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A Submission to the House of Representatives
Standing Committee on Social Policy and Legal
Affairs on the Intellectual Property Laws
Amendment Bill 2013 (Cth)

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**A SUBMISSION TO THE HOUSE OF REPRESENTATIVES STANDING
COMMITTEE ON SOCIAL POLICY AND LEGAL AFFAIRS**

***THE INTELLECTUAL PROPERTY LAWS
AMENDMENT BILL 2013 (CTH)***



Angelina Jolie has highlighted questions of access to gene patents

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BIOGRAPHY

I am an Australian Research Council Future Fellow, working on Intellectual Property and Climate Change. I am an associate professor at the ANU College of Law, and an associate director of the Australian Centre for Intellectual Property in Agriculture (ACIPA). I hold a BA (Hons) and a University Medal in literature, and a LLB (Hons) from the Australian National University. I received a PhD in law from the University of New South Wales for my dissertation on *The Pirate Bazaar: The Social Life of Copyright Law*. I am a member of the ANU Climate Change Institute. I have published widely on copyright law and information technology, patent law and biotechnology, access to medicines, clean technologies, and traditional knowledge. My work is archived at *SSRN Abstracts* and *Bepress Selected Works*.

I am the author of *Digital Copyright and the Consumer Revolution: Hands off my iPod* (Edward Elgar, 2007). With a focus on recent US copyright law, the book charts the consumer rebellion against the *Sonny Bono Copyright Term Extension Act* 1998 (US) and the *Digital Millennium Copyright Act* 1998 (US). I explore the significance of key judicial rulings and consider legal controversies over new technologies, such as the iPod, TiVo, Sony Playstation II, Google Book Search, and peer-to-peer networks. The book also highlights cultural developments, such as the emergence of digital sampling and mash-ups, the construction of the BBC Creative Archive, and the evolution of the Creative Commons. I have also participated in a number of policy debates over Film Directors' copyright, the *Australia-United States Free Trade Agreement* 2004, the *Copyright Amendment Act* 2006 (Cth), the *Anti-Counterfeiting Trade Agreement* 2010, and the *Trans-Pacific Partnership*.

I am also the author of *Intellectual Property and Biotechnology: Biological Inventions* (Edward Elgar, 2008). This book documents and evaluates the dramatic expansion of intellectual property law to accommodate various forms of biotechnology from micro-organisms, plants, and animals to human genes and stem cells. It makes a unique theoretical contribution to the controversial public debate over the commercialisation of

biological inventions. I edited the thematic issue of *Law in Context*, entitled *Patent Law and Biological Inventions* (Federation Press, 2006). I was also a chief investigator in an Australian Research Council Discovery Project, 'Gene Patents In Australia: Options For Reform' (2003-2005), and an Australian Research Council Linkage Grant, 'The Protection of Botanical Inventions' (2003). I am currently a chief investigator in an Australian Research Council Discovery Project, 'Promoting Plant Innovation in Australia' (2009-2011). I have participated in inquiries into plant breeders' rights, gene patents, and access to genetic resources.

I am a co-editor of a collection on access to medicines entitled *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, 2010) with Professor Kim Rubenstein and Professor Thomas Pogge. The work considers the intersection between international law, public law, and intellectual property law, and highlights a number of new policy alternatives – such as medical innovation prizes, the Health Impact Fund, patent pools, open source drug discovery, and the philanthropic work of the (RED) Campaign, the Gates Foundation, and the Clinton Foundation. I am also a co-editor of *Intellectual Property and Emerging Technologies: The New Biology* (Edward Elgar, 2012), with Alison McLennan.

I am the author of a monograph, *Intellectual Property and Climate Change: Inventing Clean Technologies* (Edward Elgar, September 2011). This book charts the patent landscapes and legal conflicts emerging in a range of fields of innovation – including renewable forms of energy, such as solar power, wind power, and geothermal energy; as well as biofuels, green chemistry, green vehicles, energy efficiency, and smart grids. As well as reviewing key international treaties, this book provides a detailed analysis of current trends in patent policy and administration in key nation states, and offers clear recommendations for law reform. It considers such options as technology transfer, compulsory licensing, public sector licensing, and patent pools; and analyses the development of Climate Innovation Centres, the Eco-Patent Commons, and environmental prizes, such as the L-Prize, the H-Prize, and the X-Prizes. I am currently

working on a manuscript, looking at green branding, trade mark law, and environmental activism.

I also have a research interest in intellectual property and traditional knowledge. I have written about the misappropriation of Indigenous art, the right of resale, Indigenous performers' rights, authenticity marks, biopiracy, and population genetics.

EXECUTIVE SUMMARY

The amendments contained in the *Intellectual Property Laws Amendment Bill 2013* (Cth) are designed to provide safeguards in relation to patent law and the public interest.

In the 2012 case on plain packaging, the Chief Justice of the High Court of Australia, Robert French, emphasized that the role of intellectual property law is to promote public objectives.¹ His Honour observed: ‘There are and always have been purposive elements reflecting public policy considerations which inform the statutory creation of intellectual property rights.’² Discussing the role of patent law, Chief Justice Robert French commented:

The *Patents Act* 1990 (Cth) provides that a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention. Those exclusive rights are ‘personal property and are capable of assignment and of devolution by law.’ The origin of patents for inventions can be traced back to the Statute of Monopolies of 1623, declaring all monopolies void, subject to the exception in s 6 of that Statute that: ‘any letters patents and grants of privilege for the ... making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use’. That provision still forms part of the definition of ‘patentable invention’ in the *Patents Act* 1990 (Cth). Its purpose was succinctly stated by Cornish, Llewellyn and Aplin: ‘the terms of the section make it plain that an act of economic policy was intended: the objectives were the encouragement of industry, employment and growth, rather than justice to the ‘inventor’ for his intellectual percipience.’³

His Honour stressed: ‘Registered trade marks, designs, patents and copyright in works and other subject matter give rise to, or constitute, exclusive rights which are property to which s 51(xxxi) of the Constitution can apply’.⁴ Chief Justice Robert French stressed

¹ *JT International SA v Commonwealth of Australia* (2012) HCA 43 (5 October 2012).

² *Ibid.*, [30].

³ *Ibid.*, [33].

⁴ *Ibid.* [35].

that ‘they are all rights which are created by statute in order to serve public purposes’.⁵ His Honour recognized: ‘They differ in their histories, their character and the statutory schemes which make provision for them.’⁶

The *Intellectual Property Laws Amendment Bill* 2013 (Cth) is designed to provide for greater public safeguards in respect of access to patented inventions. The reforms are particularly important in the field of public health and access to essential medicines. In her second reading speech, the Honourable Yvette D’Ath, Member for Petrie, and Parliamentary Secretary for Climate Change, Industry and Innovation, commented upon the purposes of the legislative package:

The key to our intellectual property system is striking the right balance between encouraging innovation and providing equitable access to new technologies. A well-balanced IP system advances the interests of Australian innovators, by lowering business costs and by making it easier to access export markets. It also allows Australians to provide assistance to developing countries when it is needed most. And, to ensure that the balance is maintained, it is a system that has safeguards to ensure that intellectual property rights cannot be used to unduly restrict the community's access to new technologies. The *Intellectual Property Laws Amendment Bill* 2013 contains a package of measures that will make the Australian IP system more responsive to the needs of consumers, more efficient for Australian entrepreneurs, and more supportive of other countries facing health emergencies.

In a press release, Yvette D’Ath emphasized: ‘Safeguards that protect the community's access to new technologies are an integral part of Australia's patent system.’

In addition to the legislative reforms, D’Ath has commented that the Government would also undertake a number of measures to further clarify the patent system and strengthen mechanisms for oversight. She announced the Government will:

- appoint a Patent Audit Committee to advise on patent policy settings and undertake audits of patent approvals for certain technology groups,

⁵ Ibid. [35].

⁶ Ibid. [35].

- commence consultations on a new objects clause for the Patents Act, and
- consult on excluding certain inventions that would be offensive to the public.

D'Ath stressed: 'It is important that the patent system strikes the right balance between encouraging innovation and providing equitable access to new technologies'. She observed: 'The Gillard Government continues to review the operation of the patent system to ensure it operates in the interests of all Australians.'

It is worth emphasizing that a number of the proposed reforms in the *Intellectual Property Laws Amendment Bill 2013* (Cth) have been mooted in a range of inquiries. The Australian Law Reform Commission recommended that the crown use provisions should be revised in its 2004 inquiry into gene patents. In 2005, the Advisory Council on Intellectual Property also reviewed the Crown Use provisions. In 2013, the Productivity Commission in its report on patent law and compulsory licensing was enthusiastic about modernizing the crown use provisions. The establishment of an access to medicines regime in Australia is long overdue.

It is a decade since the World Trade Organization established the *WTO General Council Decision 2003* and a mechanism for the export of essential medicines. In 2004, there has been discussion about access to essential medicines in the context of the debate over the *Australia-United States Free Trade Agreement 2004*. In 2008, the Joint Standing Committee on Treaties recommended that Australia should ratify the *WTO General Council Decision 2003*, and expeditiously implement a regime to allow for the export of essential medicines. It is a matter of urgency that Australia fulfil its international obligations, and establish a fast, effective, and flexible mechanism for access to essential medicines – particularly in respect of HIV/AIDS, tuberculosis, and malaria.

The Advisory Council on Intellectual Property also undertook an inquiry into Plant Breeder's Rights enforcement. The reforms in the *Intellectual Property Laws Amendment Bill 2013* (Cth) pick up that inquiry.

The reforms in the *Intellectual Property Amendment Bill 2013* (Cth) are necessary and urgent. The bill addresses matters of great significance – both for Australia and overseas. It is important to bring balance to Australia’s intellectual property regime, and to demonstrate our commitment to implementing international norms. It is a matter of urgency that such legislative reforms should be passed, before Parliament is prorogued.

Ideally, in the future, the Australian Parliament should consider further issues raised by the Productivity Commission in respect of patent law and compulsory licensing. There is also a need to develop a flexible mechanism to allow for compulsory licensing to deal with a wide range of issues of humanitarian aid and development.

