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The problems of biobanking and the law of gifts

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INTRODUCTION

The practice of biobanking is of major importance to biomedical research in modern Western economies. However, biobanking is troubled by a number of ethical and legal concerns including issues of consent, control and privacy. Recent developments in the networking of biobanks and the sharing of samples and data have exacerbated these issues. This paper outlines these problems and then examines how they can be understood through the law of gifts.

Much of the debate on how tissue is donated to biobanks has occurred without reference to the law of gifts. This is most probably due to the *res nullius* rule, which, until recently, has prevented unprocessed human tissue from being considered an object of property.¹ But recent changes to the common law's approach to human tissue now invite a reconsideration of the role that gifts law can play in tissue banking (and tissue donation more generally).² This paper will proceed on the assumption that tissue which has not been subject to work and skill may nevertheless be held as property and that the decision to donate to a tissue bank can be treated as an example of a legally recognised gift.

The paper begins with an example of tissue banking and the legal and ethical issues which it raises. Most prominent amongst these difficulties is the focus on tissue banking on informed consent, a doctrine originally designed to deal with negligence advice and bodily

¹ *Doodeward v Spence* (1908) 6 CLR 406; *Dobson v North Tyneside Health Authority* [1997] 1 WLR 596 R v *Kelly and Lindsay* [1999] QB 621.

² *Yearworth v North Bristol NHS Trust* [2010] QB 1; *Bazley v Wesley Monash IVF Pty Ltd* (2011) 2 Qd R 207; *Re Edwards* (2011) 81 NSWLR 198; *Re H (No 2)* [2012] SASC 177; *Re Section 22 of the Human Tissue and Transplant Act 1982*; *Ex parte C* [2013] WASC 3.

interferences in medical treatment and research. While understandable, the focus on informed consent has created a number of problems particularly in areas of unspecified research, unanticipated findings and privacy.

The chapter then moves to reviewing the basic law of gifts by examining the elements of gifts in both law and equity and the requirements for conveying them. The chapter also explains the law's capacity to recognise different conditions in gifts that limit the also creates the possibility of conditional dispositions which allow for donors to maintain some rights over the tissue, with the possibility of a form of interest which would enable the donor to regain possession and control of their tissue if there was a breach. This paper argues that an application of the law of gifts is a flexible and useful way of reconceptualising the ethical and legal difficulties of biobanking.

BIOBANKS AND BIOBANK NETWORKS

What are biobanks and what do they do?

Biobanks (also known as tissue banks, biorepositories or tissue repositories) are collections of human body materials that can be used in medical treatments (eg, blood banks, cornea banks) research, teaching, law enforcement (eg, DNA collections) and museums. The body tissues that make up biobanks may be removed from healthy donors, from patients in the course of medical diagnosis or therapy, or from bodies post-mortem.

By collecting and storing large numbers of tissue samples from healthy populations and/or patients with a particular disease, researchers are able to correlate characteristics of the tissue with the aetiology, prognosis or treatment responsiveness of a disease. Advances in science and laboratory technology such as tissue immortalisation, rapid genome sequencing, genome-wide association studies (GWAS), mass spectrometry and tissue microarrays, together with a deeper understanding of systems biology and advances in information technology enable researchers to extract enormous amounts of genetic or other molecular data from tissue samples, and to find clinically significant patterns in these data.³

Biobanks facilitate 'translational' research because they enable researchers to identify 'biomarkers' that tell them which patients are most likely to develop a disease and/or respond to a particular treatment. In this way, prevention and therapy can be 'targeted' or 'personalised' to those who express a particular biomarker. Many cancer cells, for example, express particular genes or proteins that contribute to the aetiology, prognosis or treatment responsiveness of the tumour. Once these markers are discovered, pharmaceutical companies can develop 'targeted' therapies, such as 'Herceptin' for breast cancer and

³ P H Watson, J E Wilson-McManus, et al, 'Evolutionary concepts in biobanking - the BC BioLibrary.' (2009) *Journal of Translational Medicine* 7; R W G Watson, E W Kay, et al, 'Integrating biobanks: addressing the practical and ethical issues to deliver a valuable tool for cancer research' (2010) 10 *Nature Reviews Cancer* 646; BM Knoppers, J R Harris, et al, 'From Genomic Databases to Translation: A Call to Action' (2011) 37 *Journal of Medical Ethics* 515.

'Gleevec' for chronic myeloid leukaemia, and those funding medicines can limit access to those who are most likely to respond to these (often very expensive) treatments.⁴

The globalisation of research and the increasing involvement of the pharmaceutical and biotechnology industry in research have also been provided a major impetus for the development and expansion of biobanks. To support the discovery of biomarkers, most clinical trials now include the collection and storage of tissue as part of their standard protocol.⁵ But while the biomedical and commercial value of biobanks have been widely recognized by industry, government and philanthropic bodies it has also become clear that the storage and use of biobanked materials in research continues to stimulate numerous unresolved and emerging ethical and legal tensions.

