

SUBMISSION TO THE PRODUCTIVITY COMMISSION IN RESPONSE TO  
THE

***PRODUCTIVITY COMMISSION ISSUES PAPER -  
INTELLECTUAL PROPERTY ARRANGEMENTS***

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NOVEMBER 2015

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Professor Dianne Nicol and Dr Jane Nielsen are both members of the Law Faculty at the University of Tasmania. Professor Nicol is director of the Centre for Law and Genetics and Dr Nielsen is a senior member. The Centre developed out of a project funded by the Australian Research Council (ARC) from 1994 to 1997. The primary focus of the project was the ethical and legal implications of advances in genetic technology. Since then, the Centre has had ongoing funding from the ARC discovery grants program and has expanded its areas of research to include broader issues associated with commercialisation of genetic technology, access to healthcare and biobanking.

Input into intellectual property law reform inquiries has been one of the major aspects of the Centre's activities. Nicol's expertise rests firmly in the area of intellectual property law. She has taught courses in IP Law, equity, media law, IT law and biotechnology and the law, and supervised many PhD candidates in this area. She has a PhD in cell and developmental biology from Dalhousie University in Canada and an LLM in intellectual property law from the University of Tasmania. Her research interests particularly focus on the interface between innovation, research and access to healthcare in biomedicine. Nielsen works closely alongside Nicol in the area of intellectual property law. Her research interests are in the areas of intellectual property, competition law and torts, and she has had a substantial teaching role at the faculty, teaching in these areas.

Both authors are currently working together on an ARC funded project into material transfer agreements. This, in large part, assesses the effect of intellectual property on transfer of materials and data and the follow on impact on research and innovation. Together Nicol and Nielsen have also conducted a project on patent pooling in biotechnology along with colleagues from Swinburne University and Japan which was completed in 2013. Nicol has also undertaken ARC funded research on cooperative strategies for managing intellectual property in biotechnology and published extensively in the patent and intellectual property fields. Nielsen has moved into other areas of innovative technology and has independently been pursuing projects particularly in the areas of biotechnology and 3D printing.

Nicol was appointed as one of three panel members on the Pharmaceutical Patents Review Report in 2012-2013. Previously she was also appointed to the Advisory Board for the Australian Law Reform Commission (ALRC) inquiry into gene patenting and human health and was a consultant to that inquiry. She regularly makes submissions to public inquiries with other members from the Centre for Law and Genetics, and Nielsen has been involved in at least a dozen of these submissions. They have both also been invited to give oral evidence from time to time.

## **Preliminary comment**

As our area of expertise relates specifically to patent law, we have primarily addressed some of the questions in the Issues Paper relating to patents. In answering some of the more general inquiries we also draw primarily on this experience. While we would have liked to have provided the Productivity Commission with a more detailed and broadly based submission, we regret that the time constraints resulting from the deadline for submissions do not provide us with the capacity to respond more fully.

Throughout our submission, we reference the specific question we are addressing and the page number of the Issues Paper on which it appears.

We note that there has been a raft of patent and other intellectual property (IP) inquiries in recent years, as acknowledged by the Productivity Commission in the Issues Paper. This review provides an opportunity for further high-level and holistic consideration of Australia's IP arrangements. We note, though, that in many instances, and particularly in relation to specific areas of inquiry (patents, design etc.), regard should be had to the careful deliberations of those other bodies, with particular emphasis on the evidence they have collected and the recommendations they have made.

We further note that IP is a diverse area of law that responds to many different pressures and policy levers in its provision for the protection of creative and innovative subject matter. As such, it is not always appropriate to generalise across the whole field of IP law. Rather, in many instances consideration of specific aspects of IP in isolation may provide more nuanced responses and actionable recommendations.

## A Framework for assessing IP arrangements

*p7. The Commission welcomes feedback on the framework it proposes employing to guide its assessment of IP arrangements and for recommending welfare-enhancing reforms.*

In our view the framework proposed is adequate for the assessment being undertaken. We defer to those with specific expertise in relation to this question.

### **Effectiveness: do IP rights target additional innovation and creative output?**

*p8. Do IP rights encourage genuinely innovative and creative output that would not have otherwise occurred? If not, how could they be designed to do so? Do IP rights avoid rewarding innovation that would have occurred anyway? What evidence and criteria should be used to determine this? Are IP arrangements in other jurisdictions more effective in generating additional creative output?*

There exists a large body of economic research that has attempted to analyse whether or not intellectual property (IP) encourages innovation, and to provide an analytical framework, including appropriate measurements on which to base this analysis. However, we are not aware of any comprehensive framework for addressing the question of whether IP rights encourage genuinely innovative and creative output. Nor are we aware of the existence of an appropriate measure of the overall impact of IP to determine whether creative or innovative outputs would nevertheless have occurred in its absence.

