The price of market access: patents in AUSFTA and since

Abstract: New generation trade agreements reach far behind borders, affecting many areas of domestic policy not previously associated closely with trade. One of the most uneasy of these areas is intellectual property, particularly patent monopolies. The USA has been a major force behind the extended reach of patent monopolies using preferential trade agreements. The patent and data exclusivity provisions of the AUSFTA were proposed by the USA. This paper provides detailed evidence about how such 'TRIPS+' policies compare to a balanced patent policy – one equally favouring creators and users of technology. Australia has never had an active patent agenda, but since AUSFTA has been willing to accept in its bilateral and regional trade deals highly prescriptive rules that tie the hands of future governments. The overall trend has thus been towards increasing imbalance, with Australian patent policy now having a very broad reach and very low eligibility standards. This particularly affects the cost of medicines, where large numbers of relatively uninventive patents surround a blockbuster drug and delay the market entry of generic alternatives. In addition to outlining the costs of Australia’s current patent policy approach, the paper concludes by highlighting a more balanced and less costly way forward.

Keywords: patents; trade policy; innovation policy; AUSFTA; TPPA

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Introduction

AUSFTA is a new generation comprehensive trade agreement that goes well beyond tariffs and tariff barriers. The new agenda items were mostly proposed by the USA, which had already negotiated several such agreements. For Australia it was newer territory. Some of the non-trade items – such as greatly extended copyright terms and linking patents with data protection – were highly controversial. There was less public discussion of the patent provisions.

Patent monopolies sit uneasily in a free trade context as patents, by their nature, are anti-competitive. Yet, in a remarkable feat of negotiation, intellectual property policies were tied to free trade treaties as a result of the new single undertaking in the 1994 Marrakesh Agreement (which established the WTO). The WTO’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was largely proposed by a small number of global companies whose profits were highly dependent on copyright and patent policy (Drahos 2002; Sell 2003). These interest groups failed to achieve their full agenda in TRIPS. Shortly after the conclusion of the Uruguay Round, the US began negotiating a series of preferential trade agreements, all including substantially greater provisions on patents (Drahos 2001; Sell 2011). These agreements cover only a small proportion of US trade, and are mostly with small or low income countries. The most significant of these is AUSFTA. Although Australia counts for only one percent of US trade, its status as a long-established high-income country was important for legitimizing the US patent agenda.

The purpose of this paper is to assess the AUSFTA patent and data protection provisions against the background of the kind of patent policy that would most benefit Australians and Australian inventors.

TRIPS mandates that the needs of both creators and users of technology be balanced in a manner that benefits society as a whole (Article 7). However the proponents of the TRIPS+ patent agenda represent only the interests of patent holders. The language in which their pro-patent proposals is couched conflates the new proposed standards with increased innovation, invention and economic prosperity (Neuwelt et al. 2015). Evidence for such a relationship is at best varied and contingent. Yet the official Australian website claims unambiguous benefits from “a strong
intellectual property regime".\(^2\)

Australia was a “friend of intellectual property” in the Uruguay Round negotiations which led to TRIPS. The reasons are unclear. The rational position for a country with Australia’s negative balance on licensing fees and royalties\(^3\) would be to oppose any broadening of the patent system. The Department of Foreign Affairs and Trade (DFAT) has never justified the position Australia took and still appears not to understand that changes to the patent system impact on the economy as a whole (Productivity Commission 2010: 262-264). Given ample warnings about the potential negative impacts of intellectual property provisions from the nation’s expert body, it would seem that, on patent-related issues, DFAT suffers more from a case of ‘willful blindness’ than from ‘failure to understand’.

The paper proceeds with a brief discussion of the key elements of a balanced patent policy – one that aims to provide incentives for useful new technology that would not otherwise not occur, without impeding other inventors or creating higher than necessary costs. This is compared with the patent policy prescriptions which Australia promoted as a friend of TRIPS. In section 3 the patent and data protection provisions of AUSFTA are discussed and compared with balanced provisions and the TRIPS provisions. The AUSFTA patent policy changes are then traced through subsequent Australian trade agreements (Section 4). The paper concludes with a discussion of the implications of unbalanced patent policy and a consideration of whether the Trans Pacific Partnership (TPP) negotiations will see yet further imbalance.

**Balanced patent policy and the TRIPS Agreement**

The patent system is complex, rife with specialized language, and many ordinary words take highly specialised meanings. These factors operate to exclude many analysts from attempting to understand the patent system. But its essence is very simple. It is a bargain between society and inventors to provide 20-year monopolies in exchange for beneficial new knowledge. The underlying assumption is that the benefits from the new knowledge (dynamic efficiency gains) will exceed the losses from reduced competition (static efficiency losses).

