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# Editor: Thomas Faunce\*

# UNIVERSITY OF WESTERN AUSTRALIA v GRAY: AN ACADEMIC DUTY TO COMMERCIALISE RESEARCH?

In an era of tightening university budgets and pressure to commercialise academic knowledge, many higher education institutions see the exploitation of new inventions and discoveries, through the use of patents, as an additional revenue stream. To that end, many such organisations have in place policies and by-laws which regulate "ownership" and disclosure of inventions created by employees. This can be seen as a continuation of an ongoing process of shifting universities from institutes of "pure research" to commercial operations, seeking to maximise financial gains from the efforts of their researchers. However, new opportunities present new risks. One of the last Federal Court decisions by the High Court of Australia's new Chief Justice, Justice French, in University of Western Australia v Gray [2008] FCA 498 explores some of the challenges which Australian university administrators and policy developers will need to overcome if an appropriate balance between private interests and public good is to be maintained in this context.

# INTRODUCTION

Despite more than a decade of declining federal funding to public universities, research outputs from Australia's public tertiary institutions remain "above the level expected of a country with Australia's population".<sup>1</sup> Recognising that intellectual property exports can generate significant returns to the national economy, successive federal governments have encouraged Australian universities to pursue policies which will encourage individual researchers to "consider the most appropriate way of exploiting the IP generated from publicly funded research".<sup>2</sup> No longer just concerned with "pure research", universities have become, and have been legally recognised as, trading entities.<sup>3</sup> Although acknowledging this, French J in *University of Western Australia v Gray* [2008] FCA 498 maintained that an academic is more than a mere employee of a university – he or she is a "member" (at [1361]) – with the consequence that there is no presumed duty to further the "commercial interests" of the university (at [1362]).

Whether this "16th century" conception of academia and research remains relevant in the 21st century will require further legal and policy debate. It should be noted, for instance, that the commercialisation of research-driven innovations can bring more than additional direct revenue for the staff involved or their institution. As a witness for the plaintiff in *University of Western Australia v Gray* testified (at [230]), it can bring "kudos and reputation from academic publication in the peer reviewed literature" as well as additional funding [and support for] PhD students".

However, the institutional quest to prioritise financial rewards for university researchers who commercialise their research outside of the institution which funded part, or all, of their work may ultimately undermine the broader educational objectives of the university. Moreover, concomitant

<sup>&</sup>lt;sup>\*</sup> BA LLB (Hons), B Med, PhD; Associate Professor, ANU College of Law and Medical School; Director, Globalisation and Health Project, The Australian National University.

<sup>&</sup>lt;sup>1</sup> Health and Medical Research Strategic Review, *The Virtuous Cycle: Working Together for Health and Medical Research: Final Report* (AGPS, Canberra, 1999), quoted in Nicol D, "Genetic Research and Commercialisation" in Freckelton I and Petersen K (eds), *Disputes and Dilemmas in Health Law* (Federation Press, Sydney, 2006) p 262.

<sup>&</sup>lt;sup>2</sup> Australian Research Council, National Principles of Intellectual Property Management for Publicly Funded Research, www.arc.gov.au/pdf/01\_01.pdf viewed 9 February 2006 in Nicol, n 1, p 263.

<sup>&</sup>lt;sup>3</sup> Quickenden v O'Connor (2001) 109 FCR 243; University of Western Australia v Gray [2008] FCA 498 at [1362].

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requirements of patent exploitation operating to promote secrecy and non-disclosure of research may undermine the spirit of discovery which underpins the ethical foundations of the publicly funded tertiary system and its mission to serve the public good.

# THE FACTS OF UNIVERSITY OF WESTERN AUSTRALIA V GRAY

Professor Bruce Gray was a full-time professor of surgery at the University of Western Australia (UWA) from 1 January 1985 (at [314]). Prior to taking up the Chair of Surgery, he had undertaken extensive research into metastatic liver and bowel cancer with a particular focus on whether "microsphere technology" could provide a way to prevent metastases from the bowel to the liver.

The court discussed Dr Gray's research into microspheres, which were described (at [2]) as

in the general size range of 10 to 50 microns, injected into the blood vessels of the liver to deliver anti-cancer therapies to the sites of tumours. Microspheres were directed to those sites with the aid of a vasoactive agent which temporarily promoted blood flow into the tumour blood vessels at the expense of blood flow into normal liver tissue.

