

Bond University
Research Repository



Beyond the corporeal
Extending propertisation of body parts to derivative information

Bonython, Wendy; Arnold, Bruce Baer

Published in:
Journal of Law and Medicine

Published: 01/01/2016

Document Version:
Early version, also known as pre-print

[Link to publication in Bond University research repository.](#)

Recommended citation(APA):
Bonython, W., & Arnold, B. B. (2016). Beyond the corporeal: Extending propertisation of body parts to derivative information. *Journal of Law and Medicine*, 23(3), 688-709.

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

For more information, or if you believe that this document breaches copyright, please contact the Bond University research repository coordinator.

Author details:

Assistant Professor Wendy Bonython

PhD, JD, BSc (Hons), GCTE, GDLP

Law School, University of Canberra

Room 11A16, University of Canberra ACT 2601

Wendy.bonython@canberra.edu.au

02 6201 5770

Assistant Professor Bruce Baer Arnold

JD, GCTE

Law School, University of Canberra

Room 11A15, University of Canberra ACT 2601

Bruce.arnold@canberra.edu.au

02 6201 2710

Beyond the Corporeal: extending propertisation of body parts to derivative information

ABSTRACT

Jurisprudential consideration of property in the human body has typically conceptualised it as tangible, of finite lifespan, with limited end uses. This article offers an alternative conceptualisation: the body as information – intangible, infinite, and perpetual.

Global markets in health ‘big data’ – including population genomic data – trade this information. Emerging jurisprudence on source rights in this information are derived from jurisprudence based on the traditional, tangible, finite conceptualisation of the body – itself controversial – criticised in part for disregarding property rights vesting in the self, while recognising them in strangers. .As such, it provides an uncertain foundation for extension to govern rights over derivatives, enabling disregard of legitimate concerns about health, commercialisation and genetic privacy, concerns compounded by the intergenerational nature of genetic information. A more nuanced approach, recognising that donors and strangers alike hold only weak custodial rights over access, use, and dissemination of tissues and derivative information, is required.

Beyond the Corporeal: extending propertisation of body parts to derivative information

ARTICLE

Introduction

What is a body? Something tangible: flesh, bone, blood and other matter akin to the ‘stuff of life’ that is processed by abattoirs and thus, like a non-human animal, addressed in terms of sale, gift and theft? Dust enlivened by the divine, a frail and imperfect vessel for the soul, something that cannot be commodified? An entity, akin to a USB drive or CD-ROM, that embodies genomic data that may have a commercial value and may be commercially exploited without ongoing supplies of tissue from a specific person? This article argues that much of the jurisprudence and legal scholarship about property in bodies is underdeveloped, an underdevelopment that centres on disagreement about the status of body parts/products — organs, blood, teeth, bone, semen, ova — as physical entities rather than the data manifest in that flesh.¹

The article seeks to advance discussion about property as an abstraction and about law regarding property in the corporeal, including its suitability as a foundation for development of law regarding property in information derived from the corporeal. In particular, it highlights questions about rights and interests in the body as data. It considers the legal transformations caused by separation of tissue from the source; ‘donation’ of that tissue to a stranger; and conversion of that tissue into data, in what is a linear progression of events. It is the latter part of this progression which has not yet received adequate attention from lawmakers or scholars.

¹ In this article the authors refer to ‘body parts’ and ‘tissues’ to cover bone, teeth, blood, skin, tendons, corneas, lungs and other organs that may be transferred from one person (pre or postmortem) – for example as an organ transplant or blood transfusion – or abstracted as a genetic profile or used as the basis of a cell line.

Exploiting, Excluding and Identifying

Historically at common law there is no property in the body.² This principle is derived from the common law maxim *nullius in bonis*.³ It is referred to in much of the jurisprudence dealing with corpses and anatomical specimens,⁴ has been critiqued in the scholarly literature⁵ and reflects religious and philosophical teaching from a time before organ transplants, assisted fertilisation and blood transfusions fostered conceptualisation of body parts as entities that might be propertised.⁶ Prior to the emergence of genomics there was no common or statute law recognition of the body as data — particularly as a manifestation of genetic data — that could be identified, interpreted and thence potentially propertised through patent or *sui generis* intellectual property law.⁷

In 1908, the High Court of Australia in *Doodeward v Spence (Doodeward)*⁸ recognised an exception to the ‘no property’ principle, arising when ‘skill or talent’ has been applied to a whole cadaver or isolated tissue.⁹ In essence, where an undefined but sufficient processing

² Sperling D, *Posthumous Interests: Legal and Ethical Perspectives* (Cambridge University Press, 2008) 88 for example refers to the “somewhat automatic and reflexive reply” to questions about property in a cadaver.

³ Coke E, *The Third Part of the Institutes of the Laws of England* (Brooke, 1797) 203; Blackstone W, *Commentaries on the Laws of England: Vol II — ‘Of Things’* (Clarendon Press, 1766) 429.

⁴ *Williams v Williams* [1882] 20 Ch D 659. See *Doodeward v Spence* [1908] HCA 45; (1908) 6 CLR 406 and *R v Kelly & Anor* [1999] 2 WLR 384.

⁵ Among recent critiques see Quigley M, ‘Propertisation and Commercialisation: On Controlling the Use of Human Biomaterials’ (2014) 77(5) *Modern Law Review* 677; Grubb A, ‘‘I, Me, Mine’’: Bodies, Parts and Property’ (1998) 3(4) *Medical Law International* 299. More broadly see Goold I, ‘Why does it matter how we regulate the use of human body parts?’ (2014) 40(1) *Journal of Medical Ethics* 3; Gaines J, ‘The Absurdity of Property in the Person’ (2013) 10(2) *Yale Journal of Law & the Humanities* 14; Herring, J, and Chau, P-L, ‘Relational bodies’ (2013) 21 *Journal of Law and Medicine* 294; .Goold I, ‘Property or not property? The spectrum of approaches to regulating the use of human bodily material’(2013) 21 *Journal of Law and Medicine*299;

⁶ Idiosyncracies regarding trade in mediaeval and early modern Europe of bones, blood and flesh of religious figures and *mumia* (ie recycling of mummified human remains for medicinal purposes) are noted below.

⁷ Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC Report 99) (Australian Law Reform Commission, 2004) 11 and 546. For an overview of questions regarding property and privacy in relation to tissue samples see Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* (ALRC Report 96) (Australian Law Reform Commission, 2003) 469 and 525.

⁸ *Doodeward v Spence* [1908] HCA 45; (1908) 6 CLR 406.

⁹ *Doodeward v Spence*, n8, per Griffith CJ at 414.

of a body or a body part occurred, that physical artefact would be recognisable in law as property on an exceptional basis. Since then, Australian and UK law has incrementally increased the circumstances under which property will be recognised in bodies or in tissue or other materials taken from bodies.¹⁰

Many of those decisions have relied on the *Doodeward* exception as the foundation for recognition of property.¹¹ A notable difference is *Yearworth v North Bristol (Yearworth)*.¹² In *Yearworth* the England and Wales Court of Appeal recognised property as arising in stored but otherwise unprocessed human biological material, in this instance semen. The Court preferred its finding to rest on a “broader basis”¹³ than the *Doodeward* exception, which it described as

an exception to a principle, itself of exceptional character, relating to the ownership of a human corpse. Such ancestry does not commend it as a solid foundation. Moreover a distinction between the capacity to own body parts or products which have, and which have not, been subject to the exercise of work or skill is not entirely logical.¹⁴

¹⁰ *Re H, AE (No 2)* [2012] SASC 177; also *Milenkovic v McConnell* [2013] WASC 421, which likened the cremation of a body to the efforts of preserving a foetus in *Doodeward*, and *Jocelyn Edwards; Re the estate of the late Mark Edwards* [2011] NSWSC 478.

¹¹ Skene L, ‘Proprietary Interests In Human Bodily Material: Yearworth, Recent Australian Cases On Stored Semen And Their Implications *Kate Jane Bazley v Wesley Monash IVF Pty Ltd* [2010] QSC 118; *Jocelyn Edwards; Re the estate of the late Mark Edwards* [2011] NSWSC 478’ (2012) 20(2) *Medical Law Review* 227; Nwabueze R, ‘Legal paradigms of human tissues’ in Christian Lenk (ed), *Human Tissue Research: A European Perspective on the Ethical and Legal Challenges* (Oxford University Press, 2011) 87, 88; and Hilmer S, ‘Property in a Human Body: A Common Law Approach’ (2005) 2(5) *Journal of International Biotechnology Law* 185.

¹² *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37, [2010] QB 1, [2009] 3 WLR 118, [2009] 2 All ER 986 CA. See also Harmon S, ‘Yearworth v. North Bristol NHS trust: a property case of uncertain significance?’ (2010) 13(4) *Medicine, Health Care and Philosophy* 343; Goold I, Skene L, Herring J and Greasley K, ‘The human body as property? Possession, control and commodification’ (2014) 40(1) *Journal of medical ethics* 1; and Cynthia Hawes, ‘Property interests in body parts: Yearworth v North Bristol NHS trust’ (2010) 73(1) *The Modern Law Review* 130.

¹³ *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37, at 45(e).

¹⁴ *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37, at 45(d).

Yearworth discussed property in terms of ownership of the material, rather than as a lesser interest, and, on the facts available, recognised that interest as vesting in the source¹⁵ of the material, a conclusion the Court was able to draw from the circumstances of the case.

The Court did not conceptualise the semen as data, in contrast to a geneticist who would recognise the material as a mechanism for the delivery of genetic data — a mechanism that is primarily valuable because of the data embodied in the material and (and thus potentially exploitable) by anyone who can ‘read the code’ found in any material containing DNA. Instead, in *Yearworth* the Court addressed the semen in the same way that it would address ownership of any other chattel.

What is property?

Although Australian cases have referred to *Yearworth*, Australian law regarding property in bodies and tissues remains uncertain. It centres on possession and exclusion regarding tangible material, rather than the questions about rights and interests that are posed by developments such as direct-to-consumer global genomic databases and national initiatives such as the UK 100,000 Genomes Project.¹⁶

In *Zhu v Treasurer of the State of New South Wales*¹⁷ the High Court of Australia stated:

“Property” is a comprehensive term which is used in the law to describe many different kinds of relationship between a person and a subject-matter; the term is

¹⁵ We use the term ‘source’, rather than ‘donor’, to describe the person from whom the material originated, and ‘stranger’ to describe all others with no biological relationship to the material, noting the specific legal meaning of ‘donor’, which will be discussed later in the article.

¹⁶ 100,000 Genomes Project at <http://www.genomicsengland.co.uk/the-100000-genomes-project/>. See also Haga S, ‘100k Genome Project: sequencing and much more’ (2013) 10(8) *Personalized Medicine* 761; and Burn J, ‘Should we sequence everyone’s genome? Yes’ (2013) 346 *BMJ: British Medical Journal* f3133.

¹⁷ *Zhu v Treasurer of the State of New South Wales* [2004] HCA 56; (2004) 218 CLR 530. See also John Tarrant, ‘Characteristics of Property Rights’ (2008) 16 *Australian Property Law Journal* 51, 59.

employed to describe a range of legal and equitable estates and interests, corporeal and incorporeal.¹⁸

In law, property refers to the rights relating to a thing, rather than the thing itself. Recognition of property may see a party exercising absolute control over the thing; or it might entail limited weaker rights with respect to the thing,¹⁹ the practical effect of which is dependent on the exercise of other, stronger, rights over the thing by others.²⁰

Recognition of property relies on a legal determination (identification of relevant rights and interests) and a policy determination (that recognition of those rights is appropriate).