Emerging problems in biobanking practice

Key among the problems of biobanking is the issue of consent. While it used to be the norm for residual tissue removed in the course of diagnosis or therapy to be used for research without consent,⁶ it is now widely accepted that donors need to be asked for permission to store and use their samples.⁷ Ethical disagreements about consent frequently centre on the tension between individual autonomy, or respect for persons, and the 'common good' – a tension that is seen to be particularly significant in the context of biobanking research because this often depends upon the participation of large numbers of people (including healthy populations), many of whom are unlikely to benefit from the results of the research. This tension is increased by the fact that pharmaceutical and biotechnology companies are increasingly creating their own biobanks as part of their basic research and clinical trial activities, with the intention of benefiting shareholders rather than tissue donors.⁸ In this context, it is arguably important to ensure that donors are fully informed of the potential risks and benefits of their donation.⁹

Informed consent is a legal and ethical doctrine concerned with ensuring that medical practitioners inform patients about the material risks of treatment and research interventions. It is primarily focused on providing a patient with enough information so they can decide whether or not to become involved in a course of treatment or research. Given

⁴Watson, Wilson-McManus *ibid*; Watson, Kay, et al, *ibid*.

⁵ BM Knoppers, M n H Zawati, et al, 'Sampling Populations of Humans Across the World: ELSI Issues' (2012) 13 *Annual Review of Genomics and Human Genetics* 395.

⁶ Morrell B, Lipworth W, Axler R, Kerridge I, Little JM, 'Cancer as rubbish: Donation of tumour tissue for research' (2011) 21 *Qualitative Health Research* 75-81.

⁷ Clayton EW et al, 'Informed Consent for Genetic Research on Stored Tissue Samples' (1995) 22 *Journal of the American Medical Association* 1786; Trommelmans L, Selling J and Dierickx K, 'The Importance of the Values Attached to Cells for a Good Informed Consent Procedure in Cell Donation for Tissue Engineering Purposes' (2009) 10 *Cell and Tissue Banking* 293.

⁸ Knoppers, Zawati et al, n 3.

⁹ S Cervo, J Rovina, R Talamini, T Perin, V Canzonieri, P De Paoli, A Steffan, 'An effective multisource informed consent procedure for research and clinical practice: an observational study of patient understanding and awareness of their roles as research stakeholders in a cancer biobank' (2013) *BMC Med Ethics* doi: 10.1186/1472-6939-14-30.

that most tissue is collected during a medical or research intervention it makes sense, on one hand, that the same model of consent be employed to tissue banking. However, on the other hand, it can also be argued that informed consent is an inappropriate model to adopt for biobanking because donors will be asked to consent to having their tissue used in unspecified future research where the risks are completely unknown.¹⁰ Moreover the tissue is not longer part of the donor's body so concepts of the harm and benefit of research necessary take on quite different forms. Given the lack of knowledge about what will happen to the tissue in the future consent processes must be very broad, so broad that they arguably bear little resemblance to an 'informed' consent process.¹¹

A number of other ethical issues arise in the context of biobanking research. First, because even a single cell contains a donor's entire genome, steps need to be taken by researchers to ensure that information derived from donated tissue does not find its way into the hands of, for example, employers and insurance companies.¹² Second, there is the issue of whether and how research findings should be reported to tissue donors.¹³ While it is standard for consent forms to say that donors will not benefit personally from donating their tissue to biobanks, it is unclear when information becomes clinically significant and thus when researchers have an obligation to return information to tissue donors and/or their health care professionals.¹⁴ Third, some cultural groups see human tissue as having particular moral

¹⁰ C Stewart, J Fleming and I Kerridge, 'The law of gifts, conditional donation and biobanking' (2013) *Journal of Law and Medicine* (forthcoming); T Caulfield, R Brown R and E Meslin, 'Challenging a Well Established Consent Norm? One Time Consent for Biobank Research' (2007) 4 *Journal of International Biotechnology Law* 69; Caulfield T, 'Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales' (2007) 18 *Kings Law Journal* 209; M Otlowski, 'Developing an Appropriate Consent Model for Biobanks: In Defence of "Broad" Consent' in J Kaye and M Stranger (eds), *Principles and Practice of Biobank Governance* (Ashgate, Aldershot, 2009); and National Health and Medical Research Council of Australia, *Biobanks Information Paper* (2010) 23-25;

¹¹ CJ Allen, M Yann, P Granados 'Data Sharing, Biobanks and Informed Consent: A Research Paradox' (2013) 7 *McGill Journal of Law and Health* 85.