During his tenure at UWA, Dr Gray investigated three particular microsphere technologies. The first was referred to as SIR-spheres (Selective Internal Radiation), designed to "transport a short-lived radioisotope to irradiate cancerous tissue" (at [3]). Other technologies included "DOX-sphere", which transported the anti-cancer drug doxorubicin to a tumour, and "thermo-spheres", which (at [3])

involved the delivery of microspheres of magnetic material into the cancerous tissue and heating them by the external application of an alternating or rotating magnetic field. It relied upon a phenomenon known as "magnetic hysteresis".

In 1997 Dr Gray assigned various intellectual property rights to Sirtex Medical Ltd (Sirtex), a company created to commercialise the microspheres technologies. Sirtex became a publicly listed company in 2000, by which time Dr Gray had been made a director. By 1999 the university was aware of Dr Gray's involvement with an external company and the Vice-Chancellor sent a letter to Dr Gray informing him that the university was of the opinion that it had a claim over the patents arising from his research (at [5]). Dr Gray did not reveal this letter to Sirtex's officers. In 2004 UWA sent a letter of demand to Dr Gray and Sirtex alleging (at [6]):

that the inventions the subject of the intellectual property rights which Sirtex had acquired were developed or made in the course of Dr Gray's employment at UWA and that of other academic researchers working with him.

On 21 December 2004, UWA commenced litigation in the Federal Court against Dr Gray, Sirtex and another party, the Cancer Research Institute (CRI). CRI and UWA later entered into a settlement agreement and French J's decision in *University of Western Australia v Gray* made no orders against it. The case was marked by numerous claims and cross-claims and involved significant court time (at [8]). Relevantly, however, UWA's claims against Dr Gray were that:

- Dr Gray had breached his contract of employment with it by failing to comply with disclosure and associated obligations imposed by its *Patents Regulations* which had been made in 1971 and their successors, the *Intellectual Property Regulations 1997*; and
- Dr Gray had breached his fiduciary obligations to UWA (at [9]).

UWA also filed a claim against Sirtex on the grounds that "Sirtex had been knowingly concerned in those breaches by Dr Gray and had provided knowing assistance to him in those breaches by the issue of shares to him" (at [9]). Both UWA's and Dr Gray's counter-claims against Sirtex and the university, respectively, were dismissed. French J held that not only did UWA have no proprietary interest in any of the inventions pleaded (at [1556]), but that, as Dr Gray was employed to research and did not have a "duty to invent" (at [1366]), his employment contract did not contain an implied term that the university had any right to his subsequent inventions (at [1367]).

Under s 10 of the *Fair Trading Act 1987* (WA), a director is prohibited from engaging in misleading or deceptive conduct. Sirtex cross-claimed against Dr Gray, arguing that his failure to disclose the 1999 letter from UWA amounted to a breach of his duties as a director under ss 180 and 181 of the *Corporations Act 2001* (Cth) and s 10 of the *Fair Trading Act 1987* (WA). French J upheld Sirtex's claim against Dr Gray.

## **CONTRACTS OF EMPLOYMENT BETWEEN UNIVERSITIES AND ACADEMICS**

In *University of Western Australia v Gray* [2008] FCA 498, French J examined the law as it related to contracts of employment and the extent to which a "duty to invent" could be implied in Dr Gray's contract. The general position of the common law is that "copyright generated by an employee in the course of employment belongs to the employer".<sup>4</sup> However, in the absence of an express or implied term in the contract of employment, an employer has no automatic right over the inventions of an employee (at [112]).<sup>5</sup> Two exceptions to this principle have emerged. First, where an employee is hired for the purpose of invention (or to solve a specific or general problem) and utilises the resources and time of their employer, any subsequent inventions belong to the employer.<sup>6</sup> This exception was referred to as an "implied duty to invent". French J discussed in obiter (at [162]) that:

Absent express contractual provisions, if a person were employed by a university specifically to produce an invention, then there would be at least a presumption of a term implied by law that the rights in relation to the invention will belong to the university. For example, if a post-graduate student is engaged by the university to design a particular device or an improvement to an existing device, any right to apply for a patent in relation to such device or improvement will belong to the university.

The second exception is where the employee owes a fiduciary duty to act in the best interests of the employer, or to further the commercial success of the employer. Quoting Nettle J's decision in *Victoria University of Technology v Wilson* (2004) 60 IPR 392 with approval, French J commented (at [152]):

[T]he law will not impose on a manual worker restrictions, the real effect of which would be to interfere with the worker's freedom to use spare time as he or she chooses. A chief executive officer of a listed public company is in a different position.

One view to be drawn from these cases is that the higher up or more central an employee is within a company or institution, the more likely it is that any invention of theirs – if relevant to the employer's area of business – will be the property of their employer.