Because the patent incentive operates by stopping other inventors from exploiting their independent inventions, it needs to be designed carefully.\(^4\) An efficient patent system would grant patents only to those inventions which would not have occurred without the patent incentive and which provide sufficient social benefit to offset the losses from granting the monopoly. Both qualifiers are important and warrant further explanation.
Would not otherwise occur: It is self-evident that if someone would create and commercialise an invention without a patent, then no patent should be granted, because of the negative impact of the patent monopoly on other inventors. There is substantial evidence that most industrial inventions would be developed and commercialised without patents (López 2009). Despite this, US courts have led a move to grant patents for previously unpatentable things – particularly software and genetic discoveries. Although the US Supreme Court is now indicating that this has gone too far and should be wound back, US trade negotiators continue to run with an expansionary agenda.5

Patents are most likely to be needed where research and development costs are high and the resulting product is simpler and easier to copy. In such situations competitors can quickly enter the market, pricing below the original product as research does not have to be undertaken. The prime example is pharmaceuticals and other fine chemicals. It is not surprising then to find that it is the pharmaceutical industry which is driving the patent and data protection provisions in preferential trade agreements.

Provide net benefits to society: But even for pharmaceuticals, granting a monopoly only makes sense if the benefits exceed the costs. Clearly this is the case for entirely new drugs which deliver a substantial health benefit. It is less clear for ‘me-too’ drugs, though there can be improvements in health outcomes with the development of alternative versions of genuinely new drugs. It is questionable, however, whether there is any societal benefit in granting a patent to an umpteenth version of a low-dose combination oral contraceptive, such as Bayer's patent for a contraceptive sold in Australia as Yaz.6 Yet in April 2013 the Federal Court of Australia upheld such a patent.7 And it is certain that the social cost of the many minor patents surrounding a blockbuster drug – delaying generic competition – more than exceeds any benefits. Such evergreening patents take the form of new doses, formulations, combinations, or uses and are a key component of pharmaceutical lifecycle management, substantially increasing profits at the cost of consumers and taxpayers (Moir and Palombi 2013). The limitations and costs of Australia’s current patent policy approach are discussed in greater detail below. Suffice to note here the importance of achieving a balanced patent policy. While there are many other aspects to such a policy (Moir 2014), the three most important elements are:

- limiting patents to inventions which would not otherwise occur
  (proxied by a technology limit, which partly aligns with high development costs);
- ensuring that real inventiveness is required
(as this is a proxy for the societal benefit of new knowledge); and

- limiting privileges to sale in the market where the patent holds
  (to minimize unnecessary damage to competition).

As we will see, the TRIPS agreement, while not perfect, left countries significant scope to pursue a balanced patent policy approach.

**The TRIPS Agreement**

TRIPS was one of the most contentious aspects of the Uruguay Round trade negotiations. Partly as a result of this, the treaty has a certain degree of balance, incorporating safeguards such as an objectives statement. Article 7 reads as though it was written particularly for patent policy:

> “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” (TRIPS Article 7).

Most patent systems fail this standard. Their inventiveness standard is so low that many granted patents deliver only costs not benefits (Moir 2013b). By ignoring the technology limitation, they grant patents that would have occurred anyway. A plethora of complex rules tilt the whole system in favour of patent grant (FTC 2003: 8).

One policy element that is fundamental to ensuring balance in a patent system is limitation to technology. This premise is so basic that it has rarely been written down. Its absence has allowed courts, both in the USA and in Australia, to broaden the scope of patent policy in ways that were never envisioned by lawmakers and have never been subjected to any evidence-based analysis. Key business participants in the advisory structures of the Office of the US Trade Representative gain considerable profits from the extension of patents to non-technology areas such as software, and TRIPS+ patent proposals often embody such extensions.

This is in contrast to the clear language in TRIPS that allows countries to limit patent policy to technological inventions. Indeed TRIPS clearly specifies that software developments should be granted copyright protection (Article 10). TRIPS allows countries the sovereign right to limit patents to technological inventions. It also allows other exclusions from patentability – diagnostic and other methods for the treatment of humans or animals; and plants and animals.

By strongly enforcing the limitation of patents to technological inventions, a patent system can approximate a limitation to inventions with high development costs – those which would not occur in the absence of patents. This increases the efficiency and effectiveness of a patent system.
and acts to reduce unbalanced outcomes.

TRIPS also allows full flexibility in implementing the compulsory patentability criteria of novelty, inventiveness and utility. Where there is not a direct benefit, such as improved health outcomes, it is the new knowledge or know-how embodied in a patented invention which is the principle benefit society gains to offset the monopoly costs. A high inventiveness standard acts to limit unnecessary monopolies, which incur costs but provide no benefits.

A high inventiveness standard does nothing to disadvantage businesses who are at the forefront of new technology developments. Genuine inventions would have patent protection but rent-seeking would be substantially reduced. A high standard would radically reduce the volume of patents granted for trivial ‘inventions’, including evergreening pharmaceutical patents, This would substantially improve the efficiency and effectiveness of the patent system. As over 90 per cent of Australian patents are granted to foreign entities, such a change would have an unambiguously positive outcome both for Australia and for Australian inventors.\(^{10}\)

There is one major area where TRIPS presents an impediment to achieving balance in a patent system. TRIPS mandates a very broad range of privileges for patent holders. WTO compliant patents allow the holder to prevent third parties from “making, using, offering for sale, selling, or importing for these purposes” the patented item. Such sweeping privileges widen the anti-competitive effects of patent systems and go well beyond the incentives needed to induce inventions which would not otherwise occur.