Recommendation 1

The Australian Parliament should pass the Crown Use provisions in the *Intellectual Property Laws Amendment Bill 2013* (Cth) as a matter of urgency to provide safeguards for the public interest in respect of patent law. Crown Use could be particularly useful in addressing access to gene patents; questions about information technology; patent trolls and vexatious litigants; and matters of public interest, relating to agriculture, food security, and the environment.

Recommendation 2

The Australian Parliament should implement the access to medicines scheme in the *Intellectual Property Laws Amendment Bill 2013* (Cth) in order to meet its obligations under the *WTO General Council Decision 2003*.

It is essential that the export of essential medicines be allowed to both members of the WTO, and non-members (such as East Timor). This is the case with the Canadian regime.

In the future, the Australian Parliament should consider further patent law reforms to facilitate technology transfer and the export of

humanitarian inventions to developing countries and least developed countries.

Recommendation 3

The Australian Parliament should implement the procedural reforms in respect to plant breeder's rights enforcement in the Federal Circuit Court *Intellectual Property Laws Amendment Bill 2013* (Cth).

Recommendation 4

The Federal Government should consider the role of IP Australia as a regional hub for intellectual property administration and policy. A Trans-Tasman patent attorney regime could be workable. Nonetheless, there is a need to ensure that patent attorneys are subject to strong regulation to deter gaming behaviour and improve patent quality.

Recommendation 5

The administrative changes and technical amendments to the *Patents Act 1990* (Cth) should be supported.

1. Crown Use

A. Biotechnology

In the United States, Angelina Jolie has recently highlighted the importance of access to genetic testing – particularly in respect of BRCA1 and BRCA2:

Breast cancer alone kills some 458,000 people each year, according to the World Health Organization, mainly in low- and middle-income countries. It has got to be a priority to ensure that more women can access gene testing and lifesaving preventive treatment, whatever their means and background, wherever they live. The cost of testing for BRCA1 and BRCA2, at more than \$3,000 in the United States, remains an obstacle for many women.⁷

Her statements have highlighted the international debate over gene patents, and their impact upon research, patient care, and health-care.

In 2013, the Supreme Court of the United States held oral hearings in a landmark case on patent law and cancer. The question before the court was whether human genes are patentable.

The American Civil Liberties Union and the Public Patent Foundation challenged the validity of two patents held by Myriad Genetics on genes implicated in breast and ovarian cancer. The action was brought on behalf of medical associations, geneticists, breast cancer and women's health groups, and patients.

The case has been going through the US courts for some years now. In 2010, a district court judge held that Myriad Genetics' patents were invalid because they claimed products of nature. In 2011, the Court of Appeals for the Federal Circuit overturned that ruling with a majority of two to one.

⁷ Angelina Jolie, 'My Medical Choice', *The New York Times*, 14 May 2013, http://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html?_r=0

In 2012, the Court of Appeals for the Federal Circuit reaffirmed the decision, and the Supreme Court of the United States then agreed to hear an appeal.

The court received written submissions from the parties involved as well as others representing a wide array of interests, including pharmaceutical companies, the biotechnology industry, medical associations, patient groups, and civil society activists. Even famous scientists such as James Watson (the co-discoverer of DNA) and Ananda Chakrabarty made submissions.

The court heard oral arguments on the merits of the case. You can click [here](#) for the transcript of the hearing.

‘The fight to take back our genes’

The American Civil Liberties Union and the Public Patent Foundation framed the dispute as one about human rights, public health, and freedom of speech. Their lawyers sought to give voice to the concerns of cancer patients, researchers, doctors, and pathologists.

They argued that human genes are products of nature, adding that ‘Myriad has a monopoly on clinical testing of *its* genes in the US, dictating the type and terms of BRCA genetic testing ... Myriad’s claims have had a proven chilling effect on research, as laboratories are dissuaded pursuing scientific work that requires using the patented genes.’

The judges appeared wary of accepting a broad prohibition on biotechnology patents under US law. One of the judges, Justice Scalia, asked: ‘Why would a company incur massive investment if it cannot patent?’ The lawyer for the civil liberties union responded that ‘taxpayers paid for much of the investment in Myriad’s work.’

Indeed, there has been much concern that the contribution of public sector researchers, such as Mary-Claire King, who did a lot of the basic science research that led to the patents, has been neglected in considerations of the patents' validity.

Myriad Genetics

Myriad Genetics has insisted that 'Congress intended statutory subject matter to 'include anything under the sun that is made by man.' It noted that gene patents have been granted by the United States Patent and Trademark Office for 30 years. The lawyer representing the company said, 'countless companies and investors have risked billions of dollars to research and develop advances under this promise of stable patent protection.'

One of the judges, Justice Breyer, disputed that 'anything under the sun' was patentable, noting that 'We've rejected [the doctrine] more often than we've followed it'. Justice Kagan observed that the 'United States Patent and Trademark Office seems patent happy'. She asked, if Myriad Genetics could patent genes, could it also patent all kinds of parts of the human body, such as chromosomes, cells, the liver or a piece of kidney.

As indicated by the range of briefs submitted to the court, the ruling will no doubt impact upon medicine, biotechnology, nanotechnology, biomarkers, and personalised medicine. According to researchers, it could also have significant impacts on other fields of technology, such as 'agricultural biotechnology, environmental biotechnology, green-tech, the use of organisms to produce alternative fuels and other applications.'

Uneasy compromises

The brief of the United States Solicitor-General took the middle ground:

Although the incentives created by the patent laws have spawned enormous public benefits, the product-of-nature exception serves important public purposes as well.

Although Justice Alito expressed reservations about the United States Government's shifting position, Justices Sotomayor, Kennedy and Breyer all seemed interested in its stance. Justice Breyer observed:

Patent law is filled with uneasy compromises, because on the one hand, we do want people to invent; on the other hand, we're very worried about them tying up some kind of whatever it is, particularly a thing that itself could be used for further advance.

The judges neglected some important issues in the case. The word 'health', for instance, is missing from transcripts indicating that the public health dimensions of the case were not fully explored at the hearing.

An international conflict

There has been much international conflict over Myriad Genetics, and its patents in respect of BRCA1 and BRCA2. Cancer Council Australia also filed a submission to the US Supreme Court, observing that its ruling would be helpful 'in providing input into the development of societal opinions and patent law in Australia.'

In February 2013, the Federal Court of Australia rejected a challenge to the validity of Myriad's BRCA1 patent. The US ruling will undoubtedly be debated in the appeal by Cancer Voices Australia to the Full Federal Court of Australia.

And that litigation will spark further policy debates over gene patents in Australia. Whatever the outcome, let's hope the US decision will modernise patent law, so that it will promote the progress of science, while safeguarding human rights, patient care and public health.

The Intellectual Property Laws Amendment Bill 2013 (Cth)

In its 2004 report on gene patenting, the Australian Law Reform Commission recommended that there be reforms to Crown Use.⁸ The Commission commented: 'Although they are rarely used, Crown use provisions are an important mechanism through which government and its agencies may, in specific cases, address concerns that gene patents are hindering research or the provision of healthcare'.⁹ The Commission commented: 'Policies should be developed about the circumstances in which it is appropriate for government to invoke Crown use for the purposes of promoting human health.'¹⁰

In 2005, the Advisory Council on Intellectual Property¹¹ reported on crown use.

Recommendation 1 – The Need for Prior Consent

1.1 The patents and designs legislation should be amended to align with the requirements of Article 31 (b) of the TRIPS Agreement by ensuring that prior to any use of a patent or design the Crown or authorised user should:

- Make genuine efforts to obtain authorisation from the right holder;
- Exploit the IP on reasonable commercial terms; and
- Seek to make an agreement on the terms of use within a reasonable period of time.

These requirements may be temporarily waived in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

1.2 A temporary waiver claimed on the grounds of 'public non-commercial use' should only be available for Crown entities operating solely in the public interest and should not be available to hybrid public/private organisations that predominantly operate for profit.

⁸ Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99. Sydney: Australian Commonwealth, 2004, 620
<http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>

⁹ Ibid.

¹⁰ Ibid.

¹¹ Advisory Council on Intellectual Property, *Review of Crown Use Provisions for Patents and Designs*, Canberra: Advisory Council on Intellectual Property, November 2005.

The Australian Government should seek to amend the Patents Act 1990 (Cwlth) to require:

- the Crown to attempt to negotiate use of the patented invention prior to invoking Crown use
- the Crown to provide the patentee with a statement of reasons no less than 14 days before such use occurs
- Crown use to be approved by a Minister (the relevant Federal Minister or State Attorneys-General)
- that in instances of Crown use, the patentee is entitled to remuneration determined on the same basis as that for a compulsory licence.

The first two requirements should be able to be waived in emergencies. However, in all cases patentees should be provided with immediate notice that their patents have been used, and a statement of reasons as soon as practical thereafter.

In its 2013 report, the Productivity Commission has been an enthusiastic supporter of the reform of Crown Use. The Commission comments:

The Patents Act contains specific provisions for the Australian and State Governments and their agencies (including local governments) to use a patented invention (Crown use) or acquire it (Crown acquisition) without the owner's authorisation. Only two cases of Crown use have been contested in a court, both of which were allowed — use of a central bearing structure for rail carriages by the NSW Government in 1964, and a water meter assembly by Brisbane City Council in 1994. While governments may have acquired patents on a voluntary basis, to the Commission's knowledge they have never compulsorily acquired a patent through the Crown acquisition provisions. This is probably because Crown use is sufficient to exploit an invention and is less costly, since the patent holder does not have to be compensated for a loss of earnings from using the patent itself and licensing it to third parties. The Commission has, therefore, focused on Crown use. Governments will generally find Crown use to be a less costly and time-consuming option than compulsory licensing. There is currently no requirement to first attempt to negotiate with the patent owner and, if unsuccessful, apply to the Federal Court for authorisation to use an invention. A patent owner can apply for a court determination on the compensation it receives but, unlike compulsory licensing, there is currently no explicit requirement for this to be 'just and reasonable'.¹²

¹² Productivity Commission, *Compulsory Licensing of Patents*, Inquiry Report No. 61, Canberra, 2013.

