1

Bodies of Value

1 Introduction

Human biomaterials can be valuable in different ways: valuable for their contribution to science and medicine, valuable commercially, and valuable to the persons from whom they are removed. The values attached to such materials have evolved over time; something that, in no small part, has been driven and mediated by advances in biotechnology and medicine. One consequence of this is the emergence of novel challenges for the law, including questions of how the law ought to resolve disputes over the use and control of biomaterials. It is the transformation in the use and value of biomaterials which prompts the enquiry at the heart of this book. This, along with recent legal decisions, means that questions of what ought and ought not to be done to and with our bodies and bodily tissues need to be more fully explored. In particular, questions regarding who ought or ought not to be able to control the uses (and abuses) of these are important.

Property, as we will see, is one way of securing control over biomaterials; albeit often this has been utilised to the benefit of third parties. When we say that a resource falls within the domain governed by property relations we are acknowledging a particular way of controlling that resource. This recognition brings such resources within the purview and protections of existing property institutions. Those who argue that persons should be seen as having property in their separated biomaterials think that individuals ought to have this type of control therein, as well as any consequent protections in their exercise of that control. The effect of being denied property in, and ownership of, our separated bodily tissues, is that we are prevented from having adequate control over (our interests in) them. This is a pressing concern where that control is ceded to other parties, such as researchers and biotech companies. This book is thus an exploration of property as applied to human biomaterials. Specifically, it offers a new, philosophically grounded, defence of the position that

persons ought to be seen as the holders of property rights in their separated biomaterials (at least initially).

2 On Control and Conflict

Below are two stories: one of a woman and one of a man whose respective cells and blood revolutionised medical science and medicine. Both stories are about control; control over one's body and bodily tissues, and control over one's legacy. To be more exact, one of the accounts given is really about *lack* of control over these things and how it can be lost at the hands of medicine and medical research. I also outline several legal cases, from three common law jurisdictions – the United States, England and Wales, and Australia – all of which involve disputes over human tissue. Together these stories and cases reveal how, with advancing technology, human tissues, cells, and other biomaterials can be put to a multitude of novel uses, often not foreseen by the person who is the source of those materials. Through them we can see how this changing biotechnological landscape creates and confers new value(s) on these materials, something which is brought into sharp focus by the commercial and quasi-commercial interests of a variety of actors.

2.1 Immortal Cell Lines and Antibodies

In January 1951, Henrietta Lacks was diagnosed with cervical cancer. It turned out to be a particularly aggressive form of the cancer, from which Henrietta died within nine months.[1] Three months earlier when she had given birth to her fifth child, there had been no mention of the tumour in her medical notes.[2] During the investigation of her signs and symptoms and subsequent treatment at Johns Hopkins hospital several tissue samples were taken of the cancerous cervical tissue. These samples were given to George and Margaret Gey who were, at the time, working on creating an immortal cell line. Attempts to do this with human cells had not been successful up to this point.[3] However, Henrietta's cells (called HeLa) were unlike any others the Geys had worked with; they simply grew and grew and grew (at an almost alarming rate).[4] It would later emerge that the cells grew so prolifically that they could get carried on dust particles and

[1] For the story of Henrietta Lacks and the HeLa cell line see R. Skloot, *The Immortal Life of Henrietta Lacks* (London: Pan Books, 2010).
[2] *Ibid.*, p. 20. [3] *Ibid.*, pp. 40–48. [4] *Ibid.*, p. 47.

infect other cell cultures.[5] Within a short time, HeLa cells were being mass produced and shipped around the country for use in research. At first they were used for research on the poliovirus and later for other kinds of research. To name but a few, the use of HeLa cells has contributed to advances in cell culture techniques,[6] the discovery of the number of chromosomes in cells and, consequently, chromosomal abnormalities,[7] the understanding of how viruses function,[8] and the discovery that strains of human papillomavirus cause cervical cancer.[9] They are currently used for research and traded all over the world.[10] Henrietta Lacks never knew that her cells were being used for these purposes. The first time her name appeared in print in connection with the cells was twenty years later.[11] Additionally, her family only found out about the cells in 1973.[12]