In respect of compulsory protections for clinical trial data, TRIPS allows WTO members substantial flexibility. Article 39 allows for protection for undisclosed (clinical trial) information used to gain marketing approval for pharmaceuticals. This article is broadly worded, allowing countries room to determine what arrangements best suit their economy and society. The key term “unfair commercial use” is capable of widely differing interpretations.

**AUSFTA provisions on patents and data exclusivity: enshrining imbalance**

Australia did not enter into any post-WTO preferential trade agreements until the early 2000s. It then negotiated three agreements almost simultaneously. These were the Thailand Free Trade Agreement (TAFTA), the Singapore Free Trade Agreement (SAFTA) and AUSFTA. The TAFTA agreement differs substantially from SAFTA and AUSFTA in respect of intellectual property (IP) provisions. The TAFTA IP text is just two pages, imposing no new obligations on either party.
This contrasts strongly with the IP provisions in both SAFTA and AUSFTA, which are long and contain considerable prescriptive detail. The USA’s FTA with Singapore entered into force on 1 January 2004, and it seems probable that the very different IP chapter in SAFTA was directly influenced by what Singapore had already agreed with the USA. As will be seen below, most recent preferential Australian trade agreements also follow the new detailed and prescriptive US pattern. This new Australian pattern has clearly been strongly influenced by US policy. Weatherall (2015, this volume) has pointed out that AUSFTA marks a break in the Australian approach to negotiating copyright. It also marks a radical change in Australia's approach to patents in trade treaties.

While the provenance of these new provisions was American, Australia had no active patent policy position to fall back on in responding to them. Domestically there has never been an economic review of the patent system. Even with the major changes consequent on TRIPS, no review was undertaken, and the government has thus fallen back on the simple position that if a proposal does not require any legislative amendment, then it is unproblematic. This ignores the substantial evidence available that the current design of the patent system, both in Australia and in the USA, is in urgent need of reform. The current design does not serve the needs of either Australian inventors or Australian consumers (Moir 2013a).

Against this background, ready acquiescence to eliminate all future reform possibilities is concerning. The recent Competition Policy Review has recommended an overarching review of intellectual property, including principles underlying the inclusion of IP in trade agreements and how any such negotiating mandates should be established (Harper et al. 2015: 41). Highly prescriptive regulations in international treaties severely limit the scope for such much-needed domestic reform.

AUSFTA deals with patent issues in a single article (Article 17.9), with 15 sub-sections and multiple sub-sub-sections (Table 1). It starts with the very unbalanced requirement that patentable inventions must now include “any new uses or methods of using a known product”. The TRIPS exclusion of plants and animals is dropped. Both provisions re-appear in the TPP negotiations. Neither required any policy change in Australia, but both are symptomatic of an unbalanced system.

Where a product has been previously patented it has been provided with the right of preventing all commercial uses of that product for up to 20 years. This includes preventing all methods of commercial use. So a new patent for a specific use of a known thing is double-dipping. It
supports evergreening – pharmaceutical patents for ‘inventions’ such as new forms, dosages and methods of use of known compounds. They have very low levels of inventiveness but can substantially delay generic competition (Moir and Palombi 2013). Such patents are unlikely to provide any health improvements. But they do radically increase the cost to Australian taxpayers and consumers through the delayed entry of generic pharmaceuticals. Writing these domestic regulatory details into an international treaty ties the hands of future governments with respect to options for patent reform.

As noted above TRIPS provides extensive privileges to a patent holder. AUSFTA further extends these (Table 1). AUSFTA prevents parallel importation, specifically limits the use of patent information before patent expiry to a single ground and provides patent term extensions to offset delays in both patent processing and marketing approval. None of these limitations are in TRIPS.

While TRIPS provisions on compulsory licenses (CLs) are extensive, they are not highly prescriptive. The AUSFTA provisions substantially narrow the range of circumstances when CLs can be used. The AUSFTA text removes anti-competitive conduct as a ground for revoking a patent. This text has no effect, as a side letter allows revocation due to anti-competitive conduct as long as this follows a judicial proceeding. This approach of writing details into treaty text, but then negating them though separate documents allows the text to be used to demonstrate commitments which have not actually been made. In agreeing to this deceitful strategy, Australia provides support to the US to broaden agreement to a limitation which it will not itself agree.

AUSFTA covers many other patent matters on which TRIPS is silent. These are both procedural (grace periods and amendments), and substantive (full disclosure and fair basis). AUSFTA mandates the US definition of 'utility' – this “specific, substantial and credible” approach is contentious (Thambisetty 2009). Finally, AUSFTA contains commitments to reduce differences in law and practice, participate in international patent harmonisation efforts and establish a framework to progress towards mutual exploitation of search and examination work.

