**Do patents impede the provision of genetic tests in Australia?**

**Dianne Nicol and John Liddicoat**

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**Abstract**

Objective: Health policy and law reform agencies lack a sound evidence-base of the impacts of patents on innovation and access to healthcare to assist them in their deliberations. This paper reports the results of a survey of managers of Australian genetic testing laboratories that asked a series of questions relating to the tests they perform, whether they pay to access patented inventions and whether they have received notifications from patent holders about patents associated with particular tests.

Results: Some diagnostics facilities are exposed to patent costs, but they are all located in the private sector. No public hospitals reported paying licence fees or royalties beyond those included in the price of commercial test kits. Some respondents reported having received enforcement notices from patent holders, but almost all related to the widely known breast cancer-associated patents. Respondents were also asked for their views on the most effective mechanisms to protect their ability to provide genetic tests now and in the future. Going to the media, paying licence fees, ignoring patent rights and relying on the government to take action were widely seen as most effective. Litigation and applications for compulsory licences were seen as some of the least effective mechanisms.

Conclusion: These results provide an evidence-base for development of health policy and law reform.

**Key question summary**

1. What is known about the topic?

The impact of patents on the delivery of genetic testing services remains unclear in Australia.

2. What does this paper add?

The survey reported in this paper suggests that, aside from well-known enforcement actions relating to the BRCA patents, there is little evidence that providers of genetic testing services are being exposed to aggressive patent enforcement practices.

3. What are the implications for practitioners?

While patent enforcement actions may increase in the future, a range of strategies are available to providers of testing services to protect them against adverse consequences of such actions. There are ongoing law reform activities aimed at improving these strategies.

**Introduction**

The past fifteen years have seen rapid escalation in filing of patents claiming rights to gene sequences and other aspects of diagnostic testing associated with disease. There is ongoing debate as to the precise quantum of these so-called gene patents,1,2 and the extent to which they block, delay or increase the cost of genetic testing services.3 Enforcement actions by Myriad Genetics, Inc relating to its BRCA 1 and BRCA 2 patents have been the singular focus of concern for many years.4 Studies in the USA in the early 2000s suggested that enforcement of patents related to a diversity of genetic diseases was having a negative impact on the provision of genetic testing services in that country;5,6 later studies suggest this problem is continuing.7 This remains an area of active debate and consideration in that jurisdiction.8 Studies in other countries suggest that patent enforcement against genetic testing laboratories is of less immediate concern.9,10,11 Nevertheless, isolated reports of enforcement actions by particular patent holders continue.12

New technological developments including whole genome sequencing and multiplex testing are rapidly increasing the availability and reducing the cost of genetic testing, and increasing the number of disorders than can be tested at any one time.13 These developments have led to renewed concerns that genetic testing laboratories could face an imminent barrage of patent enforcement actions.14,15 This, in turn, has caused renewed interest in challenging the validity of gene patents in the courts,16 legislating to exclude genes from patenting,17,18,19 and exploring other strategies to ensure that genetic testing remains accessible and affordable.20

The scale of the purported ‘gene patent’ problem remains unclear in Australia, as does the extent to which patents provide a necessary incentive for investment in the development of new biomedical drugs, therapies and diagnostics. Policy makers and law reform agencies lack a sound evidence-base of the positive and negative impacts of patents on innovation and access to healthcare to assist them in determining the best way forward. This paper reports the results of a survey of laboratories offering genetic tests in Australia. These results provide an evidence-base to assist law and policy reform, including an active inquiry by the Productivity Commission into compulsory licensing (one form of patent use without authorisation from the patent holder).21

**Background**

This research follows a study of patenting and licensing practices in the Australian medical biotechnology industry in 2002-2003,22,23 which included a survey of managers of genetic testing laboratories. Contrasting with US studies, that survey provided little evidence that holders of patents related to genetic diagnostics were actively enforcing them against Australian laboratories. No laboratory reported receipt of notifications from patent holders relating to the BRCA genes. Of the 11 respondents (36 percent of the sample) who reported that they paid royalties or licence fees to patent holders, most (nine out of 11) related to polymerase chain reaction (PCR) methodology for amplifying DNA. Eight (26 percent) also reported that they received notifications related to PCR. One reported receipt of a notification relating to a specific diagnostic test for haemachromatosis, which was not further pursued.