In 1970, before Henrietta Lacks' name was published in relation to the HeLa cell lines, Ted Slavin started selling his blood to different biotech companies. Ted's blood serum had extremely high levels of Hepatitis B antibodies; this had been caused by repeated exposure through blood transfusions in the 1950s. Ted suffered from haemophilia, which was the reason for the repeated transfusions.[13] Around the early 1970s, companies began developing testing kits for Hepatitis B. In order to conduct research into these, they required a supply of serum with antibodies to the Hepatitis B virus. As such, Ted realised that his blood was valuable to these companies; he contacted several companies and started selling his blood for up to $10/ml. Furthermore, he set up a company to collect and sell blood from other people in similar situations.[14] Since Ted's

[5] *Ibid.*, pp. 176–180. [6] *Ibid.*, pp. 114–115. [7] *Ibid.*, pp. 116–117. [8] *Ibid.*, p. 113.
[9] *Ibid.*, pp. 242–243. [10] *Ibid.*, pp. 108–121. [11] *Ibid.*, pp. 198–199.

[12] *Ibid.*, pp. 206–217. In saying this I am attentive to the comments regarding the historical context made recently by Duncan Wilson. He cautions against assessing the historical circumstances surrounding the HeLa cell line through our contemporary ethical lens. He argues that to do so 'projects a current view of the world backwards and overlooks how historical actors lived and worked in a different moral climate' ('A troubled past? Reassessing ethics in the history of tissue culture' (2016) 24 *Health Care Analysis* 246, 256). Nevertheless, by contrasting the Lacks story with that of Ted Slavin, as well as contemporary legal cases, we can appreciate how different historical contexts and times can impact on issues of use, control, and conflict which are central to the analysis in this book.

[13] B.S. Blumberg *et al.*, 'Ted Slavin's blood and the development of the HBV vaccine' (1985) 312 *New England Journal of Medicine* 189. See also Skloot, *Immortal Life*, pp. 230–231 and R. Skloot, 'Taking the least of you', *New York Times Magazine* (16 April 2006), www.nytimes.com/2006/04/16/magazine/16tissue.html?pagewanted=all (accessed 27 November 2017).

[14] Blumberg *et al.*, 'Ted Slavin's blood'. For a legal case involving the sale of blood see *Green* v. *Commissioner* 74 TC 1229 [1980]. The case involved Margaret Green who repeatedly

haemophilia often meant he could not work, this provided him with a means to earn some money.[15] In addition to the companies which were trying to develop commercial testing kits, public laboratories were also conducting research into blood-borne viruses. Accordingly, Ted contacted Dr Baruch Blumberg at the National Institutes of Health (NIH) and agreed to provide samples at no cost for research purposes. Dr Blumberg was the Nobel Prize-winning scientist who had discovered the Hepatitis B virus.[16] Along with colleagues at the NIH, he used Ted's blood 'in research on the radioimmunoassy test, tissue fluorescence techniques, the development of a vaccine against Hepatitis B virus, and the prevention of primary cancer of the liver'.[17] Ted Slavin died in 1984.

2.2 Spleens, Genes, and Prostates

In 1976, around the time that Ted Slavin was selling his blood to biotech companies, John Moore was diagnosed with hairy cell leukaemia. At the time, he lived in Alaska working on the oil pipeline.[18] The form of leukaemia that Moore had was rare. For this reason, he was referred to Dr Golde at the University of California, Los Angeles (UCLA) medical school where Dr Golde removed his spleen. Later, John Moore moved to Seattle, but for nearly seven years he continued to make regular trips to UCLA to see Dr Golde. At these visits samples of blood and bone marrow, amongst other tissues, were collected; Moore thought that this was part of his ongoing care. When, during visits, he started being asked to sign consent forms, which included a waiver of his pecuniary interests, he began to ask questions. Eventually, he contacted a lawyer, whereupon he discovered that Dr Golde and colleagues had been conducting research on his tissue.[19] As it turned out, in 1979, they had created a cell line (the 'Mo' cell line) from Moore's tissue. On the 30 January 1981, the regents of UCLA filed for a patent covering the cell line itself, along with a variety of methods for producing products from the cells.[20]