Prior to AUSFTA, Australia already had a very unbalanced patent system, strongly favouring the interests of patent-holders over consumers and other users of technology. The breadth of the patent system had been widened through judicial action; the very low inventiveness standard fell further, again due to judicial action (Lawson 2007); and granted privileges were extensive, particularly for pharmaceuticals. In other words the Australian patent system was very like that in the USA. By writing bad policy into an international treaty, AUSFTA substantially increases impediments to much-needed reform in both Australia and the USA.
Patent law harmonisation is superficially appealing. But in practice it simply seeks to extend anti-competitive laws globally without any evaluation of their impact on innovators (Kingston 2004). The provisions are highly detailed and prescriptive, amounting to heavy-handed over-regulation, limiting innovation, improvement and responses to future changes. As Weatherall (2014) has shown for the copyright provisions, such over-prescription can have negative impacts. The texts contain nothing about agreed outcomes, as is now the norm in efficient and pro-innovation regulation.

Data protection is another area in which the AUSFTA entrenches an imbalanced patent system. TRIPS provides protection for clinical trial data.\[^{15}\] Article 39 allows substantial room for countries to determine what arrangements best suit their economy and society. In particular countries are free to define what constitutes “unfair commercial use.”

In contrast AUSFTA mandates a strict 5-year protection from competition for “undisclosed test or other data concerning safety or efficacy” used as a basis of marketing approval. This broadens the range of data protected and eliminates the option of exceptions and flexibilities. The AUSFTA wording – a new product that does not contain a chemical entity previously approved for marketing – allows more products to claim the 5 years of marketing data protection than was possible under TRIPS. The relevant US industry advisory body (IFAC-3) notes this wording change as a victory.\[^{16}\]

AUSFTA not only strengthens data protection for new pharmaceuticals. It also mandates three years of market protection where a regulatory authority requires additional data for approving a product other than a new product. This effectively extends data protection to variations to already launched drugs. AUSFTA specifically states that the data protections apply even where underlying patents have expired.

The data that must be protected are data that demonstrate whether or not a product is safe and more efficacious than a placebo. As it would be unethical to require generic manufacturers to undertake duplicate clinical trials,\[^{17}\] limiting their use by other parties has the effect of potentially delaying generic entry to the market. In many ways this government benefit provides a more robust support to pharmaceutical profitability than do patents. Patents can be challenged in court, but data protection provisions cannot.

The final provisions of Article 17.10 extend the impact of data protection by introducing “patent linkage” to Australia. First developed in the USA in 1984, patent linkage provisions have the effect of turning the drug safety authorities into an arm of patent enforcement and placing
obligations on generic entrants to notify patent owners of their planned entry to the market.

**Other Australian trade agreements: amplifying imbalance**

Since 2003 Australia has concluded preferential trade agreements with Singapore, Thailand, the USA, Chile, Malaysia, ASEAN and New Zealand, Korea and Japan. An agreement with China has been announced, but at the time of writing no details about content were available.

All these preferential agreements are 'comprehensive' – they deal with matters well beyond trade and investment. All have IP provisions. These generally focus on copyright, especially in an electronic context; trademarks; enforcement of copyrights and trademarks; and general cooperation. Only a few address patent and data protection policy.

Some address relatively minor patent matters – such as grace periods and classification systems, while others address important issues of balance such as opposition and revocation procedures (see Table 1).

Of more importance in achieving balance in patent policy are opposition and revocation provisions, requirements about what must be granted patents, and full disclosure. Korea – which also has an FTA with the USA – repeats the AUSFTA requirement to grant patents for “any new uses or methods of using a known product”, thus extending the breadth of the patent system. As with AUSFTA, KAFTA limits the grounds for revocation of a patent, and specifies the details for full disclosure. Again the hand of the US is evident in these provisions. The Chile agreement simply allows for both revocation and opposition. Such procedures are critical elements of balance, allowing well-funded competitors to challenge patent which should not have been granted.

The Malaysia Australia Free Trade Agreement (MAFTA) includes a major TRIPS+ issue that goes beyond the AUSFTA provisions or anything yet demanded by the USA: the introduction of presumptive validity for patents. Presumptive validity creates a higher threshold of proof for anyone wanting to challenge the validity of a patent. This provision is despite the fact that the Australian patent statute specifically states that a patent granted in Australia cannot be presumed valid. As DFAT claims to work on the basis of current domestic policy in negotiating IP provisions this commitment is astonishing. In the USA the presumption of patent validity has been a major impediment to the challenge of patents with very little inventiveness (Jaffe and Lerner 2004). The fact that this presumption does not exist in Australia is one of the few remaining elements of balance in Australia's patent system. It may be that DFAT was not
made aware of this statutory provision. No steps have yet been taken to make the necessary legislative amendments, though MAFTA came into force in 2013.

**Implications, including for the TPP, and alternative ways forward**

One of the most important facts about free trade is that it is *domestic* reforms which deliver the most benefit; improved market access is a minor gain to very limited sections of the community.\(^{19}\) The reason is that domestic reforms increase competition and so reduce costs across the board, benefitting consumers and businesses alike. Tariff barriers act to increase prices. It has been repeatedly documented that the national cost of supporting an industry through tariff barriers is substantially greater than the national cost of supporting the same level of industrial activity through direct subsidies.\(^{20}\)

Recent analyses of the impact of pharmaceutical product patents show that patents operate very like tariff barriers. They protect producer monopolies with consequent high prices. There are three recent economic studies with show that, as with tariffs, it would be far cheaper to directly subsidise pharmaceutical research than to grant them patents.