Honore's landmark work characterising the concept of ownership²¹ identified the 'incidents' of ownership — de facto indicia of property²² — as follows: the right to possess (exercise physical control of a thing); the right to use; the right to manage; the right to income; the right to the capital; the right to security; the incident of transmissibility; the incident of absence of term; the prohibition of harmful use; and liability to execution.²³ In considering the incidents of ownership — as the ultimate property right capable of coexisting with other lesser rights — Honore provided a list of indicia of property, relevant to not only ownership, but also establishing whether other, lesser, rights exist.

¹⁸ *Zhu v Treasurer of the State of New South Wales* [2004] HCA 56; (2004) 218 CLR 530, 577.

¹⁹ *Yanner v Eaton* [1999] HCA 53; (1999) 201 CLR 531, at 21.

²⁰ *Armory v Delamirie* [1722] EWHC KB J94 per Pratt CJ: "The finder of a jewel, though he does not by such finding acquire an absolute property or ownership, yet he has such a property as will enable him to keep it against all but the rightful owner".

²¹ Honore AM, 'Ownership' in Anthony Guest (ed), *Oxford Essays in Jurisprudence* (Oxford University Press, 1961) 107, 108.

²² Honore, 112. This inference is based on ownership as the pinnacle of property interests, and all other, lesser interests, being so deemed because the holder has too few of those incidents of ownership to be identifiable as an owner, an approach which is consistent with common law prioritisation of competing claims.

²³ See Goold I, 'Sounds Suspiciously like Property Treatment: Does Human Tissue Fit within the Common Law Concept of Property?' (2005) 7 *University of Technology Sydney Law Review* 62, which considers the application of each of the incidents to human tissue.

Honore's model — which has been approved by the courts²⁴ — recognised that not all of the 'incidents' of ownership must be present for ownership to exist, that some incidents can be inconsistent with the nature of the subject matter under consideration, and yet still the law will regard that subject matter as being 'owned'. The model permits recognition of rights of multiple parties in the same subject matter, including holders of weaker rights. It thus describes a nuanced and sophisticated understanding of ownership — a bundle of rights which may vary from instance to instance, rather than a comprehensive set which must necessarily coexist — as a part of the broader body of property.

A wide range of interests, from ownership through to relatively 'weak' rights and interests of equitable origin — demonstrated by the presence of comparatively fewer 'incidents' of ownership — have been recognised and prioritised by the courts.²⁵ Some commentators have suggested that the absence of remedies specific to owners — as distinct from other types of right or interest holder — have obviated the need for the courts to recognise ownership, instead providing remedies based on prioritisation of lesser claims, thereby rendering the concept of ownership redundant.²⁶

Perhaps reflecting the postulated redundancy of ownership as a legal concept, recent Australian cases which have considered property claims associated with tissue excised from

²⁴ See eg *Mitsui & Co (Australia) Ltd v Commissioner of Taxation* [2011] FCA 1423; *Brown (on behalf of the Ngarla People) v State of Western Australia* [2012] FCAFC 154; *Western Australia v Ward* [2000] FCA 191; *NRMA Ltd and Ors v Morgan and Ors* [1999] NSWSC 407 for cases referring to the 'bundle of rights' concept of property. The 'sticks', or rights in the bundle are the incidents identified by Honore. See Johnson D R, 'Reflections on the Bundle of Rights' (2007) 32(2) *Vermont Law Review* 247, 253; Alta Charo R, 'Body of research — ownership and use of human tissue' (2006) 355(15) *New England Journal of Medicine* 1517; and Gold ER, *Body parts: Property rights and the ownership of human biological materials* (Georgetown University Press, 1996) 6.

²⁵ Bennett Moses L and Gollan N, '“Thin” property and controversial subject matter: Yanner v Eaton and property rights in human tissues and embryos' (2013) 21 *Journal of Law and Medicine* 307 offers a conceptualisation of property that would allow recognition without necessarily entailing commercial sale.

²⁶ Swadling W, 'Property: General Principles' in Birks P (ed), *English Private Law Vol 1* (Oxford University Press, 2000) 203, 218.

bodies and information derived from those excised materials include *Jocelyn Edwards: Re the estate of the late Mark Edwards*,²⁷ *Cancer Voices Australia v Myriad Genetics Inc*²⁸ and *Clark v Macourt*.²⁹ It is notable that these cases have generally avoided statements of ownership,³⁰ instead prioritising the claims of those appearing before them, largely on the basis of possession. Furthermore, in none of the cases where an interest has been recognised did that interest vest in the ‘donor’ of the tissue. In *Jocelyn Edwards*³¹ the court did not recognise the property rights of the source of the material as the basis for finding ownership vested in the source’s administrator,³² but rather based recognition of the administrator’s claim to possession on the absence of any competing claim.³³

In *Cancer Voices*, the Federal Court dismissed a challenge to the patenting by Myriad Genetics of naturally occurring DNA sequences that have been isolated from cells, noting that a patent is a property right, albeit one that attaches to intangible, rather than tangible, subject matter. In *Clark*, the High Court of Australia treated straws of frozen semen as an ‘asset’ in a contractual dispute over the sale of a business from one medical practitioner to another. Other cases recognising property in biological materials include *Roche v Douglas as*

²⁷ *Jocelyn Edwards: Re the estate of the late Mark Edwards* [2011] NSWSC 478. See also Loane Skene, ‘Proprietary Interests In Human Bodily Material: Yearworth, Recent Australian Cases On Stored Semen And Their Implications *Kate Jane Bazley v Wesley Monash IVF Pty Ltd* [2010] QSC 118; *Jocelyn Edwards; Re the estate of the late Mark Edwards* [2011] NSWSC 478’ (2012) 20(2) *Medical Law Review* 227.

²⁸ *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65. See also Harmon S, ‘From conflicting narratives to legal conflicts Patenting and irreconcilable differences on the idea of ‘biovalue’’ (2012) 12(3/4) *Medical Law International* 191; So D and Joly Y, ‘Commercial Opportunities and Ethical Pitfalls in Personalized Medicine: A Myriad of Reasons to Revisit the Myriad Genetics Saga’ (2013) 11(2) *Current pharmacogenomics and personalized medicine* 98; and Hartland L, ‘*Cancer Voices Australia v Myriad Genetics Inc*’ (2013) 25(9) *Australian Intellectual Property Law Bulletin* 191.

²⁹ *Clark v Macourt* [2013] HCA 56. See Giancaspro M, ‘Reproductive Tissue and Contract’ (2014) *Journal of bioethical inquiry: An interdisciplinary forum for ethical and legal debate* 1.

³⁰ *Yearworth* is a notable exception; however arguably the same result could have been supported by finding that the men had a right to immediate possession of their sperm, as a necessary implication of the assisted reproduction processes in which they were participating.

³¹ *Jocelyn Edwards; Re the estate of the late Mark Edwards* [2011] NSWSC 478.

³² *Jocelyn Edwards; Re the estate of the late Mark Edwards* n31, at [87].

³³ *Jocelyn Edwards; Re the estate of the late Mark Edwards* n31, at [91] and [149].

*Administrator of the Estate of Edward John Hamilton Rowan*³⁴ and *Pecar v National Australia Trustees Ltd*,³⁵ both of which ordered surrender of excised tissue for testing to establish parentage for the purposes of resolving a succession dispute.

In other jurisdictions, samples of blood and urine which have been taken, and subsequently removed, have been regarded as instances of interference with the right to possession — including in the context of a suspect in a police matter who retook his own sample.³⁶

Clearly, therefore, courts are recognising some property in excised tissues and information derived from them, although the basis for doing so is prioritisation of claims, rather than findings of absolute ownership.

From the morbid to the marketplace?

Commercial value is one factor the courts consider in deciding whether property should be recognised in novel substrates.³⁷ A key driver for the gradual recognition of even limited property in bodies and tissues is advances in technology, and marketization of application of that technology.

Trade in human bodies, and their constituent parts, is not a new phenomenon. Religious relics — body parts removed from the corpses of saints — have long been revered in Europe and elsewhere for their ability to attract pilgrims and the economic benefits accompanying

³⁴ *Roche v Douglas as Administrator of the Estate of Edward John Hamilton Rowan* [2000] WASC 146.

³⁵ *Pecar v National Australia Trustees Ltd* (Unreported, Supreme Court of NSW, Bryson J, 27 November 1996).

³⁶ *R v Rothery* [1976] Crim LR 691; *R v Welsh* [1974] RTR 478. See Nils Hoppe, *Bioequity – Property and the Human Body: Property and the Human Body* (Ashgate, 2013) 88.

³⁷ Bennett Moses L and Gollan N, ‘Thin’ Property and Controversial Subject Matter: *Yanner v. Eaton and Property Rights in Human Tissue and Embryos* (2013) 21 *Journal of Law & Medicine* 1. See also Quigley M, ‘Property: The future of human tissue?’ (2009) 17(3) *Medical Law Review* 457.

them.³⁸ Historical practices such as anthropodermic bibliopegy (ie using human skin as book bindings),³⁹ *mumia* (ingestion of genuine/fake mummy parts as a medicine)⁴⁰ and trade in collectibles such as Napoleon's penis,⁴¹ and anatomical specimens⁴² illustrate the long standing — if somewhat macabre — reality of the commercial value attached to human beings and their corporeal derivations. Anatomical research was long synonymous with grave-robbing, to provide doctors and scientists with fresh materials to use in developing their rapidly-expanding field of knowledge.⁴³ In more recent times, advances in medical knowledge have resulted in demand for increasingly specialised body parts, including organs for donation, tissue samples for creation of cell lines, bones for dental or other prostheses, and DNA samples for gene sequencing, to name a few.⁴⁴ That demand has on occasion been reflected in mass media reports of the 'theft' of body parts⁴⁵ or of cadavers, whether for

³⁸ Geary P, *Furta Sacra: Theft of relics in the central Middle Ages* (Princeton University Press, 1978). See also Felice Lifshitz, 'The migration of Neustrian relics in the Viking Age: the myth of voluntary exodus, the reality of coercion and theft' (1995) 4(2) *Early Medieval Europe* 175; Trainor K, 'When is a theft not a theft? Relic theft and the cult of the Buddha's relics in Sri Lanka' (1992) 39(1) *Numen* 1; and Bentley J, *Restless Bones: the story of relics* (Constable, 1985).

³⁹ Nambudiri N, and Nambudiri V, 'Anthropodermic Bibliopegy: Lessons From a Different Sort of Dermatologic Text' (2014) 150(1) *JAMA Dermatology* 41.

⁴⁰ Dannenfeldt K, 'Egyptian mumia: the sixteenth century experience and debate' (1985) 16(2) *The Sixteenth century journal* 163; Sugg R, 'Corpse medicine: mummies, cannibals, and vampires' (2008) 371(9630) *The Lancet* 2078; Gordon-Grube K, 'Anthropology in Post-Renaissance Europe: The Tradition of Medicinal Cannibalism' (1988) 90 *American Anthropologist* 405; and Scholz-Böttcher B, Nissenbaum A and Rullkötter J, 'An 18th century medication "Mumia vera aegyptica" – Fake or authentic?' (2013) 65 *Organic Geochemistry* 1.