sold her blood to a blood bank. The issue in the case was whether expenses incurred as a result of this were tax deductible. The Court concluded that some expenses were eligible. For a discussion of this see A. Hyde, *Bodies of Law* (Princeton: Princeton University Press, 1997), pp. 57–62.

[15] Skloot, *Immortal Life*, p. 231. [16] *Ibid.* [17] Blumberg *et al.*, 'Ted Slavin's blood'.
[18] Skloot, *Immortal Life*, p. 227. [19] *Ibid.*, p. 229.
[20] *Moore* v. *Regents of the University of California* 51 Cal.3d 120 at 127 [Cal, 1990] [*Moore*, Supreme Court].

Dr Golde and his colleague Shirley Quan, a researcher at UCLA, were listed as the inventors of the cell line. Subsequently, the patent was issued on the 30 March 1984.[21]

In 1984, the year that Ted Slavin died, John Moore filed a lawsuit against Dr Golde, the researchers, the regents of UCLA, and the pharmaceutical companies who bought the patent licences. The case was tried on thirteen causes of action; these included an action in conversion:[22] '[c]onversion involves an intentional dealing with "goods" that is seriously inconsistent with the possession or right to immediate possession of another person'.[23] Thus, for Moore's claim in conversion to succeed, the Court would have had to have found that his tissues were in fact his property or, at least, that he had immediate rights of possession with regards to them. Moore claimed that 'he continued to own his cells following their removal from his body, at least for the purpose of directing their use'.[24] The majority in the Court of Appeal of California (second district) seemingly agreed with his submission and upheld the action in conversion, maintaining that a 'patient must have the ultimate power to control what becomes of his or her tissues'.[25] However, the Supreme Court of California subsequently overturned the ruling.[26] The reasoning of the Court in reversing the appellate decision largely rested on the perceived negative impact on research that permitting individuals to claim property in their own tissues might have. It was the opinion of the Court that imposing a liability in conversion on researchers could hamper research and its potential benefits to society.[27] The fidelity of this reasoning, as we will see later in the book, is questionable. The defendants were not conducting gratis research solely for wider societal benefit; they had, in fact, filed a number of patents pursuant of the research, which restricted access to its benefits (at least in the absence of the ability to pay for it). Somewhat ironically, the majority in *Moore*, in their judgment

[21] *Ibid.*
[22] See *ibid.* at 128: (1) conversion; (2) lack of informed consent; (3) breach of fiduciary duty; (4) fraud and deceit; (5) unjust enrichment; (6) quasi-contract; (7) bad faith breach of implied covenant of good faith and fair dealing; (8) intentional infliction of emotional distress; (9) negligent misrepresentation; (10) intentional interference with prospective advantageous economic relationships; (11) slander of title; (12) accounting; and (13) declaratory relief.
[23] C. Witting, *Street on Torts*, 14th edn (Oxford: Oxford University Press, 2015), p. 280.
[24] *Moore*, Supreme Court at 134.
[25] *Moore* v. *Regents of the University of California* 249 Cal. Rptr. 494 at 508 [1988] at 508 [*Moore*, Court of Appeal].
[26] *Moore*, Supreme Court at 134–147. [27] *Ibid.* at 144.

regarding conversion, referred to the continued use of the HeLa cell lines as support for the lack of authority for imposing a tortious liability. Justice Arabian, concurring with the majority decision, commented that Moore 'has asked us to recognize and enforce a right to sell one's own body tissue for profit'.[28] However, as will also become apparent later, this is to misconstrue the nature of Moore's claim. Instead, the Court of Appeal seemed to get to the nub of the issues when it stated the 'appeal raises fundamental questions concerning a patient's right to the control of his or her own body'.[29]