Despite this low patent enforcement activity, 45% of respondents expressed concern that gene patents may negatively affect access to genetic testing services and 52% expressed concern that they could negatively affect prices.22 The survey was conducted after publicity surrounding the announcement of a strategic alliance between Myriad and Genetic Technologies Ltd (GTG), a small biotechnology company based in Melbourne, providing GTG with an exclusive licence to the relevant BRCA patents in Australia and New Zealand.9 Although there was widespread concern at the time that the receipt of enforcement notices from GTG was imminent, in July 2003 the then CEO of GTG confirmed that the company has no intention of enforcing the patents on behalf of Myriad. The spectre of enforcement of the BRCA patents was raised again in 2009, when it was reported that some organisations received notifications relating to them.12 Although this attempt at patent enforcement was subsequently abandoned, it led to renewed interest in patent law reform.

Later in 2009, the Australian Senate referred an inquiry into gene patents to the Senate Community Affairs Reference Committee, the final report of which was released in November 2010.12 The Committee called for collection of data, research and analysis concerning genetic testing and treatment in Australia, together with a number of patent law reforms. The Senate inquiry followed a more extensive inquiry by Australian Law Reform Commission (ALRC) in 2003-2004. The ALRC’s final report included many of the same law reform recommendations as the later Senate report.24 Of particular note, the ALRC recommended that genes should not be excluded from patenting. In November 2011 the Federal Government made a formal response to both reports,largely accepting their recommendations.25

Independently, a Private Members Bill was introduced into the Australian Senate in November 2011, seeking to exclude genes and other biological materials from patenting. The Senate Legal and Constitutional Affairs Legislative Committee was asked to consider the proposed legislation. The opinion of the majority in the final report was that the Bill should not be supported, largely because of its broad scope, and the imprecise language of its provisions.18,19 There are some indications that a modified Bill dealing exclusively with the exclusion of gene sequences in their native form will be tabled in the Australian parliament in 2013.26 In these circumstances, the need for an updated evidence-base on the impact of patents on innovation and access to healthcare is as crucial now as it has ever been.

**Methods**

*Survey Instrument*

The survey used Survey Monkey software. Ethical approval was given by the Tasmanian Human Research Ethics Committee. The survey covered a range of topics, but this paper focuses specifically on enforcement of patents against diagnostic laboratories and current and future concerns and protections associated with those enforcement activities.

*Survey Design*

Before the survey was drafted, interviews were conducted with managers from four leading Victorian diagnostics providers. This provided the authors with insights into current contentious issues in genetic diagnostics, allowing them to frame questions relevant to diagnostic providers, as well as providing further context in interpreting the results of the survey.

*Recruitment*

Intended participants were managers of human genetic diagnostic laboratories accredited by the National Association of Testing Authorities (NATA) (http://www.nata.asn.au/index.php). They were identified from four webpages on the NATA website listing laboratories that are involved in molecular genetics, genetic testing, biochemical genetics and cytogenetics. Once international laboratories and laboratories listed multiple times were removed, 50 remained. Attempts were made to contact all laboratories to obtain contact emails of laboratory managers and to inquire if they were willing to participate in the survey. Four did not respond to calls or emails; two stated they did not conduct the types of genetic tests that were of interest (that is, they only conducted traditional cytogenetics); one conducted an aspect of the chemistry involved in genetic testing but not genetic testing as such; six stated they were part of a larger organisation and were overseen by another laboratory listed on the NATA website. Email invitations to participate were sent to each of the 37 remaining laboratory managers using the automated Survey Monkey message manager system on 16 November 2012. Reminders were sent on 7 and 19 December 2012 and the survey was closed on 31 December 2012. Of the 37 invitees, 28 accessed the survey and 24 completed it (a response rate of 65 percent).

**Survey results**

The majority of respondent laboratories were located in public hospitals (Table 1).

<insert Table 1 here>

Respondents were asked whether their laboratory paid licence fees or royalties (other than those included in the price ofa commercial kit) to provide genetic tests. Three (12.5%) responded in the affirmative, which is a significant reduction from the 36 percent in the 2002-2003 study. This may be readily explained by the fact that the PCR-related patents have now expired. Of the three in the present survey, two were from private companies and one from a publicly listed company. On this basis there would seem to be little indication that holders of patents related to genetic diagnostics are actively enforcing them against Australian genetic testing laboratories in the public sector.