The Commission noted that ‘it appears that Crown use can be applied to healthcare-related patents, given that governments have a major role in providing healthcare’ but that ‘inquiry participants were uncertain about this for several reasons.’¹³

The Commission proposed law reform:

The Commission proposes that such uncertainty be addressed by clarifying the scope of Crown use. In particular, the Patents Act should be amended to make it clear that Crown use can be invoked for the provision of a service that the Australian, State and/or Territory Governments have primary responsibility for providing or funding. It is the Commission’s intention that the primary responsibility test would take account of all providers of similar services. This would, for example, mean that genetic testing undertaken by private providers for private patients would be included in an assessment of whether governments have primary responsibility for providing or funding such testing. Given that governments are responsible for providing or funding the vast majority of genetic tests, they would be found to have primary responsibility. As a result, genetic testing would be eligible for Crown use, including when it is undertaken by private providers for private patients. The private providers could be authorised to exercise Crown use on behalf of a government, as is already allowed under s. 163(1) of the Patents Act. The introduction of the primary responsibility test should not remove the existing right of individual government bodies to exploit a patented invention under Crown use, regardless of their share of the relevant market.¹⁴

The Productivity Commission recommended that ‘The Australian Government should seek to amend s. 163 of the *Patents Act* 1990 (Cth) to make it clear that Crown use can be invoked for the provision of a service that the Australian, State and/or Territory Governments have the primary responsibility for providing or funding.’¹⁵ The Productivity Commission recommended that ‘The Australian Government should seek to amend the *Patents Act* 1990 (Cth) to require: the Crown to attempt to negotiate use of the patented invention prior to invoking Crown use; the Crown to provide the patentee with a statement of reasons no less than 14 days before such use occurs; Crown use to be approved by a Minister (the relevant Federal Minister or State Attorneys-General); and

¹³ Ibid.

¹⁴ Ibid.

¹⁵ Ibid.

that in instances of Crown use, the patentee is entitled to remuneration determined on the same basis as that for a compulsory licence.’¹⁶ The Commission commented: ‘The first two requirements should be able to be waived in emergencies’.¹⁷ However, it noted, ‘in all cases patentees should be provided with immediate notice that their patents have been used, and a statement of reasons as soon as practical thereafter.’¹⁸

Discussing the 2013 proposed reforms, Yvette D’Ath stressed: ‘Crown use is an important, although rarely used, safeguard that allows governments to access patented inventions to deliver critical public services.’ She noted that the bill will clarify that Crown use can be invoked in relation to any service that governments have the primary responsibility for funding or providing. D’Ath emphasized that there is a need for flexible mechanisms to resolve conflicts over gene patents:

Some categories of patents, such as gene patents, raise complex legal and ethical questions. The validity of these patents is currently being considered in court cases in Australia and the United States. In the meantime these changes make it clear that, if necessary, the Australian Government has the power to address unreasonable conduct by patent holders and protect patients’ access to healthcare services.

The Bill will also improve transparency and accountability of Crown use, including a requirement to negotiate and providing a basis to determine remuneration for patent holders. These amendments will give governments and business greater certainty about the operation of Crown use.

Cancer Council Australia has provided strong support for the reforms in respect of crown use – particularly to address the issue of gene patents. A press release by the organization stressed that the ‘New safeguards announced by the Federal Government will help to protect consumers from commercial monopolies over vital services such as genetic testing for cancer risk.’ Cancer Council Australia CEO, Professor Ian Olver, said he

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Ibid.

‘welcomed a bill that would clarify the application of Crown use provisions to help ensure that patent enforcement claims could not prevent governments from providing vital healthcare services’. He commented:

Back in 2008, the commercial licensee for patents on the BRCA1 and BRCA2 breast and ovarian cancer genes sought to enforce its patent claims over the state and territory laboratories that were providing those tests as a public service. While the company eventually withdrew its claim, there was uncertainty at the time over Crown use provisions or any other legal mechanism that might have been able to protect Australian women from a potential monopoly over the genes and the tests. This bill should help clarify the *Patents Act* in respect of Crown use provisions.

Professor Olver said ‘he was encouraged by the Government’s recognition that more work was required to get the balance right between rewarding innovation and ensuring equitable access to medical technology’. He commented: ‘The establishment of a patent audit committee and consultations on further changes to the Act have the potential to deliver some long overdue protection for healthcare consumers.’ Olver observed: ‘Court cases in the US and Australia are being observed with interest, but whichever way they go we will still need to change the system as genetic technology rapidly evolves.’ He concluded: ‘Today’s announcement is a step in the right direction.’

B. Information Technology and Patent Trolls

Once upon a time, Abraham Lincoln famously said that the patent system was intended to secure ‘to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.’

In recent times, there have been concerns that the patent system been abused by opportunistic companies known by the phrase ‘patent trolls’. It has been alleged that such entities have stunted innovation and spurred unnecessary patent litigation.

There have been particular fears about the rise of ‘patent trolls’ in the field of information technology. Peter Dekin, an assistant general counsel at Intel, first popularised the phrase ‘patent troll’ to describe firms, which acquired patents only to extract settlements from companies on dubious infringement claims: ‘A patent troll is somebody who tries to make a lot of money off a patent that they are not practising and have no intention of practising and in most cases never practised.’

In 2000, the developers of the Blackberry, Research in Motion, were sued for patent infringement by a Virginia-based patent holding company called NTP Incorporated. After much litigation, Research in Motion agreed in 2006 to pay the company \$US612.5 million in a full and final settlement of all claims. There was much debate as to whether NTP Incorporated was a legitimate holder of valid patents or a ‘patent troll’.

In 2005, Joe Beyers, a vice president of intellectual-property licensing at Hewlett-Packard, complained: ‘Any company that has suffered a troll attack knows how the menacing fear and uncertainty threaten the investment in innovation, customers' peace of mind, even the survival of a business.’ He contends that ‘the industry must band together to stop trolls by undermining the trolls' ability to obtain unfair value for their patents’.

In 2013, there has been much debate over aggressive patent claims in respect of podcasting.¹⁹ The Electronic Frontier Foundation observed:

EFF intends to challenge the original grant of that patent before the U.S. Patent and Trademark Office by proving that the company, Personal Audio, did not really invent anything new. Claiming it owns the patent that broadly covers podcasting technology, Personal Audio is the classic example of a patent troll that neither makes nor sells anything, but uses its patent as a weapon to threaten lawsuits and extort settlement fees. This particular troll has bullied prominent podcasts and podcasters, including How Stuff Works and Adam Carolla, in addition to smaller podcasters working out of their own homes.²⁰

‘Patent trolls have been wreaking havoc on innovative companies for some time now,’ said EFF Staff Attorney Julie Samuels, who also holds the Mark Cuban Chair to Eliminate Stupid Patents. ‘But this particular breed of troll—targeting end users, small businesses, startups, and even individuals like podcasters for simply using everyday products—is a disturbing new threat.’²¹

There has been much controversy about the firm Intellectual Ventures. This American Life has undertaken important investigative journalism on the problem of patent trolls.²²

There has been disquiet about a non-practising entity suing not-profit organisations in Vermont – including those that work on disability. Professor Timothy Wu has observed:

MPHJ Technology Investments allegedly made plenty of money last year using a rather interesting business model. First, according to a lawsuit filed by the State of Vermont, it bought patents of dubious validity that could theoretically cover basic technologies, such as the scanning of

¹⁹ Electronic Frontier Foundation, ‘EFF Launches Full-Court Press To Bust Podcasting Patent’, *Electronic Frontier Foundation*, 30 May 2013,

<https://www.eff.org/press/releases/eff-launches-full-court-press-bust-podcasting-patent>

²⁰ Ibid.

²¹ Ibid.

²² Laura Sydell and Alex Blumberg, ‘When Patents Attack’, *This American Life*, 2011 and 2013, <http://www.thisamericanlife.org/radio-archives/episode/441/when-patents-attack>

documents. Next, it and its subsidiaries sent threatening letters, with various misstatements of fact, to businesses and nonprofits around the country, alleging patent infringement and demanding payment. MPHJ never went to court; it is said to have just collected settlements, asking for a thousand dollars per employee of the targeted firm. It didn't invent anything. It didn't create anything. It just took advantage of our patent laws to leech money from companies that do.²³

Wu recommended that 'it is time to declare total war on patent trolls': 'The federal government, and the states, should do everything they can to exterminate them and to make anyone regret getting into such crooked work'.²⁴ He commented: 'The existence of trolls is entirely a product of government: they abuse a government program (the patent law), and continue to exist only thanks to government inaction.'²⁵

Empirical Research

Professor Colleen Chien from Santa Clara University has done important empirical research on patent trolls.²⁶ She has summarized this research in 2012:

While patent assertion entities ('PAEs' or patent 'trolls') have received a lot of attention, little of it has focused on the distributional impacts of their demands. The impact of PAEs on startups is crucial, because startups contribute to job creation and innovation, making them potential targets and sources of patents. To assess the impact of trolls on startups, I analyzed a comprehensive database of patent litigations from 2006 to the present, conducted a non-random survey of 223 tech company startups, 79 of which had received a demand, and interviewed nearly twenty entities with relevant knowledge of startup patent issues.

I find that although large companies tend to dominate patent headlines, most unique defendants to troll suits are small. Companies with less than \$100M annual revenue represent at

²³ Timothy Wu, 'How to Make War on Patent Trolls', *The New Yorker*, 3 June 2013, <http://www.newyorker.com/online/blogs/elements/2013/06/how-to-make-war-on-patent-trolls.html>

²⁴ Ibid.

²⁵ Ibid.

²⁶ Colleen Chien, 'Startups and Patent Trolls', Santa Clara Univ. Legal Studies Research Paper No. 09-12, 28 September 2012, Available at SSRN: <http://ssrn.com/abstract=2146251> or <http://dx.doi.org/10.2139/ssrn.2146251>

least 66% of unique defendants to troll suits and at least 55% of unique defendants in troll suits make \$10M per year or less. Suing small companies appears distinguish PAEs from operating companies, who sued companies with less than \$10M per year of revenue only 16% of the time, based on unique defendants. Of survey responses that had received a demand (N=79), a large percentage reported a ‘significant operational impact’: delayed hiring or achievement of another milestone, change in the product, a pivot in business strategy, shutting down a business line or the entire business, and/or lost valuation. The smaller the company, the more likely it was to report one or more significant operational impacts. To the extent patent demands ‘tax’ innovation, then, they appear to do so regressively, with small companies targeted more as unique defendants, and paying more in time, money and operational impact, relative to their size, than large firms. 40% of survey respondents stated that they were being targeted because of their use of another’s or a widely available technology.