Branstetter and colleagues (2011) estimate the consumer surplus generated in the USA by policies which facilitate early generic entry to the pharmaceutical market.\(^{21}\) They estimate consumer gains at around US$92 billion, and producers losses at some US$14 billion. Clearly the price paid by consumers is far greater than the benefit received by producers. The USA would benefit considerably if it reformed its patent system to minimise evergreening and ensure early generic competition. If the pharmaceutical industry needed support, a direct subsidy would be cheaper and more efficient.

The evidence base for this finding extends beyond the US experience. Chaudhuri and colleagues (2010) and Dutta (2011) both investigate the impact of introducing chemical product patents in India. Chaudhuri and colleagues use data on quinolones (broad spectrum antibacterial drugs) also finding that consumer effects substantially exceed producer effects. The welfare loss from product patents just for quinolones is US$144 to 450 million annually while gains to the subsidiaries of foreign firms are just US$20 to 53 million. With net losses of US$124 - 397 million annually, pharmaceutical product patents are clearly an expensive proposition. Dutta uses data for a cross-section of drugs in the Indian pharmaceutical market and finds an average price increase of 42 percent. This generates a consumer welfare loss of US$378m (an average loss of US$9 million per drug). In contrast the benefit to patent rights holders is just $1.4 million per
While these three studies focus on only one aspect of patent policy they demonstrate clearly that the social cost of patent policy is both absolutely high and substantially higher than the cost of alternative more efficient policies. The gains to producers are between an eighth and a sixth of the cost to consumers. As with tariff barriers, it would be far more efficient to directly subsidise pharmaceutical production than to grant product patents. It is deeply ironic, therefore, that such patent monopolies are required as part of the WTO’s ‘free trade’ suite of agreements.

It was powerful lobby groups who played the key role in establishing global norms on patents (Drahos 2002; Kingston 2004; Sell 2003). They are direct beneficiaries of the system they were instrumental in establishing. They also play a key role in further tilting patent policy through post-2000 preferential trade agreements (Drahos 2001; Sell 2011).

Of 27 TRIPS+ changes to patent policy agreed by Australia in preferential trade agreements, 21 were first introduced in the AUSFTA (Table 1). Two of these might be of benefit to users of new technologies, depending on how they are implemented. These are changes to the disclosure requirements and the requirement for pre- or post grant opposition processes. Depending on how the public education provisions operate, they may solely benefit rights-holders or they may also address user concerns. The other 24 changes all operate in the interests of patent owners.

Two of the TRIPS+ provisions extend the reach of the patent system, requiring patentability for things that did not have to be patented under TRIPS.

Others provide for even more extended patent owner privileges. AUSFTA provisions reduce competition during the patent term (by eliminating the right of parallel importation), restrict use of patent information before expiry, further limit use of compulsory licenses (in itself a rare event), extend patent terms (in specific circumstances) and create far stronger data exclusivity provisions. Together these add to a significant delay in the entry of competitors into the market.

Estimating the welfare impact of delayed competition requires access to substantial data, not generally available. We do however have some indirect evidence on the issue – the behaviour of innovating Australian firms with respect to patents. In 2004-05 the Australian National Innovation Survey showed that 34 per cent of Australian firms were innovating (Australian Bureau of Statistics 2007: 12). About 2,100 firms were introducing "new to the world" innovations, and about 2,800 firms "new to the Australia" innovations. It is these firms that might be expected to own patents. If all reported patent use is among such innovators, then about one in
five such firms use the patent system. Patent use is more frequent in large than in smaller innovating firms. The Australian patent system is also extensively used by overseas entities – consistently, year after year, about 92 per cent of granted Australian patents are owned by overseas entities.

A final set of TRIPS+ provisions encourage co-ordination and harmonisation of patent systems, including administrative sub-systems such as search and examination. But the system that is being harmonised is unbalanced and inefficient. In a major review of the US patent system in 2003, the US Federal Trade Commission (2003) concluded that it needed major reform. This view is supported by substantial evidence-based economic analysis, focusing particularly on problems arising from the low inventiveness requirement and the extension of patents to fields that were previously unpatentable (notably software and generic discoveries).

By bringing current low patentability standards into the AUSFTA and agreeing to a wide range of increases in the privileges granted to patent holders the Howard Government limited the capacity of all future governments to reform the patent system. The data exclusivity and patent linkage provisions created new policy, solely of benefit to patent-holders, and with direct implications for the cost of pharmaceuticals to Australians, including taxpayers.22

Few of the TRIPS+ provisions in the AUSFTA are reflected in Australia's other preferential trade agreements (Table 1). The most frequent patent-related matters in Australia's other agreements are 'education' and co-operation (especially with respect to search and examination). There is also a trend towards establishing oversight committees.

