PROPERTY IN HUMAN TISSUE AND THE RIGHT OF COMMERCIALISATION: THE INTERFACE BETWEEN TANGIBLE AND INTELLECTUAL PROPERTY

DIANNE NICOL*

This article considers the legal consequences of recognising property rights in human tissue in relation to the specific issue of control of the commercialisation of the results of research using that tissue. Ethical guidelines and privacy laws do not deal directly with this issue. Legal recognition of a tissue source's ownership of their tissue might enable actions to be brought for breach of bailment and conversion. However, this article concludes that even if these actions could be sustained, they may not provide adequate remedies to a source who objects to the commercialisation process or wants to take a share of the profits of commercialisation. Moreover, legal recognition of a source's intangible right of commercialisation may not assist if it conflicts with patent rights held by others. Other options are considered, including the imposition of a requirement in patent law to verify consent to patenting and the establishment of structures to facilitate benefit sharing.

I INTRODUCTION

There are various aspects to the issue of whether or not there should be a legally recognised right of property in the human body and in tissue extracted from the human body (whether dead or alive). Reams have been written on the philosophical justifications for recognising such property rights. My primary focus in this article is to analyse the practical and legal implications of recognising these rights in the specific context of use of human tissue donated specifically for research or supplied for research following removal for therapeutic purposes. I will attempt to show that the addition of property rights to the armoury of existing protections available to sources of tissue will not necessarily improve the source's lot, particularly when it comes to the commercialisation of the results of research using their tissue.

First, I will briefly discuss alternatives to the property approach in protecting fundamental human rights in the research context. I will then analyse in some depth the legal implications of the recognition of property rights, particularly focusing on whether this would enable the tissue source to exercise some control over the process of commercialisation of research results and entitle them to take some share of the profits of commercialisation. My analysis focuses principally

* Senior Lecturer, Law Faculty and Senior Research Fellow, Centre for Law and Genetics, University of Tasmania, Australia. I would like to thank Lynden Griggs, Ken Mackie, Don Chalmers, Margaret Otlowski, Imogen Goold and an anonymous reviewer for their comments on early versions of this article.

on the common law action of conversion, which has been the main focus of court cases in which these issues have been raised. I acknowledge that there are various other legal and equitable options in the property armoury, some of which are briefly considered. However, it is beyond the scope of this article to fully evaluate them all. Finally, I will briefly turn to other alternatives that may provide greater certainty to both sources and users of tissue in relation to these commercialisation issues. My intention in this part of the article is not to provide a definitive treatise on all of the non-property alternatives, but merely to highlight that other options do exist and that these warrant further consideration.

II THE *MOORE* AND *GREENBERG* CASES

These are live and important issues, as illustrated by the US cases of *Moore v Regents of the University of California*[1] and *Greenberg v Miami Children's Hospital Research Institute, Inc.*[2] In both cases, actions by sources of tissue in conversion were rejected on the basis that they had no property rights in their tissue.[3] The *Moore* case is so infamous that it probably does not need to be described in much detail. However, it is necessary to draw attention to some salient points. Moore was suffering from hairy cell leukemia and his spleen tissue was removed with consent for therapeutic purposes. Moore's physician, Dr David Golde, aware of the unique properties of Moore's T-lymphocyte cells and their commercial value,[4] used the cells for research purposes even though he had not obtained Moore's consent for research use. Dr Golde developed a cell line from Moore's cells, which he called the Mo cell line.[5] The cell line was patented (US Patent No 4 438 032) and significant profits were made. The potential market was estimated to be over US $3 billion by 1990.[6] Both Dr Golde and the University of California obtained significant financial benefits from the commercialisation of the invention. Moore objected to the use of his tissue without his consent, and wanted a share in the profits of the patented invention. He raised a number of causes of action, although the Californian Supreme Court only considered two grounds, first, breach of fiduciary duty and lack of informed consent and secondly, conversion. Moore succeeded on the first ground but failed to establish conversion because the majority refused to recognise that he had property rights in his removed cells.

1 51 Cal 3d 120 (Cal, 1990) ('*Moore*').
2 264 F Supp. 2d 1064 (Fla, 2003) ('*Greenberg*').
3 For a detailed review and critique of both of these cases see Donna Gittner, 'Ownership of Human Tissue: a Proposal for Federal Recognition of Human Research Participants' Property Rights in their Biological Material' (2004) 61 *Washington and Lee Law Review* 257.
4 Moore's T-lymphocyte cells over-produced certain chemicals known as lymphokines, which are involved in regulation of the human immune system. This feature made Moore's cells particularly interesting to study because over-production of the lymphokines assisted in the analysis of the gene encoding these chemicals. See *Moore*, 51 Cal 3d 120, 126-7 (Cal, 1990).
5 The Court acknowledged that the development of a cell line from primary cells is not an easy task quoting from a report from the Office of Technology Assessment that '[l]ongterm growth of human cells and tissues is difficult, often an art': *Moore*, 51 Cal 3d 120, 127 (Cal, 1990).
6 Ibid.

In this example, there is a close connection between the tissue and the patented invention. Although the cell line was an independent creation requiring skill and labour to produce, there are several important points that need to be borne in mind in the discussion that follows. First, although Moore's original spleen cells were no longer in existence at the time of the dispute, the Mo cell line was made up of the progeny of Moore's cells. Thus, it could be argued that Moore's cells continued to exist through the cell line. Secondly, the unique qualities of the cell line were directly derived from Moore's original cells: those qualities would not be present in the cell line but for Moore's original cells. Thirdly, the cell line of itself was a tangible entity (although the patented invention was, of course, intangible, and it was the invention that was commercialised). Finally, Moore did not consent to anything other than removal of his spleen for therapeutic purposes.

In the second case that we need to consider, Daniel Greenberg and others were involved as research participants in a study being conducted by researchers at the Miami Children's Hospital into Canavan's disease. This is a genetic disorder afflicting children of Eastern European Jewish descent, causing stunted development, lack of muscle tone, blinding and ultimately death.[7] The motivation of the participants was to assist in developing a method for pre-natal and carrier testing. They played an active role in the research project: they provided blood, urine and autopsy samples, information and financial support. They initiated a search for other families and established a registry of sufferers. In 1994 the gene causing Canavan's disease was isolated and a test was developed. Unknown to the plaintiffs, a patent application was also filed and issued in 1997. The hospital only allowed others to use the test if they entered into a restrictive licensing arrangement, which imposed limitations on the number of tests performed and required the payment of licence fees. Greenberg and others brought an action against the hospital in 2000 alleging lack of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment (of the patent application), conversion and misappropriation of trade secrets.

The case has now been settled, following one important decision resulting from the defendants' motion to dismiss.[8] The Court upheld the motion on all claims except unjust enrichment. Some of the key points in this decision will be discussed later. The basis for the claims was that Greenberg and others said that they had an understanding that supply was for the purpose of research leading to identification of mutations and carrier detection for the benefit of the population at large and that testing would be available on an affordable and accessible basis and that the research would remain in the public domain. They sought damages and equitable and injunctive relief.

7 For further information see the website of the Canavan Foundation, a not for profit organisation founded by parents and families of afflicted children at <http://www.canavanfoundation.org> at 8 January 2005.

8 *Greenberg*, 264 F Supp. 2d 1064 (Fla, 2003). Although the precise nature of the settlement is confidential, a joint press release issued by all parties states that the settlement provides for continued royalty-based genetic testing by certain licensed laboratories and royalty-free research by institutions, doctors, and scientists searching for a cure. See Canavan Foundation, <http://www.canavanfoundation.org/news/09-03_miami.php> at 8 January 2005.