Yet an operational change was not the only response to a demand: 22% of responders reported that, to resolve the demand, their primary response was to ‘do nothing,’ while 35% fought the demand, and 18% settled it. Based on available information, costs were highest when fighting in court was the primary response (with average expenditures of \$857K (N=7)); settling cost an average of \$340K (n=12) and fighting out of court cost \$168K (N=18), on average (Table 1).

Small companies can also benefit from a robust market in patents, both as sellers and buyers. An estimated 50% of NPE patents come from companies with less than \$200M in revenue. Patent sales can support the ongoing business, and 4% of survey responders said they had monetized their patents, and another 20% said that they had considered it. Yet while the conditions of a majority of sales is unknown, they often take place when the company is in distress or transition, as growing young companies often lack the inclination, time, or extra patents to monetize their intellectual property. When patents are sold under firesale conditions, investors, creditors, and patent focused companies share in the profits, reducing the direct returns to the inventive entity. Growing companies can also benefit from the patent marketplace as buyers, buying patents from the marketplace ‘on-demand’ and overcoming some of the advantages of incumbents.

What can be done to decrease the harms of patent assertion and increase the benefits of a robust patent market to small companies and startups? Focusing exclusively on the first question, I present new data that suggest that a number of the reforms put in place over the last year, including by the America Invents Act, are having a positive impact. Fewer defendants are being named in patent suits. The new post-grant review provisions will reduce the leverage of patent plaintiffs in some cases. However, some of these reforms are out of the reach of startups. Prior user rights benefit older companies against younger patents, but don’t help new start-ups. Startup companies are cash-poor, but challenging issued patents is expensive and time-consuming. Reforms to reduce the cost of litigation defense are laudable, and likely deter some suits from

being brought in the first place, but don't reach small companies against whom litigation is threatened, but not brought. Increasing the cost of software patents would limit the number of patents but would also disadvantage startups that patent, relative to large companies and PAEs with large budgets. The distributional impacts of reforms need to be kept in mind, and I suggest some alternative reforms for the consideration of the courts, Congress, and the market.

In 2013, Professor Colleen Chien updated her work, and provided the following summary:

Following President's Obama remarks and reintroduction of the SHIELD Act, Congress is holding hearings on patent trolls (aka patent assertion entities or PAEs) on March 14, 2013. One question concerns the prevalence of patent troll demands and other troll metrics, on which I have previously reported. These statistics draw heavily upon proprietary research as well as my own analyses, so, in the interest of full disclosure, this blog post lays out the numbers as I see them, and what I know about them:

- * PAEs brought 62% of 2012 patent litigations
- * In 2012, PAEs sued more non-tech companies than tech companies
- * In 2012 PAE defendants comprised 59% of all patent lit defendants
- * 55% of unique PAE defendants makes \$10M or less
- * ~16 publicly financed PAEs
- * Some high impact PAE patents (9 out of 10) fit the 'buy and sue' pattern

What is more important than just the numbers however are the equities - how benefits and harms are distributed and their justice or injustice – that is why there is so much heat on the PAE issue – because people who are sued say they had no ability to anticipate or avoid it. While the liquid patent market is a positive development that has also helped small companies that buy or sell patents, addressing the existing apparent inequities, especially if they continue to spread to sectors that otherwise have very little to do with patents like retail, is likely to drive patent reform.²⁷

In light of such controversy, and empirical evidence, there has been much action to address the problem by the United States Congress and the United States President.

²⁷ Colleen Chien, 'Patent Trolls by the Numbers', Santa Clara University Legal Studies Research Paper No. 08-13, 13 March 2013, Available at SSRN: <http://ssrn.com/abstract=2233041>

President Barack Obama's Reforms on Patent Trolls

In 2013, President Barack Obama and the White House have announced the introduction of a package of reforms to address the issue of 'patent trolls'.²⁸ The plan includes five executive actions and seven legislative recommendations. President Barack Obama has observed that patent trolls 'don't actually produce anything themselves' and instead develop a business model 'to essentially leverage and hijack somebody else's idea and see if they can extort some money out of them. The White House hopes that its proposals to stop 'this drain on the American economy.'

The seven legislative recommendations include requiring patent holders and applicants to disclose who owns and controls the patent; changing how fees are awarded to the prevailing parties in patent litigation; and providing consumers with better protections against being sued for patent infringement. The International Trade Commission's standard for issuing injunctions in patent cases will also be changed to make it harder for patent trolls to threaten and extort businesses. At the ITC, the risk of products being banned from the U.S. market is great. While Congress has held hearings on the issue, there has not been recent legislation. Under executive orders, the White House is making the 'real party of interest' the new default, requiring patent applicants and owners to regularly update ownership information when they are involved in proceedings before the Patent and Trademark Office. The White House says the United States Patent and Trademark Office will begin rulemaking on the issue. Furthermore, the United States Patent and Trademark Office will issue education materials to help consumers and retailers who are increasingly targeted by patent firms with letters threatening litigation.

²⁸ Michelle Quinn, 'White House Effort Targets Patent Trolls', *Politico*, 4 June 2013, <http://www.politico.com/story/2013/06/white-house-patent-trolls-effort-92174.html#ixzz2VJByKio1>

The Intellectual Property Laws Amendment Bill 2013 (Cth)

The explanatory memorandum to the *Intellectual Property Laws Amendment Bill 2013 (Cth)* has also emphasized that the Crown use provisions could be used to address frivolous and vexatious legal action:

The requirement to attempt to negotiate use of the patented invention prior to invoking Crown use may lead to unacceptable delays in the availability of the patented technology. This will be alleviated through legislative provisions which will clarify expectations, and limit the scope for vexatious legal action.

The explanatory memorandum stressed that ‘Providers of Government services will be clearer that Crown use is a potential remedy to inappropriate patent holder behaviour.’ Indeed, ‘Ministerial consideration will ensure that Crown use is only invoked where the benefits outweigh the costs and will help avoid vexatious actions.’ Furthermore, the explanatory memorandum observes: ‘The requirement for Ministerial approval provides an important check on vexatious claims and provides the Crown with the opportunity to consider the costs and benefits of invoking Crown use’.

C. Agriculture, Food Security, and the Environment

It should also be noted that the Crown Use provisions could have application in a range of other technological fields and contexts – such as in respect of agriculture, the environment, biodiversity, and climate change. Patent flexibilities such as Crown Use could be useful to help protect the public interest in food security.

The Australian Centre for Intellectual Property in Agriculture held a one day conference on Law and Future of Food on the 30 March 2012.²⁹ Dr Nick Austin, the chief executive of ACIAR, has taken a deep interest in issues associated with intellectual property and food security. Kaitlin Cordes discussed the role of human rights law in improving global food security. Elise Perset, legal counsel of CGIAR, discussed the management of intellectual property assets in CGIAR (a network of research organisations focused on agriculture and food security). Daniel Robinson explored the variation in plant variety protection laws in Asia as a response to food security concerns. Dr Paul Smith, the head of the Millennium Seed Bank at the Royal Botanic Gardens, discussed access to genetic resources and global food security. Antony Taubman, the Director of the Intellectual Property Division at the World Trade Organization, analysed, ‘TRIPS and Food: A Balanced Diet?’, and explored the complex interlinkages between intellectual property, food security, and trade.

There is scope for compulsory licensing and crown use under patent law– subject, of course, to international rules under Article 31 of the *TRIPS Agreement* 1994.

The special rapporteur on the right to food, Olivier de Schutter, has suggested that compulsory licensing could be an appropriate option in certain circumstances to address concerns about food security and climate change:

²⁹ The Australian Centre for Intellectual Property in Agriculture, *Law and the Future of Food*,

Canberra: The National Library of Australia, 30 March 2012,

http://www.acipa.edu.au/frame_conferences.html

Where patents restrict research in ways which may have an impact on food security and are an obstacle to face situations of ‘national emergency’ or other ‘extreme urgency’, for instance in the face of declining crop productivity, article 31 of the TRIPS Agreement allows compulsory licensing. Inspiration may be sought in this regard from the Patents and Plant Variety Rights (Compulsory Licensing) Regulations adopted in the United Kingdom of Great Britain and Northern Ireland in 2002, which allow applying for a licence to acquire or develop a new plant variety, which ‘constitutes significant technical progress of considerable economic interest in relation to the invention protected by the patent’. In addition, in line with the general purposes of the TRIPS Agreement, intellectual property rights may be restricted in the public interest, for instance through the doctrine of eminent domain. And developed countries may make available to developing countries any biotechnologies developed through public research without the need for a licence or other permission. In the short term, these tools may be appropriate, for instance, to limit the negative impacts of the recent trend towards patent claims made following the adaptation of specific gene traits that could confer one or more forms of stress tolerance linked to climate change (including salinity, drought or flood, heat or cold). In the long term, a procedure may have to be set up to allow the granting of non-exclusive licences to any requesting party for the use of any patented tool of biotechnology in order to ensure food security in developing countries.³⁰

Margaret Llewelyn and Mike Adcock caution that ‘Whilst there is the notion of a compulsory licence present, its use is so rare, and politically sensitive, that its role as an actual instrument to ensure protection of the public interest looks marginal’.³¹ The pair suggest that there needs to be grater thinking as to whether compulsory licensing should ‘encompass the gamut of diverse uses – addressing such matters as the public interest in respect of access to agricultural plant research as well as that of more overtly public interest orientated research such as that directed towards healthcare’.³²

³⁰ Olivier De Schutter, *Seed Policies and the Right to Food: Enhancing Agro biodiversity and Encouraging Innovation*, United Nations General Assembly, A/64/170, 2009, 12, <http://www.ip-watch.org/weblog/wp-content/uploads/2009/11/n0942473.pdf>

³¹ Margaret Llewelyn, and Mike Adcock, *European Plant Intellectual Property*, Oxford and Portland: Hart Publishing, 2006, 524.

³² Ibid. 524.