We have some specific knowledge of the relationship between patents and innovation in the biomedical field arising out of the doctrinal, policy and empirical research that we have undertaken for the past 15 years.<sup>1</sup> In this field, as well other areas of rapid technological change, we know that patents serve purposes beyond encouraging innovation. For example, they can provide incentives for investment by venture capitalists and others in start up biotechnology companies and entry into partnerships and joint ventures.<sup>2</sup>

Relaxation of the thresholds for patenting of gene sequences and other research tools in the late 20<sup>th</sup> century occurred in parallel with a surge in the number of firms entering the field. While the extent to which the availability of patent rights is actually causative of the growth in numbers of these small to medium enterprises in biotechnology is difficult to assess, the views of participants in the industry clearly support the notion that patenting is vital to their success.

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<sup>1</sup> See particularly 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 (Centre for Law and Genetics: 2003, Hobart); Dianne Nicol, *Patent Licensing in Medical Biotechnology: A Rile for Collaborative Licensing Strategies*, Centre for Law and Genetics Occasional Paper No 7 (Centre for Law and Genetics: 2010, Hobart); Dianne Nicol, Jane Nielsen, John Liddicoat, Christine Critchley and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation*, Centre for Law and Genetics Occasional Paper No 8 (Centre for Law and Genetics: 2014, Hobart).

<sup>2</sup> Dianne Nicol, Jane Nielsen, John Liddicoat, Christine Critchley and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation*, Centre for Law and Genetics Occasional Paper No 8 (Centre for Law and Genetics: 2014, Hobart), at 105.

The impact of recent US and Australian court decisions invalidating patent claims relating to nucleotide sequences (in Australia and the US) and methods of diagnosis (in the US) is still to be fully assessed. Much will depend on the ways in which the ratios of the decisions are interpreted by patent offices and future courts. At the narrowest interpretation, these decisions may have only minor impact on biomedicine, given that the technology has advanced significantly since the 1980s and 1990s, and the time when the broad sweeping claims to sequences and methods that were invalidated in these recent court decisions were being filed. Such broad claims to DNA sequence information would not be allowed now, irrespective of the nature of the patentable subject matter inquiry. In contrast, on their broadest interpretation, these court decisions could significantly affect the whole of the biotechnology industry (including both biomedicine and agricultural biotechnology), if the patent eligibility of many other products and processes of biotechnological innovation becomes uncertain.

We recognise that the relationship between patenting and innovation in this field (as in many others) is complex. We have noted in earlier submissions to the Advisory Council on Intellectual Property that there is conflicting evidence as to whether or not innovation is best served by a system that grants monopoly rights, or one that encourages a competitive environment. An optimally functioning patent system will properly balance the innovation advantage provided to patent holders with the concomitant risk of innovation blockage for follow on users. With the advent of high technology, the pace and complexity of the innovation process has increased dramatically. Complex webs of primary and follow-on innovators are emerging, making the challenge of ensuring that intellectual property functions appropriately even harder.

There is a large, but conflicting, body of theoretical economic literature on optimal patent strategies in areas of cumulative innovation. The messages from these analyses are mixed. There are those that provide compelling arguments as to why the availability of patents for subject matter at the upstream end of the research-development continuum encourages investment further downstream.<sup>3</sup> Others provide equally compelling arguments as to why this level of protection might not be optimal in areas of cumulative innovation.<sup>4</sup>

There is a risk that broad patents claiming foundational technology may result in blocking effects and that patent thickets could cause anticommons effects. Blocking can occur when the owner of a patent over foundational technology refuses to deal with a developer of downstream technology. Anticommons effects can occur both where there are numerous overlapping property rights and also where reach-through licence agreements lead to licence and royalty stacking.<sup>5</sup> The risk is that the timely delivery of new products and processes could be significantly hindered in these new areas of technology, which has both economic and social consequences.

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<sup>3</sup> Suzanne Scotchmer, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law' (1991) 5 *Journal of Economic Perspectives* 29.

<sup>4</sup> For example, see Robert Merges and Richard Nelson, 'On the Complex Economics of Patent Scope' (1995) 90 *Columbia Law Review* 839.

<sup>5</sup> Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698 at 698-699.

In the research context, we recognise that there are genuine concerns about the potential for patents to detrimentally impact on the primary research conducted in universities and other public research organizations that feeds in to the innovation cycle. In the university sector, in particular, patenting will not always be the optimal mechanism for disseminating knowledge. Concerns about hold up and anticommons impacts on innovation need to be taken seriously, even though the evidence that these are actually eventuating is mixed.<sup>6</sup> However, these concerns need to be balanced against the positive role that patents can play in encouraging innovation, particularly for small, specialised firms and their licensees.<sup>7</sup>

As we have noted in our submissions to other law reform inquiries, it is important to acknowledge that there are statutory tools for alleviating blocking and anticommons risks both pre-grant, through rigorous application of the patent criteria, and post-grant, through compulsory licensing, Crown use, competition law and other initiatives such as patent pooling and clearinghouse mechanisms. It is equally important to recognize the important role of the ex-ante policy decisions made by governments, funding agencies, universities and other research institutions and industry as to whether or not patenting is the optimal strategy for innovation and dissemination of knowledge, both for whole fields of technology and for individual inventions.

