishing in common property waters'.⁹⁰ Thorne posits as follows:

Because a market-inalienable good (and its economic value) will belong not to the owner but to the party to whom the good is donated, the good appears as common property from the perspective of those who want it. Someone who wants the market-inalienable good will engage in activities to obtain it that are remarkably similar to the activities of someone "fishing" in common property waters. A fisherman will invest his labor and capital to catch a fish by dangling a worm before it. If the fisherman is successful, the fish itself is free to him even though the fishing effort may have been costly.⁹¹

The point Thorne was trying to make here is that because something is market-inalienable does not mean that its supply will be affected. In fact, Thorne argues that the supply will depend on the level of exhortation employed which may be costly – but the reward is getting the goods for 'free'.⁹²

Suffice to say, the United States and many other countries have historically applied this approach in their donation model for research participation, as confirmed by the *Moore* decision.⁹³ According to Jefferson, 'the Moore model is predicated on the furtherance of economic rationale – such as incentivization of innovation – rather than on public or collective rights.'⁹⁴

3.2.2 Hybrid market models

Several models propose a hybrid approach. These models appear to negotiate a middle ground between donative models and a free market for human biological material. Three models developed by Gitter, Harrison and Quigley stand out:

⁹⁰ Ibid, 163.

⁹¹ Ibid, 164.

⁹² Ibid.

⁹³ David J. Jefferson 'Biosociality, Reimagined: A Global Distributive Justice Framework for Ownership of Human Genetic Material' (2015) 14 Chi-Kent J Intell Prop 357, 365.

⁹⁴ Ibid, 366.

3.2.2.1 *Gitter's model*

Richard Posner is the key proponent of universal commodification and in his work has argued for the commodification of everything – including babies and sex. Apart from the authors who support market inalienability, some authors such as Gitter advocate trading of human biological material in the market. According to her, ‘proponents of the market-inalienability model overestimate the negative impact that recognition of the property rights of human research participants would have on biomedical research. In addition, they fail to consider fully that research participants contribute considerable value to the research process, and therefore merit compensation.’⁹⁵ She also believes that those who are opposed to recognising property interest in human tissues still wrongly believe that they are not yet commodified, since currently biotech stakeholders and researchers are profiting from the process.⁹⁶ Gitter also notes that price tags are not the only measure of the worth of human biological material.⁹⁷ She argues that setting a price might actually enhance the dignity of the human tissue in some cases.⁹⁸ In this regard, Gitter posits: ‘[I]f property is viewed more accurately, in terms of control over one's body, these criticisms [regarding commodification of the human body] may be inapt. If property confers exclusive control to people over their own bodies, then their dignity is enhanced, not diminished.’⁹⁹ Consequently, her proposal to Congress is:

Congress implement a hybrid property rights/liability model that: (1) recognizes that individuals possess 'property rights in their tissue and therefore have the right to exchange it for valuable consideration, or to waive such rights if they prefer to make a gratuitous donation; 371 and (2) permits individual research participants to maintain an action for conversion of their tissue in the event that: (a) they were not informed that researchers were using their tissue for commercial purposes; or (b) they did enter into an

⁹⁵ Donna M. 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 294.

⁹⁶ *Ibid*, 300.

⁹⁷ *Ibid*, 302.

⁹⁸ *Ibid*, 303.

⁹⁹ *Ibid*.

agreement regarding the use of the tissue that is voidable under the doctrines of fraud, duress, undue influence, or mutual mistake.¹⁰⁰

Gitter appears to favour both property rules and liability rules in different contexts. She provides a guidance to Congress as follows:

In light of the fact that a market in human tissue already exists, this Article advocates congressional enactment of a hybrid approach to property rights in human tissue. The law should entitle plaintiffs to invoke a property rule where they negotiated in advance for rights in their tissue and, when necessary, to invoke a liability rule in the form of an action for conversion when researchers withheld from them vital information that would have facilitated their ability to bargain for such rights.¹⁰¹