In this example, the connection between the tissue and the patented invention is more remote than in *Moore*, although there are some similarities between the two scenarios. First, as with *Moore*, the tissue probably had to remain identifiable during the research. Either that, or it had to be coded so that it could be re-identified in order to trace family patterns of inheritance. However, once the research was completed the tissue was no longer required, and may well have been destroyed. Secondly, although the participants were sufferers or families of sufferers of Canavan disease, their tissue was not *unique*. There are many other people whose tissue has the same attributes. Thirdly, nor was there as close a connection between the tangible tissue and the intangible invention as in *Moore*. Here the result of the research was not a tangible cell line but intangible genetic information. Finally, the sources consented to the research. What they did not consent to was commercialisation of that research.

It is likely that in other cases the connection between tissue donated or otherwise obtained for research purposes and inventions derived from the research will be even more remote, both in terms of the uniqueness of the tissue and the steps involved between use of the tissue and creation of the invention. For example, most epidemiological research will require a supply of human tissue. However, it should be noted first that tissue will be de-identified and secondly that research will reveal trends rather than unique features of individual tissue extracts. Thirdly, there could be a number of intermediate steps between the original research using the tangible tissue and patenting of the intangible invention. Finally, ethical review may allow for waiver of consent. These distinctions need to be borne in mind in the following analysis.

III Protection of Human Rights: The Role of Consent and Privacy

It probably goes without saying that all sources of tissue want to have their dignity, privacy and autonomy recognised. In this regard, the behaviour of John Moore's doctor raises serious concerns. As a general rule, tissue removed for therapeutic purposes should only be used in research with the consent of the patient, particularly when the tissue continues to be identifiable. Sources of tissue want some assurance that the tissue they donate or make available for research will be used, stored, and disposed of in a way that protects these fundamental human rights. They may not turn their mind to the fact that it is likely to take many years and large sums of money for new medical treatments to become available and that commercialisation and patenting are likely to be essential to this process. If sources were informed of this commercialisation process it would not necessarily deter them from allowing research use of their tissue, particularly if they are assured that their dignity, privacy and autonomy will continue to be protected. However, they may well object if they see the researcher benefiting financially from the commercialisation of research involving their tissue (as in *Moore*) and if they see restrictions being imposed on access to the results of that research (as in *Greenberg*). In such circumstances

they may want to have some ongoing control over the commercialisation process. They may want to take a share in the profits of commercialisation (as in *Moore*) or at least to have some say in whether or not commercialisation should occur and how the profits of commercialisation are distributed (as in *Greenberg*).

A *Ethical Obligations*

There are a number of existing legal and ethical obligations that provide protection of the fundamental human rights of sources of human tissue. For example, ethical obligations imposed on biomedical researchers in Australia stem primarily from the National Health and Medical Research Council ('NHMRC') *National Statement on Ethical Conduct in Research Involving Humans* (1999) ('the National Statement'). Many other countries have mechanisms in place imposing similar obligations on researchers. In Australia, all institutions and organisations, whether public or private, that apply for and receive NHMRC or other public funding are required to establish Human Research Ethics Committees and follow the Principles set out in the National Statement for all research involving humans. The National Statement prescribes fairly stringent ethical guidelines relating to the use of human tissue for research purposes, requiring full disclosure of use, storage and disposal. Whenever human tissue is collected for purposes including research, consent for its use in research is generally required. Waiver of consent is allowed in limited circumstances. Principle 15.8 of the National Statement sets out the matters that ethics committees are required to take into account in determining whether or not to waive the consent requirement. These are:

- the nature of any existing consent relating to the collection and storage of the sample;
- the justification presented for seeking waiver of consent including the extent to which it is impossible or difficult or intrusive to obtain specific consent;
- the proposed arrangements to protect privacy including the extent to which it is possible to de-identify the sample;
- the extent to which the proposed research poses a risk to the privacy or well being of the individual;
- whether the research proposal is an extension of, or closely related to, a previously approved research project;
- the possibility of commercial exploitation of derivatives of the sample; and
- relevant statutory provisions.

B *Legal Obligations*

Legally, there is also a requirement to obtain the consent of a person prior to the removal of tissue, because any touching of a person without consent is a trespass.[9] Hence, any person removing tissue from another will be liable in trespass unless there is valid consent. However, all that is required for valid consent is that the patient or donor agrees to undergo the procedure after being informed in broad terms of the treatment.[10] It is important here to distinguish between consent to medical procedures and the concept of informed decision making. The right of a person to make informed decisions concerning treatment options derives from the duty of a health care professional to disclose the nature and consequences of the treatment and also the risks and complications involved in the procedure.[11] A failure to obtain an informed decision will only found an action in negligence and not in trespass.[12] Obviously in the research context it will be necessary to obtain consent to the removal of the tissue to avoid an action in trespass and the researcher is also under a duty to disclose all material risks. However, it would be difficult to argue that these broad consent requirements carry with them any requirement to disclose the commercial use of research results.[13]

In addition to these consent requirements, the privacy of personal information is protected in Australia through the federal *Privacy Act 1988* (Cth) ('the *Privacy Act*'). The *Privacy Act* sets up 11 Information Privacy Principles ('IPPs') covering the collection, storage, use, access to, release and challenges against information on individuals held by federal government agencies. The *Privacy Amendment (Private Sector) Act 2000* (Cth) extended the provisions of the *Privacy Act* from federal government agencies to the private sector. Under the new provisions, a list of National Privacy Principles ('NPPs') provide direction on a number of relevant matters particularly collection, storage and use of personal information held by organisations other than federal government agencies. Both the IPPs and the NPPs have specific provisions relating to sensitive information including health information. For example, NPP 10 requires specific consent for the collection of this type of information.

It should be noted that the *Privacy* Act does not apply to State government agencies. Importantly, much human genetic research is conducted within

9 *Cole v Turner* (1704) 6 Mod Rep 149. Note, however, that the courts recognise that some unconsented contact is a necessary part of normal, every day life. See, eg, *Collins v Wilcock* [1984] 1 WLR 1172. The various State and Territory Human Tissue Acts also impose consent requirements for research use of regenerative tissue removed for transplantation purposes: *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Transplant Act 1979* (NT).

10 *Reibl v Hughes* (1980) 114 DLR (3d); *Rogers v Whittaker* (1992) 175 CLR 479.

11 *Rogers v Whittaker* (1992) 175 CLR 479, 490.

12 Ibid.

13 In *Greenberg*, although the defendants accepted that a duty of informed consent attaches at some point of the researcher-participant relationship, the Court did not accept the plaintiffs' proposition that this duty of informed consent can be extended to disclosure of a researcher's economic interests. See *Greenberg*, 264 F Supp. 2d 1064, 1070 (Fla, 2003).

hospitals and universities, some of which fall within this category of State or Territory government agencies.[14] Such organisations will not be covered by the federal *Privacy Act* but by relevant State or Territory legislation.[15] As a result, there will be gaps in the legal protection of privacy in States and Territories that have not yet introduced comprehensive privacy legislation. However, the Australian Health Ministers' Advisory Council is in the process of drawing up a National Health Privacy Code, which will provide uniform standards in relation to health information across Australia.[16] Basically, the Code closely mirrors the NPPs, creating a set of NHPPs that expand on and clarify some aspects of the NPPs.

C *Privacy in the Research Context*

The National Statement recognises the importance of maintaining the privacy of personal information. It requires that ethics committees must be satisfied that appropriate provisions are in place to protect privacy. Where research is conducted using information held by Commonwealth instrumentalities, the IPPs have to be complied with and when research involves information held by private sector organisations, the NPPs have to be complied with. However, there are provisions in the *Privacy Act* that allow for non-compliance in certain limited circumstances. The relevant provisions are contained in s 95 for Commonwealth agencies and s 95A for the private sector. These are enabling sections, allowing research to be conducted that would otherwise be in breach of the legislation. Both sections have a public interest test, requiring that the public interest in the promotion of research of this kind substantially outweighs the public interest in maintaining the level of privacy protection afforded by the IPPs and NPPs.

