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Intellectual Property and Trade Treaties

Introduction

This Policy Note provides a brief overview of IP regulations in international trade negotiations and draws out some issues relevant to IP in the current trade negotiations between Australia and the European Union (EU).

What does 'intellectual property' mean?

'Intellectual property' (IP) is a fairly recently coined term.[1] It encompasses a range of government regulations limiting competition in respect of inventions, creative material, trademarks, designs, plant variety rights and geographical indications, etc. The limit on competition is designed to increase the incentive to innovate or create.

The umbrella term is not helpful in analysis as each type of regulation has quite different characteristics. Patents, for example, provide strict monopolies for 20-25 years, after which the 'invention' becomes a public good. Simultaneous independent invention is no defence against a patent infringement suit. In contrast copyright only prevents copying *per se* but provides a very long period of restraint on trade (life plus 70 years for authors who are natural persons).

IP rules are implemented through legislation, so the privileges conferred are national. However, various forms of mutual recognition or joint application provide avenues to for global rights. Since the 1886 Berne Convention,[2] copyrights apply in all signatory countries, without the need for any action. The 1970 Patent Cooperation Treaty provides an easy route for a patent to be granted in a number of countries, based on a single application. The 1989 Madrid Protocol allows for global registration of trademarks.

> In the IP world 'protection' always means protection from competition.

The global spread of IP regulations

Patent and copyright regulations originated in Europe and were initially limited, in England, to 14 years, and only covered product inventions. Gradually the scope extended – first to processes then to chemical compositions then, in some countries, to methods of medical treatment and software algorithms.[3] Patents for inventions were extended globally, partly through colonialism and partly through international treaties. The Uruguay Round trade negotiations resulted in the Agreement on Trade Related Intellectual Property Rights (TRIPS), a treaty which is compulsory for World Trade Organization members. Since then the major means of extending IP regulations has been through bi-lateral and pluri-lateral trade treaties.[4]

The main countries/blocs seeking extensions of IP to favour owners of intellectual property rights (IPRs) are the USA and the EU, with strong support from Japan. Until the recent surge in Chinese patenting these were the blocs/countries which dominated global patent and copyright ownership.

The IP extensions go beyond the provisions of the TRIPS Agreement so are often referred to as 'TRIPS-Plus' provisions. They are also referred to as 'stronger' IP rights, but it is important to note this means lower thresholds for gaining IPRs, or stronger enforcement. Both mean fewer protections for industrial users and consumers. In patents this means higher prices for medicines, for example, and greater delays in the entry of generic products. For copyrighted works it means extended copyright duration and new limits on consumers such as technological protection measures.

Both the USA and the EU have advocated 'stronger' patent policy and for the new associated 'protection' of clinical trial data. Both also advocate for extensions in copyright

1 According to google's ngram facility, the term had very little usage until around 1980 (https://tinyurl.com/ngram-intellectual-property), when certain multi-national companies started the campaign that led to the TRIPS Agreement.

2 1886 Berne Convention for the Protection of Literary and Artistic Works, last amended in 1979.

3 For a brief history of the extension of patent scope, see H Moir 2013, *Patent Policy and Innovation*, Cheltenham: Edward Elgar: ch. 3.

4 The 2004 Australian Senate Select Committee final report on the Australia-US Free Trade Agreement (AUSFTA) noted that the "IP Chapter of the AUSFTA is the largest chapter in both form and substance and requires the most significant changes to current Australian law" (p. xvii). At https://tinyurl.com/Australian-Senate-AUSFTA.

regulations; stronger trademarks regulations, particularly for 'well-known' marks, and stronger enforcement measures. The major difference between the USA and the EU is their position with respect to geographical indications (GIs).

Patents and data protection

Patents are theoretically granted only for inventions, but the test for inventiveness has been substantially lowered since the 1950s. As a result minor variations – making a fizzy version of a medicine for example[5] – can now obtain a 20-year monopoly. So while a small proportion of granted patents are for genuine inventions, the vast majority only pass a threshold test of 'marginally different'. This very low standard has been pursued globally by the pharmaceutical industry, whose greatest success has been in the 2018 Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

The CPTPP enshrines the very low inventiveness standard that originated in the USA: "whether the claimed invention would have been obvious to a person skilled, or having ordinary skill in the art, having regard to the prior art".[6] In some countries the skilled person is defined as having very limited capacity to link different but closely related bodies of knowledge.[7] In Australia the word obvious means that the skilled person "would be led directly as a matter of course to try a particular approach with a reasonable expectation of success".[8] 'Prior art' refers to a highly prescribed *sub-set* of existing knowledge. In Australia the High Court deemed that knowledge of mortice locks was not relevant to determining inventiveness for rim-mounted locks.[9]

In the current EU-Australia trade negotiations, the EU is asking Australia to grant additional patent term extensions and longer 'protection' for clinical trial data than at present.