¹² B Elger, 'Ethics and privacy of biobanks' (2013) 35 *Clinical Therapeutics* e116; G Lauss, et al, 'Towards Biobank Privacy Regimes in Responsible Innovation Societies: ESBB Conference in Granada 2012' (2013) 11 *Biopreservation and Biobanking* 319; S Burningham, 'Cell therapy research and innovation: Identifying the emerging privacy challenges' (2012) 12 *Medical Law International* 204; J Sándor, 'From Private to Public? Legal Concepts of the Right to Privacy and Ownership in the Regulation of Biobanks' in K Dierickx and P Borry (eds), *New challenges for biobanks : ethics, law and governance* (Antwerp, Intersentia, 2009) 123-36; LO Ursin, 'Biobank research and the right to privacy' (2008) 29 *Theoretical Medicine and Bioethics* 267.

¹³ SA Alessi, 'The Return of Results in Genetic Testing: Who Owes What to Whom, When, and Why?' (2013) 64 *Hastings Law Journal* 1697.

¹⁴ EW Clayton, 'Incidental findings in genetics research using archived DNA' (2008) 36 *Journal of Law and Medical Ethics* 286, 212; SM Wolf, BN Crock, et al, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 *Genetic Medicine* 361; L Black, et al, 'Funding considerations for the disclosure of genetic incidental findings in biobank research' (2013) 84 *Clinical Genetics* 397.

or religious significance. For these groups, even a tumour removed in the course of diagnosis or treatment might need to be stored or discarded according to particular rules or rituals.¹⁵

From biobanks to biobanking networks

Another recent ethical problem for biobanking relates to networking. While biobanks have historically been defined in terms of their institutional or geographical location, increasingly human specimens are becoming part of national and international networks of biobanks. This has been made possible by new scientific and computer technologies have increased our ability to categorise, organise and share samples and data, and it is now broadly accepted that biobanks have the greatest potential as resources for translational research if they are networked, nationally and internationally.¹⁶ This is simply because the larger and more integrated a biobank, the greater the power of the research that can be conducted.

As part of a global project (www.genebanc.eu) funded by the European Commission's 6th Framework Programme, Shickle and colleagues identified 6 types of non-mutually exclusive or exhaustive categories of biobanking networks which include:

- 'storage' networks - where storage facilities are shared among biobanks to reduce cost and raise quality;
- 'bring-and-share storage' networks - which offer lower fee structures for researchers to encourage sharing of resources with other researcher;
- 'catalogue' networks - which maintain a database that is searchable by external researchers seeking samples for their research;
- 'partnership' networks - which attempt to share costs and effort in recruitment;
- 'contribution' networks, where people contribute relevant specimens to disease specific biobank(s), and
- 'expertise' networks, which share expertise rather than samples.¹⁷

There are many types of research which can only be conducted if biobanks are networked. For some research questions, enormous numbers of samples are needed. For example, in the case of tissue collected from healthy populations for longitudinal analyses (observing a population for the occurrence of a disease and attempting to isolate relevant aetiological biomarkers), it is estimated that DNA of about 10000 diseased individuals needs to be analysed in order to identify a relevant genetic variant.¹⁸ Biobank networks are also crucial

¹⁵ RE Axler, R Irvine, et al, 'Why might people donate tissue for cancer research? Insights from organ/tissue/blood donation and clinical research' (2008) 75 *Pathobiology* 323.

¹⁶ J Kaye, 'From Single Biobanks to International Networks: Developing e-Governance' (2011)130 *Human Genetics* 377; J Kaye, 'Building a Foundation for Biobanking: The 2009 OECD Guidelines on Human Biobanks and Genetic Research Databases' (2010) 17 *European Journal of Health Law* 187; J Kaye, C Heeney, et al, 'Data Sharing in Genomics – Re-Shaping Scientific Practice' (2009) 10 *Nature Reviews Genetics* 331.

¹⁷ D Shickle, M Griffin, et al, 'Inter- and intra-biobank networks: classification of biobanks' (2010) 77 *Pathobiology* 181.

¹⁸ M Asslaber and K Zatloukal, 'Biobanks: transnational, European and global networks' (2007) 6 *Briefings in Functional Genomics and Proteomics* 193.

in the study of rare diseases, where a single researcher cannot possibly collect enough samples,¹⁹ and even common diseases such as cancer and heart disease are increasingly seen to comprise a number of rare disease subsets characterised by, for example, specific genetic polymorphisms.²⁰ Networks are also essential in cases where it is socially and logistically difficult to obtain tissue—for example collecting post-mortem brain tissue in the face of a decline in the number of autopsies conducted and more stringent consent requirements for tissue retention.²¹ Pharmaceutical companies also need large networks of biobanks in order to meet the regulatory requirement that they study samples and data from populations of different ethnic origins in the course of their clinical trials.²² Finally, it has become increasingly clear that single biobanks, particularly those maintained by single institutions, are rarely sustainable and are inefficient—duplicating the resources and activities of other similar biobanks.²³

While the networking of biobanks undoubtedly holds major scientific, commercial and social promise networking raises similar ethical and legal concerns to the practice of individual biobanks. However, these issues becomes far more complex when research is globalised and tissues are shared across borders.²⁴ The primary concern, as described by Hoeyer, is that:

The move towards large-scale population-based biobanks and huge international collaborations might very well ... cut the ties between the individual patient and the research community in ways that make researchers less accountable to donor interests.²⁵

¹⁹ YR Rubinstein, SC Groft, et al, 'Creating a global rare disease patient registry linked to a rare diseases biorepository database: Rare Disease-HUB (RD-HUB)' (2010) 31 *Contemporary Clinical Trials* 394; ML Oster-Granite, MA Parisi, et al, 'Down syndrome: national conference on patient registries, research databases, and biobanks' (2010) 104 *Molecular Genetics and Metabolism* 13.