In the downstream pharmaceutical context, the issues are somewhat different because the focus is primarily on the development of market-ready products, rather than broadly applicable research tools. Producers of new chemical entities and new biologics insist that strong patent rights are vital to encourage innovation in this field because of the high research and development costs. Generic producers, conversely, argue that patent rights need to be circumscribed and of limited duration to ensure that the best treatment options are available to healthcare consumers at prices they can afford. Nicol and colleagues made a series of recommendations in the final report of the inquiry into pharmaceutical patents to reform the patent system to better support pharmaceutical innovation and product development.<sup>8</sup> We endorse the recommendations in that report, particularly Recommendation 4.1, to reduce the effective patent life of pharmaceutical patents, the various recommendations to amend particular sections in the *Patents Act 1990* (Cth) (*Patents Act*) and other recommendations providing for greater oversight, transparency and coordination with other regulatory agencies.

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<sup>6</sup> Timothy Caulfield, Robert M Cook-Deegan, F Scott Kieff and John P Walsh, 'Evidence and Anecdotes: an Analysis of Human Gene Patenting Controversies' (2006) 24 *Nature Biotechnology* 1091.

<sup>7</sup> See Dianne Nicol, 'Strong Patent Rights, Weak Patent Standards and Innovation in Biomedicine' in: Chris Arup and William van Caenegem (eds), *Intellectual Property Policy Reform: Fostering Innovation and Development* (Cheltenham, UK: Edward Elgar).

<sup>8</sup> Anthony Harris, Dianne Nicol and Nicholas Gruen, *Pharmaceutical Patents Review Report* (Canberra; 2013)

*P9 To what extent does the IP system actively disseminate innovation and creative output? Does it do so sufficiently and what evidence is there of this? How could the diffusion of knowledge-based assets be improved, without adversely impacting the incentive to create?*

*What, if any, evidence is there that parties are acting strategically to limit dissemination?*

As noted earlier in this submission, our expertise lies in the area of patent law. In particular, we have conducted quantitative and qualitative research into the extent to which the patent system assists in disseminating innovation in biomedicine. We have consistently found that holders of patents relating to biomedical innovation actively seek out licensing partners. Indeed, some of our quantitative analysis suggests that the Australian biotechnology and pharmaceutical sectors are more likely to out-license successfully than other industry sectors.<sup>9</sup>

As a general rule, in the context of drug discovery and development the Australian industry adopts a 'value adding and moving on' strategy, whereby participants develop or license-in core technology, add value and seek to license-out to larger partners for further product development, often in other jurisdictions.<sup>10</sup> So, in this sense, then, innovations are disseminated, because they are passed on to other parties that are a better equipped to bring these innovations to the market. We refer to this as **vertical dissemination**. This is the dominant form of dissemination in the drug discovery and development context. The robustness and duration of patent rights are relevant concerns for the biotechnology and pharmaceutical industries, but these are just two of the many factors that may impede the vertical dissemination of their innovations. Securing adequate long-term funding and finding licensing partners are also significant factors.<sup>11</sup>

There will be circumstances where the public interest is better served by broad dissemination of innovations (**horizontal dissemination**), rather than exclusive vertical dissemination to specific partners. This is likely to be the most optimal dissemination strategy for foundational technologies, like gene sequences, research tools and methods of diagnosis. Our research has sought to ascertain whether there is anything sub-optimal about the ways in which foundational technologies are disseminated in biomedicine. As noted earlier in this submission, concerns have been expressed in the academic and policy literature about the blocking effect on innovation that could arise either as a result of refusals to license or through restrictive licensing of foundational technologies that are subject to broad patent claims. There are also concerns that too many patents over foundational technologies could create an anticommons effect: 'tollbooths on the road to product development'.<sup>12</sup>

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<sup>9</sup> See Dianne Nicol, Jane Nielsen, John Liddicoat, Christine Critchley and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation*, Centre for Law and Genetics Occasional Paper No 8 (Centre for Law and Genetics: 2014, Hobart) at 48.

<sup>10</sup> See Dianne Nicol, Jane Nielsen, John Liddicoat, Christine Critchley and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation*, Centre for Law and Genetics Occasional Paper No 8 (Centre for Law and Genetics: 2014, Hobart) at 78-79.

<sup>11</sup> See Dianne Nicol, Jane Nielsen, John Liddicoat, Christine Critchley and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation*, Centre for Law and Genetics Occasional Paper No 8 (Centre for Law and Genetics: 2014, Hobart) at 91-92.

<sup>12</sup> An 'anticommons' arises where access to multiple, overlapping patent rights over initial innovations is

We have found scant evidence that either effect is being observed in the Australian context. As we noted in our most recent research report, even in more dense areas of research and development activity, multiple licence transactions to secure freedom to operate are rare.<sup>13</sup> Moreover, it appears that there is widespread acceptance of an unwritten rule that patent rights are unlikely to be enforced in the research context, or even at early development phases. As such, even without the experimental use exemption that was introduced by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth), it would be rare for research users of patented technology to face enforcement actions.

