

# Human gene patents: under whose control?

## *Balancing commercial patent rights and public interest is a complex matter*

IN THIS ISSUE of the Journal, Walpole and his colleagues (*page 203*) squarely raise the difficult issue of balancing public access to genetic health services with enforcement of gene patents.<sup>1</sup> They explore this issue using the case study of the hereditary breast cancer gene patents (the *BRCA* patents).<sup>1</sup> This timely and important article coincides with the work of the Australian Law Reform Commission (ALRC). On 5 June 2003, the ALRC released the final report of its joint inquiry with the Australian Health Ethics Committee on the protection of human genetic information.<sup>2</sup> The report proposes that access to genetic testing for healthcare should be better regulated, and emphasises the need for ongoing development of ethical standards, particularly in relation to consent and counselling (Recommendations 11-1 to 11-4).

The ALRC has now turned its attention to the separate, but related, issue of gene patenting and human health.<sup>3</sup> The ALRC will soon be releasing its Issues Paper and calling for submissions. It is likely that limitations on the use of disease gene patents will feature prominently in the submissions and in the ALRC's responses. The ALRC is required to report its findings by 30 June 2004.

The issues associated with gene patents and genetic services are complex and warrant detailed consideration. The role of patents is to encourage innovation, but this needs to be balanced against other values, including equitable access to healthcare. The ALRC may decide that the balance needs to be adjusted. However, a simple prohibition on gene patents is unlikely, of itself, to achieve this end. More comprehensive reform options may need to be considered, including changes to the requirements for obtaining a patent and restrictions on how patents are used. One option might be to include a requirement that the usefulness of the invention be fully examined. At present, the applicant only

needs to show that the invention has some commercial value. It may be appropriate to follow the United States' lead of requiring the applicant to prove "specific, substantial and credible utility", and restricting the scope of the patent to proven uses.<sup>4</sup>

Even if patent law is reformed, it will not necessarily assist in dealing with gene patents that are already in existence. As patents have a 20-year life, the effect of the *BRCA* patents and others could be felt for many years, unless their validity is challenged in the Federal Court. In Europe, L'Institut Curie started proceedings in October 2001, challenging the validity of the *BRCA* patents.<sup>5</sup> Since then, other individuals and organisations across Europe have joined in, including research institutes, hospitals, ministries of health, and human genetics societies. They raise a number of grounds for invalidity, including that the invention is neither new nor inventive. Genetic service providers in Australia could challenge the equivalent Australian patents. However, the costs and risks of such litigation are such that this course of action should not be embarked upon lightly.

It is equally important to consider limitations to the ways in which patents may be used. The *Patents Act 1990* (Cwlth) grants patent holders the exclusive right to make, hire and sell the invention for the life of the patent. There are few controls on how this right may be used, but the controls that do exist warrant consideration. Sections 133 and 135 of the legislation allow applications to be made for compulsory licences when "the reasonable requirements of the public" have not been met. Although subject to certain limitations, a compulsory licence protects a person from infringement action for using a patented invention without the patent holder's permission. Perhaps surprisingly, there have been few compulsory licensing applications to date.

The Act also provides protection from infringement for “Crown use”: use of the patented invention “for the services of the Commonwealth or State” where “necessary for the proper provision of those services” (section 163). Examples of the applicability of this provision include use of an invention by a state rail authority for construction of rail carriages,<sup>6</sup> and use by a local government authority of a meter for measuring water supply.<sup>7</sup> It is debatable whether Crown use extends to the provision of public genetic services.

In addition to these provisions, the *Patents Act 1990* prohibits arrangements that tie use of the invention to use of other products or processes. The role of this provision and of the competition law provisions in the *Trade Practices Act 1974* (Cwlth) both need further examination.

Although a “research exemption” is often relied on for non-commercial research use of a patented invention, there is no specific law in Australia to support it. The ALRC may recommend that patent legislation should be amended to incorporate this exemption, perhaps together with an exemption for non-commercial clinical use, or it may recommend changes to the other limitations on use discussed above. It may be preferable to adopt the suggestion of Walpole et al and empower an expert body to require broad licensing of patented tests.

In making its recommendations, the ALRC has to be mindful of Australia’s international obligations. Australia is a signatory to the World Trade Organization Agreements, one of which is the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS).<sup>8</sup> TRIPS lays down

fairly stringent requirements for the patent laws in member countries. One stumbling block may be the requirement that there should be no discrimination in the applicability of patent rights between technologies (Article 27).