3.2.2.2 Harrison's model

There are also authors who reject both market inalienability and property rights for human biological material. One such author is Harrison, who notes that '[t]he creation of a market in human tissue, which appears to follow inevitably from a private property model, would entail its own formidable ethical and practical problems. Neither the Moore-based donation paradigm nor the market-based alternative is sufficiently satisfactory to quiet professional and social concerns.'¹⁰² According to Harrison, '[i]n particular, it is time to consider alternatives that represent a middle course between regimes of donation and private property. One such alternative would take a hybrid approach: maintain a general rule of donation for research tissue at the time it is acquired and provide an objective, non-market mechanism for compensation after research use for unusual cases in which samples prove to have significant commercial utility.'¹⁰³ Interestingly, Harrison argues that payment for tissue samples for research can be justified because '[i]n our present society, however, people can freely exploit their natural beauty, talent or scientific genius, and can even be paid for material contributions to

¹⁰⁰ Ibid, 339.

¹⁰¹ Ibid, 345.

¹⁰² Charlotte H. Harrison 'Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue' (2002) 28 *Am JL & Med* 78.

¹⁰³ Ibid.

a blood or sperm bank for purposes other than research. Unless current conditions change, an argument based on equality cannot justify denying payment to contributors of tissue samples for research.¹⁰⁴ She further notes that the current system of donation of tissues and commercialisation of use relies on public ignorance and as such ‘the system has come under criticism for failing to respect the dignity and autonomy of contributors’.¹⁰⁵ The argument of price as an enhancer of dignity was also alluded to by Gitter, as discussed above. Harrison therefore suggests a balanced solution:

A more balanced solution would seek efficiencies through appropriately timed non-market mechanisms for assessing value and transferring compensation to contributors of human tissue. Both contributor and corporate interests could be served if values were determined according to predictable standards, after the commercial usefulness of a given tissue sample had been demonstrated in research and development – and only for those relatively few samples demonstrating a certain level of utility. Standards for evaluating utility could be set through the political process and interpreted in particular circumstances by an administrative agency or tribunal ... Researchers' rights to use a material would be settled once the contributor gave informed consent. Companies' rights of use, however, would be subject to an obligation to pay a reasonable share of profits to contributors of samples that met the requisite criteria.¹⁰⁶

In relation to the worth of an individual, which is key to human dignity, Harrison notes that:

Replacing the direct market approach with a liability rule, which involves an arrangement for compensation to be determined at a later date and by a neutral third party, could address each of these concerns. If the possibility of receiving compensation were delayed and placed beyond the control of patients and their doctors or researchers, concerns about both professional relationships and individual injury or unfairness could be reduced substantially. Professionals and their patients or research participants would

¹⁰⁴ Ibid, 82.

¹⁰⁵ Ibid, 84.

¹⁰⁶ Ibid, 89.

not have to argue over the "worth" of the body part. Further, the highly contingent nature of the financial reward should make it less powerful an incentive to have a sample removed under circumstances that might not be in a contributor's medical or privacy interest.¹⁰⁷

3.2.2.3 Quigley's model

The proposal propounded by Harrison is not very different from the one made by Quigley. Quigley for instance notes that donation involves exercising the rights of 'use' and 'control', which are characteristics of property.¹⁰⁸ Accordingly, Quigley states that there is need to separate the 'power of control, which may include the power to transfer' from 'the right to derive income from such transfers'. Harrison's model appeared to have done that, in that it allowed for only conditional benefits from one's biological material at a later stage – once its use has been determined. Thus, Quigley defines a different characterisation of property which focuses on 'use' and 'control' as its defining features, and notes the following:

[w]hat is at issue when we engage in property discourse are these rights; that is, people's interests in using and controlling the uses and abuses of particular objects or resources; the full-blooded owner is "entirely free [subject to property independent prohibitions] to do what he will with his own, whether by use, abuse, or transfer".¹⁰⁹

For Quigley, donations and gifting also qualify under this characterisation because:

the power to alienate one's property, that is, divest oneself in toto of all of one's rights with respect to a particular object, represents the ultimate disposition of those rights. Arguably this necessarily encompasses gifting, and as such donation, as an exercise of a person's power to transfer. Yet the

¹⁰⁷ Ibid, 92.