Although this is a rapidly expanding area of research and development, it appears that there are still 'white spaces' for innovative activities, even in the more dense areas of research and development activity.<sup>14</sup> As such, it appears that, for the most part, patent thickets do not appear to be unduly impeding product development in the Australian drug discovery and development sector. The research reported in our study supports assertions made elsewhere that R&D opportunities are more diverse and numerous than suggested in some of the literature expressing concerns about anticommons effects.<sup>15</sup> Whether the story may be different in other sectors is an interesting question that warrants further scrutiny, but for which we do not have a body of evidence.

Insofar as strategic patenting is concerned, there is evidence and a growing feeling in academic commentary that this is a real issue in the United States. The 'patent troll' issue, as it has become known, arises where patents are aggregated (primarily by non-practising entities) for the purpose of revenue raising. This phenomenon has generated a vast body of literature. Patent 'trolling' results from the disaggregation of complementary patents, all of which are required in order to develop a single, downstream product.<sup>16</sup> It has therefore become a problem in areas of information technology.<sup>17</sup> It is less pronounced in other industries such as biotechnology where this requirement is not as evident.

The trolling problem must be given some jurisdictional context. There are incentives in the US patent system that make trolling an attractive option, and these incentives either do not

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required to enable follow-on research to proceed: multiple bargains must be struck, resulting in stacking transaction costs: M. Heller and R. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, at 699.

<sup>13</sup> See Dianne Nicol, Jane Nielsen, John Liddicoat, Christine Critchley and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation*, Centre for Law and Genetics Occasional Paper No 8 (Centre for Law and Genetics: 2014, Hobart) at 89-90.

<sup>14</sup> Dianne Nicol, Jane Nielsen, John Liddicoat, Christine Critchley and Tess Whitton, *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation*, Centre for Law and Genetics Occasional Paper No 8 (Centre for Law and Genetics: 2014, Hobart) at 89-90.

<sup>15</sup> See, eg, David E Adelman and Kathryn L DeAngelis, 'Patent Metrics: the Mismeasure of Innovation in the Biotech Patent Debate' (2007) 85 *Texas Law Review* 1677.

<sup>16</sup> Mark Lemley and Carl Shapiro, 'Patent Holdup and Royalty Stacking' (2007) 85 *Texas Law Review* 1991 at 2009-2010.

<sup>17</sup> Mark A Lemley and A Douglas Melamed, 'Missing the Forest for the Trolls' (2013) *Columbia Law Review* 2118 at 2148-2149 and 2173.



exist, or are less pronounced than in other jurisdictions, particularly the EU and Australia.<sup>18</sup> This leads to the suggestion that aggregation in these jurisdictions is unlikely to lead to the trolling problems we have seen debated in the US literature. However a recent study in the UK suggests that while the patent troll problem is much less pronounced than in the US, it nonetheless exists.<sup>19</sup> Hence, we should not be complacent in common law jurisdictions that the trolling problem will never emerge. It is something of which we must be cognisant, as it has the potential to have a profound effect on innovation.

## Patents

*p18. What evidence is there that patents have facilitated innovations that would not have otherwise occurred, or have imposed costs on the community, including by impeding follow-on innovation?*

*Are there aspects of Australia's patent system that act as a barrier to innovation and growth? If so, how could these barriers be addressed?*

The difficulty in answering the questions posed on page 18 the Issues Paper has been broadly acknowledged. As noted earlier in this submission, there is a significant body of economic evidence specifically considering the innovative role of patents with which the Commission will be familiar.<sup>20</sup> Not being economists, we cannot contribute to the highly nuanced debate about the optimal strength of the patent system in economic terms. We note, however, that Nielsen has synthesised some of this literature from the legal perspective.<sup>21</sup>

There are safeguards to protect against patents impeding innovation including legislative exemptions (such as the experimental use exemption), and the existence of a compulsory licensing scheme. In relation to the former, this exemption has limited applicability, given that it exempts research *on* an invention rather than research *with* an invention (we do, however, draw attention to our earlier comment that in practice patents are rarely enforced against research users – indicating that the practice based exemption may actually be broader than the legislative exemption). In respect of the latter, the compulsory licensing scheme has been the subject of extensive review.<sup>22</sup> Despite a number of shortcomings, this system has undergone very little change. While it operates to provide some protection against the restrictive use of patents, its cumbersome nature means that this protection is

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<sup>18</sup> See, eg, 'Patent Trolls: As American as Apple Pie?' (1 August 2012) in Patentology, <http://blog.patentology.com.au/2012/08/patent-trolls-as-american-as-apple-pie.html>. For example, the ability to make generous damages awards and the fact that costs are generally not awarded are two matters that might have influence here.

<sup>19</sup> Christian Helmers, Brian Love and Luke McDonagh, 'Is There a Patent Problem in the UK?' (2014) 24 *Fordham Intellectual Property, Media and Entertainment Law Journal* 509.

<sup>20</sup> For a recent paper see Dan L Burk, 'The Law and Economics of Intellectual Property: In Search of First Principles' (2012) 8 *Annual Review of Law and Social Science* 397.

<sup>21</sup> Jane Nielsen, 'Innovation in Medical Biotechnology: Mapping the Intersection of Intellectual Property and Competition Law' (2007) 35(6) *Australian Business Law Review* 407.