Moreover, the Special Rapporteur has maintained that there is a need to ‘consider using antitrust legislation in order to combat excessive concentration in the input providers’ market, which entails the risk of abuse of dominant position by the seed companies concerned and the setting of prices at levels which may be unjustifiably high and unaffordable for poor farmers.’³³

In his work, *TRIPS-Related Patent Flexibilities and Food Security: Options for Developing Countries*, Carlos Correa makes a number of recommendations in respect of patent exceptions in relation to agriculture.³⁴

First, Correa contends that there is a need for an innocent bystanders’ defence, given that ‘the presence of a trait in a plant protected by a patent may or may not be intentional, as a patented gene trait may disseminate by natural means and appear in plantations unintentionally’.³⁵ Referring to the dispute in *Monsanto Canada Inc. v. Schmeiser*,³⁶ Correa recommends that ‘national laws should exempt from liability unintentional infringement caused by the dissemination of patented genetic materials’.³⁷ Such an option would also be a means of addressing the concerns of organic farmers – such as those represented by the Public Patent Foundation – about patent infringement resulting from unintentional use of patented plants.

³³ Olivier De Schutter, *Seed Policies and the Right to Food: Enhancing Agro biodiversity and Encouraging Innovation*, United Nations General Assembly, A/64/170, 2009, 12, <http://www.ip-watch.org/weblog/wp-content/uploads/2009/11/n0942473.pdf>

³⁴ Correa, C. 2012. *TRIPS-Related Patent Flexibilities and Food Security: Options for Reform*, Geneva: Quaker UN Office and the International Centre for Trade and Sustainable Development. Available at: <http://ictsd.org/i/publications/146808/>

³⁵ Ibid at 13.

³⁶ *Monsanto Canada Inc. v Schmeiser* (2004) SCC 34; 2004 SCC 34.

³⁷ Correa, 13.

Second, Correa contends that patent law should clarify the position of farmers' rights, much like the plant breeders' rights regime. He observes that some countries have clarified the position of the treatment of patent rights in respect of reproductive materials: 'French law, for instance, makes it clear that plant material can be multiplied or reproduced where it has been legally put on the market by the patent holder or with his or her consent, where this was the purpose for which the material has been marketed; the obtained material, however, cannot be subsequently used for further reproduction or multiplication'.³⁸ Correa observes that a farmers' privilege to save and reuse seeds under patent law would be a 'key component of a legal regime sensitive to food security policies, since it would reduce costs of production and promote the diversification of the sources of supply of seeds'.³⁹ He recommends that 'national patent laws should, where plants and/or their components are patentable, introduce exceptions equivalent to the farmers' privilege under Plant Variety Protection'.⁴⁰ Again, the policy option of a farmers' privilege would be of benefit to the organic farmers represented by the Public Patent Foundation – it would help alleviate concerns about farmers being sued for patent infringement in respect of saved seed.

Third, Correa discusses intellectual property exceptions in respect of research and breeding relating to agriculture. He notes that a breeders' exemption is a mandatory feature under the *UPOV Convention*, and 'optimizes variety improvement by ensuring that germplasm sources remain accessible to all the community of breeders'.⁴¹ Correa recommends:

The continuous improvement of plant varieties requires freedom to undertake research and breeding where patented materials are involved. Exceptions to this effect should be adopted even where a country opts not to grant patents on plants (or plant varieties). Even if it opts not to do so, such exceptions should be included if the patentability of plant components is permitted.

³⁸ Ibid at 13.

³⁹ Ibid at 13.

⁴⁰ Ibid at 13.

⁴¹ Ibid at 14. Correa is quoting from the UPOV Council at this point.

National laws may permit the commercialization of the newly obtained varieties, on the basis of non-remunerative exceptions.⁴²

He notes, though, that ‘the compatibility of an exception under patent law – equivalent in its scope and effects to the breeders’ exception – with the TRIPS Agreement (articles 28 and 30) has not been tested yet’.⁴³

A related issue is the defence of experimental use. The defence of experimental use has been interpreted very narrowly by the United States courts in a number of matters.⁴⁴ The Supreme Court of the United States, though, has taken a broader view of the defence safe harbour in relation to regulatory activities for pharmaceutical drugs.⁴⁵ Other jurisdictions have sought to engage in patent law reform in respect of patent exceptions. After a long policy debate,⁴⁶ the Australian Government established a statutory defence of experimental use under the *Intellectual Property Laws Amendment (Raising the Bar) Act* 2012 (Cth). There is a need to provide a broad and flexible research exemption to protect experimental researchers from the predatory behaviour of ‘patent trolls’.

Arguably, Crown Use could be a useful patent flexibility to address issues, such as food security.

⁴² Ibid at 14.

⁴³ Ibid at 14.

⁴⁴ *Madey v Duke University* 307 F. 3d 1351 (2002).

⁴⁵ *Merck KGaA v Integra Lifesciences I, Ltd* 545 U.S. 193 (2005).

⁴⁶ Rimmer, M. 2005. The freedom to tinker: patent law and experimental use. *Expert Opinion on Therapeutic Patents*, 15(2), 167-200.

There has been much debate about access to clean technologies. The recent United Nations report on post 2015-development, *A New Global Partnership*, discussed some of these issues.⁴⁷ The report commented:

It is crucial that technologies and innovations be widely shared. Low- and middle-income countries have the chance to leapfrog the old model of development and choose more sustainable growth. But they face two significant constraints: technology and finance. Cleaner and more efficient technologies are often patented by private corporations. Finance is also a problem: the benefits of more efficient technologies come from future savings, while the costs are concentrated at the beginning. If developed countries take the lead in applying these technologies, costs will fall and the technologies will become more accessible to developing countries.

To overcome these constraints, governments can use a mix of taxes, subsidies, regulations and partnerships to encourage clean-energy innovation. Partnering countries can use open-innovation forums to accelerate the development of clean-energy technologies and rapidly bring them to scale. These open-source forums should be linked to real public-works projects that can offer financing, and the chance for rapid adoption and broad deployment.⁴⁸

A mechanism such as Crown Use could be useful in addressing issues in respect of access to clean technologies in exceptional circumstances.

Recommendation 1

The Australian Parliament should pass the Crown Use provisions in the *Intellectual Property Laws Amendment Bill 2013 (Cth)* as a matter of urgency to provide safeguards for the public interest in respect of patent law. Crown Use could be particularly useful in addressing access to gene patents; questions about information technology; patent trolls and vexatious litigants; and matters of public interest, relating to agriculture, food security, and the environment.

⁴⁷ United Nations, *A New Global Partnership: Eradicate Poverty and Transform Economies Through Sustainable Development*, New York: United Nations, 2013, http://www.un.org/sg/management/pdf/HLP_P2015_Report.pdf

⁴⁸ Ibid., 45.

2. Access to Essential Medicines

It has taken 10 years for the Australian Government to prepare legislation - *IP Laws Amendment Bill 2013 (Cth)* - to implement the *WTO General Council Decision 2003*.

It would be fair to say that, over the course of the last decade, the Australian Government has been unaccountably slow to respond to the urgent and pressing public policy issues in respect of patent law and access to essential medicines. It is hard to fathom the reasons for this procrastination. There has been bipartisan support for both the *Doha Declaration on the TRIPS Agreement and Public Health 2001*, and the *WTO General Council Decision 2003*, during the terms of office of the Howard Government and the Rudd and Gillard Governments. The public health epidemics in relation to HIV/AIDS, tuberculosis, malaria, and tropical diseases have caused great hardship particularly in developed countries and least developed countries. Moreover, there has been a spate of troublesome new infectious diseases, such as the SARS virus, avian influenza, and porcine influenza.

Nonetheless, the Australian Government has been slow in reforming its patent regime to address the pressing public health concerns associated with access to essential medicines. In addition, it must be said that the domestic pharmaceutical industry – both the brand name companies and the generic industry – have not been as constructive or co-operative as it might be.

This has been surprising – particularly as the Australian Government has been so good at addressing intellectual property and public health in respect of the plain packaging of tobacco products. The Australian Government has also made significant patent law reforms in respect of the *Raising the Bar* legislation – most notably, with the introduction of a general defence of experimental use.

The Doha Declaration on the TRIPS Agreement and Public Health 2001

At a meeting in Qatar in November 2001, the members of the WTO adopted the *Doha*

Declaration on the TRIPS Agreement and Public Health 2001.⁴⁹ This acknowledged ‘the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.’ Article 4 emphasized ‘that the *TRIPS Agreement* does not and should not prevent Members from taking measures to protect public health.’ It highlighted a number of measures to promote access to essential medicines - most notably, compulsory licensing, in which a patent holder can be compelled to provide access to a patented invention in return for a royalty. The *Doha Declaration on the TRIPS Agreement and Public Health* 2001 also emphasized the need for member nations to resolve outstanding issues over patent law and access to essential medicines. Article 6 provides: ‘We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the *TRIPS Agreement*’. It furthermore urged: ‘We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.’

In August 2002, the Trade Minister Mark Vaile endorsed the *Doha Declaration on the TRIPS Agreement and Public Health* 2001, saying:

As the WTO Director General Supachai Panitchpakdi has noted, this is an historic agreement. It is a further demonstration that the WTO is able to respond to the public-health problems faced by developing countries, and to make its contribution to broader domestic and global action to address this crucial social issue. I have consistently said, particularly since the Sydney WTO informal ministerial meeting in November last year, that all WTO member countries had a moral obligation to resolve this issue. The problems poorer countries face in dealing with ravaging diseases such as HIV/AIDS, malaria and tuberculosis are immense. After many months of work, all WTO members have agreed an outcome that will allow these countries better access to affordable medicines. This decision is one endorsed by all WTO members. Now we must move past old battle lines and all work to ensure the solution makes its contribution to dealing with the public health problems poorer countries face.⁵⁰

⁴⁹ WTO Doc WT/MIN (01)/DEC/2 (2001).