The AUSFTA text was largely written by the USA. The leaked IP text of the proposed TPP23 reflects US authorship too, with the hand of the pharmaceutical industry clearly evident. Many of the provisions in the AUSFTA are evident in the draft TPP (see Table 2). The TPP thus attempts to broaden the number of nations agreeing to TRIPS+ provisions, but with a more demanding agenda than AUSFTA. This ratcheting down of patent standards to even lower levels of inventiveness is clear in the US and Japanese proposal that patents may not be denied solely because they do not "result in enhanced efficacy of the known product" (Article E.1(a)). This wording is clearly designed to remove limits to pharmaceutical patents such as that used in Section 3(d) of the Indian Patent Act.24 This wording clearly indicates that – all protestations to the contrary – the standard for patent grant is far too low.

The TPP also seeks to extend the monopoly privileges granted to patent owners, with all but two of the extensions in the AUSFTA re-appearing in the TPP (Table 2).25 Some of the moves towards
greater harmonisation that were evident in the AUSFTA also re-appear in the TPP. But of the six items that appear in Australia's other agreements (items 22 to 27 in Table 1) only two appear in the TPP. Again this provides evidence of the key role played by the USA in drafting the provisions in all such treaties.

The patent system operates by making the dissemination of new technology more expensive, including by preventing independent invention. It is therefore critical that patent policy be as parsimonious as possible – that patents are only granted where needed and where there is a net benefit. This is far from the case in any patent system in the world. There are many interests lined up against reforming the patent system to focus on the job it is meant to do – encourage inventions with positive spillovers that would not otherwise occur. Harmonisation simply makes the already hard job of patent reform even harder. It ties the hands of future governments limiting their room for effective reform of domestic law. The simplistic view of many of IP negotiators that there is no harm in agreeing to provisions which simply mirror current practice is based on the entirely false premise that the current system is worth preserving forever. In Australia, an immediate pause on harmonisation efforts to allow a thorough review of the current system is the first step towards nationally beneficial reform. While TRIPS mandates a patent system, it also requires that it be balanced. A patent review might take as its starting point the breadth of the system and the inventiveness requirement – both substantially increase the costs of a patent system without providing any discernable benefit to Australian inventors and innovators.
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<thead>
<tr>
<th>Provision</th>
<th>AUSFTA Article 17.</th>
<th>Other</th>
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<td>9.1 KAFTA</td>
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<td>2  “plants and animals other than micro-organisms” not mentioned as excludable from patentability</td>
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<td>9.2 KAFTA</td>
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<td>3  Parallel importation not allowed (national exhaustion)</td>
<td></td>
<td>9.4</td>
</tr>
<tr>
<td>4  Bases for revoking or cancelling patents narrowed</td>
<td></td>
<td>9.5 Chile; KAFTA</td>
</tr>
<tr>
<td>5  Limitation on use of patent data before expiry to marketing approval applications</td>
<td></td>
<td>9.6</td>
</tr>
<tr>
<td>6  Limiting grant of compulsory licenses</td>
<td></td>
<td>9.7</td>
</tr>
<tr>
<td>7  Term extensions for regulatory delays</td>
<td></td>
<td>9.8b</td>
</tr>
<tr>
<td>8  Term extensions for examination delays</td>
<td></td>
<td>9.8a</td>
</tr>
<tr>
<td>9  Strict 5 year new product data exclusivity</td>
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<td>10.1</td>
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<td>10 Extension of data exclusivity from undisclosed to other data</td>
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<tr>
<td>11 Additional 3 years data exclusivity for any product where marketing authority requires new data</td>
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<td>10.2</td>
</tr>
<tr>
<td>12 Drug approval authority to play role vis-à-vis patents</td>
<td></td>
<td>10.4</td>
</tr>
<tr>
<td>13 Onus on generic manufacturers to advise brand companies when entering market</td>
<td></td>
<td>10.4</td>
</tr>
<tr>
<td>14 12 month grace period</td>
<td></td>
<td>9.9 Chile; KAFTA</td>
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<tr>
<td>15 Amendments: at least once</td>
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<td>9.10 JAEPA*</td>
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<tr>
<td>16 Full disclosure “without undue experimentation” requirement</td>
<td></td>
<td>9.11 KAFTA</td>
</tr>
<tr>
<td>17 Fair basis: disclosure “reasonably conveys”</td>
<td></td>
<td>9.12 KAFTA</td>
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<tr>
<td>18 Use US “specific, substantial and credible” utility criteria</td>
<td></td>
<td>9.13</td>
</tr>
<tr>
<td>19 Reduce differences in law and practice</td>
<td></td>
<td>9.14</td>
</tr>
<tr>
<td>20 Participate in international harmonisation</td>
<td></td>
<td>9.14</td>
</tr>
<tr>
<td>21 Framework for mutual use of search and examination results</td>
<td></td>
<td>9.15 Malaysia; JAEPA</td>
</tr>
<tr>
<td>22 Pre-and/or post-grant opposition</td>
<td></td>
<td>Chile</td>
</tr>
<tr>
<td>23 Use patent classification system</td>
<td></td>
<td>Chile</td>
</tr>
<tr>
<td>24 Granted patents to be “presumptively valid”</td>
<td></td>
<td>Malaysia</td>
</tr>
<tr>
<td>25 Co-operate on / streamline administration</td>
<td></td>
<td>Thai; AANZFTA; JAEPA</td>
</tr>
<tr>
<td>26 Co-operate on “IP” education</td>
<td></td>
<td>SAFTA; Thai; AANZFTA; JAEPA</td>
</tr>
<tr>
<td>27 Oversight committee</td>
<td></td>
<td>AANZFTA; KAFTA; JAEPA</td>
</tr>
</tbody>
</table>