Clearly, there are no simple answers to questions about what patents should be granted and what restrictions should be imposed on the ways in which granted patents are used. The ALRC faces a challenging year.

**Dianne Nicol**

Lecturer, Faculty of Law  
University of Tasmania, Hobart, TAS

*Competing interests:* I am a member of the Advisory Committee to the Australian Law Reform Commission’s inquiry *Gene Patenting and Human Health*. The views expressed in this editorial are mine and are not in any way connected with the Australian Law Reform Commission or the Advisory Committee.

1. Walpole IR, Dawkins HJS, Sinden PD, O’Leary PC. Human gene patents: the possible impacts on genetic services healthcare. *Med J Aust* 2003; 179: 203-205.
2. Essentially yours: the protection of human genetic information in Australia. ALRC Report 96. Canberra: Australian Law Reform Commission and Australian Health Ethics Committee, 2003. Available at: [www.alrc.gov.au/publications/finalreps.htm](http://www.alrc.gov.au/publications/finalreps.htm) (accessed Jun 2003).
3. Australian Law Reform Commission. Gene patenting [ALRC inquiry website]. Available at: [www.alrc.gov.au/inquiries/current/patenting/](http://www.alrc.gov.au/inquiries/current/patenting/) (accessed Jun 2003).
4. Manual of patent examining procedure. 8th ed., Feb 2003 revision. Washington, DC: United States Patent and Trademark Office, 2003; §2107. Available at: [www.uspto.gov/web/offices/pac/mpep/index.html](http://www.uspto.gov/web/offices/pac/mpep/index.html) (accessed May 2003).
5. L’Institut Curie. Oppositions Myriad Genetics. Available at: [www.curie.net/home/presse/actu\\_list.cfm/lang/\\_fr/affaire/3.htm](http://www.curie.net/home/presse/actu_list.cfm/lang/_fr/affaire/3.htm) (accessed Jun 2003).
6. *General Steel Industries Inc v Commissioner of Railways (NSW)* (1964) 112 CLR 125.
7. *Stack v Brisbane City Council* (1995) 32 IPR 69.
8. TRIPS (Trade-related aspects of intellectual property rights) material on the WTO website. Available at: [www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm) (accessed Jul 2003). □

## Pre-eclampsia: a lifelong disorder

*Some women with pre-eclampsia develop hypertension and cardiovascular disease in later life*

PRE-ECLAMPSIA AWARENESS WEEK (August 17–23) is an opportune time to reflect on what we know about this malady. Why does it develop? Can it be predicted or, more importantly, prevented? What will happen to affected women and their babies with further pregnancy? And, finally, does pre-eclampsia have long-term health effects?

About one in 10 pregnancies is complicated by hypertension: about 3%–4% have pre-eclampsia, a similar proportion have gestational hypertension and 1%–2% have pre-existing chronic hypertension. The latter is apparent when hypertension is present in the first half of pregnancy, whereas pre-eclampsia and gestational hypertension usually occur later. Despite pre-eclampsia being a placental disease, the mother rather than the fetus may bear the brunt, with, commonly, increased blood pressure, abnormal kidney (proteinuria or renal insufficiency) or liver function (elevated transaminases or severe right upper quadrant or epigastric pain), neurological disturbances including convulsions (eclampsia), and thrombocytopenia or disseminated intravascular coagulation. The fetus may be affected by growth

restriction (about one in four cases), and about 20 per 1000 cases die either *in utero* or as a result of prematurity.

### Why does pre-eclampsia occur?

There appears to be an ill-defined genetic predisposition to pre-eclampsia, with some studies suggesting an autosomal recessive inheritance. However, discordance for pre-eclampsia among monozygotic twins questions some of the genetic postulates. Paternal influence on fetomaternal genetic mismatch is important, and being born of a pre-eclamptic pregnancy increases the likelihood for males of fathering an infant whose gestation will also be complicated by pre-eclampsia.

Immune theories abound, largely arising from epidemiological observations that pre-eclampsia is more common in a first pregnancy, and that changing partners for a subsequent pregnancy increases the risk of pre-eclampsia in women with a previous normal pregnancy and decreases the risk in women with previous pre-eclampsia.<sup>1</sup> Prolonged sexual cohabitation before pregnancy appears to protect against