⁵⁰ Mark Vaile, ‘Vaile Welcomes Breakthrough on Essential Medicines’, Department of Foreign Affairs and Trade, 31 August 2002, http://www.trademinister.gov.au/releases/2003/mvt067_03.html

The WTO General Council Decision 2003

On 30 August 2003, the member governments of the WTO reached an agreement on implementing the paragraph of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 that calls for a solution to compulsory licensing for member states without manufacturing capabilities.⁵¹ The decision has been known as the *WTO General Council Decision 2003*. Article 2 emphasized that a member country could export pharmaceutical products made under compulsory licences within the terms set out in the decision. Article 3 emphasized the need for ‘adequate remuneration’ with respect to such compulsory licences. Article 4 stressed that eligible importing members should take reasonable measures to address the risk of trade diversion, and prevent re-exportation of the products. Article 5 observed that members should ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision. Article 6 enables a pharmaceutical product produced under a compulsory licence in one country to be exported to the markets of developing countries who share the health problem in question. Article 7 stressed the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration.

In the lead-up to the World Trade Organization Ministerial in Hong Kong in December 2005, the Member States endorsed the proposal to transform the *WTO General Council Decision 2003* – described as a ‘waiver’ - into a permanent amendment of the *TRIPS Agreement* 1994.⁵² In an accompanying statement to the decision, the WTO General Chairman, Pascal Lamy made a number of comments.⁵³ He promoted the amendment in these terms:

⁵¹ General Council, ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’, 1 September 2003, WT/L/540, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

⁵² WTO General Council, *Amendment of the TRIPS Agreement*, WT/L/641, 8 December 2005, http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

⁵³ Pascal Lamy ‘Chairperson’s Statement’, December 2005, http://www.wto.org/english/news_e/news05_e/trips_319_e.htm

The agreement to amend the TRIPS provisions confirms once again that members are determined to ensure the WTO's trading system contributes to humanitarian and development goals as they prepare for the Hong Kong Ministerial Conference. This is of particular personal satisfaction to me, since I have been involved for years in working to ensure that the TRIPS Agreement is part of the solution to the question of ensuring the poor have access to medicines.⁵⁴

There has been an extension for acceptances of this regime as at 2011. At present, there would appear to be little enthusiasm for codifying the WTO General Council Decision, given its failure to facilitate the export of pharmaceutical drugs.

A small number of developed countries, members of the BASIC group, and regional groups have established domestic regimes to implement the *WTO General Council Decision* 2003. According to the World Trade Organization, here are the countries which have established regimes:

- **Norway:** Amendments to Sections 49 and 50 of the Patent Act of 15 December 1967 No.9 and to Patent Regulations of 20 December 1996 No.1162 provide the legal basis to act as an exporting Member — document [IP/C/W/427](#)
- **Canada:** Amendments to the Patent Act and Food and Drugs Act, as well as the Use of Patented Products for International Humanitarian Purposes Regulations provide the legal basis to act as an exporting Member — notifications [IP/N/1/CAN/P/5](#), [IP/N/1/CAN/P/6](#) and [IP/N/1/CAN/P/7](#), and document [IP/C/W/464](#)
- **India:** Section 92-A of the Patents (Amendment) Act 2005 provides the legal basis to act as an exporting Member — notification [IP/N/1/IND/P/2](#)
- **European Union/European Communities:** Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems provides the legal basis for EU Member States to grant compulsory licences for export of patented medicines — notification [IP/N/1/EEC/P/5](#)

⁵⁴ WTO, 'Members OK Amendment to Make Health Flexibility Permanent', Press/426, 6 December 2005, http://www.wto.org/english/news_e/pres05_e/pr426_e.htm.

- **Hong Kong, China:** the Patent (Amendment) Ordinance No.21 of 2007 provides the legal basis to act as an exporting Member, as well as importing Member in situations of extreme urgency — notifications [IP/N/1/HKG/P/1/Add.6](#) and [IP/N/1/HKG/17](#)
- **Switzerland:** Articles 40d and 40e of the consolidated version of the Federal Law on Patents for Inventions of 1 July 2008 and the Ordinance on Patents for Invention provide the legal basis to act as an exporting Member. Further terms and conditions are addressed by Article 111 of the Patent Ordinance — notifications [IP/N/1/CHE/P/9](#) and [IP/N/1/CHE/4](#)
- **Philippines:** Section 93-A of the Republic Act No. 9502 (also known as the ‘Universally Accessible Cheaper and Quality Medicines Act 2008’) and Rule 13 of the Implementing Rules and Regulations of Republic Act No. 9502 provide the legal basis for the grant of a special compulsory licence for the import of patented drugs and medicines, as well as for their manufacture and export — notification [IP/N/1/PHL/I/10](#)
- **Singapore:** Sections 2, 56, 60, 62 and 66 of the Patents Act 2005 Revised Edition provide the legal basis to act as an importing Member in situations of national emergency or other circumstances of extreme urgency — notification [IP/N/1/SGP/P/Rev.1](#)
- **Albania:** Article 50 of the Law No.9947 of 7 July 2008 on Industrial Property provides the legal basis to act as an exporting Member — notification [IP/N/1/ALB/I/2](#)
- **Croatia:** Articles 69a to 69h of the amended Patent Act of 2009 provide the legal basis to act as an exporting Member — notification [IP/N/1/HRV/P/2](#)
- **China:** Articles 50, 53 and 57 of the amendment to the Patent Law of the People’s Republic of China, which was adopted on 27 December 2008 and entered into force on 1 October 2009, provide the legal basis to act as an exporting Member. In addition, Article 49 provides the legal basis to act as an importing Member in situations of national emergency or other circumstances of extreme urgency, or if public interest so requires — notification [IP/N/1/CHN/P/2](#). Further details, such as the definition of a pharmaceutical product, are addressed in chapter V of the Revised Rules for the Implementation of the Patent Law — notification [IP/N/1/CHN/P/3](#).
- **Rep. of Korea:** Article 107 of the Patent Act and Presidential Decree No. 23306 of 26 July 2010 on ‘Provisions Regarding the Expropriation and Implementation of the Patent Right’ provide the legal basis to act as an exporting Member, as well as an importing Member in situations of national emergency or other circumstances of extreme urgency — notification [IP/N/1/KOR/P/4](#).
- **Jordan:** Articles 22 and 23 of the Amended Patent Law number 28 of 2007 provide the legal basis to act as an exporting Member – notification [IP/N/1/JOR/P/2](#).
- **Japan:** At the annual review of the Paragraph 6 System in October 2010, the delegation of Japan also reported orally to the TRIPS Council on the domestic rules which constitute the basis for it to act as an exporting Member under the System. The Guideline for Administering Award System and Article 93 of the Japanese Patent Act (notification [IP/N/1/JPN/P/8](#)), which provides for the grant of non-exclusive licences for reasons of public interest, were referred to as the legal basis for

the grant of compulsory licences in accordance with international obligations, including the TRIPS Agreement, the 2003 Decision and the Protocol Amending the TRIPS Agreement, and thus for the purposes of the System.

However, a significant number of key developed countries have egregiously not implemented domestic regimes under the *WTO General Council Decision 2003*. Most notably, the United States, and Japan have shown little enthusiasm in establishing regimes to facilitate the export of pharmaceutical drugs to developing countries. The partial, uneven implementation of the *WTO General Council Decision 2003* by developed countries has raised questions about both its efficacy and its legitimacy.

Export of Pharmaceutical Drugs

In July 2007, Rwanda became the first country to notify the World Trade Organization of its intention to import essential medicines under the *WTO General Council Decision 2003*. The Delegation of Rwanda informed the TRIPS Council thus:

Based on Rwanda's present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine (hereinafter referred to as the 'Product') manufactured in Canada by Apotex, Inc. However, because it is not possible to predict with certainty the extent of the country's public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate. Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda's territory with respect to the Product.

There have been no other successful instances of imports of essential medicines under the *WTO General Council Decision 2003*.

The Australian Policy Discussion

In 2007, the Joint Standing Committee on Treaties in the Australian Parliament recognised: ‘Providing better access to medicines to the world’s poorest people is a worthy subject for an international treaty’.⁵⁵ The Committee agreed with ‘the Department of Foreign Affairs and Trade that Acceptance of the protocol by Australia would demonstrate our support for the ability of developing countries and least developed countries to respond effectively to public health emergencies.’ The Committee observed:

The Committee supports acceptance of the Protocol, followed by any necessary amendments to the *Patents Act 1990* (Cth) to allow for compulsory licensing to enable export of cheaper versions of patented medicines needed to address public health problems to least-developed and developing countries. The Committee encourages the consultations to be coordinated by IP Australia later this year and urges the Government to actively support the provision of patented medicines to least developed and developing countries.

However, the Committee also noted that it shared my concerns ‘that the TRIPS Protocol requires intricate, time-consuming and burdensome procedures for the exportation of medicine, when what is needed is a simple, fast and automatic mechanism’.

Nearly three years after the Joint Standing Committee on Treaties report, in April 2010, IP Australia released its consultation paper, *Implementing the TRIPS Protocol*. It is unclear whether the proposed regime in its current form will be able to satisfy the need for a simple, fast, and automated export mechanism. Moreover, it would seem unlikely that a compulsory licensing mechanism in isolation will be sufficient to provide for the timely export of essential medicines. What is needed is an integrated approach to the issue – which draws upon not only compulsory licensing mechanisms for domestic use and export; but also provides for a broad defence of experimental use and a liberal safe

⁵⁵ Joint Standing Committee on Treaties, *Protocol Amending the TRIPS Agreement*, Canberra: Australian Parliament August 2007, <http://www.aph.gov.au/house/committee/jsct/9may2007/report/chapter9.pdf>

harbour for research and regulatory approval in respect of pharmaceutical drugs. There is also a need for the deployment of such flexible and creative mechanisms as patent pools, public sector licensing, medical prizes, and Health Impact Funds. There is a need to reform the remedies under patent law, in light of recent pronouncements of the Supreme Court of the United States on the need to carefully exercise discretion before granting injunctions. The Australian patent regime also needs stronger penalties to deter the practice of ‘evergreening’ in relation to pharmaceutical drugs, medicines, and other inventions related to the provision of health care.

In 2011, the Minister for Innovation, Senator Kim Carr, and the Minister for Trade, Dr Craig Emerson, put out a press release, observing ‘the Government would introduce legislation to allow Australian courts to grant compulsory licences to manufacture and export patented pharmaceuticals to countries trying to deal with epidemics and other types of health crises.’⁵⁶ The press release noted:

The United Nations estimates that nearly two billion people do not have access to essential medicines. In 2008, an estimated 285 million people were infected with malaria, HIV/AIDS or tuberculosis, causing 4.2 million deaths. Many of the countries that are suffering such epidemics are developing or least-developed countries with limited resources and manufacturing capabilities.