⁴¹ Bierman S, 'The peripatetic posthumous peregrination of Napoleon's Penis' (1992) 29(4) *Journal of Sex Research* 579.

⁴² Huxley A and Finnegan M, 'Human remains sold to the highest bidder! A snapshot of the buying and selling of human skeletal remains on eBay, an Internet auction site' (2004) 49(1) *Journal of Forensic Sciences* 17; Cheney A, *Body Brokers: Inside America's underground trade in human remains* (Broadway Books, 2006) and Skegg P D G, 'Human corpses, medical specimens and the law of property' (1975) 4 *Anglo-American Law Review* 412.

⁴³ Madoff R, *Immortality and the Law: The Rising Power of the American Dead* (Yale University Press, 2010); Richardson R, *Death, Dissection and the Destitute* (Routledge, 1987); and Muinzer T, 'A Grave Situation: An Examination of the Legal Issues Raised by the Life and Death of Charles Byrne, the 'Irish Giant'' (2013) 20(1) *International Journal of Cultural Property* 23.

⁴⁴ Waldby C and Mitchell R, *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism* (Duke University Press, 2006).

⁴⁵ Scheper-Hughes N, 'Alistair Cooke's bones' (2006) 22(6) *Anthropology Today* 10; Charatan F, 'FDA shuts down human tissue company' (2006) 332(7540) *BMJ: British Medical Journal* 507; Hoeyer K, 'After novelty: The mundane practices of ensuring a safe and stable supply of bone' (2010) 19(2) *Science as Culture* 123 and 'Tradable body parts? How bone and recycled prosthetic devices acquire a price without forming a 'market'' (2009) 4(2) *BioSocieties* 239.

medical exploitation or for ransom.⁴⁶ It coexists with questions about the ethics and legality of the 'plastination market',⁴⁷ and about the repatriation of human remains in Australian and overseas anthropological collections.⁴⁸

Despite the long history of trade in corpses and body parts, the common law has struggled to develop a coherent approach to establishing rights in the body once life has left it, or once it has been separated from a living donor.⁴⁹ Theft of relics from graves and religious communities was – and remains – an offence under ecclesiastical law.⁵⁰

The defining doctrine was articulated by Sir Edward Coke:

⁴⁶ Examples include the cadavers of Abraham Lincoln, Elvis Presley, Benito Mussolini, Juan and Eva Peron, Alexander Stewart, Charles Chaplin and the mother of an executive targeted by UK animal rights activists. See for example Hickey J, 'Robert Todd Lincoln and His Father's Grave Robbers: Or Left in the Lurch by the Secret Service' (1984) 77(4) *Illinois Historical Journal* 295; Fanebust W, *The Missing Corpse: Grave Robbing a Gilded Age Tycoon* (Praeger, 2005); Cantor N, *After We Die: The Life and Times of the Human Cadaver* (Georgetown University Press, 2010); Verdery K, *The Political Lives of Dead Bodies: Reburial and Postsocialist Change* (Columbia University Press, 1999); and Upton A, "'Go On, Get Out There, And Make It Happen': Reflections on the First Ten Years of Stop Huntingdon Animal Cruelty (SHAC)' (2011) *Parliamentary Affairs* gsr027.

⁴⁷ Jones D and Whitaker M, 'Engaging with plastination and the Body Worlds phenomenon: A cultural and intellectual challenge for anatomists' (2009) 22(6) *Clinical Anatomy* 770; Leiboff M, 'A beautiful corpse' (2005) 19(2) *Continuum* 221; Lisa Giunta, 'The Dead on Display: A Call for the International Regulation of Plastination Exhibits' (2010) 49 *Columbia Journal of Transnational Law* 164. See also *R v. Gibson* [1991] 1 All ER 439. More broadly see Kenyon Mason J and Laurie G, 'Consent or property? Dealing with the body and its parts in the shadow of Bristol and Alder Hey' (2001) 64(5) *The Modern law review* 710.

⁴⁸ Fforde C, Hubert J and Turnbull P (eds), *The dead and their possessions: repatriation in principle, policy and practice* (Routledge, 2004); Jenkins T, *Contesting human remains in museum collections: the crisis of cultural authority*. Routledge, 2010); Turner Y (ed), *Biological anthropology and ethics: from repatriation to genetic identity* (SUNY Press, 2005); Winski J, 'There Are Skeletons in the Closet: The Repatriation of Native American Human Remains and Burial Objects' (1992) 34 *Arizona Law Review* 187; and Turnbull P, 'Ramsay's Regime: The Australian Museum and the Procurement of Aboriginal Bodies, c. 1874-1900' (1991) 15 *Aboriginal History* 108.

⁴⁹ Rights in the foetus were equally problematical, with one author referring to the trade in 'educational specimens' and a shift over the past 80 years from exhibition of foetal remains as "curiosities and specimens inspiring wonder and awe into 'babies' and 'human bodies' deserving sympathy and burial". Dubow S, *Ourselves Unborn: A History of the Fetus in Modern America* (Oxford University Press, 2011) 39 and 41. See also Morgan L, *Icons of life: A Cultural History of Human Embryos* (University of California Press, 2009).

⁵⁰ Roman Catholic Canon law for example specifies at §1190 §1 – "It is absolutely forbidden to sell sacred relics" and at §1190 §2 – "Relics of great significance and other relics honored with great reverence by the people cannot be alienated validly in any manner or transferred permanently without the permission of the Apostolic See."

The burial of the cadaver, that is *caro data vermibus* (flesh given to worms) is *nullius in bonis* and belongs to ecclesiastical cognizance.⁵¹

Coke applied *nullius in bonis* to the fate of the cadaver after burial, rather than immediately after death, the practical implications of which were that it permitted those with a duty to bury the cadaver to exercise possession of it up until the time of interment.

Sir William Blackstone, writing in his *Commentaries on the Laws of England*, some 120 years later, expanded:

Though the heir has property in the monuments and escutcheons of his ancestors, yet he has none in their bodies or ashes.⁵²

In Coke and Blackstone's times, practical uses for bodies were limited to the nefarious and ungodly. The doctrine's failure to identify rights-holders with respect to buried cadavers was a significant issue in the 18th Century, when the supply of bodies legitimately available to anatomists and medical schools was inadequate to meet demand. This unmet need fostered the enterprises of the so-called 'resurrectionists', who would retrieve corpses from churchyards and deliver them to anatomists for dissection, in exchange for payment. As the right to possession of a body ended at or before the time of interment, resurrectionists could retrieve and sell recently interred bodies without committing a serious offence under common law, provided they left the burial clothes behind,⁵³ the reasoning being that the

⁵¹ Coke E, *The Third Part of the Institutes of the Laws of England* (Brooke, 1797) 203.

⁵² Blackstone W, *Commentaries on the Laws of England: Vol II — 'Of Things'* (Clarendon Press, 1766) 429.

⁵³ *Haynes Case* (7 Coke 113); *R v Lynn* (2 Term R 733).

body was the property of no one, so no offence against the rights of ownership or possession had been committed.⁵⁴

The passage of the 1832 *Anatomy Acts* in Britain⁵⁵ effectively resolved the issue, by making it lawful for dissectors to source cadavers from poorhouses and hospitals rather than exclusively from executed prisoners.⁵⁶

Similarly reflecting commercial value of the corpse was the occasional use of bodies as security for unpaid debts. Frequently cited examples include detainment of John Dryden's corpse by his creditors before reburial in St Pauls, and seizure of the body of Sir Bernard Taylor.⁵⁷ Arrest of a corpse for debt was finally declared unlawful in 1804.⁵⁸

As medical technology has advanced, markets trading in the body parts necessary for application of those technologies have evolved, including emergence of markets for human tissues for transplantation (eg kidneys, lungs, livers),⁵⁹ infusion (blood),⁶⁰ implantation (oocytes and sperm),⁶¹ or as the basis for clinical/diagnostic tools (eg cell lines for human

⁵⁴ *Stephen's Digest of Criminal Law* Art 292 specifically stated that 'the dead body of a human being could not be the subject of larceny', an essential element of larceny being possession.

⁵⁵ *Anatomy Act* (2 & 3 Will. IV c.75). See in particular Ruth Richardson, *Death, dissection and the destitute* (University of Chicago Press, 2000).

⁵⁶ MacDonald H, "'Humanity's discards": The New South Wales Anatomy Act 1881' (2007) 12(4) *Mortality* 365; and Knott J, 'Popular attitudes to death and dissection in early nineteenth century Britain: the anatomy act and the poor' (1985) 49 *Labour History* 1.

⁵⁷ Kuzenski W, 'Property in dead bodies' (1924) 9(1) *Marquette Law Review* 17, drawing on an 1895 dissertation by Wilber Kinzie, is recurrently cited in relation to Dryden and Taylor but his authority is problematical. See Graham McBain, 'Modernising the Law on the Unlawful Treatment of Dead Bodies' (2014) 7(3) *Journal of Politics and Law* 89.

⁵⁸ *Jones v Ashburnham* (4 Redfield's Surr. Rep. 527).

⁵⁹ Goodwin M, *Black Markets: The Supply and Demand of Body Parts* (Cambridge University Press, 2006); Harris C, and Alcorn S, 'To solve a deadly shortage: economic incentives for human organ donation' (2000) 16 *Issues in Law & Medicine* 213; and Steering Committee of the Istanbul Summit, 'Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul' (2008) 372(9632) *The Lancet* 5.

⁶⁰ Korsten L, 'The Global Market for Blood: A Proposal for Expansion and a Consistent System of International Regulation' (1993) 11 *Boston University International Law Journal* 227. See also Steinbrook R, 'The cord-blood-bank controversies' (2004) 351(22) *New England Journal of Medicine* 2255.

⁶¹ For the market in sperm with 'elite' attributes, such as that associated with Olympic athletes and Nobel Prize winners, see Almeling R, 'Selling genes, selling gender: egg agencies, sperm banks, and the medical market in genetic material' (2007) 72(3) *American Sociological Review* 319; Krawiec K, 'Sunny samaritans and egomaniacs: price-fixing in the gamete market' (2009) 72 *Law & Contemporary Problems* 59; and Swanson K,

and laboratory use).⁶² Most developed nations have government run or sanctioned programs for blood transfusion and organ donation, an evolution which has been accompanied by the development of black markets in certain organs – notably kidneys – in some parts of the world. That development has been accompanied by widespread debate on the ethics of commodification of body parts, which has commonly been conflated with the broader issue of recognising property in those body parts. In a bid to avoid ‘commodification’ and the growth of unregulated markets, many jurisdictions have legislated to prohibit paying the source of tissues and organs, instead employing ‘donor discourse’ as a means of promoting altruistic provision. In passing such legislation, the conflation of two separate, albeit related, issues has been entrenched in law; an unfortunate consequence of this is that it alienates all source rights for the sake of excluding some incidents of property which raise ethical concerns, justified or otherwise.