Any personal information derived from research involving human tissue will be protected under the privacy regime, provided that the researcher's host institution comes within the ambit of the public or private sector provisions of the *Privacy Act*, or that there is a link to these provisions through some other agency.[17] But what of the tissue itself? There is some academic support for the view that genetic samples are information, or, more likely, that they are records containing

[14] For example, the University of Tasmania is established under the *University of Tasmania Act 1992* (Tas).

[15] See, eg, *Privacy and Personal Information Protection Act 1998* (NSW); *Information Privacy Act 2000* (Vic).

[16] The Draft National Health Privacy Code (December 2002) is available at Department of Health and Ageing <http://www.health.gov.au/pubs/nhpcode.htm> at 8 January 2005. Note that some States also have specific legislation relating to health information: *Health Records and Information Privacy Act 2002* (NSW); *Health Records Act 2001* (Vic); *Health Records (Privacy and Access) Act 1997* (Vic). Other more general health related legislation also imposes privacy and confidentiality obligations.

[17] For a detailed discussion of this and other issues relating to privacy in the research context see Margaret Otlowski, 'Protecting Genetic Privacy in the Research Context: Where to From Here?' (2002) 2 *Macquarie Law Journal* 87.

information.[18] On this basis, samples would be interchangeable with the information they contain. Technologies such as bioinformatics are firmly establishing the linkage between computer technology and genetic technology and it is likely that human tissue samples will, over time, be seen increasingly as living databases of information. However, this stage has not yet been reached and the argument remains speculative.

The problem here is that it is not until the information is extracted from the tissue that the privacy regime becomes operational. This may occur some time after removal of the tissue, and may be done by a person other than the person who collected the tissue. One of the key recommendations in the recent report *Essentially Yours* by the Australian Law Reform Commission and the Australian Health Ethics Committee was that the definition of personal information in the *Privacy Act* should be extended to include genetic samples (and, by extension, human tissue).[19] If this amendment is accepted, it will require researchers to be compliant with the NPPs or IPPs at the time of collection of tissue. For example, it would require the tissue collector to explain the purpose of collection, primary and related secondary uses, and other related matters at the time of collection. In particular, NPP 2, which imposes obligations relating to disclosure of information, could be expanded to impose obligations relating to transfer of genetic samples to third parties.[20] In many respects the protection that might be afforded to sources of genetic samples (and human tissue) through this proposed extension of the *Privacy Act* is precisely the type of protection sought by advocates of property rights.

Importantly, the proposed mechanism for providing privacy protection for genetic samples is relatively simple to establish. It requires only some minor amendments to the definitions in the *Privacy Act* and to the NPPs and IPPs. However, one of the major drawbacks of the privacy regime is that its enforcement powers are relatively weak when compared with common law actions because it is complaints-driven and conciliation-based. Orders of the Privacy Commissioner can only be enforced by court action.[21] On the other hand, the complaints process does have a significant advantage over litigation in that it is quick and cheap. Indeed, it may be the only viable means of redress for many complainants.

18 See the discussion on this point in Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, Report No 96 (2003) 262-4 ('*Essentially Yours*'). It should be noted that in New South Wales the *Privacy and Personal Information Protection Act 1998* (NSW) s 4(2) and the *Health Records and Information Privacy Act 2002* (NSW) s 5(2) already include body samples in the definition of personal information.

19 Ibid Recommendations 8-1 to 8-4.

20 Ibid 271-2.

21 The first Federal Court judgment on breach of NPPs was delivered in May 2004: *Seven Network (Operations) Ltd v Media Entertainment and Arts Alliance* [2004] FCA 637 (Unreported, Gyles J, 21 May 2004).

D *Practical Application*

If a *Moore*-type scenario arose in Australia it seems certain that there would be various breaches of the National Statement. Whilst these breaches of themselves may not be legally enforceable,[22] both the researcher and the host institution could face public censure and removal of public funding for *all* projects carried out at the institution. It is likely that there could also be breaches of existing provisions in the *Privacy Act* or equivalent State legislation. The proposed extension of the *Privacy Act* to include genetic samples would provide a further layer of protection.

In a *Greenberg* scenario, on the other hand, there appear to be no obvious breaches of the National Statement or the *Privacy Act*, unless it could be established that some aspects of the research work that is undertaken for the purpose of obtaining a patent are different from the research for which consent was obtained. Similarly, in a scenario involving de-identified tissue, provided that appropriate ethical clearances are obtained and followed, there may be no concerns relating to the National Statement and the *Privacy Act* because there is no handling of personal information.

The major drawback with the privacy regime in these scenarios is that it does not address the issues associated with commercialisation of the results of research using human tissue. Hence, plaintiffs in Australia in both *Moore*-type cases and *Greenberg*-type cases would not be provided with the legal remedies that they seek. The National Statement touches on the issue of commercialisation, but it only requires disclosure of commercial interests to the ethics committee, not to the research participant.[23] Hence, whilst privacy and ethical requirements impose obligations on researchers using genetic samples and genetic information, sources may nevertheless find it particularly difficult to protect themselves against misuse of their tissue by third parties and to control the path of commercialisation. We must now to look to property law to see if it is capable of filling this void.

IV Protection of Property Rights: Bailment and Conversion

There is no doubt that the notion of having property in one's own tissue has important symbolic value. Property is likely to give people a sense that their tissue is special and that they have some residual control over what is done with it even when they have parted with possession. The problem is that most commentary stops at this point. The main advantage to sources in having recognised property rights in their tissue is that they can take court action for misuse and unauthorised use of their tissue against a researcher who acquires

[22] See Imogen Goold, 'Tissue Donation: Ethical Guidance and Legal Enforceability' (2004) 11 *Journal of Law and Medicine* 331.

[23] See particularly Principle 2.21 of the National Statement, discussed more fully in Dianne Nicol, Margaret Otlowski and Don Chalmers, 'Consent, Commercialisation and Benefit Sharing' (2001) 9 *Journal of Law and Medicine* 80.

their tissue and against any other person who comes into possession of the tissue downstream of the researcher.[24]

However, there remain serious questions as to the extent to which the property model could provide the desired outcome of giving the source of tissue control over the commercialisation process. My argument is that recognising a source's ownership of their tissue is not enough. In order to achieve desirable outcomes from the property tag there will have to be other fundamental changes in the way that tissue is supplied for research purposes. This will create considerable uncertainty in research practice, at least in the short term, and may lead to the undesirable outcome of commodifying tissue and the basic research process.

A *Establishing the Right to Bring Actions in Conversion and Breach of Bailment*

The source of tissue is likely to use the tort of conversion in an attempt to find legal redress for objectionable use of their tissue in the research context and for objectionable downstream use of the results of that research. Conversion was unsuccessfully pleaded in both the *Moore* and *Greenberg* cases because the courts refused to recognise that the plaintiffs had property rights. However, my argument is that both these decisions suggest that even if property rights exist, the law of conversion may not provide the source of tissue with what they want, particularly if what they want is to share in the profits of commercialisation, or at least control the commercialisation process.