<sup>22</sup> Including, most recently, the Productivity Commission's own inquiry, *Compulsory Licensing of Patents*, Report No 1 (2013).

likely to be very limited. In short, both of these mechanisms lack teeth, in that:

- the boundaries of the experimental use exemption are unclear and potentially quite narrow; and
- the compulsory licensing provisions have been eroded by the entry by Australia into the AUSFTA, which limits the grounds on which compulsory licences may be granted, and restricts the ability of applicants to apply to orders that would grant access to associated IP rights such as know-how.

We also again acknowledge the specific recommendations in the final report of the pharmaceutical patent inquiry that are directed to removal of some of the legislative barriers to innovation and growth. In particular, we draw attention to Recommendation 4.1, relating to effective patent life and Recommendation 7.2, relating to limitations on liability for supply infringement.

*p18. Do patents provide rewards that are proportional to the effort to generate IP? What evidence is there to show this? How should effort be measured? How does the balance of costs and benefits from patent protection compare across sectors and innovations?*

It is difficult to answer this question because responses differ depending on the type of respondent. The costs of research and development vary widely between different industries.

There is no doubt that the cost of obtaining, maintaining, defending and policing patents is prohibitive for many small players, and in order to recoup these costs, the associated benefits of exploiting the patent must be significant. Many patents lapse, suggesting that the costs of maintaining them are very high. In our qualitative research involving interviews with industry participants we heard that patent portfolios must be constantly reviewed and strategic decisions must be made about whether and when to maintain, lapse, licence or assign. Other empirical research undertaken by our group on gene patents shows that many had already been allowed to lapse long before the superior courts in the US and Australia had handed down their decisions on subject matter eligibility.<sup>23</sup> This suggests that, in at least some instances, the costs of maintaining patents of this nature outweigh the benefits.

The situation is quite different in the context of drug discovery and development, where the long development pipeline and stringent regulations increase development costs relative to other industries. Usually, incentivisation to engage in drug discovery and product development is provided by robust patent protection, as well as data exclusivity. Although there are exceptional circumstances where the long road to product development in this field can be undertaken without the benefit of patent protection, interviewees in our empirical studies consistently reported that patent protection is essential. If it is lost, it is likely to lead to project abandonment and even firm closure. This can even occur if there are minor delays in the product development process, arising from something as simple as a bad batch of reagent.

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<sup>23</sup> John Liddicoat, Tess Whitton and Dianne Nicol, 'Are the Gene Patent Storm Clouds Dissipating? A Global Snapshot' (2015) 33 *Nature Biotechnology* 347.

Whilst this aspect of our submission focuses on the challenges faced by those industry participants involved in discovery and developing innovative new chemical entities and biologics, we are not intending to ignore the difficulties faced by generic manufacturers in gaining a foothold in the market. We simply do not have empirical data on the generic sector and so cannot provide assistance to the Productivity Commission in this regard.

*p18. What scope is there to better leverage the economic benefits of patents, by taking steps to improve the diffusion of patent information?*

We respond to this question by exploring various aspects of diffusion of patent information. We first consider diffusion of information about the existence of a patent, then diffusion of the information contained in a patent, disclosure of dealings with the patent, and finally disclosure of patent-related information.

The first step in our analysis is to consider how information about the existence of a patent is communicated. Obviously, patent offices around the world are tasked with providing public databases of patent information, and they do this quite well. However, this does not mean that the information about whether and what patents exist in respect of specific goods and/or services is readily available to anyone who might need to access it. Patent searches are complex and require expert assistance. Yet patent infringement is a strict liability offence. To provide some shield to those who innocently infringe patents, there is provision in the *Patents Act* to make this plea. Section 123(1) of the Act provides that, if a court is satisfied that at the time of infringement an infringer was not aware, and had no reason to believe, that a patent for the invention existed, then the court may refuse to award damages or an account of profits. Section 123(2) provides that if patented products are ‘marked so as to indicate that they are patented in Australia’, and the products were sold or used in Australia ‘to a substantial extent’ before the date of the infringement, then the infringer is taken to be aware of the patent unless the contrary is established. The process of marking a product with patent related information is known as ‘patent marking’.

Our colleague John Liddicoat has reviewed the innocent infringement and patent marking provisions in Australia and the US. Based on this analysis, he reached the conclusion that there are deficiencies in the Australian provisions and that they should be amended in two ways: first, to require that the patent number is included in the patent mark; and second, to allow for virtual marking (marking by the provision of website information where relevant patent information is given).<sup>24</sup>

Liddicoat and Nicol have also examined the false patent marking provisions<sup>25</sup> False patent marking occurs when a product is marked with a patent but no patent rights actually apply to the marked product. Section 178 of the *Patents Act* prohibits false patent marking. Our analysis indicates that there is a lack of clarity and other imperfections in the Australian provisions. In the absence of current empirical evidence demonstrating negative effects

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<sup>24</sup> John Liddicoat, ‘Re-Evaluating Innocent Infringement in Australia: Patent Numbers and Virtual Marking’ (2014) 25 *Australian Intellectual Property Journal* 18.