²⁰ Asslauer and Zatloukal, n 18; Watson, Kay et al, n 1.

²¹ JE Bell, I Alafuzoff, et al, 'Management of a twenty-first century brain bank: experience in the BrainNet Europe consortium' (2008) 115 *Acta Neuropathologica* 497.

²² Asslauer and Zatloukal, n 18.

²³ D Catchpole, A deFazio, et al, 'The importance of biorepository networks. The Australasian Biospecimens Network-Oncology' (2007) 28 *Australasian Journal of Medical Science* 16-20. A number of networks have been established. Such initiatives to date include (among many others) the promotion of the pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) (<http://cordis.europa.eu/esfri/roadmap.htm>). This resource offers a "distributive hub structure" and includes 261 biobanks over 23 countries with a total of more than 16 million samples: D Chalmers, 'Genetic Research and Biobanks' (2011) 675 *Methods in Molecular Biology* 1. Other networks include the Organization for Economic Co-operation and Development (OECD) global Biological Resources Centres network (<http://wdcm.nig.ac.jp/brc.pdf>), the cancer Biomedical Informatics Grid (CaBIG) (<https://cabig.nci.nih.gov>), the International Cancer Genome Consortium (<http://www.icgc.org>), the Public Population Project in Genomics (P3G) (www.p3gconsortium.org), EuroBioBank (www.eurobiobank.org), EPIC, GenomEUtwin (www.genomeutwin.org), TuBaFrost (www.tubafrost.org), and BrainNet Europe II (BNE) (<http://www.brainnet-europe.org/>).

²⁴ CI Emerson, PA Singer, et al, 'Access and use of human tissues from the developing world: ethical challenges and a way forward using a tissue trust' (2011) 12 *BMC Medical Ethics*; E Smith, 'The Limits of Sharing: An Ethical Analysis of the Arguments For and Against the Sharing of Databases and Material Banks' (2011) 18 *Accountability in Research-Policies and Quality Assurance* 357.

²⁵ KL Hoeyer, 'Size matters: the ethical, legal, and social issues surrounding large-scale genetic biobank initiatives' (2012) 21 *Norsk Epidemiologi* 211, 213.

Therefore, the key problem raised by networking is how to maintain a relationship between donors and wider members of the network who have had no previous relationship with the donor.

THE LAW OF GIFTS

A gift is a voluntary transfer of property where one person, the 'donor', transfers property to another person, the 'donee' or 'volunteer'. A voluntary transfer is one that is not supported by consideration, which means that nothing of value is given in exchange for the donated property. Commonly, most people would associate money with being valuable consideration but common law and equity recognise a wide variety of behaviours which constitute consideration including promises (such as to perform a task, to marry or to forebear from suing), labour or a reciprocal transfer of property rights.

Conveying gifts

The method of conveying a gift will depend on the nature of the property which is being donated, and whether the transaction is being done legally or equitably. Since the *Statute of Frauds 1677* (UK), gifts of legal interests in land need to be by deed.²⁶ A gift of an interest in land may also need to be registered to pass the legal title to the donee, particularly in jurisdictions which have the Torrens system of title.²⁷

For personal property, gifts of choses in action (incorporeal personal property) must be in writing, and the chose must be given absolutely (which effectively precludes part ownership of a chose in action being gifted at law, ie it is not possible to give 50% of your right to royalties at law).²⁸ Contrastingly, a gift of goods does not require writing to be effective. All that is required is an intention to pass ownership of the goods and delivery of the goods (either physically or constructively).²⁹

Property can also be donated in equity. However, equity took a negative attitude to the enforcement of incomplete gifts of legal property that could have been given at law, but

²⁶ *Law of Property Act 1925* (UK), s 52; *Conveyancing Act 1919* (NSW) s 23B(1); *Law of Property Act 2000* (NT) s 9(1); *Law of Property Act 1936* (SA) s 28(1); *Conveyancing and Law of Property Act 1884* (Tas) s 60(1); *Property Law Act 1958* (Vic) s 52(1); *Property Law Act 1969* (WA) s 33(1). In Queensland the requirement is for writing: *Property Law Act 1974* (Qld) s 10(1).