Notes: # Most of these agreements refer to TRIPS and up to 14 other international “IP” treaties
* and provide reasons for refusal.
### AUSFTA patent provisions also appearing in the 2014 draft TPPA

<table>
<thead>
<tr>
<th>Substantive provisions</th>
<th>US TPPA ask</th>
<th>Opposed by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisions affecting what can be patented: “any new uses or methods of using a known product” to be patentable</td>
<td>E.1.4 (AU,JP)</td>
<td>CL/My/PE/SG/VN/BN/NZ/CA/MX</td>
</tr>
<tr>
<td>“plants and animals other than micro-organisms” not mentioned as excludable from patentability If &quot;other than microorganisms&quot; added fewer countries oppose</td>
<td>E.1.3 (JP, SG)</td>
<td>AU/NZ/VN/BN/CL/PE/My/SG/CA/MX</td>
</tr>
<tr>
<td>Provisions affecting patent privileges: Removal of anti-competitive conduct as a ground for revoking or cancelling patents</td>
<td>E.3 (JP)</td>
<td>CA/CL/MX/BN/My/AU/VN/NZ/SG</td>
</tr>
<tr>
<td>Limitation on use of patent data before expiry to marketing approval applications</td>
<td>E.13</td>
<td>Unclear and contentious</td>
</tr>
<tr>
<td>Term extensions for regulatory delays</td>
<td>Annex (E.14) ##</td>
<td>Unclear and contentious</td>
</tr>
<tr>
<td>Term extensions for examination delays</td>
<td>E.12 (SG)</td>
<td>CA/NZ/VN/CL/PE/MX/BN/AU/BN</td>
</tr>
<tr>
<td>Strict 5 year new product data exclusivity Additional 3 years data exclusivity for any product where marketing authority requires new data “undisclosed test or other data”</td>
<td>Annex (E.16) ##</td>
<td>Unclear and contentious</td>
</tr>
<tr>
<td>Drug approval role vis-à-vis patents (patent linkage)</td>
<td>Annex (E.17) ##</td>
<td>Unclear and contentious</td>
</tr>
<tr>
<td>Notification to originator companies before generic entry</td>
<td>Annex, E.17</td>
<td>Unclear and contentious</td>
</tr>
<tr>
<td>Full disclosure “without undue experimentation” requirement</td>
<td>E.8 (AU/PE/VN/JP)</td>
<td>CL/My/BN/NZ/CA/SG/MX</td>
</tr>
<tr>
<td>Fair basis if disclosure “reasonably conveys”</td>
<td>E.9 (PE/AU/JP/SG/VN)</td>
<td>CL/My/BN/NZ/CA/MX</td>
</tr>
<tr>
<td>Use US “specific, substantial and credible” utility criteria</td>
<td>E.10 (AU/MX/SG)</td>
<td>CL/My/VN/PE/BN/NZ/CA</td>
</tr>
</tbody>
</table>

### Administrative harmonisation:
- 12 month grace period | E.2
- Amendments: at least one opportunity | E.7
- Reduce differences in law and practice | B.3
- Participate in international harmonisation | B.2
- Sharing of search and examination results | B.3

### Issues not in AUSFTA but in other Australian "FTAs"
- Granted patents presumed valid | H.2.3
- Co-operate on "IP" education | B.3

Notes: Based mainly on Section E. There are also general provisions which affect patents.

# Countries in parentheses support the US position.

## Annex items are generally more contentious.
The agreements cover only 8.5 percent of US trade, mostly accounted for by the three high-income countries Australia, Korea and Singapore (Flynn et al. 2012: 109-110). Other agreements are Jordan 2000; Bahrain 2004; Chile 2004; Morocco 2004; Colombia 2006; Oman 2006; Panama 2007; and Peru 2007.


3 Australia has always run a negative balance on its trade in intellectual property (see, e.g. IPAC 1984). IP receipts over the past decade have been of the order of 0.25% to 0.5% of the current account and payments have been two to eight times larger at 1.0% to 1.5% (IP Australia 2013: 22).

4 For a more detailed analysis see Moir 2014.

5 Australian courts have followed this trend – for example adopting the much criticised State Street Bank decision to allow business method patenting (Welcome Real Time v Catuity [2001] FCA 445 (17 May 2001)). The High Court has not yet moved to prevent this.