Ethical arguments against commodification of tissues frequently claim that it is an affront to human dignity, which adopts the perspective that all humans are of intrinsic worth.⁶³

In particular, Kant’s property/dignity dichotomy is frequently invoked. According to Kant, the two attributes are inconsistent: something either has dignity, or is property. Dignity is exclusive to people, capable of reasoned willing.⁶⁴ Kantian theory assumes that separation

Banking on the Body: The Market in Blood, Milk, and Sperm in Modern America (Harvard University Press, 2014).

⁶² Skloot R, *The Immortal Life of Henrietta Lacks* (Crown, 2010); and Lock M, ‘The alienation of body tissue and the biopolitics of immortalized cell lines’ (2001) 7(2/3) *Body & Society* 63.

⁶³ See Foster C, *Human Dignity in Bioethics and Law* (Hart, 2011); Rosen M, *Dignity: Its History and Meaning* (Harvard University Press, 2012); Habermas J, ‘The Concept of Human Dignity and the Realistic Utopia of Human Rights’ (2010) 44(4) *Metaphilosophy* 444; Shell S, ‘Kant on Human Dignity’, in Kraynak R and Tinder G (eds), *In Defense of Human Dignity: Essays for Our Times* (University of Notre Dame Press, 2003) 53; and O’Neill O, *Autonomy and Trust in Bioethics* (Cambridge University Press, 2002).

⁶⁴ Kant I, *The Metaphysics of Morals* (Gregor M trans, Cambridge University Press, 1996) [trans of *Die Metaphysik der Sitten* (first published 1797)] 186; and Kant I, ‘Critique of Practical Reason’, in Kant I, *Practical Philosophy (The Cambridge Edition of the Works of Immanuel Kant)* (Gregor M trans, Cambridge University Press, 1999) [trans of *Kritik der praktischen Vernunft* (first published 1788)] 153, 189.

of body parts from the remaining person diminishes the integrity – and therefore dignity – of the whole.⁶⁵ Kant provided examples of when such separation might be warranted. They reflect medical practice in his time, when separation was either therapeutic (eg removal of a gangrenous limb) or punitive (eg removal of a hand to punish an offender and signal wrongdoing). Separation in Kant's day was of no direct benefit to another person, through for example transplantation of a cornea, kidney, heart or lung. The potential affirming the recipient's dignity by enhancing their opportunity for flourishing was, therefore, not something he considered, nor was the dignity of the source in providing that opportunity.

A further limitation of the property/dignity dichotomy is that it adopts a different notion of property from that which is commonly used by the law of contemporary liberal democratic states. In the Kantian sense, the dichotomy implies a categorisation as a 'person' (dignity) or a 'thing' (property); property is not recognised as the rights associated with that thing, but rather the thing itself.⁶⁶ The same dichotomy implies differentiation between an individual as a person, with inalienable rights, and as one or more genetic attributes.⁶⁷

Kant's 'means and ends' argument — that it is wrong to treat people as means, rather than as ends in themselves — while appealing in its apparent simplicity, is similarly misunderstood. Closer consideration shows that Kant did not absolutely prohibit using people as 'means' rather than 'ends'; rather, he objected to people being treated *solely* as means. His objection to commodification of body parts would therefore apply to creation of

⁶⁵ Powers T, 'The integrity of body: Kantian moral constraints on the physical self' in Cherry M (ed), *Persons and Their Bodies: Rights, Responsibilities, Relationships* (Springer, 2002) 209; and Chadwick R, 'The market for bodily parts: Kant and duties to oneself' (1989) 6(2) *Journal of Applied Philosophy* 129.

⁶⁶ As discussed earlier, 'property' describes the rights and interests attached to a thing, rather than the thing itself.

⁶⁷ Respect for both our own dignity and that of others requires that we refrain from 'dehumanising' people by objectifying them as their ethnicity, gender, nationality, sexuality, capability or genetic endowment. In essence, people are more than their genomic profiles, albeit elements of a specific profile might be construed as commercially valuable and potentially exploitable independent of the individual who embodies that profile.

people solely for that purpose, at the expense of recognising their intrinsic value, rather than to commodification *per se*.⁶⁸

However Kant was not merely opposed to sale of body parts; in fact, he was opposed to their alienation for any reason whatsoever. Even his support for amputation of a limb is grudging at best, as excision violates the integrity of the whole person. It is inconsistent, therefore, to accept Kantian philosophies against alienation of body parts in the context of prohibiting commercial transactions, but accept them when other forces — such as altruism, or necessity — are motivating factors. This is one critical weakness of the donor model of tissue market regulation.

The legal basis and interpretation of legislation governing human tissues relies on mischaracterisation of the ‘gift’ relationship. Legally, a donor is someone who makes a gift, or donation, with the recipient identifiable as a donee.⁶⁹ *Prima facie*, a gift requires recognition of property; the right to transfer or alienate is an incident of property, and ‘donors’ cannot gift what does legally not exist, or is not theirs.⁷⁰

Furthermore, while the everyday usage of the term might suggest that it is an absolute transfer of property, this is by no means the case in law. While a transfer made in exchange for money will not be recognised by law as a gift, it is not true that the donor necessarily alienates all their interests in the subject matter of a gift. Indeed, the ‘onerous gift’ – one

⁶⁸ Shih-Ning T, ‘The Legality of Tissue Transplants for the Benefit of Family Members in the UK and Australia: Implications for Saviour Siblings’ (2009) 10(1) *Medical Law International* 23; Shih-Ning T, ‘Young children as regenerative tissue donors: Considering the need for legal reform in light of divergent ethical approaches’ (2011) 19 *Journal of Law and Medicine* 172. .

⁶⁹ Crago N, ‘Principles of disclaimer of gifts’ (1999) 28 *Western Australia Law Review* 65.

⁷⁰ Titmuss R, *The Gift Relationship, From Human Blood to Social Policy* (Allen & Unwin, 1971) has influenced communitarian public policy discourse but is legally inadequate. For a critique see Steiner P, ‘Gifts of blood and organs: the market and “fictitious” commodities’ (2003) 44(5) *Revue française de sociologie* 147; or McLean I and Poulton J, ‘Good blood, bad blood, and the market: The gift relationship revisited’ (1986) 6(4) *Journal of Public Policy* 431.

with conditions attached still granting the donor some interests and powers over the material of the gift – is well-recognised,⁷¹ and remains current common law.

Many jurisdictions have passed legislation governing donation of bodies, organs and tissues for research and clinical purposes.⁷² All jurisdictions have characterised the transaction as ‘donation’, and all jurisdictions have specifically prohibited contracting donation of tissues and organs for monetary consideration.⁷³ The legislation outlines specific provisions for provision and withdrawal of consent; however nowhere is there an explicit recognition that donors may have other non-financial interests in the donated material. Indeed, the legislation appears to tacitly assume that donation results in complete alienation of all rights associated with that material.⁷⁴ In the absence of a specific legislative definition of ‘donor’ requiring the alienation of all rights on the part of the owner, however, it is incorrect to assume that cadaver, organ, or tissue donation necessarily indicates that the donor agrees to alienate all their interests with respect to the donated material.

If indeed we do mean donation in the broadest sense – a complete alienation of rights – there is a significant risk that donors will be exploited in a way that is inconsistent with ethical practice. Firstly, their consent to participate by contributing tissue may be based in

⁷¹See *Standing v Bowring* 31 Ch. D., 282; *Re Stratton's Disclaimer* Jenkins LJ 57; *Dewar v Dewar* [1975] 2 All ER 728; *Hill v Wilson* (1873) LR 8 Ch App 888; *Re Moss* (1977) 77 DLR (3d) 314; *Re Young* [1913] 1 Ch 272, for discussion on repudiation of onerous gifts.

⁷² See Stewart C, Fleming J, and Kerridge I, ‘The Law of gifts, conditional donation, and biobanking’, (2013) 21 *Journal of Law and Medicine* 351, for a discussion in the context of biobanking.

⁷³ See eg *Transplantation and Anatomy Act 1978* (ACT) s 44; *Human Tissue Act 1983* (NSW) s 32; *Transplantation and Anatomy Act* (NT) s 22E; *Transplantation and Anatomy Act 1979* (Qld) ss 40 and 42; *Transplantation and Anatomy Act 1983* (SA) s 35; *Human Tissue Act 1985* (Tas) s 27; *Human Tissue Act 1982* (Vic) ss 38 and 39; and *Human Tissue and Transplant Act 1982* (WA) s 29.

⁷⁴ Australia’s DonateLife website indicates this assumption. The ‘FAQs for donors’ page responds to the question “Does the person’s family have a say in who receives the organs and tissues?” with “No. The allocation of organs and tissues is determined by transplant teams in accordance with national protocols. These are based on a number of criteria, including waiting lists and who will be the best match, to ensure the best possible outcome of the donation.” This suggests the authority is of the view that on agreement to donate, all further rights of the family in respect to the disposition of the materials (and implicitly of the donor, were they in a position to exercise any rights) has been waived. <http://www.donatelife.gov.au/understanding-donation-process> (accessed 18/8/14).

incomplete information or flawed understanding. Recently it has been demonstrated that deidentified research participants can be reidentified by cross matching published study information with publicly accessible databases including telephone directories and electoral roles.⁷⁵ Consent reliant on anonymity, such as underpins organ donation, for example, is arguably now invalid.⁷⁶

This misapplication of Kant as somehow rebutting commodification of separated tissues, while remaining silent on 'donation' of the same material, fails to grasp the true utility of Kantian dignity in considering questions of this type.

Rather than focussing on the specific examples provided by Kant, it may be beneficial to look instead at what he said about the decision-making framework that should be employed for the purposes of determining some of these hard questions.

⁷⁵ Sweeney L, Abu A and Winn J, 'Identifying participants in the personal genome project by name (a re-identification experiment)' (2013)" *arXiv preprint arXiv:1304.7605*. Among other literature highlighting concerns see El Emam K (ed), *Risky Business: Sharing Health Data while Protecting Privacy* (Trafford Publishing, 2013); Benitez K and Malin B, 'Evaluating re-identification risks with respect to the HIPAA privacy rule' (2010) 17(2) *Journal of the American Medical Informatics Association* 169; and Ogbogu U, Burningham S, Ollenberger A, Calder K, Du L, El Emam K, Robyn Hyde-Lay R, Isasi R, Joly Y, Kerr I, Malin M, McDonald M, Penney S, Piat G, Roy D, Sugarman J, Vercauteren V, Verhenneman G, West L and Caulfield T 'Policy recommendations for addressing privacy challenges associated with cell-based research and interventions' (2014) 15(1) *BMC medical ethics* 7

⁷⁶ For the retrospective removal, via statute law in Australia, of anonymity for gamete donors, see: Hammarberg K, Johnson L, Bourne K, Fisher J and Kirkman M, 'Proposed legislative change mandating retrospective release of identifying information: consultation with donors and Government response' (2014) 29(2) *Human Reproduction* 286; and Victorian Law Reform Committee, *Inquiry into Access by Donor-Conceived People to Information about Donors* (Parliament of Victoria, 2012). See more broadly Tobin J, 'Donor Conceived Individuals and Access to Information about Their Genetic Origins: The Relevance and Role of Rights' (2012) 19(4) *Journal of Law and Medicine* 742; Burr J A, 'Anonymous or known donors? A brief discussion of the psychosocial issues raised by removing anonymity from sperm donors' (2013) 16(1) *Human Fertility* 44; Lalos A, Gottlieb C, and Lalos O, 'Legislated right for donor-insemination children to know their genetic origin: a study of parental thinking' (2007) 22(6) *Human Reproduction* 1759; and Blyth, E and Frith L, 'Donor-conceived people's access to genetic and biographical history: an analysis of provisions in different jurisdictions permitting disclosure of donor identity' (2009) 23(2) *International Journal of Law, Policy and the Family* 174

Kant considered the person acting in the roles of *Homo noumenon* or *homo phenomenon*. *Homo phenomenon* occurs when the person in question considers the dignity or ethics of a particular act in the context of their own personal circumstance, whereas *homo noumenon* removes that subjectivity and replaces it with an impartial consideration of the same circumstances. Kant argued that it is to treat people as means only and not ends when they are treated in ways they could not accept under conditions of informed, impartial, and rational choice as a rule of conduct for everybody (themselves included). We do not treat someone as a “means only” just because we frustrate their will, or as an end simply because we satisfy their desires. Kant required basic moral reasoning to be conducted from an impartial standpoint, abstracted from elements of the individual’s subjective situation.⁷⁷ So, by extension, is not against dignity to use the body or talents of a person to meet the purposes of the individual, unless it is done in ways that they could not impartially accept.