²⁷ *Land Titles Act 1925* (ACT) s 57(1); *Real Property Act 1900* (NSW) s 41(1); *Land Title Act 2000* (NT) s 184; *Land Title Act 1994* (Qld) s 181; *Real Property Act 1886* (SA) s 67(1); *Land Titles Act 1980* (Tas) s 39(1); *Transfer of Land Act 1958* (Vic) s 40(1); *Transfer of Land Act 1893* (WA) s 58(1).

²⁸ The original provision was *Judicature Act 1873* (UK) s 25(6). In Australia the relevant sections are *Civil Law (Property) Act 2006* (ACT) s 205; *Conveyancing Act 1919* (NSW) s 12; *Law of Property Act 2000* (NT) s 182; *Property Law Act 1974* (Qld) s 199; *Law of Property Act 1936* (SA) s 15; *Conveyancing and Law of Property Act 1884* (Tas) s 86; *Property Law Act 1958* (Vic) s 134; *Property Law Act 1969* (WA) s 20. It is possible to give a part interest in equity: *Norman v Federal Commissioner of Taxation* (1963) 109 CLR 9

²⁹ S Fisher, *Commercial and Personal Property Law* (Sydney, Butterworths, 1997) 446-447.

where the donor failed to comply with the legal requirements. Equity adopted the maxims that 'equity does not perfect an imperfect gift' and 'equity would not assist a volunteer'.³⁰ However, there are circumstances in which equity will allow equitable title to pass to a donee in such situations, namely, where the donor has both done everything necessary to be done by him/her to effect the transaction and had put the property beyond his/her recall.³¹ In such cases equity will treat the gift as having been completed and such equitable gifts grant the donee an equitable title which can be enforced against the donor and third parties.

Equity allows gifts of property which were not assignable at law to be completed as long as the donor manifested a complete and irrevocable intention to give the property.³² The classic example of such a transaction is the trust, where the legal owner either declares that they hold the property for the benefit of another, or where they transfer the property to a trustee to hold the legal title for the benefit of another. The trust was not recognised by common law courts but was enforced in equity, hence the title of the beneficiaries being classified as an equitable interest. However, the *Statute of Frauds* provisions require some of these gifts, namely trusts of land (but not personalty) and gifts of subsisting equitable interests (in both land and personalty) to be in writing.³³

Conditional gifts

Gifts can be given with or without conditions. If conditions are stipulated it is important to distinguish between those conditions that have to be satisfied prior to the gift taking effect (*conditions precedent*)³⁴ and those conditions that must be satisfied after the gift has passed (*conditions subsequent*).³⁵ A condition precedent will be recognisable because it must logically be satisfied before the gift can take effect (eg, 'I give my house to A if A reaches the age of 25 years'). A condition subsequent will be recognisable because the gift is given but able to be defeated if there is a breach (eg, 'I give the house to A as long as he continues to use it as his common residence').³⁶

In gifts subject to a condition precedent, the donor retains title to the property until the condition is satisfied. In gifts subject to conditions subsequent, the property passes to the

³⁰ R P Meagher, J D Heydon & M J Leeming, *Meagher, Gummow and Lehane's Equity: Doctrines and Remedies*, 4th ed (Sydney, LexisNexis Butterworths, 2002) 227.

³¹ *Milroy v Lord* (1862) 45 ER 1185; *Anning v Anning* (1907) 4 CLR 1049; *Corin v Patton* (1990) 169 CLR 540 at 580; *Costin v Costin* (1997) NSW Conv R 55–811; *Stone v Registrar of Titles* [2012] WASC 21.

³² *Kekewich v Manning* (1851) 42 ER 519 at 524; *Norman v Federal Commissioner of Taxation* (1963) 109 CLR 9.

³³ *Law of Property Act 1925* (UK), s 53; *Civil Law (Property) Act 2006* (ACT) s 201; *Conveyancing Act 1919* (NSW), s 23C; *Law of Property Act 2000* (NT) s 10; *Property Law Act 1974* (Qld) s 11; *Law of Property Act 1936* (SA) s 29; *Conveyancing and Law of Property Act 1884* (Tas) s 60(2); *Property Law Act 1958* (Vic) s 53; *Property Law Act 1969* (WA) s 34.

³⁴ *Errington v Errington and Wood* [1952] 1 KB 290.

³⁵ *Egerton v Earl Brownlow* (1853) 10 ER 359.