Senator Kim Carr observed: ‘The new system will enable a country that is experiencing a serious epidemic to ensure that its own population is supplied with vital treatments,’ He added: ‘The Government continues to support and encourage innovation, investment and international competitiveness by ensuring that patent owners will receive adequate compensation for any licences issued.’ Carr noted: ‘Measures will also be taken to help ensure that pharmaceuticals exported under the system reach the people that need them and are not diverted to other markets.’ Dr Emerson added: ‘Pandemics and other serious health issues remain a terrible problem in many of the world’s poorest countries.’ He

⁵⁶ Department of Innovation, Industry, Science and Research, ‘Better Access to Medicines For Countries in Need’, Press Release, 22 March 2011, <http://archive.innovation.gov.au/ministersarchive2011/carr/MediaReleases/Pages/BETTERACCESSTOMICINESFORCOUNTRIESINNEED.html>

commented: ‘Anything Australia reasonably can do to alleviate the suffering in these countries should be done and we are delighted to be able to help through this initiative.’

In 2012, IP Australia published a draft version of the bill

In 2013, the Australian Government introduced the *Intellectual Property Amendment Bill* 2013 (Cth). The explanatory memorandum emphasized that the regime would promote Australia’s obligations to protect to the right to health under international human rights law:

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises the right of everyone to enjoy the highest attainable standard of physical and mental health. The ICESCR provides that as part of achieving the full realisation of this right, States Parties shall take necessary steps to prevent, treat and control epidemic, endemic, occupational and other diseases.

Article 24 of the Convention on the Rights of the Child (CRC) highlights the right of a child to enjoy the highest attainable standard of health. Article 24(4) of the CRC provides that in achieving this right, countries that are party to the CRC shall undertake the promotion and encouragement of international co-operation having particular consideration for the needs of developing countries.

The amendments to the *Patents Act* under Schedules 2 and 3 to the Bill, enable the export of generic versions of patented medicines to developing countries that are experiencing serious public health issues and that have no capacity to manufacture the medicines or purchase them in the normal manner. The amendments will advance the human right to health for everyone, including children, in developing countries by assisting with the treatment of serious health problems such as HIV/AIDS, malaria and tuberculosis.

I would certainly agree that the regime would assist Australia in meeting its international obligations to protect the human right to health for everyone – including children.

Trilateral Report: WTO, WIPO, and WHO

In 2013, three major international institutions – the World Trade Organization, the World Intellectual Property Organization, and the World Health Organization – released a joint

report, *Promoting Access to Medical Technologies and Innovation*.⁵⁷ The joint report comments:

A wide range of policy options and flexibilities are built into the international IP regime that can be used to pursue public health objectives. These options are not self-actuating at the international level, though, and attention and action are needed at the domestic level as to how best to implement such flexibilities, so that the national IP regime responds to each country's individual needs and policy objectives. Key options include transition periods for LDCs, differing IP exhaustion regimes, refining the criteria for grant of a patent, pre-grant and post-grant opposition procedures, as well as exceptions and limitations to patent rights once granted, including regulatory review exception ('Bolar' exception) to facilitate market entry of generics, compulsory licences and government use. Countries have used these instruments to improve access to medicines for both communicable and non-communicable diseases. WTO members have agreed to amend the TRIPS Agreement to permit a wider use of compulsory licensing for access to medicines, clearing a potential legal barrier for countries that need to import medicines produced abroad under a compulsory licence, through the grant of special compulsory licences for export under what is termed the 'Paragraph 6 System'.⁵⁸

The report observes: 'While the legal scope for flexibilities is now clearer, thanks also to the Doha Declaration on Public Health, and some flexibilities are widely implemented (such as 'Bolar' exceptions), policy debate continues on the use of measures such as compulsory licensing.'⁵⁹

The report notes that the Paragraph 6 system is an additional flexibility aimed at enhancing access to medicines:

Paragraph 6 of the Doha Declaration mandated the TRIPS Council to find a solution to the difficulties faced by countries with insufficient or no manufacturing capacities in the

⁵⁷ World Health Organization, World Intellectual Property Organization, and World Trade Organization, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, Geneva: United Nations, 2013, http://www.wto.org/english/tratop_e/trips_e/trilat_5feb13_e.htm

⁵⁸ Ibid., 13.

⁵⁹ Ibid., 14.

pharmaceutical sector in making effective use of compulsory licensing. This resulted in the 2003 WTO General Council decision to establish the framework for special compulsory licences, which is an additional flexibility aimed at enabling exports of medicines to these countries. The System – informally dubbed the ‘Paragraph 6 System’ – initially took the form of a waiver of certain conditions regarding compulsory licences. In 2005 WTO members adopted it by consensus as the Protocol Amending the TRIPS Agreement. This outcome, providing an additional legal pathway for access to medicines, has special significance as the sole amendment proposed to any of the WTO multilateral trade agreements since their adoption in 1994. The System has already been available for use since the 2003 waiver decision and will become a permanent feature of the TRIPS Agreement once two thirds of WTO members formally notify their acceptance. A wide cross-section of the WTO membership has already taken this step, with many notices of acceptance received from developing countries, including several LDCs, and virtually all developed countries.⁶⁰

The report noted that the new System has been endorsed in a number of multilateral forums – including: the 2008 *WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (GSPA-PHI); The Ministerial Declaration – 2009 High-Level Segment of the Economic and Social Council of the United Nations; the 2011 *UN Political Declaration on HIV/ AIDS: Intensifying our Efforts to Eliminate HIV/AIDS*; and the 2012 Declaration ‘The future we want’, an outcome document from the United Nations Conference on Sustainable Development (‘Rio+20’).

Recommendation 2

The Australian Parliament should implement the access to medicines scheme in the *Intellectual Property Laws Amendment Bill 2013* (Cth) in order to meet its obligations under the *WTO General Council Decision 2003*.

It is essential that the export of essential medicines be allowed to both members of the WTO, and non-members (such as East Timor). This is the case with the Canadian regime.

In the future, the Australian Parliament should consider further patent law reforms to facilitate technology transfer and the export of

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Ibid., 177.

humanitarian inventions to developing countries and least developed countries.

3. Plant Breeders' Rights

Schedule 4 of the *Intellectual Property Laws Amendment Bill* 2013 (Cth) amends the *Plant Breeder's Rights Act* 1994 (Cth) to provide plant breeders' rights owners with an alternative to enforcing their rights in the Federal Court. Schedule 4 of the Bill enables Plant Breeder's Rights actions to be heard in the Federal Circuit Court. The amendments pick up recommendations by the Advisory Council on Intellectual Property on Plant Breeder's Rights enforcement.

There has been much debate over the topic of enforcement of plant breeder's rights, as well as enforcement of patents in respect of agriculture, farming, and biotechnology. I made a submission to the Advisory Council on Intellectual Property in the inquiry into plant breeder's rights enforcement, making a number of points.

In my opinion, the Advisory Council on Intellectual Property should investigate whether it is feasible and viable to implement a legislative scheme for the collective administration of plant breeders' rights. A collecting society for plant breeders' rights would involve an organisation that administers the rights of individual plant breeders. It could grant permission to use propagating material and set conditions for their use. Such collective management would be a tool that rights-holders could employ when the individual exercise of the rights is impractical or inefficient.

Such a regime could address a number of concerns raised by the inquiry into plant breeders' enforcement. The exclusive role of the Plant Breeders' Rights Office is to determine the validity of applications for plant breeders' rights. It would be inappropriate for this independent arbiter to be involved in the management and enforcement of plant breeders' rights. An independent collecting society for plant breeders' rights would fulfil this separate role. The seed industry has expressed concerns that many of its members – especially individual plant breeders and small-to-medium businesses – lack the capacity or expertise to enforce plant breeders' rights. A collecting society for plant breeders' rights would be able to bring infringement actions on behalf of its members. The seed

industry has also raised concerns about the ability of their members to manage and exploit plant breeders' rights. A collecting society would help facilitate transactions between the owners of plant breeders' rights, and the users of plant breeders' rights. Furthermore, there is a need to provide formal, legislative backing for the industry practice of end-point royalties. There is a need to amend the *Plant Breeders' Rights Act* 1994 (Cth) to provide for statutory licensing in respect of end-point royalties. A collecting society for plant breeders' rights would be an appropriate independent body to administer statutory licenses in respect of end-point royalties.

The Advisory Council on Intellectual Property should also take into account some of the issues and challenges, which have arisen in respect of the collective administration of intellectual property rights. The Federal Government – and the agricultural industry – would have to make a significant outlay to start-up such a collecting society. There would be a need to determine the nature of such a collective administration – in particular, whether it would be a voluntary system; a compulsory system; or a mix of the two. A collecting society in respect of plant breeders' rights would enjoy a dominant position in the marketplace. There would be a need to obtain authorisation from the Australian Competition and Consumer Commission in respect of the operation of the scheme. Furthermore, there would be a need for proper regulatory oversight of a collecting society in respect of plant breeders' rights. Voluntary codes of conduct have proven to be an ineffective means of governing collecting societies in the context of copyright law. There would need to be an administrative body empowered to establish, either mandatorily or at the request of an interested party, the royalties to be paid for the use of plant breeders' rights, when the administration of such copyright is entrusted to a collective-administration society.

The Advisory Council on Intellectual Property should seek to preserve the special identity of the plant breeders' rights regime. It would be inappropriate to discard unique doctrinal features – such as the criteria for distinctiveness, uniformity, and stability; the cascading rights of plant breeders; the doctrine of essential derivation; and the special

exceptions for farm-saved seed. The plant breeders' rights regime should be a viable alternative to the patent regime.

The Advisory Council on Intellectual Property should clarify the 'cascading rights' of plant breeders. The *Cultivaust* litigation illustrated that there needs to be further elucidation as to the circumstances in which plant breeders' rights cascade from propagating material to harvested material and products arising from the harvested material. In particular, it is worth defining what a reasonable opportunity to exploit propagating material involves. As a matter of clarification, the *Cultivaust* litigation involved questions of the exhaustion of plant breeders' rights – rather than matters of the farmers' privilege. The Full Federal Court was critical that the trial judge confused the two issues. Unfortunately, the issues paper compounds the error of the trial judge – by conflating questions of 'cascading rights' and farm saved seed (in 4.1 of the issues paper). It would be preferable if the Advisory Council on Intellectual Property decouple the issues of a reasonable opportunity to exploit propagating material from matters of farm-saved seed. One should not confuse rights with exceptions.