The next case is that of *Greenberg* v. *Miami Children's Hospital Research Institute*.[30] The Greenbergs had two children, both of whom suffered from Canavan disease and died. Canavan disease is a degenerative disease of genetic origin predominantly affecting those of Ashkenazi Jewish origin. It usually results in severe neurological symptoms and early childhood death. Having had an affected child, the Greenbergs wanted a way to identify carriers of the gene in order to facilitate prenatal testing and so approached one of the defendants, Dr Matalon.[31] The causal gene was identified in 1993 by researchers at Miami Children's Hospital. Obtaining the tissue samples in order to conduct the research and compile the resultant database was largely made possible due to the efforts of the Greenbergs. They had spent much time and effort recruiting other families suffering from the disease so that they could provide tissue samples and family medical histories. Furthermore, the Greenbergs, along with the other plaintiffs in the case, had provided financial backing for the research. They did this on the 'understanding and expectations that such samples and information would be used for the specific purpose of researching Canavan disease and identifying mutations in the Canavan disease which could lead to carrier detection within their families and benefit the population at large'.[32] However, in 1994, the researchers filed for patents relating to the gene for Canavan disease and any applications relating to prenatal testing.[33]

The plaintiffs alleged that the Miami Children's Hospital had also threatened to take action against other centres offering testing for Canavan disease. Further, the Miami Children's Hospital was 'negotiating exclusive licensing agreements and charging royalty fees', the effect of which would have been to restrict access to the test.[34] The plaintiffs claimed several causes of action, including one for conversion. In relation

[28] *Ibid.* at 148. [29] *Moore*, Court of Appeal at 498. [30] 264 F.Supp.2d 1064 [2003].
[31] *Ibid.* at 1066. [32] *Ibid.* at 1067. [33] *Ibid.* [34] *Ibid.*

to this, the Court denied that the plaintiffs had a property interest in their tissue samples and genetic information, citing the judgment in *Moore* in support of this.[35] The Court claimed that to allow the claim 'would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital'.[36]

In 2007, the US Eighth Circuit Court of Appeals gave its ruling in the case of *Washington University* v. *William J. Catalona*.[37] Unlike the previous two cases, this case involved an action by a university against a former researcher and participants in his research. Dr Catalona had previously worked at Washington University. During his time there he collected samples both from healthy patients and those with prostate cancer for his research on the genetic basis of prostate cancer. These samples formed part of the collection held in the Genito-Urinary Biorepository at the University. In 2003, Dr Catalona moved to Northwestern University, whereupon he wrote to his patients and others asking for their permission to transfer their samples. Of these, approximately 6,000 agreed.[38] Unlike in *Moore* and *Greenberg*, in this case, whether or not the samples could be or were property was not at issue. The judgment in *Catalona* even acknowledged certain rights of ownership for the *sources* of the tissue, referring to them as *inter vivos* gifts. According to the District Court, '[t]he elements of an *inter vivos* gift are: 1) present intention of the donor to make a gift; 2) delivery of property by donor to donee; and 3) acceptance by donee whose ownership takes effect immediately and absolutely.'[39] The question at hand, therefore, was whether Dr Catalona or any of the research participants *retained* a property interest in the materials such that they could direct its use. The Court of Appeals, in agreement with the District Court, held that they did not and that these interests had passed to Washington University upon donation of the material, which now owned the samples held in the Biorepository.[40] The consequence of this, as explained by Graeme Laurie and colleagues in the context of *Moore*, is that 'while persons are denied recognition of a property interest in excised parts of our bodies, third parties may not only gain such an interest but can go on to protect it using forms of property law'.[41]

[35] *Ibid.* at 1074. [36] *Ibid.* at 1076.
[37] 490 F.3d 667 [2007] [*Catalona*, Court of Appeals]. [38] *Ibid.* at 672.
[39] *Washington University* v. *William J. Catalona* 437 F.Supp.2d 985 [2006] at 997 [*Catalona*, District Court].
[40] *Catalona*, Court of Appeals at 673–677.
[41] G.T. Laurie, S.H.E. Harmon, and G. Porter, *Mason and McCall Smith's Law and Medical Ethics*, 10th edn (Oxford: Oxford University Press 2016), p. 494.