³⁶ *Wynne v Fletcher* (1857) 53 ER 423

donee, but the donor retains a right to resume the title if there is a breach, that nature of which depends on whether the condition subsequent creates a determinable interest.³⁷

Conditions subsequent and determinable interests

What is a determinable interest? A distinction can be drawn between an absolute gift that is subject to a condition subsequent and gift which grants a determinable interest that automatically ends on the breach of a condition. The absolute gift which is subject to a condition subsequent, in effect, grants a complete interest, that is then divested on the breach of the condition. In contrast, a determinable interest is one granted with the condition built into it so that the interest is itself defined by the breach of the condition. Such a determinable interest is viewed as naturally coming to an end when the condition is breached.³⁸

The differences between these two types of condition relate purely to the form and wording of the disposition.³⁹ For example, a trust 'to A for life, but if A ceases to use the property as a hotel, then to B' is considered to create an interest which is subject to a condition subsequent.⁴⁰ The life interest is granted to B, but can be artificially cut short by the event of B no longer using the property as a hotel. However, if the trust was worded 'to B for life until B ceases to use the property as a hotel', B's life interest is always limited in time to the event of the property no longer being used as a hotel. If and when the property is no longer used as a hotel, B's estate comes naturally to an end.

While these semantic distinctions are unlikely to loved by anyone but property lawyers, they have practical effects. Firstly, in the cases of a determinable interest in land the donor always retains an interest in the property (a 'possibility of reverter' or 'reverter' interest) which continues even through the property has been given and which flowers back into full ownership automatically on breach. In contrast, a breach of a condition subsequent gives the donor a right to resume title ('a right of re-entry') but only if it is exercised. The donor's interest is therefore notionally stronger in cases of determinable interests than in cases of conditions subsequent.

Secondly, there are a number of other public policy rules which might strike down a condition.⁴¹ If the condition is part of a determinable interest it is not possible to separate out the condition from the gifts and the entire gift will fail, causing it to revert back to the

³⁷ N Cox 'Conditional Gifts and Freedom of Testation: Time for review?' (2001) 9 *Waikato Law Review* 24.

³⁸ *Hood v Oglander* (1865) 55 ER 733 at 737.

³⁹ *In re Scientific Investment Pension Plan Trusts* [1999] Ch 53.

⁴⁰ See P Radan and C Stewart, *Principles of Australian Equity and Trusts* 2nd ed (Sydney, LexisNexis, 2013) Chap 17.

⁴¹ These will not be discussed here but include the rule against restraints on alienation the rule against perpetuities, the rule against illegal gifts and public policies against certain conditions such as those which forbid marriage encourage divorce, the separation of parent and child, and conditions which encourage immoral meretricious sexual relations: Stewart, Fleming and Kerridge, n 10.

donor. If, however the gift is not subject to a conditional limitation but merely a condition subsequent, the condition is severable and the striking down of the condition will leave the gift to stand, free of the offending condition.

Conditional gifts and goods

So far the examples of conditional gifts given above have been ones involving gifts of land. Can gifts of personal property be subject to conditions which create rights similar to reverters or rights of re-entry? Holdsworth says that the common law never recognised that a donor of a conditional gift of goods retained a property interest in them (like a possibility of reverter).⁴² A gift of goods for a limited time (such as a life estate) was said to be a gift forever and the donee was free to do with the property as he or she pleased.

However, there are exceptions to this general rule. For example, common law enforced conditions subsequent for gifts of goods in contemplation of marriage. Such gifts are said to be made on the condition that if the marriage does not proceed the goods (such as the engagement ring) will be returned.⁴³ It is not clear whether the common law recognised any estate in the donor prior to the failure of couple to marry but, in any event, equity will ordinarily step in and hold the property on a resulting or constructive trust. This indicates that the donor, at the very least, retains an equitable interest (probably because the donee is bound by conscience to give back the gift).⁴⁴

Equity also provided a number of other mechanisms for granting a proprietary interest to the donor in a conditional gift. The simplest way was for the gift to take the form of a trust. Trusts of goods can be subject to conditions on how the beneficial interest is to be enjoyed (eg 'I give the car to A on trust for B until B marries'). Once B marries the trust would end and the property would revert on a resulting trust back to the donor.

Equity would also recognise a condition which created a personal equitable obligation on the part of the donee to perform some act if they have been given property. In some circumstances the courts will interpret a conditional disposition as imposing a personal equitable obligation on the donee, such as the payment of an amount of money — for

⁴² WS Holdsworth, *A History of English Law* 4th edn (London, Methuen, 1936) vol VII, 470. This limit applies to gifts inter vivos but not gifts made in a will: N Crago, 'Bequests of Tangible Chattels in Succession' (1999) 28 *Western Australian Law Review* 199, 201. Blackstone disagreed with this and felt a conditional gift made inter vivos could create future interests at law, if contained in a deed: W Blackstone, *Commentaries on the Laws of England* (Oxford, Oxford University Press, 1765-1769) Vol 2 398. This position was been adopted in America, arguably because of the slave trade where there was pressure to recognize future interests in slaves (which were, in most States, classed as goods): J C Gray, 'Future interests in Personal Property' (1901) 14 *Harvard Law Review* 397; LM Simes, 'Future Interests in Chattels Personal' (1930) 39 *Yale Law Journal* ; P Bordwell, 'Interests in Chattels Real and Personal' (1936) 1 *Missouri Law Review* 119.