The integrity of the farm saved seed provisions under the *Plant Breeders' Rights Act* 1990 (Cth) should be respected and preserved. Such exceptions serve an important practical and symbolic function. The defence provides recognition of an old-tradition of saving seeds in farming. The farm-saved seed exception also provides legitimacy to the *Plant Breeders' Rights Act* 1990 (Cth), especially amongst rural and regional sectors. There would be a political outcry amongst agricultural communities if the farm-saved seed provisions were curtailed, replaced, or annulled. It is recommended that the *Plant Breeders' Rights Act* 1990 (Cth) be amended to provide that an agreement, or a provision of an agreement that excludes or modifies the farmers' privilege have no effect. It is recommended that the *Plant Breeders' Rights Act* 1990 (Cth) be amended to ban genetic restriction use technologies, which have the effect of excluding or modifying the farmers' privilege. It is recommended that a farmers' privilege should be included in the *Patents Act* 1990 (Cth). It should specify that farmers are permitted to save and sow seeds from

patented plants, as long as these progeny are not sold as commercial propagating material.

The other key exceptions in the *Plant Breeders' Rights Act* 1990 (Cth) – such as the defence of experimental use, the equitable remuneration provisions, and the safeguards for reasonable access to plant varieties – should also be retained.

Furthermore, the concept of essential derivation should be preserved under the *Plant Breeders' Rights Act* 1990 (Cth), as it serves a useful function. My colleague, Jay Sanderson, has analysed the concept of 'essential derivation', which is a doctrinal feature of plant breeders' rights regimes. The concept of 'essential derivation' serves to stratify and differentiate the regimes of intellectual property. Due to the concept of essential derivation, plant breeders' rights are more attractive to traditional plant breeders; whereas patent protection is more appropriate for genetic engineers. Sanderson argues that there is a need to clarify the meaning of the doctrine of 'essential derivation'. He considers the first decision on 'essential derivation' in the Civil Court of the Hague in the Netherlands in *Astée Flowers v Danziger*, which involved a dispute in relation to the *Gypsophila* plant variety. Sanderson considers the limits of science in elucidating the meaning of essential derivation. He calls for a qualitative, fact-based assessment of the notion of 'essential derivation'. This would be a sensible course of reform.

The *Plant Breeders' Rights Act* 1990 (Cth) provides an impressive arsenal of civil and criminal remedies in respect of infringement of plant breeders' rights. There is no pressing need to add to this array of remedies. Plant breeders and the seed industry need to be better prepared and willing to use civil remedies (the addition of a collecting society may help in this course). Criminal remedies are reserved for exceptional circumstances in matters of intellectual property (which is only right and proper). It would be sensible to add alternative dispute resolution mechanisms to the *Plant Breeders' Rights Act* 1990 (Cth). It seems to me that both owners and users of plant breeders' rights are reluctant to be involved in court conflicts. Mediation would be helpful to avoid unnecessary conflicts in the agricultural sector. The *Plant Breeders' Rights Act* 1990 (Cth) does not require

exceptional remedies, like those accorded to the Australian Competition and Consumer Commission and the Australian Securities and Investments Commission. Such measures would seem ill-suited to the litigation arising in respect of plant breeders' rights.

At present, the *Plant Breeders' Rights Act* 1990 (Cth) provides exclusive protection for 20 years for plant varieties, and 25 years for trees and vines. The Plant Breeder's Rights Advisory Committee has released an Issues Paper about extending the duration of plant breeder's rights protection.

In other intellectual property regimes, there has been much controversy about the extension of intellectual property rights, without regard to empirical economic evidence. The history of patent term extensions is instructive. In 1994, Australia extended its patent term for 16 to 20 years in compliance with the *TRIPS Agreement* 1994. The Productivity Commission suggested that such an extension provided windfall gains to existing patent holders, without any concomitant consumer benefit. In 1998, Australia passed further laws, allowing for patent term extensions for pharmaceutical drugs for up to another 5 years. Such measures were entrenched by the *Australia-United States Free Trade Agreement* 2004.

There has been much criticism that such patent term extensions have not been justified in terms of the research and development costs of pharmaceutical drug manufacturers. The copyright term extensions in the European Union, the United States, and Australia have had an adverse economic impact. Economist Phillipa Dee suggested that lengthening the duration of copyright protection in Australia would lead to significant increase in royalty payments to overseas copyright holders.

In this context, it is doubtful that lengthening the duration of plant breeder's rights would serve as much incentive for plant breeders. A lack of uniformity of duration between plant varieties could create additional uncertainty and confusion amongst farmers, growers, and researchers. It would be productive to help encourage plant breeders to develop business plans to efficiently exploit plant breeder's rights in the time available.

There remains an uneven knowledge of plant breeders' rights and related intellectual property rights in the agricultural sector. As a result, technology developers may have unrealistic expectations of what intellectual property rights can achieve. Moreover, farmers and growers may inadvertently infringe plant breeders' rights, because of a lack of awareness of their rights and responsibilities. There is a need to improve the literacy of plant breeders, technology developers, and business managers in respect of plant breeders' rights. Similarly, there is scope for further education programmes for farmers, growers, researchers, and scientists. Moreover, there is a need for a better knowledge of plant breeders' rights amongst rural advisors – including solicitors, accountants, and consultants.

The Advisory Council on Intellectual Property recommended:

- making a new right applying to the purchase of propagating material available to PBR owners, to enable the industry to collect royalties more efficiently;
- including PBR matters within the jurisdiction of the second tier of the Federal Court to provide PBR owners with an appropriate forum for enforcing their rights;
- establishing an Expert Panel to provide guidance and opinions on PBR issues and law;
- introducing an Information Notice system that enables PBR owners to obtain information from alleged infringers on the source of plant material;
- introducing powers to enable Customs to seize goods at the border that allegedly infringe PBR; and
- introducing exemplary damage provisions into the *Plant Breeder's Rights Act 1994* (the PBR Act).

ACIP also recommended that no changes be made to the farm saved seed provisions.

The Australian Government responded to the recommendations of the Advisory Council on Intellectual Property (some were supported; some were partly supported; and some were rejected). The Australian Government supported the recommendation the Federal Magistrates Court should hear matters dealing with plant breeders' rights: 'The Government has previously agreed that the jurisdiction of the Federal Magistrates Court should be extended to include trade mark and design matters. The Government believes that PBR matters are no

more complex than trade mark and design matters. As such, the Government will seek to extend the jurisdiction of the Federal Magistrates Court to include PBR matters.’

In this context, the reforms contained in the *Intellectual Property Laws Amendment Act 2013 (Cth)* on plant breeders’ rights seek to implement this recommendation by the Advisory Council on Intellectual Property, which was accepted by the Federal Government.

Recommendation 3

The Australian Parliament should implement the procedural reforms in respect to plant breeder’s rights enforcement in the Federal Circuit Court *Intellectual Property Laws Amendment Bill 2013 (Cth)*.

4. Trans-Tasman Patents

Schedule 5 amends the *Patents Act* 1990 (Cth) to ‘provide for single application and examination processes for trans-Tasman patents’. The explanatory memorandum comments:

A single pathway to patent protection across countries will remove unnecessary administrative processes and create a more streamlined process for inventors in Australia and New Zealand. Schedule 5 will also allow for a single trans-Tasman patent attorney regime which will include common qualifications for registration as a patent attorney, a single trans-Tasman IP Attorneys Board and a single trans-Tasman IP Attorneys Disciplinary Tribunal.

This is an interesting development in terms of patent administration and regulation of patent attorneys.

In his book on *The Global Governance of Knowledge*, Professor Peter Drahos from RegNet at the Australian National University has made a number of recommendations in respect of administrative reform both of intellectual property offices and the regulation of patent and trademark attorneys.⁶¹ He emphasizes, in his book, that a critical issue is addressing gaming behavior by patent attorney:

In short, there is not in the US, and probably not anywhere else, a professional ethical obligation on patent attorneys to game the system in ways that destroy market competition in important areas such as pharmaceuticals. Patent offices, if they wished, address this problem through a voluntary code of conduct that would have real bite if it were linked to an enforcement pyramid that was based on their powers of deregistration. That would be a much more cost-effective approach to the problem of patent quality because it would be a preventive strategy aimed at changing the behavior of patent attorneys in order to improve the quality of patent applications at the point of entry into the system. By not improving input quality and then allowing many such applications through their systems, patent offices pass on the costs of doubtful patents to other actors, actors whose costs of fighting poor patent quality are much greater than the cost of such a preventive approach by patent offices. Doubtful patents are cheap to obtain. They are expensive to fight.

⁶¹ Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients*, Cambridge: Cambridge University Press, 2010.

Faced by the threat of patent litigation many people will pay to make a problem to go away rather than fight their way out of it. Those that do fight have a long battle irrespective of whether they win or not.⁶²

Drahos recommends the need for stronger regulation of the patent attorney profession: 'Patent offices equipped with powers of deregistration could do much more to change the gaming behavior of patent attorneys'.⁶³

Recommendation 4

The Federal Government should consider the role of IP Australia as a regional hub for intellectual property administration and policy. A Trans-Tasman patent attorney regime could be workable. Nonetheless, there is a need to ensure that patent attorneys are subject to strong regulation to deter gaming behaviour and improve patent quality.

⁶² Ibid., 313-4.

⁶³ Ibid., 314.

5. Fixing the Bar

Schedule 6 makes ‘minor administrative changes to the *Patents Act*, *Trade Marks Act* and *Designs Act* to repeal unnecessary document retention provisions which are already adequately governed by the *Archives Act* 1983 (Cth); and makes minor technical amendments to the *Patents Act* 1990 (Cth) to address oversights in the drafting of the *Intellectual Property Laws Amendment (Raising the Bar) Act* 2012 (Cth)’.

Recommendation 5

The administrative changes and technical amendments to the *Patents Act* 1990 (Cth) should be supported.