<sup>25</sup> John Liddicoat and Dianne Nicol, ‘Re-Evaluating False Patent Marking in Australia’ (2012-2013) 22(2) *Journal of Law, Information and Science* 128.

caused by false patent marking, we have recommended that modest amendments should be made, namely: the penalty should be clarified as a large nominal fine; the ACCC should be given jurisdiction to enforce s 178(2) under the *Patents Act*; the requirement in s 178(2) that the Minister's consent be obtained before prosecution can be commenced should be removed; and marking a product with a patent number that is now expired, but prior to expiry was validly applied to the product, should not constitute false patent marking.

In the context of diffusion of information about the content of the patent – the written description and claims - we acknowledge that significant improvements have been made to the IP Australia website and the searchable databases in recent years, which have resulted in improved access to patent documents. There have also been significant changes to the legislative requirements for disclosure and claiming. Section 40 of the *Patents Act* was amended by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth). We strongly supported these amendments in submissions to earlier inquiries. We submit that it is too early to assess whether the new provisions are performing optimally, but note that they will need to be reviewed in the near future.

With regard to disclosure of dealing with a patent, we submit that there is some scope to improve transparency as to patent licensing. In a previous submission by Nicol and Liddicoat to the inquiry into the IP Australia Exposure Draft, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 we supported changes to the legislation to require registration of exclusive licences, to make exclusive dealings more transparent. There is a requirement to register an interest through s 187 of the *Patents Act*: 'Particulars of standard patents in force, and other prescribed particulars relating to standard patents (if any), must be registered in that part of the Register dealing with standard patents.' Section 103 of the Act imposes a further requirement for consent of a registered mortgagee or exclusive licensee for amendments. However, there is no clear requirement for exclusive licences to be registered, even though s 120 of the Act allows exclusive licensees to bring infringement actions. We suggest that imposing a registration requirement may enhance transparency of patent dealings, as it would encourage holders of exclusive licences to register their interests.

Diffusion of information linked with patent information can also be problematic. We are currently undertaking research on the legal mechanisms to compel disclosure of patent-related materials and data. This is becoming an issue of growing international concern in relation to access to databases of genetic variation data. Companies like Myriad Genetics have acquired valuable and unique databases of information matching gene variations with disease by maintain exclusivity of their patent rights. Dan Burk notes that effectively, in this regard, patents become tools for data aggregation.<sup>26</sup>

Our analysis suggest that there is no real legal mechanism to gain access to proprietary genetic data relating to sequence variants and clinical information. Strong trade secrecy regimes in most jurisdictions mean that providers of testing services are able to maintain a

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<sup>26</sup> Dan L Burk, 'Patents as Data Aggregators in Personalized Medicine' (2015) *Boston Journal of Science and Technology Law* (in press).

monopoly position whether they rely on patent protection or not. Provisions in the *AUSFTA* seemingly prevent courts making any order permitting access by an unauthorised user. Article 17.9.7(b)(iii) specifies that Australia's laws relating to compulsory licensing:

may not require the patent owner to provide undisclosed information or technical know-how *related to* a patented invention that has been authorised for use in accordance with this paragraph.<sup>27</sup>

This raises questions as to the philosophical justifications underlying patent law and the law of trade secrecy, and the balance within each of these regimes with regard to protection versus access. This is an area that requires further analysis and discussion, particularly given the potential impact of these regimes on the provision of healthcare.

*p18. Is the patent system sufficiently flexible to accommodate changes in technology and business practices?*

Our submission is that the patent system is sufficiently flexible to accommodate changes in technology and business practices, and in any case TRIPS requires patent legislation to be technology neutral.<sup>28</sup>

The judgment of French CJ, Kiefel, Bell and Keane JJ (the plurality) in *d'Arcy v Myriad Genetics, Inc* (2015) HCA 35 (*d'Arcy*) provides some guidance on the application of the Australian subject matter requirement to new areas of technology. Essentially, their Honours said that in areas that open up new fields of patent protection, the patentable subject matter requirement involves more than simple application of the two factors that traditionally have been applied in Australia (whether there is an artificially created state of affairs and whether the invention has economic utility). Rather, it is necessary to consider a range of other factors such as the effect on innovation of opening up a new field to monopoly rights and the coherence of national and international patent law. This signals that the courts and the patent office need to look at broad public policy considerations when considering the appropriate bounds of patents, as they apply to new areas of technology.

*p18. Do the criteria for patentability in the Patents Act 1990 (Cth) help the patent system to meet its objectives? Would introducing economic criteria for patentability and/or gradually reducing the duration of patent protection substantially improve the efficiency and effectiveness of the patent system?*

We submit that the criteria for patentability do assist the *Patents Act* to meet its objectives especially since the Raising the Bar Amendments, but the legislation would still benefit from the inclusion of an objects clause. This was considered by IP Australia in their Patentable Subject Matter Consultation Paper on an Objects Clause and Exclusion from Patentability. We submit that the inclusion would better facilitate interaction between the patent system and competition policy in reference to the benefit of society as a whole.

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<sup>27</sup> *AUSFTA* art 17.9.7(b)(iii). Emphasis added.

<sup>28</sup> TRIPS Art 27(1).