If the premise that dignity applies to all is accepted — as seems to be indicated by its frequent use in human rights and international law writings — then is it not incumbent on users of dignity to apply the concept to all parties connected with a circumstance? If opponents of commodification argue that it is undignified for a source to receive payment for donating tissues, the reciprocal questions— whether it is dignified for a recipient of these goods to receive them freely, to do with as they will — should also be considered.

⁷⁷ Korsgaard C, *Creating the Kingdom of Ends* (Cambridge University Press, 1996); and Dean R, *The Value of Humanity in Kant's Moral Theory* (Clarendon Press, 2006).

Commercialisation of the stuff of life?

Efforts to conceptualise tissue donation as altruistic, including legislation barring payment for samples,⁷⁸ fail to acknowledge the significant commercial value of tissue collections. Although the legislation governing human tissues in all Australian jurisdictions prohibits certain commercial transactions, the legislation effectively limits the rights of sources to consideration for their tissue, but does not prevent others commercialising the derivative products or benefits of that material once they have received it.⁷⁹

Although much of the ethical debate about commodification of body parts has focussed on organs and blood, the opportunities to turn a profit from trading in these finite tangible goods is limited. The same cannot be said for ‘immortalised’ products derived from tissues: these products may be tangible – such as cell lines – or intangible – such as genetic sequence data which, when combined with the genetic sequences of others, can form a database of genetic sequences of enormous potential value.⁸⁰ The potential for commercial exploitation of these immortalised products is unfettered by the constraints associated with the original tissue; similarly, the potential for exploitation of original sources is similarly limitless. Indeed, it is this latter development that is the foundation of the nascent direct-to-consumer genetic testing sector, a sector whose privacy and consumer protection implications are presenting regulators around the world with significant legal challenges.⁸¹

⁷⁸ See Buckley R, ‘Illegal transactions: chaos or discretion?’ (2000) 20(2) *Legal Studies* 155.

⁷⁹ See note 73 above.

⁸⁰ Gotweis H and Peterson A(eds), *Biobanks: Governance in Comparative Perspective* (Routledge, 2008); Greely H, ‘The uneasy ethical and legal underpinnings of large-scale genomic biobanks’ (2007) 8 *Annual Review of Genomics and Human Genetics* 343; and Cambon-Thomsen A, ‘Assessing the impact of biobanks’ (2003) 34(1) *Nature genetics* 25.

⁸¹ Edwards K and Huang C, ‘Bridging the Consumer Medical Divide: How to Regulate Direct to Consumer Genetic Testing’ (2014) 44(3) *Hastings Center Report* 17; Allyse M, ‘23 and Me, We, and You: direct-to-consumer genetics, intellectual property, and informed consent’ (2013) 31(2) *Trends in biotechnology* 68; Nicol D and Hagger M, ‘Direct-to-consumer genetic testing – a regulatory nightmare? Will the current framework

The current legislative model of altruistic donation imposed under legislation arises from a time when those tissues had finite lifespans and uses, i.e. transplantation or dissection for research. It requires an arbitrary and artificial creation of value in the tissue once it has been separated from the source, to allow that value to vest in collectors of that tissue, rather than the source of the tissue, while clumsily ignoring the implied declaration of property necessary to enable transfer of the tissue as a 'gift'. Perpetuation of these artificial – and questionable – value creation steps is required to extend the existing body of jurisprudence to encompass derivative products of tissues including immortalised cell lines, and genetic information, which attract additional intellectual property rights, as well as converting finite existing rights into rights which potentially exist in perpetuity.

The well-documented story of Henrietta Lacks and the HeLa cell line, and the cases of *Moore v Regents of the University of California*,⁸² and *Greenberg v Miami Children's Hospital*,⁸³ provide clear illustrations of the potential for exploitation of donors in the face of vast commercial profit by strangers under the current system. More recent decisions such as *Myriad* which extend recognition of intellectual property rights to derivative information to 'strangers' at the expense of 'sources' further illustrate the need for legislation to alter the current direction of legal development.

Moore dealt with a claim brought by a patient diagnosed with a rare form of T-cell leukaemia (known as 'Hairy T-Cell') against his treating physician, a laboratory technician, a

protect consumers effectively?' (2013) 198(9) *Medical Journal of Australia* 501; and Downing N and Ross J, 'Innovation, Risk, and Patient Empowerment: The FDA-Mandated Withdrawal of 23andMe's Personal Genome Service' (2014) 311(8) *JAMA* 793.

⁸² *Moore v Regents of the University of California* 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.2d 479, cert. denied 499 U.S. 936 (1991). See Caulfield T and McGuire A, 'Policy Uncertainty, Sequencing, and Cell Lines' (2013) 3(8) *G3: Genes| Genomes| Genetics* 3.8 1205; and Bovenberg J, *Property rights in blood, genes and data: naturally yours?* (Martinus Nijhoff Publishers, 2006).

⁸³ *Greenberg v Miami Children's Hospital Research Institute* 264 F. Supp. 2d 1064 (S.D. Fla. 2003). See Greenfield D, 'Greenberg v. Miami Children's Hospital: unjust enrichment and the patenting of human genetic material' (2006) 15 *Annals of Health Law* 213.

biotechnology company, and the University of California, who employed both the doctor and the technician. The crux of the dispute was that the doctor, recognising the potential of cells isolated from the plaintiff's spleen to be used to create a cell line valuable for research, obtained the patient's consent to remove the spleen without disclosing his intention to create the cell line. Once created, the doctor, technician, and university asserted intellectual property rights over the cell line and commercialised it through the biotechnology company.⁸⁴ The plaintiff was not told that his cells had been used to create the cell line, nor did he ever consent to any stage of its creation and commercialisation.

The court found that the plaintiff could bring a claim for breach of fiduciary duty against the doctor – the only one who directly engaged with the plaintiff during the process of obtaining consent – but not against any of the other defendants. However the key part of the decision was the finding that the plaintiff had consented to the removal of his spleen (notwithstanding that he was not fully informed of the doctors' intentions) and so no claim for conversion of the primary cells from which the cell line was made could be made out, because conversion requires interference with possession without consent. Furthermore, the cells constituting the cell line itself were never a part of the plaintiff: they underwent transformation during the creation of the cell line, and so the plaintiff never had possession of them, similarly failing to establish a claim for conversion.

There are a couple of key points to note in this outcome. Firstly, the court seems to have decided that the fraudulent representations (which were probably in the form of omission rather than outright misrepresentation) were insufficient to invalidate the consent of the

⁸⁴ Healey J and Dowling K, 'Controlling conflicts of interest in the doctor-patient relationship: Lessons from Moore v. Regents of the University of California' (1990) 42 *Mercer Law Review* 989; and Dickens B, 'Living tissue and organ donors and property law: more on Moore' (1992) 8 *Journal of Contemporary Health Law & Policy* 73.

plaintiff to the removal of the cells.⁸⁵ While this is consistent with Australian case law on consent in trespass claims – particularly obtaining consent for sex without disclosure of diagnosis of sexually transmitted diseases or marital status, for example,⁸⁶ – obtaining consent under these circumstances may well be treated as equitable fraud by Australian courts, and give rise to equitable remedies including an account of profits.⁸⁷

Secondly, the Supreme Court appears to be relying on actual possession (rather than constructive possession) in considering the secondary cell line. Arguably a plaintiff in Moore’s position could argue that he intended to exercise control over his spleen, and implicitly had determined its fate in assuming that it would be used for biopsy and routine destruction as medical waste. Recognition of some donor rights in derivative information and biological materials may be an approach that would enable a wronged plaintiff – as Moore undoubtedly was – to exercise some rights over the destiny of the tissue, which would arguably be a more equitable result than the one indicated by the Supreme Court ruling.⁸⁸ If a model recognising derivative rights over materials and information from donated bodies and parts was recognised, constructive possession may well be found.

In *Greenberg*, the plaintiff donated tissue from his dead children, and assisted in fundraising and creation of a register of sufferers of Canavan disease for the purpose of identifying the genetic defect responsible for the disease, and developing a genetic test to diagnose it, with

⁸⁵ Traynor M, ‘Comment: The Unjust Enrichment Claim in *Moore v. Regents*’ (1990) 9(4) *Biotechnology Law Report* 240.

⁸⁶ In the context of non-disclosure of STD status, legislation such as the *Public Health Act 1991* (NSW) s 13(1) and *HIV/AIDS Preventive Measures Act 1993* (Tas) s 20 now requires disclosure, potentially punishable by criminal penalty. See *Kanengele-Yondjo v R* [2006] NSWCCA 354.

⁸⁷ A claim based on negligence in obtaining consent as per *Rogers v Whitaker* (1992) 175 CLR 479 would be difficult to sustain, as it is unlikely a plaintiff in Moore’s position could demonstrate that he had suffered harm, unless the splenectomy was not clinically required.

⁸⁸ It is interesting to note that Moore’s claim essentially disappears after this judgement; we found little record of abandonment of the claim or settlement in our research. An obituary marking his death notes that he received a ‘token’ settlement from UCLA: see <http://articles.latimes.com/2001/oct/13/local/me-56770>.

the intention of making the test available free of charge through a support foundation to anyone who required it. Subsequent to developing the test, the researcher who developed it, and his employer, the Miami Children's Hospital, obtained a patent, requiring anyone who wanted to administer the test to obtain a licence.

Perhaps even more so than *Moore, Greenberg* demonstrates the unfairness of refusing to recognise any property in donated tissues. In this case, the reasons for the donation were truly altruistic; the act of patenting the test in light of those objectives seems little short of unconscionable.

From cells to DNA datafiles ...

In 2013, the US Supreme Court was asked to rule on a dispute over the enforceability of a number of patents issued to biotechnology company Myriad genetics, including patents over the DNA sequence of the BRCA1 gene. BRCA1 is associated with specific patterns of breast and ovarian cancer, and is strongly heritable. The case — *Association for Molecular Pathology v. Myriad Genetics*⁸⁹ — was brought by a key professional association of molecular pathologists, as well as university-based researchers and other clinicians in response to efforts by Myriad to exercise a monopoly over the BRCA1 diagnostic market, through exercise of its patents.