¹⁰⁸ Muireann Quigley 'Propertisation and Commercialisation: On Controlling the Uses of Human Biomaterials' (2014) 77 Mod L Rev 677.

¹⁰⁹ Ibid, 692.

alienability of one's property (rights) by transfer need not include market alienability.¹¹⁰

Accordingly, '[s]eparating the powers of control from the right to income allows us to admit property, without necessarily having to permit biomaterials, to be traded on the market (tout court)'.¹¹¹ In conclusion, Quigley observes that full ownership does not analytically demand the right to contract to the transfer of property in exchange for income or some other value in kind. If we are to oppose commercial activities relating to human biomaterials, it ought not to be on the basis that they are not the appropriate objects of property. We already engage in activities, such as tissue donation, which arguably rely on them being such.¹¹²

4. Why collective property rights in terms of state ownership of human biological material are desirable for Kenya

Obviously, Kenya like many other countries, does not apply market models to human body parts and it is doubtful that they would be amenable to apply the same to human biological material. In this regard, the realistic model that may be applicable in Kenya must first be that which does not sanction free markets in human biological material. In this regard, several options are available – including open access and human heritage. However, I believe the most attractive model is the state ownership model as developed by Jefferson.¹¹³ In Africa, the key genomic research need is to advance biotech innovation. It is therefore important that any human biological material that is available should be made accessible to the private sector – to allow for ease of access. Restricting ownership to either an individual research participant or a private company may not be desirable since the material will become inaccessible. However, if the state retains ownership, the state can ensure that all stakeholders play a role in producing appropriate innovations, which can then be owned by those institutions, and then an appropriate framework for benefit sharing can be developed. Furthermore, I believe that

¹¹⁰ Ibid, 693.

¹¹¹ Ibid, 700.

¹¹² Ibid, 702.