In its submissions, UWA alleged that Dr Gray's contract of employment implied a duty to invent and, consequently, he held the patents over any inventions developed in the course of his employment on trust for the university (at [144]-[157]).<sup>7</sup>

Upon taking up the Chair at UWA, Dr Gray signed a standard university employment contract setting out his duties and responsibilities. In particular, his duties were, among other things (at [320] emphasis added):

- (i) to teach, to conduct examinations and to direct and supervise the work in his field in accordance with the Statutes and regulations of the University and the directions of the Senate;
- (ii) to undertake research and to organise and generally stimulate research among the staff and *students*; and
- (iii) to perform such other appropriate work as the Senate from time to time determines.

It was this particular clause upon which the university relied to support its argument that the duty to "undertake research and to organise and generally stimulate research" could be construed as a duty to invent.

French J agreed with Monotti and Ricketson<sup>8</sup> that there was a "lingering discomfort with equating an academic's general duty to research with a duty to invent, even though the research is that from

<sup>7</sup> See also Spencer Industries Pty Ltd v Collins (2002) 54 IPR 434.

<sup>8</sup> Monotti AL and Ricketson S, Universities and Intellectual Property: Ownership and Exploitation (Oxford University Press, Oxford, 2003).

<sup>&</sup>lt;sup>4</sup> Lamb v Evans [1893] 1 Ch 218 at 225 (Lindley LJ), quoted in University of Western Australia v Gray [2008] FCA 498 at [112].

<sup>&</sup>lt;sup>5</sup> See also Marshall and Naylor's Patent (1900) 17 RPC 553.

<sup>&</sup>lt;sup>6</sup> Victoria University of Technology v Wilson (2004) 60 IPR 392; Worthington Pumping Engine Co v Moore (1902) 20 RPC 41; British Reinforced Concrete Engineering Co Ltd v Lind (1917) 34 RPC 101; Triplex Safety Glass Co Ltd v Scorah [1938] Ch 211; Sterling Engineering Co Ltd v Patchett [1955] AC 534; and Spencer Industries Pty Ltd v Collins (2003) 58 IPR 425.

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which an invention might reasonably be expected to result" (at [159]). In coming to his conclusion, his Honour discussed how "academic freedom" and patent protection are distinct philosophies. The goals of academia and research centre on contributing knowledge to a common body of literature and, to that end, peer-review, experimental replication and open access to data are promoted. In order to apply for a patent, however, inventors are usually required to ensure secrecy and non-disclosure, values anathema to traditional notions of "academic freedom". Although LaRoche, Collard and Chernys (cited by French J) have argued that "full and complete disclosure of the patent [specification]" satisfies the objections of patent law's intrusion into academia,<sup>9</sup> the growth of evergreening techniques and "data exclusivity" clauses in international trade agreements and Australian legislation<sup>10</sup> demonstrates a movement away from the original philosophy behind patenting.

The unfortunate irony of the decision in *University of Western Australia v Gray*, however, is that in denying UWA's claim to rights over Dr Gray's inventions, the patent holders were – once again – private companies under no obligation to make those inventions equitably accessible to all. Indeed, an area for further consideration is whether it is better for publicly funded institutions to automatically acquire proprietary rights over their employees' inventions as a "by-product" of their research (at [230]), or to encourage researchers to commercialise their discoveries by forming private companies.

# THE NEED FOR AN "EXPERIMENTAL USE" EXEMPTION OR DEFENCE

While University of Western Australia v Gray did not specifically address the topic of patent infringement exemptions, the case does highlight a worrying trend in Australian research which may be potentially deleterious to the public good and to the objectives of tertiary-level research institutions. Where universities adopt business-like approaches to intellectual property, they also assume the risks associated with intellectual property rights management. As University of Western Australia v Gray demonstrates, reliance upon general university statutes, regulations or policies may not be sufficient to ensure that "ownership" (a difficult concept in patent law) falls to the institution. Additionally, a failure to properly manage intellectual property assets may require a university to not only forfeit any claim and potential windfall from a patentable invention, but to subsequently accept the cost of licensing the invention back for later "experimental use" by other academics. Unlike the United States,<sup>11</sup> Canada<sup>12</sup> and the United Kingdom,<sup>13</sup> there is no experimental use defence to patent infringement in Australia. It is here neither enshrined in legislation – as in Britain or Canada – nor under the common law, as in the United States. Indeed, there is presently no consistency as to the limits of any "experimental use" within the above-mentioned jurisdictions.

In the United States the defence of experimental use suffered a significant setback in *Madey v Duke University* 307 F 3d 1351 (2002) where it was held that "use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defence".<sup>14</sup> Conversely, in the United Kingdom it has been extended to cover activities which "may have a commercial end in view".<sup>15</sup> Within Australia, only two general statutory patent exemptions exist and are contained in ss 119 and 119A of the *Patents Act 1990* (Cth) respectively.