After making its way through the preliminary courts, the US Supreme Court finally made a ruling that naturally occurring DNA sequences could not be the subject of patents, but cDNA

⁸⁹ *Association for Molecular Pathology v. Myriad Genetics Inc* 569 U.S. 12-398 (2013). See Kepler T, Crossman C and Cook-Deegan R, 'Metastasizing patent claims on BRCA1' (2010) 95(5) *Genomics* 312; Cho M, 'Patently unpatentable: implications of the Myriad court decision on genetic diagnostics' (2010) 28(11) *Trends in biotechnology* 548; and Evans B, 'Mining the human genome after *Association for Molecular Pathology v. Myriad Genetics*' (2013) 16 *Genetics in Medicine* 504.

sequences – modified synthetic versions of the same DNA sequence — potentially could. Interestingly this judgment is eerily reminiscent of that contained in *Doodeward*, where a critical factor noted by most commentators was the application of skill or effort on the part of the preserver in effecting a transformation of the specimen from a foetus to a specimen. Perhaps unsurprisingly, the possible patentability of cDNA is the aspect of the *Myriad* that seems to have resonated most strongly. What the US Supreme Court did not do in *Myriad* was rule on the validity of the patenting of cDNA sequences themselves: a requirement of patent law is that a patent can only be issued if the subject matter is novel, and not something that would be an obvious next step to the informed observer. There is a strong argument that making cDNA from an isolated naturally-occurring DNA sequence is not merely obvious to most molecular biologists, but is indeed standard practice as a component of many molecular biology techniques.

This decision deviates significantly from the decision of Nicholas J in *Cancer Voices Australia v Myriad Genetics Inc*,⁹⁰ which was handed down shortly before. That case, which sought to challenge the validity of Myriad's patents over the same gene sequences under Australian patent law found that the patents were valid, with Nicholas J relying on the ratio from *National Research Development Corporation v Commissioner of Patents*,⁹¹ which found that a 'product' could be patentable if "it consists in an artificially created state of affairs":

There is no doubt that naturally occurring DNA and RNA as they exist inside the cells of the human body cannot be the subject of a valid patent. However, the disputed claims do not cover naturally occurring DNA and RNA as they exist inside such cells.

⁹⁰ *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65. See Lucy Hartland, 'Cancer Voices Australia v Myriad Genetics Inc' (2013) 25(9) *Australian Intellectual Property Law Bulletin* 191; and Rimmer M, 'The Empire of Cancer: Gene Patents and Cancer Voices' (2013) 22(2) *Journal of Law, Information, and Science* 1

⁹¹ *National Research Development Corporation v Commissioner of Patents* [1959] HCA 67; (1959) 102 CLR 252.

The disputed claims extend only to naturally occurring DNA and RNA which have been extracted from cells obtained from the human body and purged of other biological materials with which they were associated.⁹²

As such, Nicholas J found that isolation and purification of a naturally occurring DNA sequence was sufficient to demonstrate patentability, as the DNA sequence did not exist in that form in nature.

In the absence of human intervention, naturally occurring nucleic acid does not exist outside the cell, and “isolated” nucleic acid does not exist inside the cell. Isolated nucleic acid is the product of human intervention involving the extraction and purification of the nucleic acid found in the cell. Extraction of nucleic acid requires human intervention that necessarily results in the rupture of the cell membrane and the physical destruction of the cell itself. And purification of the extracted nucleic acid requires human intervention that results in the removal of other materials which were also originally present in the cell. It is only after both these steps are performed that the extracted and purified product may be properly described as “isolated” in the sense that word is used in the disputed claims.⁹³

Notably, however, the Australian decision does not canvas the novelty requirement for patentability; as with the US decision, it may well be that litigation on ‘novelty’ will ultimately defeat the patentability of gene sequences.

⁹² *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [136].

⁹³ *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 at [108].

An appeal against the decision to the Full Court of the Federal Court was unsuccessful.⁹⁴ It means that any DNA sequence isolated from human tissue under ordinary laboratory methodology for the purposes of sequencing could potentially be patented by the sequencing entity, under Australian law. This would, mean that companies such as DTC providers can patent gene sequences for the purposes of establishing a monopoly diagnostic market in much the same way as Myriad has sought to do.

Ironically, those donors who contributed their DNA to these providers may well find themselves unable to access diagnostic tests developed based on their own DNA. In the world of stem cell technology, it is not hard to imagine a future where biopsied or donated biological materials are used to develop new biomaterials and synthetic organs by commercial entities, potentially beyond the reach of those whose donation made their development possible.

Tissue donor, or custodian of the family's genetic jewels?

Burgeoning commercial interest in large-scale human genetic data is largely attributable to technological advances in the fields of molecular biology and computational informatics. In 2000, simultaneous completion of a draft sequence of the entire human genome was announced by the Human Genome Project⁹⁵ – a publicly-funded international consortia of scientists who had been painstakingly chipping away at the project since 1987 – and Celera,⁹⁶ a privately funded company spear-headed by its founder J Craig Venter, whose

⁹⁴ *D'Arcy v Myriad Genetics Inc* [2014] FCAFC 115, consistent with *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50.

⁹⁵ Bodmer Wand McKie R, *The book of man: the Human Genome Project and the quest to discover our genetic heritage* (Oxford University Press, 1997).

⁹⁶ Rabinow P and Dan-Cohen T, *A Machine to Make a Future: Biotech Chronicles* (Princeton University Press, 2005); Shreeve J, *The Genome War: How Craig Venter Tried to Capture the Code of Life and Save the World*

genome the company sequenced.⁹⁷ The Human Genome Project was forecast to cost around US\$3 billion dollars;⁹⁸ Celera reportedly required just US\$300 million of private funding to complete their version, which incorporated sequence data already in the public domain. Since September 2001, the cost of sequencing a whole human genome has fallen from US\$95,263,072 to US\$5096 in October 2013,⁹⁹ corresponding with an increasing number of completed whole genome sequences.¹⁰⁰

In that time, the idea of using whole genome sequence data as a diagnostic tool, particularly directed at preventative health care, has gained credibility. No longer the stuff of science fiction, whole genome sequencing may well become mainstream within decades, as the cost of sequencing fall, and the utility of sequencing increases.¹⁰¹

Genetic sequencing services available to customers of direct to consumer genetic testing providers are more limited in scope than whole genome sequencing, focussing on fragments of the genome associated with, or identified as candidates for, involvement in the development of particular traits or conditions.

Although buccal swabs or saliva samples are commonly used as source material from which the DNA is extracted for sequencing, it is important to note that virtually any body tissue could be used. In particular, it is likely that some curators of established tissue banks may

(Knopf, 2005); and Kling J, 'Where the future went' (2005) 6(11) *European Molecular Biology Organization Reports* 1012.

⁹⁷ Venter C., Adams M, Myers E., Li P, Mural R, Sutton G., Smith H, 'The sequence of the human genome' (2001) 291(5507) *Science* 1304; and J Craig Venter, *A Life Decoded: My Genome: My Life* (Penguin, 2007).

⁹⁸ Collins F, 'Medical and societal consequences of the human genome project' (1999) 341(1) *New England Journal of Medicine* 28.

⁹⁹NHGRI <https://www.genome.gov/sequencingcosts/>

¹⁰⁰ Check E, 'Celebrity genomes alarm researchers' (2008) 447(7143) *Nature* 358. Watson, Venter, etc- other famous people who have been WGS

¹⁰¹ Shendure J and Ji H, 'Next-generation DNA sequencing' (2008) 26(10) *Nature biotechnology* 1135. For a popular account see Davies K, *The \$1,000 genome: the revolution in DNA sequencing and the new era of personalized medicine* (Simon and Schuster, 2010).

seek to 'digitise' their collections in future, by sequencing all the samples making up the collection. In doing so, curators of tissue collections are supplementing – and possibly replacing – their physical tissue collections with limited lifespan and transferability, with an intangible data file, capable of infinite transmission, and perpetual existence. In contrast, commercial providers of genetic sequencing services place no value on the tissue samples they collect, apart from the sample as a vessel from which genetic data can be extracted.

Transformation of tissue into derivative products, including cell lines or genetic data, significantly changes the legal status of those tissues, either by artificially 'creating' rights that didn't exist while the tissue was part of the source, or changing the nature of the rights attached to the substrate from property rights to intellectual property rights.¹⁰² Immortalisation of the derivative product – as either a data file or a cell line – may additionally create property which can theoretically exist infinitely in perpetuity, barring destruction of the data file or extinction of the cell line.

As *Moore* and *Greenberg* demonstrated, that transformation can provide 'stranger' commercial entities with rights that never existed while the tissue was part of the source, and fell outside the scope of contemplation at the time the source agreed to provide the material. Failure to recognise source rights – a consequence of the donation model of regulating to prevent commodification of human tissue – means that initial recognition of those rights only occurs once the material enters the hands of the stranger; the source has

¹⁰² Lewis M, 'Laboratory specimens and genetic privacy: evolution of legal theory' (2013) 41(1) *The Journal of Law, Medicine & Ethics* 65; and Tallacchini M, 'Human Tissues in the "Public Space": Beyond the Property/Privacy Dichotomy' in Pascuzzi G, Izzo U and Macilotti M(eds), *Comparative Issues in the Governance of Research Biobanks* (Springer, 2013) 87; and Hawkins N, Kanellopoulou N, Kaye J, Melham K, Boddington P, Curren L, and Gowans H, 'Ownership of Biomedical Information in Biobanks' in *Comparative Issues in the Governance of Research Biobanks* (2013) 77.

no rights over the material and, logically, will be unable to exercise rights over anything derived from that material.

As we have discussed above, the ‘altruistic’ model of tissue ‘donation’ is inherently problematic, and conflates ethical concerns about commodification of human tissues with alienation of all source rights in a way that is inconsistent with the legal meaning of a gift. Historically it has been argued that recognition of donors in financial terms would compromise the altruism of the act of donation, and expose people to coercion.¹⁰³ This argument is problematic for several reasons, including the assumption that financial incentive is the only form of coercion that could arise in this context – disregarding emotional pressure, or a sense of social obligation of the type that, ironically, is often employed by government campaigns to increase participation;¹⁰⁴ because there are other motivating factors aside from altruism which might persuade people to donate blood or organs for clinical use – ‘pay it forward’; ‘it might be me in future’; ‘blood saved my life’; and finally, research by some investigators¹⁰⁵ which indicates that there is a sense of reciprocity about the transaction of donating blood or tissue for research purposes. Rather than being altruistic, there is an expectation that the donor, or the donor’s community, will derive some benefit as a result of their participation, a motivation which was certainly in evidence in *Greenberg*.

Furthermore, it only prohibits recognition of the commercial value of tissues at the supply end of the transaction; recipients of ‘donated’ tissue are free to transfer the material to

¹⁰³ Notably the US and other jurisdictions permit financial compensation for donation of sperm, but not blood.

¹⁰⁴ Conly S, *Against Autonomy: Justifying Coercive Paternalism* (Cambridge University Press, 2012); Thaler T and Sunstein C, *Nudge: Improving Decisions about Health, Wealth, and Happiness* (Yale University Press, 2008); and Sunstein C, *Why Nudge? The Politics of Libertarian Paternalism* (Yale University Press, 2014).