2.3 *Sperm as Property*

Sometime on the evening of the 28th or early morning of the 29th of June 2003, a refrigerated storage system at Bristol Southmead Hospital malfunctioned. The supply of liquid nitrogen, which ordinarily maintained the system at minus 196°C, fell below the required level. Tanks within the system contained samples of frozen semen which subsequently thawed and the sperm contained therein were irreversibly damaged. Among the damaged samples were those of Jonathan Yearworth and five other men who had undergone chemotherapy treatment for cancer at the hospital. Since the hospital has a fertility unit licensed under the Human Fertilisation and Embryology Act 1990,[42] the men had been offered the option of having samples of their semen frozen and stored for use at a later date due to the potential damaging effect of the chemotherapy on their fertility. Acting on the advice received, the six men produced samples for storage. Five of the men, and the widow of the sixth, subsequently brought an action against North Bristol NHS Trust seeking a remedy in negligence. Personal injury and property-based arguments were heard in this respect. The case reached the Court of Appeal whereupon counsel for the claimants was asked to present arguments in bailment in addition to personal injury and property.[43] Generally speaking, a bailment can occur where a party takes possession of an item of another's personal property. This possession brings with it a duty of care in respect of the goods/chattel in question. Where goods which have been bailed are subsequently damaged, an action can be brought. In *Yearworth*, a landmark ruling was made; it rejected the personal injury arguments, but concluded that 'the men had ownership of the sperm for the purposes of their present claims'[44] and, as a result, that the Trust was liable for the damage caused. As we will see in Chapter 4, this case has challenged the previous (seemingly entrenched) legal position that individuals could not have property rights in their own tissues. While not the first time that the courts have determined that body parts or tissues are capable of being treated as property at law, *Yearworth* is the first time that the person who is the tissue's source has been unequivocally recognised as the legitimate holder of property rights. *Yearworth* is also

[42] At the time of the ruling, the amendments contained in the Human Fertilisation and Embryology Act 2008 were not in force, but they would not have had any substantive effect on the judgment if they had been.
[43] *Yearworth and Others* v. *North Bristol NHS Trust* [2009] EWCA Civ 37.
[44] *Ibid.* at [45 (f)(v)].

significant for opening the door to property determinations in other cases.

Three recent Australian cases, *Bazley* v. *Wesley Monash IVF Pty Ltd*,[45] *Jocelyn Edwards; Re the estate of the late Mark Edwards*,[46] and *Re H, AE*[47] draw on and extend the reasoning developed in the *Yearworth* case.[48] All three involve applications by the wives of the deceased for the posthumous possession of sperm, which they intended to use for the purposes of *in vitro* fertilisation (IVF). In *Bazley*, the deceased died of liver cancer and had been undergoing chemotherapy before his death. Prior to commencing the chemotherapy he had samples of his semen stored.[49] Upon being told that the IVF unit could not continue to store the semen after death, an application was made to the Court by the wife of the deceased requesting that they be required to continue doing so.[50] In *Edwards*, the deceased had been seeking IVF treatment with his wife. After his death she obtained a court order for the extraction and storage of the sperm.[51] She then sought a further order for the release of the stored samples specifically for the purposes of IVF.[52] However, this did not proceed as the New South Wales Assisted Reproductive Technology Act 2007 requires the express consent of gamete providers for the use of their gametes after death for these purposes.[53] Subsequent to this a different order was sought to the effect that Ms Edwards was entitled to possession of the sperm samples.[54] The order did not deal with what might happen to the sperm afterwards. The facts of the third Australian case, *Re H, AE*, are similar to those in *Edwards*. In this case, following his death in a motor accident, an order had been made for the extraction and storage of the deceased's sperm.[55] This was then followed by an order releasing the sperm to the applicant (the deceased's wife) for IVF purposes.[56] The courts in all three cases held that rights of possession to the sperm vested in the applicants;[57] although, as we will see in Chapter 4, the scope and implications of these decisions are quite narrow.