6 At the time Yaz was marketed MedlinePlus (a US National Library of Medicine service), http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601050.html#brand-name-2 listed brand names for 83 different low-dose combination oral contraceptives.


8 The TRIPS requirement that all technologies be treated equally (a core demand from the pharmaceutical industry) also impedes balanced patent policy. Technologies are very different – some are hard to copy, some easy. The empirical evidence shows that patents are only needed in limited technology areas (López 2009). Yet WTO members are forced to provide patents in technology areas where they are not needed.

9 Though microorganisms must be eligible for patents. If plants are not protected under patent law they must be granted a form of sui generis protection (TRIPS Article 27(3). Inventions that create morality or ordre public problems can also be refused patents.

10 There are widespread evidence-based criticisms of the very low inventiveness requirement in the US system (see, for example, Jaffe and Lerner 2004; Quillen Jr. 2006). The USA would, too, benefit unambiguously by lifting the inventiveness requirement to ensure at least some new knowledge was a requirement for patent grant. This would, however, prevent evergreening patents.

11 A 1984 review, which was meant to be economic, drew the dissenting comment from its sole economist that the report “does not live up to its claim to have adopted an economic perspective and to have applied economic criteria” (IPAC 1984: 79-80). The 2000 IPCRC review simply assumed that inventiveness was required before grant of a patent, a false assumption which calls its findings into grave doubt (IPCRC 2000). Since then there has been only one attempt at an independent inquiry (Harris et al. 2013), and that review systematically refused to look at the issue
of inventiveness. The government has advised parliament that patents, because they provide a powerful exclusive right, are granted only for things that are "a significant advance over what is known or used" (Explanatory Memorandum to the 2011 Intellectual Property Laws Amendment (Raising the Bar) Bill). This statement is factually incorrect, as demonstrated both by the rules in the patent Examiner's manual and by the many trivial patents regularly granted (Moir 2013a).

12 25 years for pharmaceutical products. As it takes some time to get the patented product to market, the effective monopoly period is lower. The average effective period of market monopoly derived from a patent over a new breakthrough drug is 14 years in the USA (Harris et al. 2013: 83).

13 These other matters are also important to patent balance, but are not discussed here for reasons of space.

14 See, for example the discussion on manufacturing for export in the Pharmaceutical Patent Review (Harris et al. 2013

15 Data protection provisions in TRIPS and the AUSFTA cover both clinical trial data for pharmaceuticals and safety data for agricultural chemicals. In both cases the term of protection for agricultural chemicals is ten years not five. Agricultural chemicals are outside the scope of this paper.

16 "IFAC-3 welcomes the regulatory-related definition of a “new product” contained in Article 17.10.1(d) as being a product that does not contain a chemical entity that had been previously approved in Australia as providing an important clarification of the term “new chemical entity” found in TRIPS Article 39.3.” (IFAC 2004: p,14, emphasis added).

17 Article 20 of the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects prohibits the continuation of trials when conclusive results are known (18th World Medical Association General Assembly, Art. 20, http://www.wma.net/en/30publications/10policies/b3/17c.pdf). One can presume that it is also unethical to commence such trials when there are already conclusive results.

18 "Nothing done under this Act or the PCT guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else" (Patents Act 1990, S.20(1)). Despite this, in 2012, Yates, J stated that “[r]egistration of the patent is, of itself, prima facie evidence of validity” (Novartis v Hospira [2012] FCA 1055 per Yates J, paras 51, 91-94).

19 Despite this, DFAT focuses almost exclusively on “market access” issues, an emphasis salient on its trade webpage.

20 Indeed this was a primary reason that the UK's entry to the European Economic Community was so delayed. The UK's agricultural policy was based on subsidies, with substantial imports from Australia and New Zealand keeping consumer prices low. In the period before Australia reduced almost all tariff barriers, the Productivity Commission (then the Industries Assistance Commission) wrote many reports demonstrating that this basic economic fact holds across all industries.

21 See Holovac (2004) for a full discussion of how the 1984 Hatch-Waxman Act operates to encourage generic producers to challenge weak patents and gain early entry to the market.
See the various submissions to the 2012-13 Pharmaceutical Patent Review (PPR), particularly that from Alphapharm, and also Moir and Palombi 2013. As IP Australia has dismantled the PPR website, copies of the submissions can be obtained from the author. The official papers are at http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf.

The leaked 2014 version is used in this analysis (https://www.wikileaks.org/tpp-ip2/#article_e4). The 2014 and 2013 (https://wikileaks.org/tpp/) versions are very similar; as is the leaked 2011 version, which has been extensively analysed by Flynn et al. 2012.

This section takes wording from the European Medicines Agency’s procedures to make unpatentable inventions where there is no enhanced efficacy of a known product. The discussion in Novartis AG v Union of India and others, Civil Appeal Nos. 2706-2716 of 2013, Supreme Court of India reviews the background to this part of the act (http://supremecourtofindia.nic.in/outtoday/patent.pdf).

The two that are missing from the 2014 draft are restrictions on the use of compulsory licenses and restrictions on parallel importing.