*p18. Is the existing coverage of patents optimal? Are there areas of innovation that should be included/excluded? Should the duration of patent protection take into account how the development of IP was funded?*

Here we focus specifically on matters relating to ethics, we submit that it is proper for there to be scope for dealing with ethical concerns in patent law, provided that these concerns relate solely to exploitation of the invention, as prescribed in TRIPS. It is important to separate out ethical concerns relating to patenting of technology and ethical concerns relating to the technology itself. The latter should not be dealt with through the patent system but through direct regulation of research and development activities. But there will be some instances where it would be contrary to morality to allow the patent system to be used to facilitate the commercial development of certain technologies. We expect that, as a general rule, very few patent applications will fall foul of an exclusion centred on ethical grounds. This is certainly the experience in Europe (although the applicability of this provision for excluding patents for inventions relating to embryonic stem cell technology is an area of continuing uncertainty). As such, we submit that the clear purpose of this exclusion should be well articulated, so that the non-expert reader does not see it as a panacea for problematic enforcement practices. Nevertheless, we submit that it is appropriate that such an exclusion to be explicitly provided for in our patent legislation. For too long there has been debate around the applicability of the 'general inconvenience' exclusion (incorporated into Australian law from section 6 of the *Statute of Monopolies 1624*) for dealing with matters of morality and public policy. This uncertainty would be removed by the introduction of a clear and explicit exclusion for inventions, the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public. We support the wording that was proposed by IP Australia in *IP Australia Patentable Subject Matter Consultation Paper on an Objects Clause and Exclusion from Patentability*.

We also refer back to our submission relating to the *d'Arcy* case, and welcome the holding of the plurality that a range of factors need to be taken into account when determining patent eligibility in new areas of technology.

In our submission, there is no reason to take into account how IP was funded in determining the duration of patent protection: to do so would be contrary to Australia's obligations under TRIPS, Art 33.

*p18. Are there any issues with the administrative arrangements of IP Australia for assessing and granting patents?*

In our view, the administrative arrangements surrounding the assessment and granting of patents are largely satisfactory, and patent examiners well equipped to successfully undertake the process of examination. Our only comment relates to the need for patent examiners to remain abreast of areas of technological developments, and the difficulty this presents in terms of patent examination. What would assist in this respect is increased funding, allowing for more examiners, greater levels of specialisation and more training. If renewal fees are increased for patents in the later years of their lives, these increases in revenue could supplement the budget for patent examiners.

We note that IP Australia will need to consider how to implement the requirement in the

decision of the plurality in *d'Arcy* that a range of factors need to be considered when determining patent eligibility in new areas of technology.

We have previously supported proposals for an advisory panel to assist the Commissioner on Patents in making determinations as to patent eligibility. Although ACIP suggested in its Options Paper on Patentable Subject Matter that the purview of Advisory Panel should be limited to consideration of social filters, we have suggested that the Advisory Panel should be given a wide mandate to consider any contentious patent matters. Further, we submit that the Panel should not be restricted to consideration of specific patent applications, but should be able to provide advice to the Commissioner on broader policy considerations. In this respect, setting up a panel in the form of a statutory body like the National Competition Council (NCC) might be considered. The NCC has as its primary roles the provision of advice about competition policy matters, and recommendations to the Australian Competition and Consumer Commission.

Establishing an Advisory Panel with a statutory basis would allow the functions of the Panel to be reviewed and, if necessary, altered over time. Expanding the remit of the Panel to matters outside the social filters would reduce the administrative burden of establishing such a Panel. Allowing the Panel to research patent issues and provide non-binding advice to the Commissioner of Patents would also seem to us to be sensible given the number of inquiries conducted in respect of patent law issues over recent times, and the ever-changing nature of patentable subject matter.

### **Enforcing IP rights**

*p28. Are IP rights too easy or hard to enforce in Australia, and if so, why?*

IP rights are hard to enforce for the reasons alluded to in the Issues Paper, pp27-28. The answer to this question no doubt depends on the nature (and value) of the right being infringed, and the financial strength of the IP holder and the infringer. Australia is not unique in this regard: IP rights are notoriously expensive to defend due to the costs associated with court proceedings and difficulties detecting infringement. While a simple cease and desist letter is inexpensive and simple to send, following up on this is impossible for some rights holders.

As noted previously, our experience lies in the patent field. In our interviews with Australian biotechnology patent holders, it became evident that many lack the resources to monitor, let alone litigate infringement. Infringement is often ignored,<sup>29</sup> and research institutions, in particular, indicated a willingness to ignore patents because the implications were not

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<sup>29</sup> Very few cease and desist letters were being received by interviewees, particularly research institutions. A high level of infringement by these parties was tolerated; 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 (Centre for Law and Genetics: 2003, Hobart) at 214-218.

particularly concerning.<sup>30</sup> In some cases, infringement might be a precursor to a patent licensing agreement once infringement is detected. The other side of the coin is that a licence agreement will not always be possible for those prepared to run the infringement gauntlet, and the cost implications could be formidable.

The problem is likely to be more acute in areas of digital technology, as infringement becomes almost impossible to detect and the infringement issue becomes increasingly global. On this point we defer to those with specific knowledge of these issues.