⁴³ *HAX v TV* [2009] QCA 401; *Papathanasopoulos v Vacopoulos* [2007] NSWSC 502; *Keays v Carter* [2003] WASC 23; *Cohen v Sellar* [1926] 1 KB 536; *Jacobs v Davis* [1917] 2 KB 532.

⁴⁴ *Ikeuchi v Liu* [2001] QSC 054; *Kais v Turvey* (1994) 17 Fam LR 498.

example, an annuity — to a third party.⁴⁵ Sometimes the obligation to the third party will be less definite, such as an obligation to ‘support’ or ‘take care’ of a third party, or make sure they ‘want for nothing’.⁴⁶ The donee in such gifts is subject to a personal equitable obligation which is enforceable but which does not create a property right in the donor or a third party beneficiary.⁴⁷ Nor does a breach of the obligation give rise to a forfeiture of the gift, unless the donor takes action for specific performance of the condition.⁴⁸

APPLYING GIFTS LAW TO BIOBANKING

How then might gifts law be applied to donations of human tissue for biobanking? The starting point is to determine the proprietary nature of human tissue – is it real property, a chose in action or a good? Clearly, human tissue is not real property, except, possibly, in those rare cases where it has been buried or frozen in the ground.⁴⁹ Apart from those rare occasions, human tissue is a physical thing which can be possessed and which is not attached to land. The most natural property category would therefore be goods, which in terms means that a gift can be made of tissue according to the general law of goods (subject to the requirements of applicable human tissue legislation).

However, a single focus on goods may be misleading because biobanking not only includes a gift of the tissue but permission to derive products such as immortal cell lines and genetic sequences from the tissue. Donors may also give access to their health records with permission for those records to be used in data linkage. On that basis, it is possible to conceive that a tissue donor may not only be donating the tissue as a good, but also giving a number of related choses in action.

The next step would be to determine the nature of any conditions attached to the gift. It is in this area that property law has a great advantage over the law of informed consent. Informed consent is *positively permissive* (eg, ‘I consent to research protocol X, which carries a risk of Y’). The duty of informed consent requires that the researcher provide information on what may happen to the tissue and the attendant risks involved, even though this is extremely difficult or impossible to know in tissue banking because very little or nothing is known about the risks of unspecified research. In contrast, the law of conditional gifts is *negatively permissive*. It focuses on the expressed and implied limits of what is permitted by the donor (eg ‘I donate my tissue to A so long as it is not used for human cloning’). Such limits have the advantage of being capable of expression when the gift is given, unlike a

⁴⁵ *O’Sullivan Partners (Advisory) Pty Ltd v Foggo* [2012] NSWCA 40 at [93]–[99]; *Re Hodge* [1940] Ch 260; *Re Williams*; *Williams v Williams* [1897] 2 Ch 12 at 19; *Rees v Engelbach* (1871) LR 12 Eq 225.

⁴⁶ *Re Moore* (1886) 55 LJ Ch 418; *Broad v Bevan* (1823) 38 ER 198; *Hammond v Hammond* [2007] NSWSC 106.

⁴⁷ *Gill v Gill* (1921) 21 SR(NSW) 400.

⁴⁸ *Kauter v Kauter* [2003] NSWSC 741; *Messenger v Andrews* (1828) 38 ER 885; *Gregg v Coates* (1856) 53 ER 13.

⁴⁹ Buried items are considered fixtures and therefore part of the land: *Elwes v Brigg Gas Co* (1886) 33 Ch D 562.

statement by a donee about material risk for research which hasn't been invented yet. By focusing on what the donor does not want there is a better chance of the donee behaving in a way that respects the donor's autonomy.

If the participant is unconcerned about future research and does not seek to limit it, there needs to be very few conditions laid out in the gift. Conversely, if the donor has very specific concerns about the types of research the tissue will be used to perform (such as cultural or religious concerns) these can be set out in the donation (for eg, 'I give my tissue to A on the condition that the tissue and its derivative products not be used for research involving embryonic stem cells'). Similarly, if the donor has concerns about being contacted if there are unanticipated findings these again can be set out as a condition. The flexibility of gifts law allows for these different concerns to be accommodated.

Are there some conditions which should always be implied in a gift to a biobank? As with the example above of gifts in contemplation of marriage, it might be argued that there are conditions which should always be implied in any gift to a biobank because of the inherent nature of what is being given. At the very least, gifts of human tissue would arguably be made on the condition that the donor will be able in most cases to remove the tissue from biobank, or have it destroyed, should they change their mind, at least before the tissue has itself been consumed by the research. Another obvious condition would be that the donor's health information be kept confidential to the researchers accessing the tissue bank. Another condition may be the requirement that any research that is conducted on the tissue must be approved by an human research ethics committee.⁵⁰

The only reported case of a court considering a conditional gift of human tissue is *Washington University v Catalona*.⁵¹ In this case a researcher recruited several thousand participants to provide tissue for a study into the genetics causes of prostate cancer. When the researcher decided to relocate to another institution he wanted to take the tissue bank with him. However Washington University claimed that the tissue bank had been created by its employee and, as such, the bank belonged to it. The participants argued that they had donated their tissue on the condition that it only be researched on by that particular researcher. Washington University disputed that saying that the tissue had been donated to it as an institution and not to an individual.