The International Generic and Biosimilar Medicines Association (IGBA), in its submission to DFAT, notes that "IP is only one of the two variables of the equation that fosters innovation, with competition being the other."[10] Referencing the US Federal Trade Commission's 2003 report on innovation and the European Commission's 2009 report on pharmaceuticals, the IGBA argues that there is a need for *reduced* protection to bring the patent and data protection systems back into balance. The IGBA notes the additional costs imposed on the generics pharmaceutical industry by the *AUSFTA,* and argues strongly that systems promoting the grant of low-quality patents should be resisted. The IGBA considers that demands to broaden patent term extensions and extend exclusivity for clinical trial data should be resisted.

Balance in the patent system is important because it is when the invention is broadly adopted that benefits, such as productivity increases, spread through society.

Patent term extensions (PTEs)

TRIPS mandates a 20 year term for all patents. In some countries, the pharmaceutical industry has successfully lobbied for an extra five years, arguing delays in granting market approval. Usually this additional privilege is limited to genuinely new medicines – new chemical entities (NCEs). Current Australian policy allows PTEs of up to five years for NCEs. It limits the maximum effective patent life to 15 years – a year longer than that in the USA.[11] The government's 2013 Pharmaceutical Patent Review (PPR) analysed patent term extensions at length.[12] The PPR found such term extensions expensive in terms of additional costs to the Pharmaceutical Benefits Scheme. The PPR recommended the maximum effective patent life be reduced to 10-12 years, with the maximum term extension remaining at five years.

In the AUSFTA, PTEs are required, but neither length nor scope are specified. This gives the Australian government considerable room to improve this aspect of patent policy.

The EU is asking for the scope of PTEs to be broadened to cover "any substance or combination of substances" that is used for treatment of humans or animals.[13] This would cover many more pharmaceuticals than are currently eligible. The PPR specifically recommended against any extension in eligibility for PTEs. This is sound evidence-based advice and the evidence has not changed since 2013.

Exclusivity for clinical trial data

As generic medicines have the same active ingredients as the original proprietary medicine (by definition), it makes sense that generic manufacturers use the original clinical trial data in seeking marketing approval for their medicines. But originator companies argue that such clinical trial data – although required by public authorities for public purposes – constitutes private data and that governments should protect these data from use by others. The compromise outcome in the hard-fought US 1984 Hatch-Waxman Act included a period of five years during which generic companies may not use originator's clinical trial data for marketing approval purposes.[14] Such data protection privileges are limited to new chemical entities, i.e. genuinely new medicines. They have spread globally through treaties.

Australia already has TRIPS-Plus standards limiting the use of clinical trial data to support generic and biosimilar market entry. The EU seeks to more than double this period of exclusivity, demanding a mandatory period of eight years before such data can be used to support a *request* for market authorisation from the Therapeutic Goods Administration (TGA). Further the EU wants an additional two years before generics can *actually enter* the market, and another year if there are new uses of the original product. The EU is also asking that this 8+2+1 data exclusivity period apply to a much broader range of products, not just genuinely new medicines.

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5 Australian patent 712325 was for the effervescent form of the known medicine omeprazole or S-omeprazole. This was one of 53 low quality patents surrounding the original compound patent (529654). See Harris et al. (footnote 12): 226.

6 CPTPP Article 18.37, footnote 30.

7 This limited capacity was lifted by the US Supreme Court in 2007 to allow at least ordinary creativity (KSR v. Teleflex, 127 S.Ct. 1727 (2007)).

8 IPAustralia, 2009, *Toward a Stronger and More Efficient IP Rights System,* Consultation Paper: 12.

9 Australian High Court, Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2), [2007] HCA 21.

10 https://www.dfat.gov.au/sites/default/files/igba-aeufta-submission.pdf: 2.

11 Effective patent life is the period between the marketing approval for the new medicine and the first generic/biosimilar entry.

12 T Harris, D Nicol, and N Gruen, 2013, Pharmaceutical Patents Review Report, Canberra: chs 4 and 5. At https://tinyurl.com/final-PPR-report.

13 Draft Article X.41. There is also a similar proposal for PTEs for "plant protection products" in draft Article X.42.

14 K Behrendt, 2002, "The Hatch-Waxman Act: balancing competing interests. or survival of the fittest?" *Food and Drug Law Journa*l, 57(2): 247-271.

The EU also asks that the data exclusivity period start from marketing approval grant in Australia, not in the world. This would reward delays in providing products in Australia with extended periods of monopoly.

Measures to re-balance patent policy

At present the only pro-consumer measure in Australian patent law is the provision that granted patents should not be assumed to be valid. Priority re-balancing measures are: disclosure of the best method of making the invention; penalties for the misuse of patent privileges; 'Bolar' exceptions so generics can be prepared for market entry immediately on patent expiry; waiver of the patent 'right' that prevents manufacture for export to countries where the patent is not in force; and last, but not least, raising the standard for patent grant so that patents are only granted for genuine inventions. There are no measures in the draft text that would help re-balance patent policy.