*p28. To what extent can Australian firms enforce their IP rights internationally? Does this differ across regions and/or countries?*

This depends, of course, on whether Australian firms have applied for protection in other jurisdictions (excepting copyright which arises independently of registration/application). Enforcement procedures differ across jurisdictions, further increasing the complexity and cost issues associated with enforcement.

*p28. Are there particular issues relating to IP enforcement that are different from the general community's ability to access Australia's justice system, and if so, what are they?*

An IP holder wishing to enforce an IP right in Australia has no choice but to embark upon a costly legal journey. Many aspects of our justice system are well equipped to provide more accessibility to the public, or have evolved to better facilitate access to the justice system. The existence of administrative procedures in particular areas of law are a good example of this. Tribunals provide a cost-effective avenue for many aggrieved members of the public. For example, the Australian Competition Tribunal has the capacity to review decisions of the Australian Competition and Consumer Commission.

While we do not believe it would be appropriate for IP Australia to hear enforcement matters in respect of IP, we do submit that the establishment of a specialist Tribunal to hear IP matters, including enforcement matters, would enhance the IP system enormously. One option would be to expand the operation of the Copyright Tribunal to hear issues relating to infringement, and/or to hear matters relating to other forms of IP. Insofar as expertise is concerned, Federal Court judges are no doubt well equipped to hear disputes relating to IP. However this expertise is gained through its jurisdiction to hear these matters. A specialist Tribunal would have the capacity to accumulate expertise at a greater rate if IP matters were the sole province of the Tribunal. For this reason, we submit that consideration should be given to the establishment of a specialist Tribunal to hear IP matters, specifically those relating to enforcement.

*p28. Is Australia's enforcement system well balanced, or weighted in favour of one group?*

Australia's enforcement system is undoubtedly weighted in favour of those with the resources to fund enforcement action. The blanket nature of the enforcement system also favours those who have outlaid significant amounts to gain IP protection. Patent holders,

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<sup>30</sup> 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 (Centre for Law and Genetics: 2003, Hobart) at 214-218, 222-224.



particularly commercial parties, are much better equipped to defend their IP than many copyright holders, for example. Pharmaceutical firms are a good example of a powerful group that has pursued generic producers for patent infringement. It is this aspect of the enforcement system that means there is a real imbalance for different IP holders.

### **International obligations constrain domestic flexibility**

*p30. The Commission seeks input on the impact of Australia's international IP obligations on domestic innovation, production, trade and consumption. Has a move towards stronger IP rights served Australia's economic interests? Is there a case for Australia to pursue stronger IP rights in excess of minimum standards for particular types of rights or specific technologies?*

*What are the main constraints on IP policy imposed by the TRIPS Agreement and other international agreements? What scope is there to adjust Australia's domestic IP legislation without violating the provisions of TRIPS and other international agreements?*

There is no doubt that Australia's ability to adjust its IP legislation is limited as a result of its international obligations. This is the case for every signatory to international IP agreements. For example, TRIPS constrains the ability of signatories to adjust IP legislation in relation to patent criteria, the duration of patent protection, and exclusions from patentability (to name just a few). Australia made a number of changes to its patent legislation in order to become TRIPS compliant, although these changes were not as significant as those required by other signatories.

Perhaps more concerning is the impact of bilateral and regional treaty obligations on Australia's IP legislation, and the impediments they pose to making further legislative changes. These obligations might not always be beneficial to Australia. The AUSFTA, for example, presents a real impediment to changing the compulsory licensing provisions contained in the *Patents Act*. These obligations mean that the compulsory licensing provisions to which Australia is now a signatory exceed those required by TRIPS. This may directly impact on Australian innovators given that few modifications which would expedite the process of applying for a compulsory licence are now possible. A majority of Australian IP (particularly patents) is held by non-residents, particularly in the biomedical field.<sup>31</sup> In other words, Australian inventors are net importers of technology.

*p30. What mechanisms other than adjusting the scope and duration of IP rights could be used to more effectively influence domestic IP settings?*

There are few mechanisms to adjust Australia's domestic IP legislation unless these changes take place within the confines of Australia's international and bilateral obligations.

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<sup>31</sup> 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 (Centre for Law and Genetics: 2003, Hobart); IP Australia, *Australian Intellectual Property Report 2015* (Commonwealth of Australia, 2015: Canberra). With the exception of trademarks (see p16 of that report), most IP is held by non-residents: during 2014, for example, 18,102 patents were granted to non-residents and just 1,199 to residents: *Australian Intellectual Property Report*, at 9. This trend is typical of the statistics in recent years.

As to mechanisms that might be used to influence domestic IP settings, there are several options available. For example, competition law offers one avenue for addressing inequities in access brought about by strong IP protection.

*p30. What principles should guide decision making for future international negotiations on IP rights?*

In entering future negotiations for bilateral or regional agreements, Australia should be mindful of the effects of negotiating terms that are disadvantageous to Australian industry bearing in mind the fact that we are users of technology. This will become more important as the use of digital technologies increases in frequency and IP rights over these technologies proliferates.