The essence of conversion is dealing with goods in a manner that is repugnant to the plaintiff's *possession or immediate right to possession* of the goods.[25] Clearly, to succeed in this action the source will have to establish that they have the immediate right to possession, since they do not have actual possession. It is therefore essential to inquire into the legal nature of the transfer of tissue from the source to the researcher. To succeed in conversion the source would have to prove that ownership of the tissue has not been relinquished: that the tissue has not been absolutely gifted or abandoned. In legal terms, it would seem that perhaps the only way that the source could do this would be to establish that a bailment exists: that one person (the bailee: the researcher or another person who has acquired possession) is voluntarily and knowingly in possession of the goods (the tissue) of another person (the bailor: the source).[26]

If a bailment is found to exist the source could pursue an action for breach of bailment where the researcher deals with the tissue in a manner contrary to the bailment. If successful, the source would be entitled have the tissue returned to them or, alternatively, to have the tissue destroyed, and also to obtain damages for

[24] Assuming that the source has not handed over their entire bundle of property rights in the tissue in consenting to the collection of the tissue. This point is discussed further below.

[25] Various torts textbooks provide good coverage of the law of conversion. See, eg, F Trindade and P Cane, *The Law of Torts in Australia* (3rd ed, 1999) 137-59; R P Balkin and J L R Davis, *Law of Torts* (3rd ed, 2004) 65-106.

[26] Norman Palmer's treatise on bailment is the best source of information on these issues. N E Palmer, *Bailment* (2nd ed, 1991).

the *actual loss* suffered by them, if any. The source could also bring an action for conversion for more repugnant dealings, which may entitle them to damages for the *full value* of the tissue without having to prove any actual loss.[27] Moreover, the source could pursue further personal and proprietary avenues (for example, tracing)[28] against third parties who come into possession of the tissue.

Bailments are generally express contractual arrangements between the two parties. However, there is nothing in the relationship between a researcher and a research participant to suggest that any such express arrangement exists: theirs is nothing like a hire purchase or lease agreement. Indeed, it would be difficult to describe the relationship as contractual at all. Currently, sources provide tissue for research freely, either by direct involvement in a particular research project or by consenting to the research use of tissue removed for therapeutic, pathological or transplantation purposes. Some sources may have special reasons for being involved in research, particularly if they or their relatives are likely to benefit from new treatments. In *Greenberg*, for example, sources were all families of sufferers of Canavan disease. Others may participate because they recognise a broader public benefit in the research both directly, by providing new treatments to alleviate suffering caused by disease and indirectly, by increasing our understanding of how the human body functions. As such, the relationship between the source and researcher could perhaps better be described as one of gift rather than contract.

Norman Palmer acknowledges that the key feature of the modern view of bailment is voluntary and willing possession.[29] There is no requirement to establish that an explicit contractual bailment arrangement exists. Bailments can be gratuitous in nature, from the perspective of the bailee (depositum or gratuitous safekeeping) and the bailor (commodatum or gratuitous loan). These gratuitous bailments are generally recognised as being non-contractual.[30] The latter gratuitous loan type bailment is most likely to be applicable to the topic under investigation.[31] Its core features are:

> the loan of a chattel for the exclusive benefit of the borrower, on the condition that he will return the chattel to the lender, or redeliver it at his instructions, in accordance with the agreement between the parties.[32]

B *Existence of a Bailment Relationship*

Bearing this in mind, could any form of bailment exist in the *Moore* and *Greenberg* scenarios? As a first step in establishing that a bailment exists, the source must show that the researcher has only acquired possession of the tissue, not ownership. Moreover, it must be shown that the researcher is knowingly and willingly in possession of the tissue owned by the source: they must know that

27 I will come back to this distinction between actual loss and full value later.
28 Palmer, above n 26, 287-97.
29 Ibid 2-3.
30 Ibid 56.
31 Ibid 630-76.
32 Ibid 630.

the source owns it. There is no bailment if the researcher genuinely and reasonably believes that they own the tissue (or that there is no ownership of that tissue at all). Existing law tends to support the proposition that if property rights in human tissue exist at all, the researcher rather than the source holds those rights, particularly when the tissue has been subjected to work and skill.[33] The problem thus created is that it will be exceedingly difficult to establish that human tissue obtained for research purposes is the subject of a bailment unless its is generally acknowledged that the source of tissue has ownership of it. It would seem, therefore, that the first successful property case is, nevertheless, doomed to fail. However, this would change once (if) a definitive judicial pronouncement is made to the effect that sources have ownership of their own extracted tissue.

Even if it is accepted that sources have ownership of their tissue, it would still be necessary to establish a promise of re-delivery of possession by the researcher, or, in the alternative, a promise to destroy the tissue at the request of the source. Present research practice is that once the tissue has been donated, there is no re-delivery to the source. There are also practical reasons why re-delivery is not desirable, particularly if the tissue is a biohazard. In the past, bailment requirements were strictly interpreted: a bailment could only exist where there was a promise by the bailee (either express or implied) to re-deliver the goods to the bailor. However, as Palmer notes, these requirements are now interpreted much more leniently by the courts and hence a bailment can exist even though both parties intend that the tissue is to remain with the researcher.[34] Nevertheless, there remains considerable uncertainty as to what will and will not constitute a legally recognised bailment, as opposed to a transfer of ownership. If and when this new property right is determined by the courts to exist, matters such as ownership, repossession and/or destruction will need to be agreed to by the source and the researcher before new tissue is excised or otherwise obtained by the researcher for research purposes. The situation will be more problematic for existing tissue collections. Unless bailment terms can be agreed to retrospectively, there will be ongoing uncertainty as to legitimate use of the tissue.

C *Establishing What Actions Will Amount to Conversion and Breach of Bailment*

Perhaps the most common way that a bailment is breached is when the bailee uses the bailor's goods as their own.[35] These acts may also give rise to an action in conversion, but only if they are serious enough to be 'repugnant to the owner's

[33] See particularly *Doodeward v Spence* (1908) 6 CLR 406. For a detailed analysis of the case law see Paul Matthews, 'Whose Body? People as Property' (1983) 36 *Current Legal Problems* 193 and Roger S Magnusson, 'Proprietary Rights in Human Tissue' in Norman Palmer and Ewan McKendrick, *Interests in Goods and Services* (2nd ed, 1998). See also Loane Skene, 'Arguments Against People Legally "Owning" Their Own Bodies, Body Parts and Tissue' (2002) 2 *Macquarie Law Journal* 165.

[34] Palmer, above n 26, 3-7.

[35] *Craig v Marsh* (1935) 35 SR (NSW) 323. See also the discussion in Trindade and Cane, above n 25, 152-3.

right of possession'.[36] There is a lack of authority for successful conversion actions where the relevant dealings are with material derived from use of the goods rather than use of the goods themselves.

In the *Moore* scenario, if a bailment could have been established,[37] it is likely that the only permissible use of Moore's cells was their destruction. Dr Golde used Moore's cells to make a cell line, which would seem to be repugnant to the bailment and hence would allow an action in conversion. However, it is more difficult to characterise subsequent actions involving the cell line as falling within the bailment. It is pertinent to consider the following activities, some or all of which may have occurred in the *Moore* case and are likely to occur in similar scenarios:

- research on the cell line;
- transfer of progeny of the cell line to other parties;
- deposit of the cell line in a cell bank;
- patenting of inventions resulting from research on the cell line; and
- licensing of the patent to other parties.

A bailment will come to an end when the goods that are bailed no longer exist.[38] The question here is whether the creation of the cell line would continue the operation of the bailment. There is authority for the proposition that the progeny of animals and plants created during a bailment are the property of the bailor not the bailee.[39] Using this analogy it could be argued that the cell line comprises progeny of the original cells and therefore belongs to the source as bailor and not the researcher as bailee. If this is the case then the activities described in the first three dot points above may be actionable in conversion. However, the fact that considerable skill and effort are required to create the cell line[40] may not support this analogy with plant and animal cases. Here, the only activity that would fall within the conversion would be the original research aimed at creating the cell line. In either case, it would be difficult to argue that the activities described in the last two dot points, namely patenting of research results and licensing of the patent fall within the notion of 'dealing with goods'.