<sup>14</sup> Australian Law Reform Commission, n 11 at [13.14].

<sup>15</sup> Monsanto Co v Stauffer Chemical Co [1985] RPC 515; Australian Law Reform Commission, n 11 at [13.19].

<sup>&</sup>lt;sup>9</sup> LaRoche K, Collard C and Chenys J, "Appropriating Innovation: The Enforceability of University Intellectual Property" (2007) 20 Intellectual Property Journal 135 at 140-141.

<sup>&</sup>lt;sup>10</sup> For example, the *Therapeutic Goods Act 1989* (Cth), s 25A.

<sup>&</sup>lt;sup>11</sup> Roche Products Inc v Bolar Pharmaceutical Co 733 F 2d 858 (1984) but see Madey v Duke University 307 F 3d 1351 (2002); Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Final Report, No 99 (2004) at [13.13]-[13.15].

<sup>&</sup>lt;sup>12</sup> Micro Chemicals Ltd v Smith Kline & French Inter-American Corp (1971) 25 DLR (3d); Australian Law Reform Commission, n 11 at [13.16]-[13.17].

<sup>&</sup>lt;sup>13</sup> Patents Act 1977 (UK), s 60(5); Monsanto Co v Stauffer Chemical Co [1985] RPC 515; Australian Law Reform Commission, n 11 at [13.18]-[13.20].

#### 119 Infringement exemptions: prior use

- (1) A person may, without infringing a patent, do an act that exploits a product, method or process and would infringe the patent apart from this subsection, if immediately before the priority date of the relevant claim the person:
  - (a) was exploiting the product, method or process in the patent area; or
  - (b) had taken definite steps (contractually or otherwise) to exploit the product, method or process in the patent area.

#### 119A Infringement exemptions: acts for obtaining regulatory approval of pharmaceuticals

- (1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:
  - (a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that:
    - (i) are intended for therapeutic use; and
    - (ii) are not medical devices, or therapeutic devices, as defined in the *Therapeutic Goods Act* 1989; or
  - (b) purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

Despite the absence of any express legislative intention to exempt "experimental use" from actions for patent infringement, many Australian researchers believe that a general exemption exists,<sup>16</sup> although they were unable to answer whether it covered only "basic research ... or commercial research".<sup>17</sup> The common law within Australia is undeveloped on the point of "experimental use"<sup>18</sup>.

It would be risky for Australian universities to assume that the low number of suits for patent infringement by experiment will continue. In the 20 years to 2004, patent infringement suits increased tenfold and, with the continued growth in patenting, such a trend is likely to continue into the foreseeable future.<sup>19</sup> Absent an "experimental use" exemption, universities must ensure that they not only implement appropriate intellectual property safeguards (such as express contractual provisions) but that they do not, through neglect or carelessness, "abandon" any processes which were implemented to streamline the acquiring and commercialisation of intellectual property assets (at [11]). The University of Western Australia's failure to properly enforce its own *Intellectual Property Regulations* and *Patent Regulations* was highlighted by French J as going against the claim by UWA that Dr Gray had breached his contractual obligations(at [11]). French J concluded (at [11]):

In contractual terms UWA failed to maintain the mechanism necessary for the performance of the notification obligations said to have been imposed upon its staff by the importation into their contracts of the terms of the Patents Regulations. This conclusion adversely affected UWA's contract claims against Dr Gray for alleged non-compliance with the Patents Regulations.

Clearly, in an era where public institutions are embracing the opportunities of commercial patenting, every endeavour should be made to ensure that potential inventions are not lost to private interests as the costs of mounting a patent challenge (even a successful one) will remain prohibitively high.

## PUBLIC FUNDING AND THE SOCIAL BENEFITS OF OPEN RESEARCH

In dismissing UWA's claim that a duty to invent existed as a term implied by law in Dr Gray's contract of employment, French J held (at [160]):

Given the nature of universities and the public purposes served by such as UWA, there is no basis for implying into the contracts of employment of its academic staff a duty not to disclose the results of research even if such disclosure could destroy the patentability of an invention. Absent such a duty and

<sup>&</sup>lt;sup>16</sup> Australian Law Reform Commission, n 11 at [13.37]; McBratney AA, Nielsen K and McMillan F, "Australia Experiments with 'Experimental Use' Exemption" (2004) 22(8) *Nature Biotechnology* 1023 at 1024.

<sup>&</sup>lt;sup>17</sup> Australian Law Reform Commission, n 11 at [13.38].