¹⁰⁵ Tutton R, ‘Gift Relationships in Genetics Research’ (2002) 11(4) *Science as Culture*, 523-542.

others for commercial consideration. As a vehicle for the prevention of exploitation, therefore, the model is deeply flawed.

The emphasis on the financial implications of recognising property in donated tissues has occurred at the expense of other considerations that may be important to the source. In alienating the right to receive financial compensation, all other rights – including the right to attach conditions to the gift – have similarly been alienated from the source of the tissue. Titmuss,¹⁰⁶ in his landmark book on blood donation, highlighted the anonymity of donation as one of the program's outstanding features, fundamental to the integrity of altruistic blood donation in the UK. By being anonymous, donors don't know – and can't control – who receives their 'gift'.

But is the enforced anonymity of the scheme either necessary, or even beneficial? It is argued that anonymity prevents the decision of a donor to donate being influenced by 'irrelevant considerations' such as age, gender, or ethnicity of the potential recipient. A counter argument may well be that it is a denial of dignity. It denies the autonomy of the donor – by denying them access to information that they may view is relevant to their 'informed consent, and is paternalistic because it assumes that donors are incapable of making 'the right decision' if they are informed of all the information they may feel is relevant.¹⁰⁷ Furthermore, it presupposes there indeed *is* such a thing as 'the right decision'. A donor may feel passionately that they don't want their organs to go to a former smoker, for example – knowing that they have no control over that decision – and that their wishes

¹⁰⁶ Titmuss R, *The Gift Relationship, From Human Blood to Social Policy* (Allen & Unwin, 1971).

¹⁰⁷ Angrist M, 'Eyes wide open: the personal genome project, citizen science and veracity in informed consent' (2009) 6(6) *Personalized Medicine* 691. See however Brownsword R, 'The cult of consent: fixation and fallacy' (2004) 15(2) *King's Law Journal* 223; Bray M, 'Personalizing Personalty: Toward a Property Right in Human Bodies' (1990) 69 *Texas Law Review* 209; and Hughes P, 'Presumed consent: state organ confiscation or mandated charity?' (2009) 21(1) *HEC Forum* 1.

may not even be heeded – may influence some people to decide *not* to donate their organs, removing a whole body's worth from the potential supply, rather than simply attaching a condition to the one the donor might want to be specific about. Furthermore, there is already evidence of some donors, donor family members, and recipients, tracking down the other parties to the organ donation transaction, in response to a survivor need that is not being fulfilled under the current system of anonymity. While the model undoubtedly owes much to Rawls' 'veil of ignorance',¹⁰⁸ it begs the question as to whether its importation into tissue and organ donation – and by extension genetic information – is appropriate. In pursuit of a misguided ideal of 'altruism', tissue and organ 'donors' have been forced to sacrifice all their rights, including rights to privacy, and the rights to attach conditions to, or even be informed of the ultimate fate of, that donated material.

This issue is of enormous significance once tissue is transformed into genetic data. The paradoxical combination of individuality and commonality represented by DNA presents unique legal and ethical challenges, extending beyond the issues typically associated with donated tissue.

Significant portions of an individual's genome are shared with their blood relations. This commonality means that it is potentially possible to examine the DNA sequence of one person, and make predictions about the likely genetic sequences of their relatives – past, current, and future. The power to draw inferences about health and other traits of individuals related to the original tissue source from data extracted from that source, without direct involvement from the individual, demonstrates the importance of getting rights protection for sources and, by extension, their relatives, right. The consequences of

¹⁰⁸ Rawls R, *A Theory of Justice* (Harvard University Press, 1st ed, 1971) 136.

getting it wrong are more significant, as a result of the greater number of people potentially affected by exploitation of donors, and the fact that the substrate material (data) can exist in perpetuity, and be transferred and distributed an infinite number of times.

To date, consumer protection issues have been the main focus of regulatory attention with respect to large scale genetic testing. Concerns about the quality of the information sources receive in exchange of their contribution have dominated discussion about the technology. In some respects, these concerns are essentially a teething problem: as more people participate, the robustness of predictions based on genetic sequence data will improve, as an implication of obtaining a bigger dataset. The immediate issue, therefore, is ensuring that participants recognise that they are paying to participate in as yet unvalidated research, for the most part, rather than receiving clinically validated information which should inform decision-making about health and lifestyle.¹⁰⁹

More significant concerns – particularly around source privacy, third party (source relative) rights, and the right to remain informed – are likely to be of longer duration.

Historically, deidentification of participant information has been ethically approved as a way of ensuring altruistic participation and denying any obligation on the part of researchers to communicate personal results to participants in research. By deidentifying data, participants could rely on anonymity to protect their privacy, and researchers were relieved of any obligation to contact participants in the event they discovered anything that should be

¹⁰⁹ Roberts S and Ostergren J, 'Direct-to-consumer genetic testing and personal genomics services: a review of recent empirical studies' (2013) 1(3) *Current genetic medicine reports* 182; Murray M, 'Why We Should Care About What You Get for "Only \$99" From a Personal Genomic Service' (2014) 160(7) *Annals of internal medicine* 507; Kalf R, Bakker R and Janssens C, 'Predictive ability of direct-to-consumer pharmacogenetic testing: when is lack of evidence really lack of evidence?' (2013) 14(4) *Pharmacogenomics* 341; Merz J, Kriss A, Leonard D and Cho M, 'Diagnostic testing fails the test' (2002) 415(6872) *Nature* 577; and Adams S, Evans J and Aylsworth A, 'Direct-to-consumer genomic testing offers little clinical utility but appears to cause minimal harm' (2013) 74(6) *North Carolina Medical Journal* 494

brought to the attention of the participant. As has been demonstrated throughout the literature on direct to consumer genetic testing, there are significant concerns about privacy protection for donors, and also relatives of donors, who may find that the commonality of their DNA with a related donor makes their own genetic sequence easily identifiable – including any medical conditions they may be likely to develop.¹¹⁰ Empirical studies have demonstrated that ‘deidentification’ of genetic data is insufficiently robust – genetic sequence data, combined with some generic level demographic information can be sufficient to reidentify specific individual donors simply through the use of publicly available records, such as phone directories and electoral rolls.¹¹¹

Reliance on deidentification as a de facto protection for participant privacy, in lieu of recognising source rights, is consequently problematic. Furthermore, some research participants want their personal results, indicating that altruism may not be the only factor motivating participation.

In commercial genetic testing services, there is no comparable deidentification, and consumers pay for the information they receive. The alienation of rights that seems to accompany the ‘donation’ discourse simply doesn’t apply, as consumers pay for the service. It is problematic to assume that, in addition to providing tissue samples and funds to offset the costs of extracting data from those samples, consumers impliedly agree to waive any other rights – including a right to genetic privacy, transfer to a third party, or the rights of

¹¹⁰ Chadwick R, ‘The right to know and the right not to know. Ten years on’ in Rehmann-Sutter C and Müller H (eds), *Disclosure dilemmas: Ethics of genetic prognosis after the ‘right to know/not to know’ debate* (2009) 9; Andorno R, ‘The right not to know: an autonomy based approach’ (2004) 30(5) *Journal of Medical Ethics* 435; Laurie G, *Genetic privacy: a challenge to medico-legal norms* (Cambridge University Press, 2002); and Chadwick R, Levitt M and Shickle D (eds), *The Right to Know and the Right Not to Know: Genetic Privacy and Responsibility* (Avebury, 1997).

¹¹¹ Schmidt H, and Callier S ‘How anonymous is anonymous? Some suggestions towards a coherent universal coding system for genetic samples’(2012) 38 *Journal of Medical Ethics* 304.

third party relatives to privacy – without express agreement. Indeed, even if they did agree to do so, it is arguable whether such agreement would be valid, particularly in the context of third party relative's rights. Nonetheless, this seems to be the direction the law is currently developing in, relying on the questionable foundations provided by the jurisprudence in tissues to date.

The Icelandic company DeCODE provides a good illustration of some of the implications of the 'no property in sources' principle when applied to genetic information derived from excised biological materials.

Iceland's historical geographical isolation makes it an attractive target for large scale genetic analysis its population. DeCODE Genetics was established to obtain and sequence genomic DNA samples from Icelanders to establish a data collection which could then be used to identify new candidate genes associated with disease, and better target research and development into novel therapies.¹¹² Creation of the data collection was supported by a government decision to allow the company unprecedented access to the health records of Icelanders, to supplement the genetic data they collected. The onus was placed on individuals to opt-out if they did not want their medical records released to the company. The commercial value of the database cross-matching genetic sequence data with health records is significant, both in actual terms through licensing agreements with other biotech companies who want to interrogate the database for their own research purposes, and through indirect benefits, as the company compiling the database will in most cases use it to identify candidate genes and therapies which will ultimately generate intellectual property assets in the forms of new pharmaceuticals and diagnostic tests.

¹¹² Fortun M, *Promising Genomics: Iceland and DeCODE Genetics in a World of Speculation* (University of California Press, 2008).

After experiencing significant financial trouble, DeCODE was sold to an American biotechnology company. Key amongst ethical concerns raised by commentators at the time of the sale was the question of control of the considerable database of Icelandic genetic information, and the effect of the sale on any benefits to the Icelandic population that was an incentive for donor participation in establishing the collection of biological materials.

DeCODE genetics has recently undertaken a recruitment drive to expand its genomic DNA collection to 100,000 Icelanders – nearly a third of the total population. Contributors – unable to receive financial recognition for their personal contribution to what will ultimately become a valuable resource – receive a T-shirt. Control of that information will rest in a foreign owned company. Icelanders as a population will have limited rights over the genomic database of their population; and individual contributors will have no rights at all, apart from any arising under contract law, or consumer protection or privacy legislation in the event that it applies to foreign owned companies.¹¹³ Essentially, ‘donors’ of genomic DNA are ‘giving’ commercial entities their biological materials – sometimes with money – in exchange for, at best, genetic data of questionable value. The recipients, in contrast, acquire a commercially lucrative database that can be both exploited by them for development of novel therapies and diagnostics, or sold or licensed to other companies. Donors have no say over who future licensees accessing their genetic and health data may be.¹¹⁴ They cannot specify that the information can only be sold to not-for profit, or public, users, or to whomever is willing to pay the fees. They cannot specify that their information is only to be

¹¹³ F Merz J, McGee G and Sankar P, “‘Iceland Inc.’?: On the ethics of commercial population genomics’ (2004) 58(6) *Social Science & Medicine* 1201.

¹¹⁴ Knoppers B, ‘Consent to ‘personal’ genomics and privacy. Direct-to-consumer genetic tests and population genome research challenge traditional notions of privacy and consent’ (2010) 11(6) *European Molecular Biology Organization Reports* 416; and Arnason V, ‘Coding and consent: moral challenges of the database project in Iceland’ (2004) 18(1) *Bioethics* 27. A perspective is provided by English V and Sommerville A, ‘Presumed consent for transplantation: a dead issue after Alder Hey?’ (2003) 29(3) *Journal of Medical Ethics* 147.

used for certain purposes, such as researching cures for cancer, rather than profiling relationships between genes and behaviour for the purposes of discrimination or stereotyping. Effectively, once the ‘donor’ hands over their sample, all their rights – and protections – end.