In the *Greenberg* scenario, the relevant dealing with the tissue was research aimed at isolating the gene responsible for Canavan disease. This research was conducted with the consent of the sources, and hence if a bailment existed there would not have been a breach unless the research work undertaken went beyond the scope of the consent. Downstream dealings included patenting the genetic

36 Palmer, above n 26, 211. A number of the most important Australian authorities are discussed by Young J in *Flowfill Packaging Machines Pty Ltd v Fytore Pty Ltd* (1993) Aust Torts Reports ¶81-244, 62,518-22. The benefit of an action for conversion is that the remedies are more generous to the bailor, as discussed below.

37 This would have required the Court to have recognised both that Moore had property in his tissue and the essential features of bailment were present. This was no small task, particularly given that Moore failed at the first hurdle (see the decision of the majority in *Moore*, 51 Cal 3d 120, 134-48 (Cal, 1990)).

38 Palmer, above n 26, 110.

39 Ibid 1279.

40 See above n 5.

information uncovered by the research and licensing the patent. Again, it would be difficult to describe either of these as dealings with the goods themselves. The patent creates a new statutory property right in the invention, which is quite independent of and distinct from any property rights that might exist in the original tissue.

In a scenario involving de-identified tissue there can be no bailment relationship, because if tissue is de-identified there is no possibility of re-delivery and hence one of the crucial features of bailment is missing. The only breach of bailment that might arise is if the researcher who obtained the original tissue from the source transfers it to another researcher without the consent of the source. This act of transfer could be in breach of the bailment.

D *Establishing the Remedies for Conversion and Breach of Bailment*

In the three scenarios described above, if the tissue has been converted or otherwise dealt with in breach of the bailment (about which there is considerable uncertainty), the next question is what can be recovered by the source. The general rule where there has been breach of bailment is that the bailor can recover the goods and obtain compensation for the actual loss incurred.[41] Where there is a conversion, damages are based on the full market value of the goods. In exceptional circumstances, damages may be either decreased or increased beyond the value of the goods, as discussed below. Nevertheless, the overriding principle is that damages should be awarded by way of compensation.[42]

The remedies for breach of bailment are likely to provide only limited benefits to the source. In all three of our scenarios, the original piece of removed tissue may no longer be in existence, in which case it obviously could not be recovered. This will not necessarily be of particular concern to the source, who may actually prefer to have the tissue destroyed rather than to have it returned to them, unless they want to be able to re-use the same piece of tissue. The return of tissue is likely to be a far more important concern in non-research related property cases. For example where a deceased child's organs have been removed parents may desire their return for spiritual, emotional and other reasons. In the research context, unless non-regenerative tissue has been removed (as was the case for John Moore), the source will have replaced the removed tissue by natural processes. Return of the tissue would not serve any useful purpose other than assuring the source that the researcher no longer has possession of it. The problematic issue from the source's perspective is that if their tissue has regenerated, they have not actually lost anything tangible and hence there is no actual loss to be compensated.

41 Palmer, above n 26, 1270-75.
42 *Butler v Egg Pulp Marketing Board* (1966) 114 CLR 185, 191.

In a *Moore*-type scenario, the situation is slightly different because non-regenerative tissue is removed, albeit with consent.[43] Hence, it may be more important in this scenario for the source to regain possession. If the cell line is considered to be the progeny of the original cells then this may be recoverable but the court would have to recognise the skill and effort put in to the development of the cell line by the researchers. The source would still have difficulty in establishing actual loss. In fact the value is more likely to have been enhanced. It could be argued that, if the cell line is returned to the source, they should pay compensation to the researchers because otherwise the source receives a windfall. The situation is complicated further by the existence of the patent. I will discuss later the question of whether the source has any rights relating to the patent. Without those rights, and depending on the scope of the patent, return of the cell line of itself may be of little commercial value to the source because any commercial use may infringe the patent.

An estimation of damages in conversion cases involving human tissue is also fraught with difficulty because of the widespread revulsion associated with commodification of human tissue.[44] The measure of compensation for the value of goods is generally the replacement cost to the plaintiff, which would be a fairly meaningless figure in scenarios involving human tissue.[45] In most cases, at the time that the tissue is acquired by the researcher it has little or no commercial value of itself. It is only when the researcher has put in skill and labour that the tissue acquires some form of monetary value. The *Moore* case is exceptional in this regard because his tissue clearly had unique features that gave it monetary value even without the input of further skill and labour. In other cases, although collections of tissue obtained from multiple sources may have considerable value, each individual tissue sample may be worth very little of itself. Take, for example, the case of *United States of America v Prince Kumar Arora*,[46] in which the defendant Arora intentionally destroyed cells that were being cultured by a colleague. He was found liable in conversion on the basis that a living cell line is a property interest capable of protection. In that case the property interest was recognised by the Court as being owned by the National Institutes of Health, the employer of Arora's colleague. The Court held that compensatory damages should include two components, one for the value of the cells and the other for the cost of creating new cells. However, at a mere US$450.20, this was hardly a significant impost.[47]

[43] Recognising that the consent only extended to removal, not to subsequent use.

[44] See, eg, Radhika Rao, 'Property, Privacy, and the Human Body' (2000) 80 *Boston University Law Review* 359. For an alternative viewpoint see Gittner, above n 3, 298-304.

[45] However, it is acknowledged that there is some circularity to this argument. It is difficult to put a value on human tissue because it is not recognised as an item of property. If it were recognised as property then the market would soon put a value on it. Indeed, it has been posited that difficulties in assessment of value justify the utilisation of property rules in legal disputes rather than liability rules because it is more efficient for the market than for the courts to make this determination. See James E Krier and Stewart J Schwab, 'Property Rules and Liability Rules: the Cathedral in Another Light' (1995) 70 *New York University Law Review* 440.

[46] 860 F Supp 1091 (Mld, 1994).

[47] It should be noted that a sum of US$5 000 was also awarded in punitive damages.

The courts have allowed damages in excess of the market value of goods in some instances. For example, if goods can be hired on the open market, the courts generally allow recovery of lost profits from hiring in addition to return of the goods or full market value of the goods.[48] Such damages may be allowed even when the defendant can show that the plaintiff may not have been able to hire out the goods for the whole period during which they were held.[49] There is also some authority for the proposition that where the defendant sells goods and receives benefit from the sale, the plaintiff should be able to recover the sale price, rather than the replacement cost.[50] These damages are often referred to as restitutionary or 'gain stripping'.[51] Consequential damages are also available for reasonably foreseeable losses consequential to the act of conversion. However, it is unclear whether the courts would be willing to award damages for consequential benefits to the defendant. In effect, such damages are both restitutionary and consequential in nature.

The question of availability of restitutionary/consequential damages is squarely raised here: if a defendant earns profits from the exercise of their skill and labour in using the goods, and if the plaintiff did not have the requisite skill to be able to earn those profits in their own right, is the plaintiff entitled to a share in the profits? There would seem to be no authority directly on point. Even using restitutionary principles, recovery of damages for profits earned by the defendant in this way would seem to be too remote from the act of conversion, unless the profits are derived from the particular attributes of the goods in addition to the particular skill of the defendant, as was the case in *Moore*. In such a case it may be appropriate for the plaintiff to take a share of the profits. Taking these scenarios one step further, the profits earned from the commercialisation of a patented invention developed from research involving tissue owned by the plaintiff are even more remote, and recovery would seem to be even more unlikely.

Hence, even if property is recognised in human tissue, there will be significant difficulties for sources in establishing rights to repossession, repugnant dealings and entitlement to damages.[52] The *Moore*-type scenario is most likely to be successful, but even then it is difficult to see how conventional property rights will assist in controlling commercialisation.

48 *Flowfill Packaging Machines Pty Ltd v Fytore Pty Ltd* (1993) Aust Torts Reports ¶81-244.