Copyright

Copyrights grew out of patent law and developed in England as an arrangement between the monarchy and the *Worshipful Company* of *Stationers*. The monarchy effectively out-sourced censorship (which at the time focused on religion and treason) in exchange for monopoly rights. This arrangement pre-dated police forces and the Company of Stationers was given rights of entry and seizure. This 'right' was subsequently extended internationally. In the USA the right was transferred to the police in 1902, making copyright offences criminal, despite copyright being a civil commercial privilege.[15] Again this facet of copyright law spread internationally.

Discussions of copyright policy focus on creators, alleging that it is authors and creators who benefit from copyright law. The limited evidence available suggests, however, that it is publishers and distributors who are the main beneficiaries.[16]

In the AUSFTA, Australia agreed to extend copyright by 20 years for authors who are natural persons. This extension to life plus 70 years was hotly disputed,[17] and imposed unnecessary costs on consumers, particularly educational institutes and libraries.

In the current trade negotiations, the EU is asking for a similar extension in the copyright term for cinematographic and audiovisual works. The EU is also asking for a ban on parallel imports for literary works, and a resurrection of rental rights. The Australian Digital Alliance, a major voice for consumers of copyright material has argued to DFAT that all these EU demands should be strongly resisted.[18] The SBS's submission to DFAT addresses the EU demand for significantly extended copyright privileges for performers and notes this issue has not yet been fully analysed in Australia. The SBS expresses concern that the proposed text could "potentially limit the amount of distinctive content that SBS may publish". The SBS also opposes the proposed extension in copyright term for audiovisual works.

[15] See M Boldrin and D K Levine, 2008, *Against Intellectual Monopoly*. Cambridge: CUP: ch 2.

[16] D Court, 2013, *Shakespeare's fortune: why copyright has failed authors and how it might be reformed*, PhD thesis, ANU.

[17] See Australian Senate Select Committee AUSFTA report, ch 3.

[18] This and other submissions on the proposed Australia-EU treaty are at https://www.dfat.gov.au/trade/agreements/negotiations/aeufta/submissions/aeufta-submissions.

Trademarks

Trademarks are quite different from other forms of IP. Their origin is far older and they serve to protect both the interest of producers (so that competitors could not use the same identifying mark) and consumers (so that they could readily know from whom they were buying). In 1857, the French introduced a system of trademark registration, which made it easier for producers to challenge competitors who were falsely using a given mark. This registration system was quickly adopted in England. Originally registered marks could only be 'fancy' (made up) words as all producers had the right to use the full range of existing words.[19] If a fancy word came into common use – e.g. escalator, vacuum – then the trademark was cancelled. This provision no longer seems to apply in most jurisdictions (e.g. google remains a trademark).

While initially a trademark was only a single word, it has since extended to take in logos (graphics), phrases, colours, smells and sounds and, most recently, movements.

All recent EU treaties affirm two existing international trademark treaties and protocols (Geneva 2004 and Singapore 2006). Additionally the Vietnam and Canada treaties refer to the Madrid Protocol and the Vietnam treaty refers to the Nice classification system. The proposed text for Australia mirrors the Vietnam treaty in covering all four of these agreements. All treaty texts also have an article on exceptions to trademark rights. The EU's five recent trade treaties simply provide for fair use of descriptive terms and unspecified limited exceptions, as long as the interests of trademark owners and third parties are taken into account. The proposed text for Australia has additional text identifying other trade labelling that trademark ownership cannot prevent (Article XX.22(2) and 22(3)).

Except for the Japan treaty, all texts cover registration procedures (reasons for refusal in writing with appeal option; opposition to grant processes; and electronic databases).[20] Three of the EU's recent treaties have an article concerning recommendations on well-known marks adopted by WIPO in 1999. In the Singapore and Vietnam treaties parties will "give consideration to" these; in the Japan treaty the parties "affirm the importance" of these; and in the proposed Australia text parties "shall apply" these recommendations.

The Vietnam and Japan treaties have articles on the rights conferred by a trademark, and so does the proposed Australian text. The Vietnam treaty has an article on revocation, and so does the proposed Australian text. There are two new articles in the proposed Australian text – one specifying the signs of which a trademark may consist and the other dealing with bad faith applications.

Geographical Indications

Geographical indications (GIs) were introduced in the TRIPS treaty, at the insistence of the EU, but the EU has never accepted the compromise that was the TRIPS outcome. Since 2006 it has pushed strongly for acceptance of its GI agenda in

[19] See W Kingston, 2010, *Beyond Intellectual Property: Matching Information Protection to Innovation*, Cheltenham: Edward Elgar: 25-41, for an excellent discussion of the emergence of the trademark system.