Both at trial and on appeal it was found that the tissue had been donated to the University as valid and binding gifts. The court relied on both the consent form and the surrounding circumstances of the research project, such as the practices of the researcher (particularly how he would often destroy samples in his research), as further evidence that the donors had intended to give the university property rights equating to ownership. The court was prepared to find that there was an implied condition that the donors could withdraw their tissue from the study (and, in some cases, demand that it be destroyed). However, the court

⁵⁰ Stewart, Fleming and Kerridge, n 10.

⁵¹ 490 F 3d 667 (2007).

refused to find that there was any condition (express or implied) which allowed the donors to control the identity of who performed research on the tissue.

Catalona illustrates the importance of both express and implied conditions in the donation of human tissue. While the court was prepared to find for an implied term of a right to have the property removed from the research protocol, the lack of express terms relating to who could use the tissue was fatal to the donors claims that they could control would had access. This certainly puts the onus on tissue donors to be consciously aware of what limitations they wish to place on their donations and creates concerns about the ability of donors to do so (which will discussed below)

A final illustration of why a conditional gift model is more useful than an informed consent model comes when one reflects on the biobanking network problem which was discussed above. In biobank networks third parties have access to tissue and may borrow or take tissue samples, even though they do not have direct consent to do so from the donors. In informed consent terms there is no duty to provide information about material risks because there is no relationship with the donor. Requiring the third party to seek direct consent from the donor is impractical and defeats the purpose of the network. However, by not having direct consent there is a risk that the interests of donors are further and further removed from the researcher's behaviour. Sometimes regulation may try to enforce such an obligation, such as through requiring the research to be approved of a human research ethics committee. However, research ethics committees may try to impose a 're-consent' process which (as we have said) may be impractical. Alternatively, in the Australian context, the committee may approve the research without consent (if the committee believes the research to be in the public interest) but this further divorces the donor from maintain some interest in the tissue.⁵²

If one adopts a conditional gift approach, these problems may be avoided because the donor arguably continues to have an interest in the property which should be effective against third parties in the network. If we adopt the position stated above that a gift of human tissue is a gift of goods (with some related choses in action), the conditions of the gift should be enforceable in common law, like gifts in contemplation of marriage. Equity would go on to recognise that the donors retain an equitable interest in the tissue (as it does in gifts in contemplation of marriage, or in personal equitable obligations) because it would be unconscionable for the biobank network members to take the tissue subject to conditions and then ignore them. If the conditions are breached equity could order specific performance of the obligation, equitable compensation or a constructive trust over the tissue to protect it against further interference. The only situation in which a third party may have a defence is if the third party is a bona fide purchaser for value, without notice of the conditions.⁵³ However, in a biobank network that will be highly unlikely as the original

⁵² The relevant Australian law is *Privacy Act 1988* (Cth), s 95A. See also National Health and Medical Research Council, *Guidelines approved under Section 95A of the Privacy Act 1988* (2001).

⁵³ This is known as the rule in *Pilcher v Rawlins* (1872) LR 7 Ch 259.

conditions of the gift will ordinarily be known, or should be known, by the third parties. As such they will have notice and be bound to respect the equity of the donor. Alternatively, third parties in networks are ordinarily volunteers themselves, receiving the tissue as a gift, again with the result that they are subject to the earlier equity of the donors because they are not purchasers for value.

There remain some practical concerns. The first concern is the assumption that donors are in a position to bargain for conditions being imposed. Biobanks may be tempted to create standard agreements which will be unconditional, leaving them with the greatest amount of freedom and donors with no remaining interest. One way to counter balance this problem would be to introduce implied terms, as were discussed above. These could either be introduced through the common law method (as they were in gifts in contemplation of marriage) or through statute (as they are in socially important contracts such as leases and sale of land). Implied terms would create a minimum standard of behavioural expectation.

CONCLUSION

The law of gifts provides a new way of considering gifts of human tissue to biobanks. It is by no means a panacea for all of the ethical and legal problems of biobanking. However, the advantage of a gift approach is that it respects the fact that donors wish to maintain some modicum of control over what happens to their tissue after it has been given, by recognising a continuing proprietary interest. The rules are flexible and allow for degrees of control. This gives donors some choice in how to donate their tissues and for what purposes. On the other hand, the rules are complicated and may not be easily understood by donors and who may not think to express their desires in binding ways when donating. This problem raises the further issue of what terms should the courts imply into gifts of tissue as having that provide basic protection for donors of human tissue. Thankfully, the law of gifts already has an arsenal of different approaches (implied terms, statutory protections) that might mitigate these concerns.