49 The relevant authorities are discussed in *Finesky Holdings Pty Ltd v Minister of Transport for Western Australia* (2002) 26 WAR 368.

50 *Furness v Adrium Industries Pty Ltd* (1993) Aust Torts Reports ¶81-245, 62,536-7 (Ormiston J).

51 Sam Doyle and David Wright, 'Restitutionary Damages – the Unnecessary Remedy?' (2001) 25 *Melbourne University Law Review* 1.

52 For a different slant on some of these matters see Roy Hardiman, 'Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue' (1986) 34 *UCLA Law Review* 207.

V Protection of Commercialisation Rights: Property Versus Intellectual Property

If, as seems likely, an action for conversion of the tangible tissue fails to provide the desirable outcome of control of commercialisation of results of research using the tissue, could an action for conversion of any residuary intangible property rights be brought? Some have argued that in addition to property rights in the tangible tissue, the source might also retain an intangible property right to commercialisation.[53]

A *Existence of a Proprietary Right of Commercialisation*

There is US authority for the proposition that a property right of this nature could in fact exist. In *Miles, Inc v Scripps Clinic and Research Foundation*[54] a corporation had been established by the first plaintiff and the first defendant for purposes including preparing and selling immuno-chemicals. The case involved a cell line and patented process for producing pure Factor VIII:C created by a consultant to the corporation. The consultant assigned the patent to the first defendant and granted it the right to commercialise the cell line. In addition to other actions, the plaintiffs claimed conversion of the right to commercialise the cell line. Physical possession of the cell line was not in issue.

In a motion to dismiss by the defendants, the Court accepted that there could be property in the right to commercialise a thing. The Court used the analogy of a patent. The patent holder has the exclusive right to control exploitation. It was concluded that, in much the same way, the right to commercialise a cell line is capable of exclusive possession or control.[55] However, the Court refused to accept that an intangible property right of this nature could found an action in conversion.

Similar issues to those considered in the *Miles, Inc* case were raised in an action for summary judgment in *The University of Colorado Foundation, Inc v American Cyanamid*[56] where the results of research conducted at the University of Colorado were used to assist the defendant in obtaining a patent. The plaintiffs alleged conversion on the basis that the defendant intentionally exercised dominion and control over their invention and had wrongfully deprived them of the right to control the invention. As with *Miles, Inc*, the Court here refused to

53 See Hardiman, above n 52, 260-3. See also Stephen A Mortinger, 'Spleen for Sale: *Moore v. Regents of the University of California* and the Right to Sell Parts of Your Body' (1990) 51 *Ohio State Law Journal* 499, 512-14; William Boulier, 'Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts' (1994) 23 *Hofstra Law Review* 693, 726-29.

54 810 F Supp 1091 (US Dist Cal, 1993) ('*Miles, Inc*').

55 It appears that the plaintiffs in this case were forced to rely on this argument because they had not properly protected their rights by patent or by contract.

56 880 F Supp 1387 (US Dist Col, 1995).

recognise a cause of action in conversion for interference with intangible property rights that are not attached to something tangible.[57]

Herein lies the problem with enforcing intangible property rights. Courts generally do not allow a conversion action to be brought in relation to intangible forms of property, because the core feature of the action is dealing with *goods*. Nor do the courts generally recognise bailment of intangible rights.[58] In limited circumstances courts have recognised bailment and allowed conversion actions for these forms of property, but only if they are attached to a tangible chattel. As such, negotiable instruments can be bailed because the courts recognise both the actual and exchange value of the document. It will doubtless be much more difficult to establish bailment of an intangible commercialisation right where it is separate from the physical possession of tangible tissue.

B *Competing Commercialisation and Patent Rights*

It was implicit in both the *Miles, Inc* and *University of Colorado* cases that the normal way of protecting a right to commercialisation is by means of a patent, because this gives the patent holder the exclusive right to exploit the patent for financial gain. Human tissue of itself is not patentable because there is nothing inventive about it. The downstream results of research using human tissue are patentable provided that they fulfil the essential patent criteria.[59] Patents are granted for products and processes that provide a technical solution to a technical problem. Patent protection is available in Australia for a wide range of inventions created using human tissue, including cell lines and synthetically manufactured DNA and gene sequences with a definite industrial use, products of living matter including food supplements and drugs and processes for synthesising the material or making the products.

Patents are, of course, only available to inventors. The problem for sources of human tissue is that it would be difficult to classify them as inventors for the purpose of patent law. The essence of a patentable invention is that it is something that does not occur in nature. It must be something that is 'made by man'.[60] Whilst human tissue grows in human beings, the role of the person is passive. Although the tissue is made *within* them it is not actively made *by* them. It is fairly logical to assume that unless the source plays some active role in the creation of the invention, he or she would not be considered to be an inventor for

57 Note that the plaintiffs also raised a number of other causes of action including: fraud, patent infringement, copyright infringement, unjust enrichment, wrongful naming of inventor, misappropriation and breach of confidence. The plaintiff obtained summary judgment on copyright infringement. The issues of fraud, patent infringement and unjust enrichment were not decided.

58 However, Palmer notes that it is not inconceivable for the courts to extend the doctrine of bailment in this direction at some stage in the future. See Palmer, above n 26, 13-15.

59 Novelty, inventive step and industrial applicability. See *Agreement on Trade-related Aspects of Intellectual Property Rights* [1995] ATS 38, art 27(1) and s 18 *Patents Act 1990* (Cth).

60 *Diamond v Chakrabarty* 447 US 303, 309-10 (1980).

the purpose of patent law and would have no right to be listed as such on the patent application.[61]

Here we have a situation where rights to intellectual property and other intangible property rights could exist in the same thing. The source could have a right of commercialisation of the results of research stemming from their ownership of the tissue used in the research. The researcher or a third party could have patent rights in the invention created as a result of their skill and effort in undertaking the research. Both are intangible. The question that arises is who has priority in cases where there are competing property rights.

This issue was considered in the Canadian case of *Monsanto Canada Inc v Schmeiser*.[62] Schmeiser grew canola crops containing a synthetically produced gene, which was patented by Monsanto. He grew the crops from seed saved from a previous generation of crops grown on his own land. In assessing the conflicting rights in this case, the Court referred to a number of authorities that established that the patent takes priority in such circumstances. The rights of ownership of property are compromised to the extent required to protect the patent holder's statutory monopoly. For example, when considering whether or not Schmeiser had infringed Monsanto's patent by planting and growing crops from the saved seed, McLachlin CJ and Fish J noted that:

> Infringement through use is thus possible even where the patented invention is part of, or composes, a broader unpatented structure or process. This is, as Professor Vaver states, an expansive rule. It is, however, firmly rooted in the principle that the main purpose of patent protection is to prevent others from depriving the inventor, even in part and even indirectly, of the monopoly that the law intends to be theirs; only the inventor is entitled, by virtue of the patent and as a matter of law, to the full enjoyment of the monopoly conferred.[63]

On this basis, Schmeiser's property rights to the crops grown on his own land were held to be inferior to Monsanto's patent rights.[64] By analogy, it is likely to be difficult to persuade a court that the owner of a commercialisation right takes precedence over the owner of a patent right.

C *Contractual Rights*

The strict provisions in patent legislation relating inventors and patent rights would not necessarily prevent a source from negotiating a contract providing for a right to share in patent profits in exchange for participation in research. The major stumbling block to such an arrangement is that it could be seen as being contrary to public policy on the basis that it commodifies research participation, in which case the contract would be unenforceable by the courts. However, it is

61 Section 15 of the *Patents Act 1990* (Cth) states that a patent may only be granted to the inventor, another person entitled to have the patent assigned to them (usually the inventor's employer) or other people deriving title from them.