The issue of enforcement was pursued further by asking respondents whether they had received a formalised cease and desist letter or a letter of notification from third party patent holders about their patent rights both prior to and since the beginning of 2010, to provide some evidence as to whether such notifications are increasing in quantum. Three respondents (12.5% of the sample) said that they had received notifications since the start of 2010, and nine (37.5%, including the three who responded affirmatively to the previous question) reported that they had received notifications prior to 2010.

The three who received notifications since the start of 2010 were all from public hospitals. One identified BRCA 1 and 2, but could not remember the exact date (suggesting that this could have been before 2010). The second could not precisely recall the details of the notification. The third referred to maternal cell contamination testing for prenatal samples using STR (short tandem repeat) methodology. Of the nine respondents who received notifications prior to 2010, eight were from public hospitals and one was from a private hospital. Four listed BRCA 1 or BRCA 1 and 2 as the relevant genetic tests, one identified PCR, one again could not precisely recall details of the notification and one again referred to STR methodology. Two did not provide specific responses to this question.

Respondents were then asked about the potential for patents owned by third parties to detrimentally impact on the delivery of genetic tests. Four options were provided, each of which were identified as possible problems in the earlier Nicol and Nielsen study (it should be noted that delays in processing time have arisen in the past when a patent holder demands that the test has to be performed in a particular laboratory).22 All respondents were asked to answer ‘yes’ or ‘no’ to questions about whether patents owned by third parties could result in:

* inability to utilise improvements to diagnostic tests;
* unnecessary extension of processing time;
* restrictions on giving second opinions; and
* decisions not to provide additional tests.

The first question elicited five positive responses (20.8 percent of the sample) and 19 negative responses; there was one positive response and 22 negative responses to each of the middle two questions and two positive responses and 22 negative responses to the final question. These results suggest that few respondents have concerns at the present time that patents have a detrimental impact on delivery of genetic tests.

*Concerns and protections*

Although it appears that Australian genetic testing laboratories are facing few demands licensing and royalty payments, and few notifications from patent owners, a number of respondents expressed concern about the potential for third party patents to negatively effect the provision of genetic tests in the future. On a five-point scale from extremely concerned to not concerned, six (25 percent) responded that they were extremely concerned or very concerned about this issue and four were quite concerned (16.7 percent). Even so, the majority (14 respondents, 58.3 percent) were either marginally concerned or not concerned. While a greater proportion of the nine respondents who had received notifications were more concerned than the group as a whole (33 percent, with one extremely concerned and two very concerned), the same proportion said that they were only marginally concerned (with one other respondent skipping this question and two quite concerned).

Respondents were presented with thirteen mechanisms that might be utilised to protect their laboratories from the unnecessary negative effects of third party owned patents. They were asked to rank each option on a five-point scale from extremely effective through to not effective (or not applicable). Table 2 provides responses for the sample as a whole.

<Insert Table 2 here>

Table 2 shows that there was a wide diversity of views of the applicability of the listed mechanisms. Using average ratings (with extremely effective as 4, not effective as 0, and not applicable not scored) for each category, the highest ratings were for: negotiating a licence (2.21); going to the media/public (2.0); relying on the government to take action (1.78); and ignoring patent rights (1.76). Lowest scores were for: acquiring the third party (0.63); litigating (0.70); and initiating legal action to obtain a compulsory licence (1.18). Not unexpectedly, acquiring a third party ranked highest for the ‘not applicable’ option (12 respondents) - on the basis that this would not be an option for public laboratories - followed by compulsory licensing and litigating (both nine respondents).

In general, the nine respondents who received third party notifications prior to 2010 followed the trends for the survey as a whole, although there tended to be rather more support for the option of going to the media (an average ranking of 2.43). In contrast, there was much less support for compulsory licensing, with only one respondent ranking it as moderately effective.

**Discussion**

A primary goal of this survey was to identify potential negative aspects of patents on provision of genetic diagnostics tests. As one respondent reminded us, the survey did not investigate the positive aspects of patents. This needs to be taken into account in interpreting survey outcomes.

These results show that most genetic testing is done in public hospitals and other non-profit institutions in Australia. In contrast, US studies have shown much higher levels of private sector involvement in that jurisdiction. It has been suggested previously that this difference may go some way to explaining differences in reports of patent enforcement activities between jurisdictions, with more interest on the part of patent holders in pursuing profit-making than non-profit-making entities.9 Differences in quantum of tests between jurisdictions (with far more tests performed in the USA) may also provide some explanation, on the basis that it is more worthwhile for patent holders to seek licence fees where turnover is greatest.