<sup>&</sup>lt;sup>18</sup> McBratney, Nielsen and McMillan, n 16 at 1024.

<sup>&</sup>lt;sup>19</sup> McBratney, Nielsen and McMillan, n 16 at 1024.

given a choice to invent or not invent, it is difficult to see upon what basis there can be a presumption that a term will be implied as a matter of law that the university has an entitlement to take the inventor's property rights in relation to the invention.

The question of whether publicly funded institutions should maintain a reasonable expectation to profit commercially from their research seems anachronistic in the 21st century, when spin-off companies designed to commercialise research are commonplace within universities. Yet the "public-purpose" role of tertiary institutions sits uncomfortably alongside modern commercial goals.<sup>20</sup> Such discomfort is reflected in the common law's assumptions regarding the university-academic relationship. The United States Government has introduced legislation to override the common law presumption against employer title in employee inventions where the invention arose in the course of publicly funded research. The most critical of these legislative steps is the *Bayh-Dole Act*<sup>21</sup> under which

universities and government funding agencies enter into a funding agreement which grants a right of ownership to the university subject to a number of obligations. Most importantly, the university must comply with various obligations concerning disclosure of the invention, election whether to retain title, royalty sharing and preference to small businesses and US industry.<sup>22</sup>

A limitation to the effectiveness of the *Bayh-Dole Act* is that it only attaches where a university receives public funding. While Dr Gray's Australian research was the subject of partial public funding from the CSIRO and the NHMRC, it was a private firm, Sirtex, which funded much of the commercialisation process. Although UWA's claim may have meet with more success had Dr Gray's funding been entirely public, French J remarked (at [14]):

[A]ny claim by a university to intellectual property rights whose creation has involved a team of research workers, external funding, collaborative arrangements and extended periods of conceptual and practical development is likely to pose ... difficulties.

In 2003, a report explored the extent to which the commercialisation of research was impacting upon private firms, public institutions and academics.<sup>23</sup> Though most researchers had accepted "commercialisation ... [as] a reality", it remained an "unwelcome one for some".<sup>24</sup> Many respondents indicated that patenting, and reforms designed to encourage patenting of publicly funded discoveries, impacted heavily upon their desire to publish their results in "high quality peer-reviewed journals".<sup>25</sup>

#### CONCLUSION

It seems inevitable that public tertiary institutions in Australia will continue to move towards commercial approaches to intellectual property over their research. The decision in *University of Western Australia v Gray* [2008] FCA 498 – which, at the time of writing, the university was considering appealing – highlights some of the challenges facing universities as they move from a "16th century" conception of "membership" to more modern concepts of company-employee. Whether this is in the best long-term interests of universities is yet to be known. Changes to institutional intellectual property regulations (eg to incorporate public goods points in licensing university technology) will require consideration by the senates and convocations of each institution.

<sup>24</sup> Nicol and Nielsen, n 23, p 125; see also Nicol, n 1, p 267.

<sup>25</sup> Nicol, n 1, p 267.

<sup>&</sup>lt;sup>20</sup> Australian Law Reform Commission, n 11 at [11.15].

<sup>&</sup>lt;sup>21</sup> Title 35 Patents USC Ch 18 § 200.

<sup>&</sup>lt;sup>22</sup> See generally, Christie AF, D'Aloisio S, Gaita KL, Howlett MJ and Webster EM, Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions (Australian Department of Education, Employment and Workplace Relations, 2003), <u>http://www.dest.gov.au/sectors/research\_sector/publications\_resources/other\_publications/patent\_</u> <u>ownership\_in\_publicly\_funded\_research\_institutions.htm</u> viewed 1 August 2008. This publication may need to be reviewed in light of the decision in University of Western Australia v Gray [2008] FCA 498.

<sup>&</sup>lt;sup>23</sup> Nicol D and Nielsen J, Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry (Intellectual Property Research Institute of Australia, 2003), <u>http://www.ipria.org/publications/reports/BiotechReportFinal.pdf</u>, p 128, viewed 28 October 2008.

If, however, the movement into commercial patenting is to be reconciled with the time-honoured position of universities as centres of learning, support for public goods and open access research, then government intervention, through an expansion of the "fair use" provisions in the *Copyright Act* and *Patents Act* to include academic research, may need to be considered. At the very least, patenting should be seen against its historical background: as an authorised, but limited, monopoly privilege granted temporarily and primarily in the public interest, to encourage innovation and to assist in the dissemination of knowledge.

Tim Vines

Research Associate, Globalisation and Health Project, The Australian National University Associate Professor Thomas Faunce College of Law and Medical School Director of Globalisation and Health Project, The Australian National University