62 [2004] SCC 34.

63 Ibid [43].

64 It should be noted that one of the crucial aspects of this case was that the court determined that Schmeiser either knew or ought to have known that the seeds contained Monsanto's gene.

likely to be easier to establish that such contracts are valid if the research participant already has a recognisable proprietary commercialisation right. It would be illogical to grant ownership rights with one hand but to take away the right to enforce them with the other.

This issue is coming under scrutiny as a scenario remarkably similar to that in the *Greenberg* case unfolds.[65] In this scenario, a patient group (PXE International) participating in research relating to the genetic disorder pseudoxanthoma elasticum (PXE) was able to negotiate an arrangement with researchers giving the group a share in the rights to a patent application filed by the researchers. According to Gittner, the group has negotiated rights to royalties from diagnostic tests and marketable products and control over licensing of the tests in exchange for contributing to the research effort, encouraging participation, establishing a tissue repository and raising funds.[66] Gittner notes further that although there is uncertainty as to the enforceability of the contract, to date neither party has expressed any inclination to raise this issue in court,[67] and hence it is unlikely that there will be any definitive judicial pronouncement to clarify this matter in the near future.

It is possible that contracts of this nature may become more widespread, particularly where research participants have the support of a well-resourced and knowledgeable advocacy group. For the present, however, it is unlikely that such arrangements are commonplace occurrences, and the question remains as to whether any avenue exists to provide sources of tissue with the remedies that they seek in the absence of contractual terms providing for them, or if such terms are deemed by the courts to be unenforceable.

D *Equitable Patent Rights*

It may be possible to raise an argument that a source's proprietary commercialisation right could give them equitable rights in the patent. In the area of research involving non-human genetic resources Brad Sherman has suggested that providers of those resources could be given an equitable right of remuneration in the patented invention in much the same way as interests are recognised in farm saved seed.[68] Judges of the Australian High Court have intimated that equitable rights could exist in relation to other aspects of intellectual property. In *Australian Broadcasting Corporation v Lenah Game Meats Pty Ltd*, for example, Gummow and Hayne JJ suggested that the owner of premises could have a constructive trust over cinematograph film copyright of a videotape taken during a trespass.[69] If a source could establish an equitable right of this nature, it may entitle them to a share of the profits derived from exploitation of the invention, or to have some say as to how the profits are distributed.

65 See Gittner, above n 3, 262-4, 315-25.
66 Ibid 263.
67 Ibid.
68 Brad Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery' (2003) 25 *European Intellectual Property Review* 301, 308.
69 (2001) 208 CLR 199, 102-3.

This, then, is perhaps the most favourable property argument in terms of securing a share in the profits of commercialisation for the source of tissue. However, there may also be disadvantages with this approach. As a starting point, its adoption hinges on the right case coming before the courts and the right decision being made. The broader implications of recognising a source's property in their tissue also need to be canvassed. Skene has put forward a series of compelling arguments as to why the recognition of such rights may have undesirable consequences, particularly in the research context.[70] She lists these as emotional, familial, pragmatic, economic and social.[71] There is no doubt that any judicial decision either for or against the recognition of property rights in human tissue will be controversial. The question is whether it is necessary to take the property route to get to this end point of recognising that a source should have some right to share in the profits of commercialisation of inventions derived from research using their tissue or should have some say in how those profits are distributed.

VI Protection of Equitable Commercialisation Rights: Other Options

Given the complexity surrounding the operation of common law and other principles in respect of dealings with human tissue, one obvious alternative would be to create a statutory regime recognising property in human tissue and providing a structure for enforcing the rights of sources of tissue.[72] However, if this step is to be taken then the inquiry should be broadened to investigate whether there are other options that are more appropriate than the property option.

There can be little doubt that sound research and business practice requires that patent applications are lodged for all bona fide patentable inventions so that commercial funds will be invested in the long and arduous road from research to marketing of new healthcare products. At the same time, the high level of participation in research needs to be encouraged and basic non-commercial research needs to be supported. The difficulty will be in achieving all of these ends in an appropriate manner that balances the interests of the researcher, the investor, the donor and society as a whole. The system must remain workable. It is vital to maintain the perception that research work has an important social function. It must not be seen as exploitative.

A *Restitution*

One option is to consider a broader role for restitution law. The objective of restitution is the prevention or reversal of unjust enrichments. The principle of

[70] Skene, above n 33. See also Loane Skene, 'Proprietary Rights in Human Bodies, Body Parts and Tissue: Regulatory Contexts and Proposals for New Laws' (2002) 22 *Legal Studies* 102.
[71] Skene, above n 33, 165-6.
[72] An option that was not pursued by the Australian Law Reform Commission and the Australian Health Ethics Committee, above n 18.

unjust enrichment is concerned with the restoration to the plaintiff of a benefit conferred on the defendant at the expense of the plaintiff in circumstances that make it unjust that the defendant should retain the benefit. In *Greenberg*, unjust enrichment was the only action that was upheld by the Court as having a reasonable chance of success.[73] The defendants accepted that plaintiffs had conferred benefits on them, including blood, tissue samples and information, but they contended that the plaintiffs had suffered no detriment, particularly no denial of access to testing. In contrast, the plaintiffs' argument was that when the defendants applied the benefits given to them for unauthorised purposes, they suffered detriment. The Court accepted that this argument had some merit. However, it seems crucial to this case that the relationship was one of ongoing research collaboration, more than a mere donor/donee relationship. Hence, restitutionary principles may not be broadly applicable to circumstances where consent has been given to removal of tissue for research purposes and use of tissue goes beyond what the source had in mind when donating.

B *Patent Law*

As patent law presently stands in Australia, there is no express requirement for any form of consent from the source of biological material to the use of their material in the creation of a patentable invention under the *Patents Act 1990* (Cth).[74] Nor is there any requirement on the part of the applicant to verify that research leading to the claimed invention has been conducted in accordance with nationally prescribed ethical standards. Hence if the *Moore* or *Greenberg* scenarios arose here there would be no barrier to obtaining a patent under existing patent law even if the source was not informed that any inventions arising out of the use of their tissue could be patented. It is worth noting that s 51(1)(a) of the *Patents Act 1991* (Cth) provides that the Commissioner of Patents may refuse to accept a patent request for an invention where the use of the invention would be contrary to law. As such, if further use of the invention necessitates use of the tissue without consent of the source individual *and* if lack of consent is contrary to law, the Commissioner may have a discretion to refuse the patent.

The laws in most other jurisdictions are similarly silent or vague on the requirement for consent in relation to the patentability of inventions derived from human tissue. One exception is the European Community Directive on the Legal Protection of Biotechnological Inventions.[75] The Directive expressly provides, in Recital 26, that consent should be obtained where an invention is based on biological material of human origin or if it uses such material. However, given that this provision is included in the recitals, and not in the operational part of the Directive, it does not create any mandatory obligations.[76]

[73] *Greenberg*, 264 F Supp. 2d 1064, 1072-3 (Fla, 2003).

[74] For further discussion see Nicol, Otlowski and Chalmers, above n 23.

[75] *Directive No 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions* [1998] OJ L213/13.

[76] Deryck Beyleveld, 'Regulating Morality Through Patent Law. A Critique of the EC Directive' (2000) 12 *Law and Human Genome Review* 141.