3 Uses and Values of Biomaterials

These stories and cases begin to illustrate how advancing biotechnology has fundamentally altered the way we view the human body and its parts

[45] [2010] QSC 118. [46] [2011] NSWSC 478.
[47] No 2, [2012] SASC 177, (No 3) [2013] SASC 196. [48] See Chapter 4, Section 3.
[49] *Bazley* at [1]. [50] *Ibid.* at [4]–[12]. [51] *Edwards* at [13]–[15]. [52] *Ibid.* at [17].
[53] s. 23(a); *Edwards* at [20]. [54] *Edwards* at [22]–[24]. [55] *R H, AE* (No. 2) at [2].
[56] *Ibid.* at [69].
[57] *Bazley* at [21], *Edwards* at [88] and [91], and *Re H, AE* at [58] and [60].

and products. We have moved from being simply the end users of medicine and research to each of us being a potential purveyor of it. This is due, as Margaret Brazier argues, to 'the diverse means by which we ourselves may be used as medicine'.[58] Human biological materials can be used to treat illness and disease.[59] These include blood and blood products for transfusions, organs for transplantation, and gametes and embryos for IVF and pre-implantation genetic diagnosis (PGD). PGD coupled with Human Leukocyte Antigen (HLA) typing literally allows us to create a child whose umbilical cord blood can be life-saving for their brother or sister. Stem cells represent another avenue of potentially life-altering, if not life-saving, human medicine, and may yield treatments for a huge variety of diseases. Cell therapies (including those which are stem cell based) use either modified or unmodified autologous (from the patient themselves) or allogenic (not from the patient) cells in the treatment of disease. These encompass a range of applications including a burgeoning new class of products which draw on tissue-engineering expertise,[60] combining human biomaterials with artificial scaffolds; for example, cartilage for repairing joints,[61] bladders grown from a patient's own cells,[62] and biohybrid vaginas for transplantation.[63] There are also less media-worthy and exciting uses of human biomaterials, such as those used in research into the aetiology, pathology, and treatment of disease. Meanwhile, cells and tissues are frequently used for basic medical research which is not yet near clinical application. Brazier has called these diverse uses of persons and their bodies the 'notion of humans as medicines'.[64]

[58] M. Brazier, 'Human(s) as medicine(s)' in S. McLean (ed.), *First Do No Harm* (Aldershot: Ashgate Publishing Ltd, 2006) pp. 187–202, p. 188.

[59] For a comprehensive overview of the use of human biomaterials see Nuffield Council on Bioethics, *Human Bodies: Donation for Medicine and Research* (London: Nuffield Council on Bioethics, 2011), Ch. 1.

[60] For an in-depth analysis focused on tissue engineering see J. Kent, *Regenerating Bodies: Tissue and Cell Therapies in the Twenty-First Century* (London and New York: Routledge, 2012).

[61] T. Simonite, 'Lab-grown cartilage fixes damaged knees' *New Scientist* (5 July 2006), www.newscientist.com/article/dn9483-lab-grown-cartilage-fixes-damaged-knees/ (accessed 27 November 2017).

[62] R. Khamsi, 'Bio-engineered bladders successful in patients' *New Scientist* (4 April 2006), www.newscientist.com/article/dn8939-bio-engineered-bladders-successful-in-patients/ (accessed 27 November 2017).

[63] C. de Lange, 'Engineered vaginas grown in women for the first time' *New Scientist* (2014), www.newscientist.com/article/dn25399-engineered-vaginas-grown-in-women-for-the-first-time/ (accessed 27 November 2017).

[64] Brazier, 'Human(s) as medicine(s)', p. 187.