[20] The sole variation is the lack of an appeal process in the Vietnam treaty.

all its trade treaties. The ANUCES has undertaken considerable analysis of GI policy elsewhere.[21] The EU's specific proposals for adoption of a tailor-made GI system in the proposed Australian treaty are discussed in detail in a companion ANUCES Policy Note.[22]

The Business Council of Australia (BCA), in its submission to DFAT, does not address IP issues except for GIs. Here it says "A-EU FTA negotiations should avoid concessions on geographic indicators and instead reach outcomes in other areas of the negotiations that represent win-win outcomes for both sides. Geographic indicators should be subject to strict, delineating principles." The BCA considers that GIs are a consumer protection issue, not an IP issue. The Law Council of Australia has also recommended to DFAT that it not accept the proposed GI text, as current Australian laws are adequate and no justification has been provided for extending TRIPS Article 23 provisions.

Miscellaneous IP issues

In respect of designs, IP Australia has undertaken a consultation on joining the Hague Agreement Concerning the International Deposit of Industrial Designs, and concluded that the costs of doing so would outweigh the benefits. The Law Council considers that Australia should become a signatory, which would increase the length of design protection from 10 to 15 years. But it disagrees with the EU's proposed further extension to 25 years (Article XX.27).

In respect of plant variety rights, the single proposed article calls for cooperation to *promote* enforcement of the 1991 version of the International Convention for the Protection of New Varieties of Plants (UPOV). UPOV is highly controversial and there are those who recommend re-opening the 1978 version of UPOV, as this better meets the needs of some lower income countries.[23]

There are two complex articles proposed in respect of trade secrets. Trade secrets are not covered by TRIPS, so these TRIPS-Plus proposals should be subjected to careful domestic review before any consideration is given to signing away flexibilities through trade treaties.

Enforcement

Enforcement (including border measures) provisions dominate IP chapters in EU treaties. They provide 25% of the articles in the Japan treaty (12 of 48) and the proposed Australia treaty (15 of 61). In the Canada treaty they are 41% (18 of 44) and in the Japan treaty 42% (27 of 65).

Although the proposed text states that enforcement should be effective and proportionate (Article X.48), the remaining articles are almost exclusively about meeting the needs of IP rights-holders. There is a single protection for non-commercial infringement by individuals (Article X.61(10)). There are few balancing measures for those accused of infringement.

Normally border control measures apply only to counterfeit trademarked goods or unauthorised copyright material. However the text extends this to patents. Patent infringement is a highly complex issue and alleged patent infringement can only be determined after detailed legal investigation. There are no remedies for when IP rights are abused. The Law Council, in its submission to DFAT, notes that the proposed text would require changes to four statutes.

One wonders why it is necessary to have 15 articles on enforcement and border control measures. Both Australia and the EU have long been advocates of strong enforcement of IPRs.[24] Given the deficiencies in the proposed text, and the lack of any demonstrated need for further action in this area, it would be better for these 15 articles to be deleted.

Checks and balances

What this Policy Note reveals is the tension between protecting the interests of inventors and creators and those of consumers and the public. It also reveals that international co-operation, including through trade negotiations, has been a vehicle for shifting the balance in IP towards the needs of rights holders.

TRIPs has no exceptions to its most favoured nation clause, and IP provisions in trade treaties are often implemented through changes to domestic law. Great care is needed to ensure that any such changes do not further restrict the use of inventions and created material. Competition is as important for the spread of innovation and creativity as IPRs. Within the EU domestically there are checks and balances, at least with respect to some forms of IP. But the EU has a track record of exporting only those elements which are of interest to rights holders.[25] Australia would do well to negotiate dropping the proposed IP chapter in its entirety.

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[21] See Á Török and H Moir, Understanding the real-world impact of GIs: A critical review of the empirical economic literature, ANUCES Briefing Paper, Vol.9, No.3, July 2018, and two webinars available at https://tinyurl.com/ANUCES-GI-webinars.

[22] H Moir, Regulatory systems for geographical indications, ANUCES Policy Note 5, 2020; tinyurl.com/ANUCES-Policy-Notes.

[23] See, for example, G Dutfield, 2011, Food, Biological Diversity and Intellectual Property:The Role of the International Union for the Protection of New Varieties of Plants (UPOV), Quaker UN Office, Global Economic Issue Publications, IP Issue Paper Number 9.

[24] And both were advocates for failed Anti-Counterfeiting Trade Agreement (ACTA), which was rejected by the European parliament (478 votes against, 39 for and 165 abstentions).

[25] J Drexl, H Grosse Ruse-Khan, and S Nadde-Phlix, 2014, *EU bilatral trade agreements and intellectual property: for better or worse?*, Heidelberg: Springer: 265-291.