There is also a significant question over the equity of demanding that donation of DNA for research is altruistic. Icelanders are a desirable target population because of their genetic homogeneity. But other groups, particularly ethno religious and indigenous populations, are also highly sought-after participants.¹¹⁵ In many instances, these groups already experience significant socio-economic disadvantage and research fatigue.¹¹⁶ They may consider that they are being objectified as objects of biocolonialism alongside flora and fauna.¹¹⁷ Is it, therefore, fair, that they be asked to disproportionately shoulder the burden (and even expose themselves to related risks of genetic discrimination) of participation in clinical research they may in fact never be in a position to benefit from? In *The Immortal Life of Henrietta Lacks*, Rebecca Skloot identified the unfairness of using cells taken from a dying disadvantaged black woman to create a commercially valuable medical research tool, in a world where her children could not afford to pay for healthcare.¹¹⁸ Research fatigue amongst certain groups of people is a well-documented ethical concern. It reflects a fundamental principle of ethical biomedical research, that of justice.¹¹⁹ If we accept dignity as inalienable and applying to all people equally, as a function of the intrinsic worth model

¹¹⁵ See also Van Assche K, Gutwirth S, and Sterckx S, ‘Protecting Dignitary Interests of Biobank Research Participants: Lessons from Havasupai Tribe v Arizona Board of Regents’ (2013) 5(1) *Law, Innovation and Technology* 54.

¹¹⁶ Smith L, *Decolonizing Methodologies: Research and Indigenous Peoples* (Zed Books, 1999).

¹¹⁷ Parry B, *Trading the genome: Investigating the commodification of bio-information* (Columbia University Press, 2004) 145; Sahota P, ‘Body Fragmentation: Native American Community Members’ Views on Specimen Disposition in Biomedical/Genetics Research’ (2014) 5(3) *AJOB Empirical Bioethics* 19

¹¹⁸ Skloot R, *The Immortal Life of Henrietta Lacks* (Crown, 2010).

¹¹⁹ Beauchamp T & Childress J, *Principles of Biomedical Ethics* (Oxford University Press, 6th ed, 2009). See also Rawls J, ‘The Sense of Justice’, in Samuel Freeman (ed) *John Rawls: Collected Papers* (Harvard University Press, 1999) 115.

put forward by Kant, surely the consequences of positions taken in the interests of dignity require that the consequences of those decisions be equitably born and the benefits be fairly distributed.

Where to from here?

To return to our earlier discussion of Kant, the motivation of the recipient, as a commercial entity using samples for genetic testing, to develop information or testing of future commercial value, may also be relevant in any discussion of dignity in the context of recognising property in bodies and derivative information. At the present time, the inconsistent application of ethical arguments derived from Kant serve only to deprive sources of any rights over 'donated' tissue which, if accompanied by recognition of those same rights in third party strangers to the material, can only be viewed as exploitative. Furthermore, dignity is a difficult concept – a state of absolute perfect dignity seems unlikely to exist. Perhaps, therefore, the most that can be achieved is a prioritisation of the interests of all stakeholders in a way that recognises the differences dignity may have when applied to them individually, and strives towards a best – or even least worst – outcome.

To that end, it may be timely to return to *Doodeward*, and reconsider what the judgement in that case actually said.

Griffith CJ stated that “it does not follow from the mere fact that a human body at death is not the subject of ownership that it is forever incapable of having an owner”.¹²⁰ He continued:

¹²⁰ *Doodeward v Spence* [1908] HCA 45; (1908) 6 CLR 406, 411.

In my opinion there is no law forbidding the mere possession of a human body, whether born alive or dead, for purposes other than immediate burial. *A fortiori* such possession is not unlawful if the body possesses attributes of such a nature that its preservation may afford valuable or interesting information or instruction. it is not *contra bonos mores* to retain such a specimen unburied. If one medical or scientific student may lawfully possess it, he may transfer the possession to another.¹²¹

Further,

If then, there can, under some circumstances, be a continued rightful possession of a human body unburied, I think, as I have already said, that the law will protect that rightful possession by appropriate remedies. I do not know of any definition of property which is not wide enough to include such a right of permanent possession. By whatever name the right is called, I think it exists, and that, so far as it constitutes property, a human body, or a portion of a human body, is capable by law of becoming the subject of property.¹²²

Interestingly, the feature of *Doodeward* that is commonly – and, we argue, incorrectly – identified as an ‘exception’ to the principle of no property in the body actually appears more like recognition of an equitable interest arising in the foetus, as a consequence of the investment of ‘skill and expertise’ in its preservation. Such interests have been found in all manner of property by courts, and there is an extensive body of case law about the circumstance where the actions of a person in ‘transforming’ property give them some rights in it, provided the actions were performed bona fides.

¹²¹ *Doodeward v Spence* [1908] HCA 45; (1908) 6 CLR 406, 413.

¹²² *Doodeward v Spence* [1908] HCA 45; (1908) 6 CLR 406, 414.

On this basis, we argue that *Doodeward*, rather than preserving the doctrine of no property in the body, actually rejects it in favour of a more nuanced conception of property rights in the body, tacitly accepting that interests grounded in possession and equity may be applicable.

Such a model could potentially recognise rights of sources, even if on ethical ground the prohibition of contribution for financial reward was maintained under law. The rights need not amount to absolute ownership, but could include weaker equitable – but still legally enforceable – rights, including a right to be informed of future developments, a right to be consulted about potential sale or licensing of genetic data, and rights regarding the protection of privacy, not just of the source, but also third party rights such as those that are a necessary incident of the intergenerational and interpersonal nature of genetic information. Particularly vulnerable is the right of relatives **not** to know if they are at risk of developing a serious genetic disease, based on a close family members' decision to contribute their DNA to a research program.¹²³

Conclusion

The past decade has seen unprecedented growth in investment by private entities in DNA data banks and tissue collections.¹²⁴ These investors are responding to what they perceive as a growing – and potentially profitable – market in medical research. If donor discourse, requiring complete alienation of all source rights, was originally justifiable on the basis that

¹²³ Arnold B and Bonython W, 'Relatively speaking : genetic privacy and public interest determinations 11 and 11A under the Privacy Act 1988 (Cth)' (2010) 7(1) *Privacy Law Bulletin* 2; Chadwick R, 'The right to know and the right not to know. Ten years on' in Rehmann-Sutter C and Müller H (eds), *Disclosure dilemmas: Ethics of genetic prognosis after the 'right to know/not to know' debate* (2009) 9; Andorno R, 'The right not to know: an autonomy based approach' (2004) 30(5) *Journal of Medical Ethics* 435; Laurie G, *Genetic privacy: a challenge to medico-legal norms* (Cambridge University Press, 2002); and Chadwick R, Levitt M and Shickle D (eds), *The Right to Know and the Right Not to Know: Genetic Privacy and Responsibility* (Avebury, 1997).

¹²⁴ Vaught J, Rogers J, Carolin T and Compton C, 'Biobankonomics: developing a sustainable business model approach for the formation of a human tissue biobank'(2011) 42 *J Natl Cancer Inst Monogr* 24.

the benefits of donation would be freely available, and that collections would be public, rather than private, assets, the recent trend towards patenting of cell lines and genetic tests and sequences would suggest that such is no longer the case. Furthermore, arguments that recognition of any rights of sources would be contrary to the human dignity of the source ignore the implications for the dignity of those receiving and commercialising the tissue, entrenching exploitation of source rights in a way that is ethically unsupportable.

Despite the emergence of synthetic biology, national and international law governing use of human biological materials and rights regarding the body as information remains firmly buried in the era of grave robbers. That law has proven to be inadequate in dealing with existing challenges presented by biotechnology, such as exploitation of tissue donors.

Litigation in this context is moving from the tangible to the informational, particularly in the form of disputes over intellectual property rights. As has already been indicated throughout this article, there are significant concerns about the intergenerational consequences for privacy arising from developments in genetic sequencing, particular in the context of inadequate regulation of commercialised activities.

The idea of multiple parties concurrently exercising rights in property is not new, and is something that should be explored further. Recognition of the rights of donors need not amount to absolute and exclusive ownership; as is currently the case, donors could elect to waive their rights absolutely if they so choose. For other donors, formal recognition of those rights would put them in a position where they could negotiate the circumstances of the donation in a meaningful way; either by ensuring that any medical expenses associated with donation were paid, that their privacy was adequately protected, that the information derived from their donation was used for benevolent rather than commercial purposes, or

even through to a licensing fee-based or fully commercial arrangement.¹²⁵ Currently, violation of a donor's wishes and rights can only be redressed through contract law – assuming it applies, noting the lack of consideration received by many donors – or legislative measures such as consumer protection or privacy protection laws, which may be limited.

Law and biotechnology will continue to collide in the future: disputes may shift from disagreements about the right to retrieve and use sperm isolated from a dead man, to disputes over use of a tissue biopsy as a template for 3D printing of synthetic organs, but those disputes will nonetheless remain for as long as the legal system disregards the existence of donor rights at the expense of big business.

This article has argued that, traditionally, the common law has adopted an overly simplistic and absolutist approach to property rights. From an initial position – albeit misguided – of arguing that there is no property in the body, subsequent case law has gradually recognised that there are property rights in bodies and tissue. However, much of the analysis of these decisions has failed to recognise that they are limited in scope to prioritisation of the competing claims presented to them, rather than characterisation of claims as absolute ownership, in the traditional sense of the term. Similarly, legislation has generally adopted an all-or-nothing approach to recognition of property rights in bodies and tissues – particularly in the context of financial transactions associated with the alienation or licensing of those interests, despite a substantial body of academic and public commentary highlighting inconsistencies and injustices caused by these prohibitions.

¹²⁵ Among writings on a 'genetic commons' approach see Barnett J, 'Cultivating the Genetic Commons: Imperfect Patent Protection and the Network Model of Innovation' (2000) 37 *San Diego Law Review* 987; Dickenson D, *Property in the Body: Feminist Perspectives* (Cambridge University Press, 2010); Scharper S and Cunningham H, 'The Genetic Commons: Resisting the Neo-liberal Enclosure of Life' (2006) 50(3) *Social Analysis* 195; and Schmietow B, 'Conceptualizing the commons: genetic resource management, property claims, and global innovation ethics' (2012) 8(1) *St Antony's International Review* 70.

Similarly, there are inconsistencies in the way rights and interests are protected based on the context under which the tissue was provided – i.e. police testing, clinical use, or for research – which are logically insupportable. Many of the hard line philosophical principles about dignity and justice have been misinterpreted or inconsistently applied, or have simply not been future-proof.

Finally, this article argues that increasing commercial exploitation of genetic sequence data highlights the need for a consistent framework of rights and donor recognition in the context of derivative rights. Migration of large-scale derivative biological information from the tightly-regulated university and hospital research sector to the private commercial biotechnology and data sector means that localised oversight by institutional or national ethics committees may no longer be adequate.

The current body of jurisprudence on rights associated with bodies, tissues, and derivative information is incoherent and antiquated. Australian law is uniquely positioned to reform the current system to permit recognition of donor interests falling short of absolute ownership, including by formally recognising equitable rights of the type alluded to in *Doodeward*. Such a reform is overdue; the changing nature of entities collecting large quantities of biological data derived from tissues donated by private citizens provides an ideal opportunity to commence such reform.