In contrast to this vagueness about consent requirements for patenting inventions relating to human tissue, there has been extensive debate in various international fora concerning consent to patenting of inventions relating to other natural genetic resources.[77] The international Agreement on Trade-related Aspects of Intellectual Property (TRIPS) sets benchmarks for national intellectual property laws in all members of the World Trade Organisation. There have been calls for TRIPS to be amended to make it mandatory for the country of origin and the access and benefit sharing arrangements required in the Convention on Biological Diversity (CBD) and the associated Bonn Guidelines[78] to be disclosed in any patent applications involving natural genetic resources.[79] As the CBD does not apply to human genetic resources, there has not been any consideration of the issues associated with the use of human tissue in this forum. However, it seems inappropriate and illogical to impose stringent requirements on the use of non-human genetic resources, but not on human tissue. The considerations that apply in relation to human tissue are somewhat different to those applying to other genetic resources. In particular, the crucial aspect of the consent requirement for use of human tissue would be consent of the source individual, not the source country.

One option might be the inclusion of a simple requirement for patent applications to disclose evidence of consent to patenting from the source where an invention is based on human tissue or where the invention uses such material, as provided in Recital 26 of the European Biotechnology Directive. Sherman has proposed a similar requirement for patenting of inventions utilising other genetic resources, making prior informed consent a condition of patentability.[80] As he points out, the justification for imposing requirements on patentability is that this is when the commercial parties are at their most vulnerable, and hence obligations imposed at this stage are most likely to influence industry standards. The parties need to have some certainty that the patent is valid and that ownership of the patent is clean before major financial investments are made in the product development process. Hence, such obligations are likely to encourage commercial parties to ensure that research practices upstream of their involvement are in accordance with accepted ethical standards. Sherman notes that this scheme could be expanded into other areas, including use of human genetic resources.[81] At the very least, there should be a requirement for applicants for patents to demonstrate

77 See, eg, Conference of the Parties to the Convention on Biological Diversity, *Report of the Inter-Sessional Meeting on the Operations of the Convention*, [6], UN Doc UNEP/CBD/COP/5/4 (15-26 May 2000). For a general commentary on these issues see Charles R McManis, 'Re-Engineering Patent Law: The Challenge of New Technologies' (2000) 2 *Washington University Journal of Law and Policy* 1.

78 Conference of the Parties to the Convention on Biological Diversity, *Decision VI/24: Access and Benefit-Sharing as Related to Genetic Resources*, Annex 1 *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization* <http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24> at 8 January 2005.

79 See, eg, World Trade Organisation, Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Article 27.3(b) – Communication from Brazil*, WTO Doc IP/C/W/228 (24 November 2000). Available at <http://www.grain.org/bio-ipr/?id=62> at 8 January 2005.

80 Sherman, above n 68, 305-7.

81 Ibid 308.

that where the research leading to their invention involves human tissue, it has been conducted in accordance with internationally recognised ethical standards. In Australia, for example, this might require evidence of compliance with the National Statement (or with its equivalent if the research is conducted in another jurisdiction).

C *Liability Schemes*

More complex strategies have been suggested by other commentators to provide for compensation for use of human tissue. For example, Harrison has proposed a liability scheme requiring commercial users to compensate sources in accordance with statutory standards.[82] There has been extensive academic commentary, particularly in the US, on the economic justification for use of liability rules as opposed to property rules in circumstances where there are high transaction costs. The seminal work of Calabrese and Melamed in 1972 is widely recognised as the origin of this thesis.[83] In Harrison's liability scheme, she identifies triggers for payment as patent applications and applications to the Food and Drug Administration for drug approval.

The difficulty with propositions of this nature is that although they protect non-commercial researchers from obligations to pay for the use of tissue, they do nevertheless commodify tissue. Harrison does hint at one way to deal with this problem, through the provision of collective compensation to families, disease groups and political communities.[84] This aspect of her proposal has some attraction. It is in line with proposals for benefit sharing relating to non-human genetic resources and with the Statement on Benefit Sharing relating to human genetic research, released by the Ethics Committee of the Human Genome Organisation in April 2000.[85] The Statement made six recommendations:

- that all humanity share in, and have access to, the benefits of genetic research;
- that benefits not be limited to those individuals who participated in such research;
- that there be prior discussion with groups or communities on the issue of benefit-sharing;
- that even in the absence of profits, immediate health benefits as determined by community needs could be provided;

82 Charlotte Harrison, 'Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue (2002) 28 *American Journal of Law and Medicine* 77, 95-7. For a critique of Harrison's proposal, see Gittner, above n 3, 342-3. Other commentators have suggested a range of other options. Richard Gold, for example, suggests that a non-profit non-governmental organisation could be given responsibility for licensing use of cell lines: see Richard Gold, 'Owning Our Bodies: An Examination of Property Law and Biotechnology' (1995) 32 *San Diego Law Review* 1167, 1246-7.

83 Guido Calabresi and A Douglas Melamed, 'Property Rules, Liability Rules and Inalienability: One View of the Cathedral' (1972) 85 *Harvard Law Review* 1089. Note that *Moore* is a classic example of the inalienability model. See Gittner, above n 3, 270-7.

84 Harrison above n 82, 103.

85 Available at <http://www.gene.ucl.ac.uk/hugo/benefit.html> at 8 January 2005.

- that at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation; and
- that profit-making entities dedicate a percentage (e.g. one to three per cent) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.

VII Conclusion

The main aim of modern biomedical research is an improved understanding of the causes and consequences of human disease and its overarching goal is the development of improved drugs, diagnostics and therapies. Human tissue is an essential research tool for most biomedical research. Patenting and commercialisation of inventions derived from that research provide the necessary incentive for commercial enterprises to invest in the development of new products. One consequence of this is that the research itself can become a profit making enterprise. In many research projects generic de-identified tissue is used and provided that appropriate ethical requirements are followed, it would be inappropriate for sources of this tissue to exert control over the downstream commercialisation process. However, the situation is likely to be different when the tissue supplied by the source has unique attributes, or when the source has ongoing involvement in the research process, as exemplified in the *Moore* and *Greenberg* cases, respectively. This article has focused on the legal and equitable rights of these latter sources of tissue to be involved in the commercialisation of the results of research using their tissue.

I first argued that existing and proposed regulatory mechanisms for protecting sources of human tissue used for research purposes do not necessarily provide any assistance to those individuals seeking to assert some control over the process of commercialisation of the results of research using their tissue. I then turned to an analysis of the legal consequences of recognising a source's property rights in their own tissue. I concluded that, from the common law perspective, the recognition of such rights may not actually provide the source with a legally enforceable right to be involved in the commercialisation process. The recognition of equitable rights over patents granted for inventions derived from research using the source's tissue may, however, provide some assistance to the source in this regard.

Other alternatives for achieving this end were discussed in Part VI of this article. It must be recognised that these options do have their own complications and limitations. One obvious problem is that disclosure of evidence of source consent to patenting is likely to have privacy implications if it requires that the source's personal information is disclosed to the public. It may also be difficult to put in place an appropriate mechanism to equitably distribute the benefits of commercialisation. This problem is accentuated by the fact that there is often a long time lag between the research phase and the marketing phase and many

products never actually make it to market.[86] Furthermore, we should not lose sight of the underlying purpose of patent law, which is to provide an incentive to innovate by giving the patent holder a period of time when they are free from competition in the marketplace. One difficulty with a model of benefit sharing that distributes benefits to the afflicted community is that this community is also the market for the commercial product.

None of these problems is insurmountable. It may be possible, for example, to put in place a benefit sharing arrangement involving a declining scale of royalties, reflecting the increasing input of skill and effort and decreasing reliance on the unique qualities of the source's tissue. Privacy could be protected by requiring disclosure of evidence of consent of the source to patenting, but by not putting this information on the public record.

Finally, and perhaps most pertinently, it should be noted that the problems highlighted above link in with the even bigger issue of motivating the government to legislate. There is unlikely to be any support from industry for such a measure whilst the status quo remains. Perhaps we do need a good property case after all. If nothing else, this might encourage legislators to act.

[86] These issues are discussed further in Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry*, Centre for Law and Genetics Occasional Paper No 6 (2003).