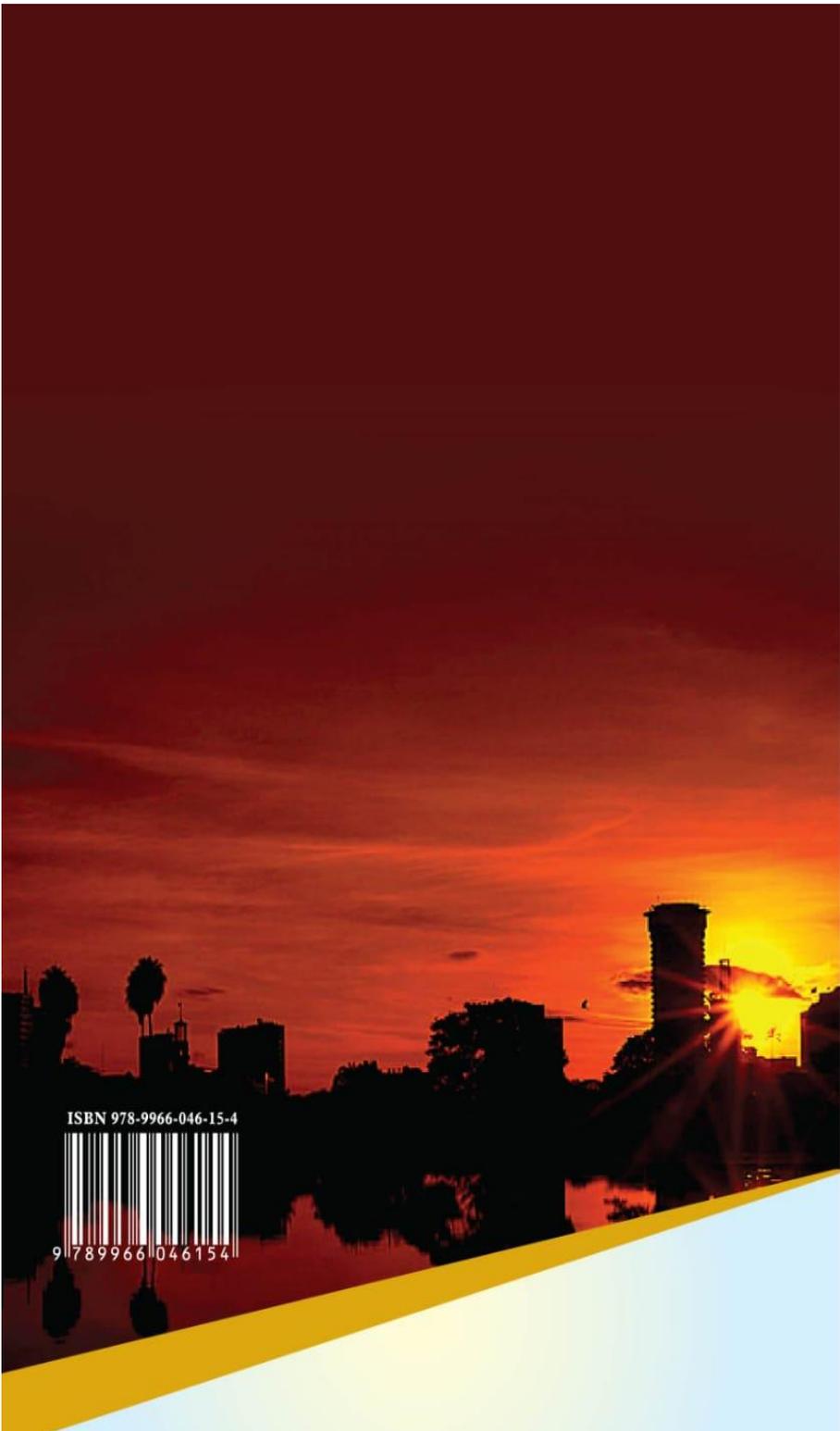
¹¹³ David J. Jefferson 'Biosociality, Reimagined: A Global Distributive Justice Framework for Ownership of Human Genetic Material' (2015) 14 Chi-Kent J Intell Prop 357.

given the need to respect the autonomy of the individual and the need to ensure that human biological material is not abused by both the state and the private sector, appropriate informed consent criteria should be developed and strictly enforced. In this manner, informed consent coupled with state ownership of human biological material should be able to facilitate genomic research in Kenya for the benefit of the country.

5. Conclusion

The issue of property rights over human biological material is indeed complex. In some Western jurisdictions, the approach has been to understand property rights from an individual point of view. In this regard, the market rhetoric has been emphasised in all the models discussed. However, there are also property rights models that are not focused on the market as a key node. In this paradigm, the emphasis has been on the common good or collective property rights. The role of the individual has been downplayed and there has been more emphasis on property rights. Such models, including open access, human heritage and state ownership are important – particularly in African states including Kenya. The state as an institution can assume property rights over human biological material collected in its jurisdiction and can ensure that the same is properly distributed to the private sector for research and innovation. The private sector may then claim ownership of data generated from such material and patent any innovations they come up with. The same data can then be made accessible to others since it is owned by the state and anyone can be licensed to use it – subject to satisfying all the applicable regulatory requirements. This is the best option for Kenya. It is best because it adds an additional layer of rights or property rights beyond the privacy and informed consent requirements. As Kapp notes, the current source of human biological material rights ‘are concentrated in the initial informed consent process and the applicable privacy protections’.¹¹⁴

¹¹⁴ Marshall B. Kapp 'A Legal Approach to the Use of Human Biological Materials for Research Purposes' (2013) 10 *Rutgers J L & Pub Pol'y* 1, 24.



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