The results of this survey show that while the number of respondents actually paying licence fees and/or royalties has decreased, more notifications of patent rights from third parties were reported than in the earlier Australian study undertaken in 2002-2003.9,23 However, many of these notifications related to enforcement of the BRCA patents, which is already known to have occurred. The majority of respondents indicated that they were unconcerned or marginally concerned about the risk that third party patent rights could affect the provision of genetic tests now or in the future. No single mechanism for shielding genetic testing from negative effects of patents was overwhelmingly preferred over any other, although negotiating a licence, going to the media/public and relying on the government to take action to facilitate use of third party patent rights by genetic testing laboratories were most highly favoured. In general, there was lukewarm support for most options, although it is interesting to note that going to the media/public is a preferred option. This is a novel finding and suggests that the court of public opinion may be more influential than legislative or policy reform.

How might this evidence assist in the law and policy reform process? This study does not provide compelling evidence to support wholesale exclusion of genes from patenting, provided that there are other effective mechanisms to guard against potential negative consequences of patent enforcement actions on provision of genetic tests. In this regard it is important to note that compulsory licensing is not a favoured mechanism for most respondents. One reason might simply be that public hospitals (where the majority of respondents reside) lack the capacity to litigate for compulsory licences themselves. Many respondents to this survey see reliance on the government to take action as being far more effective than compulsory licensing, which is initiated by private parties. The so-called Crown use provisions in Australian patent law were considered during the ALRC’s inquiry into gene patenting and human health.24 The ALRC concluded that the Crown use provisions have the potential to be particularly useful when access to a patented genetic invention is sought for the provision of public healthcare and, potentially, where access is required for public research purposes. These considerations led the ALRC to recommend that amendments should be made to section 163 (1) of the *Patents Act 1990* (Cth)to clarify that ‘for the services of the Commonwealth or of a State’ includes the provision of healthcare services or products to members of the public. Although the government did not respond favourably to this recommendation,25 the time may have come to reconsider this option.

It is often argued that the very existence of compulsory licensing provisions has the effect of bringing parties to the bargaining table and forcing negotiation. However, it is difficult to find concrete evidence that supports this rhetoric.27 These results, together with as yet unpublished findings from interviews with researchers and providers of genetic testing services support the contention that the current compulsory licensing provisions are flawed. Applications for compulsory licences are widely seen as being out of reach, with cost and uncertainty being the major deciding factors.

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**Table 1:** What type of organisation is your laboratory part of?



Note that 27 of the 28 respondents answered this question.

**Table 2:** From your perspective, what are currently the most effective mechanisms to protect your lab's ability to provide genetic tests from the unnecessary, negative affects of 3rd party owned patents? Negative effects may include: turn around times, quality, cost, improvements, second opinions and the ability to the offer a test. Please respond N/A for any of the mechanisms listed below that are not applicable to your organisation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Answer Options** | **Extremely effective** | **Very effective** | **Moderately effective** | **Not very effective** | **Not effective** | **N/A** |
| Ignoring patent rights | 3 | 2 | 5 | 2 | 5 | 3 |
| Working/inventing around patent rights | 2 | 1 | 5 | 3 | 4 | 6 |
| Going to the media/public | 4 | 2 | 4 | 4 | 3 | 3 |
| Negotiating a licence | 2 | 3 | 6 | 2 | 1 | 6 |
| Litigating - contesting infringement and/or patent validity | 0 | 1 | 1 | 2 | 6 | 9 |
| Relying on the government to litigate infringement and/or patent validity | 3 | 1 | 2 | 5 | 5 | 5 |
| Relying on the government to take action to facilitate use by your lab | 3 | 1 | 7 | 3 | 4 | 3 |
| Initiating legal action to obtain a compulsory licence | 0 | 3 | 1 | 2 | 5 | 9 |
| A pool of all relevant patents funded by an independent party, allowing labs to pay a fee based on usage | 1 | 1 | 3 | 3 | 4 | 7 |
| Invoking the research exemption | 0 | 2 | 3 | 4 | 3 | 7 |
| Commercial realities e.g. bargaining power | 0 | 3 | 4 | 3 | 3 | 7 |
| Difficulties faced by 3rd parties in enforcing patents | 1 | 1 | 6 | 1 | 5 | 6 |
| Acquiring the 3rd party | 0 | 0 | 2 | 1 | 5 | 12 |

Note that there were between 19 and 21 responses for each option.