

The High Price of “Free” Trade: U.S. Trade Agreements and Access to Medicines

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Paper accepted for publication in the Journal of Law, Medicine and Ethics

(Vol 41, Issue 1, Pages 199-223, Spring 2013)

The definitive version is available at:

<http://onlinelibrary.wiley.com/doi/10.1111/jlme.12014/abstract>

Introduction

The United States' pursuit of increasingly TRIPS-Plus levels of intellectual property protection for medicines in bilateral and regional trade agreements is well recognized. Less so, however, are U.S. efforts through these agreements, to directly influence and constrain the pharmaceutical coverage programs of its trading partners. The pursuit of increasing levels of intellectual property (IP) protection in successive bilateral and regional trade agreements has been driven, at least in part, by a U.S. desire to achieve standards of protection it anticipated from the TRIPS Agreement,¹ but failed to secure. Despite the conclusion of a global agreement on IP standards that would establish significant protections in countries that had hitherto declined them, the U.S. pharmaceutical industry viewed TRIPS as falling well short of its objectives — particularly in light of the delayed introduction of patent protection in countries that are key suppliers of generic medicines, such as India.² As a result, the proliferation of post-TRIPS bilateral and regional “free” trade agreements (FTAs) has been characterized by a progressive “ratcheting up” of IP protections for pharmaceuticals, with provisions intended to prolong monopolies, support high prices and frustrate market entry of generic medicines — all of which undermine access to affordable medicines.³

In this paper we scan the evolution of post TRIPS intellectual property rights (IPRs), with particular attention to the IP provisions of the Australia-U.S. (AUSFTA) and Korea-U.S. (KORUS) FTAs. We then turn our attention to a less well-recognized issue - U.S. efforts, through bilateral and regional trade agreements, to also gain greater influence over the domestic pharmaceutical coverage policies of its trading partners.

While provisions potentially affecting domestic health and social policy settings were arguably included in FTAs as early as NAFTA,⁴ obligations specifically addressing domestic health care and particularly drug coverage programs are a more recent phenomenon. We trace these efforts beginning with the AUSFTA, through the recently ratified KORUS, and then examine the current negotiations for the Trans Pacific Partnership Agreement (TPPA), drawing on leaked US negotiating texts available at the time of writing. We demonstrate a progression of increasingly intrusive provisions designed to protect and further the interests of transnational corporations at the expense of population health and affordable access to medicines.

TRIPS and Post-TRIPS: The Game Changes

The conclusion of the WTO TRIPS Agreement in 1995 established new enforceable minimum standards for IP protection.⁵ TRIPS was highly controversial for several reasons, not the least of which was that its intention was not to actually remove trade barriers⁶ but

also because it engendered widespread concern about the potential impact of these IPRs on public health and access to medicines, particularly in developing countries.⁷

Key among the TRIPS provisions was the requirement that WTO members make patents available “for any inventions, whether products or processes...provided they are new, involve an inventive step, and are capable of industrial application” (Art. 27.1).⁸ While TRIPS goes on to provide a little more guidance on the meanings of these terms, there remains ample scope for countries to determine for themselves their meanings. Prior to TRIPS several countries, including India, did not recognize or grant patents on pharmaceutical products, however, post TRIPS all WTO Members were obliged to recognize patents on products in all fields of technology.⁹

TRIPS nonetheless permitted certain limited — but important — exclusions to patentability (for example, for diagnostic, therapeutic and surgical methods), allowed some flexibility in the application of patentability standards, and retained certain safeguards, such as the capacity for pre-grant opposition and parallel importation.¹⁰ Moreover, although Article 39 imposed a prohibition on the “unfair” commercial use of *undisclosed* test data used in approving the marketing of pharmaceutical products, it did not specify a minimum duration for this protection.

Importantly, TRIPS attempted to strike a balance between the rights of patent holders to benefit from their inventions and the rights of countries to address health priorities through the provision of affordable medicines. Provisions for compulsory licensing were thus included under TRIPS, permitting Member States to determine the circumstances in which a compulsory license is considered appropriate, albeit accompanied by a number of checks and balances. Article 31 specifies conditions for the “use of the subject matter of a patent without the authorization of the right holder,” requiring that the issuing of a compulsory license is preceded by unsuccessful efforts to obtain authorization from the right holder on reasonable commercial terms and within a reasonable timeframe. This obligation may, however, be waived in “a national emergency or other circumstances of extreme *urgency*, or in cases of public non-commercial use” (Art. 31(b)) (whereby countries are free to determine what constitutes a national emergency or a case of extreme urgency).¹¹ The rights of WTO members to use TRIPS flexibilities to protect public health were reaffirmed in the Doha Declaration of 2001¹² and reinforced in subsequent decisions in 2002, 2003, and 2005.¹³

Forum Shifting and Ratcheting Up” — TRIPS Plus IPRs and U.S. Free Trade Agreements

The U.S. shift in focus from the multilateral arena to bilateral and regional trade agreements to pursue its IP objectives has been described as “forum shifting.” Forum shifting is the practice of transferring a negotiating agenda from one setting to another to increase opportunities for pursuing overarching objectives,¹⁴ a well-tried method of improving the odds of success by not limiting efforts to a single international forum.¹⁵ In return for concessions on market access, the U.S. would attempt to persuade other governments to voluntarily accept substantial broadening of IPRs.¹⁶ Utilizing a template approach — where the provisions of each successive agreement serve as the baseline from which to develop and expand the ambitions of the next — the U.S. has successfully pursued an agenda that can be seen as substantially ‘ratcheting up’ IPRs on medicines.

The push began in 2000 with Jordan,¹⁷ and has since advanced to the extent that TRIPS provisions begin to appear modest in comparison with today’s significantly TRIPS-Plus US IP template.¹⁸ Today that template includes wide-ranging provisions that potentially frustrate and delay generic market entry, prolong and expand patent protections, and constrain the

exercise of TRIPS flexibilities intended to support access and promote public health (see Box 1).¹⁹

Elements include extensions to the scope of patentability, including requirements to allow patenting of diagnostic, therapeutic and surgical methods (which could be excluded under TRIPS), and of new forms, uses or methods of use. Where licenses are required or royalties levied for diagnostic and treatment methods, these naturally add significantly to costs and limit access to effective treatments. Allowing the patenting of new forms, uses, or methods of using existing products also creates substantial scope for evergreening,²⁰ an abusive patenting and litigation strategy employed by some patent holders to facilitate prolonged monopolies and the extraction of excessive monopoly rents.

Patent term extension (restoration) provisions, i.e., the granting of additional patent life to compensate for administrative delays either in the granting of patents or the marketing approval process, lead to delays in generic market entry²¹ whereas limitations on patent revocation arguably facilitate evergreening of patents. The requirement for national exhaustion of patent protection facilitates the prohibition of parallel importation of patented products without the permission of the patent holder in the importing country.²²

Box 1

- Key TRIPS-Plus Elements in U.S. Bilateral and Regional FTAs
- Extensions to the scope of patentability
- Limits on patent revocation
- Patent term extension (restoration)
- Prohibition of parallel importation
- Linkage between patent status and regulatory approval
- Limitations on compulsory licensing
- Data protection, extended data protection and data exclusivity
- Obligatory accession to other multilateral IP agreements e.g. the Patent Cooperation Treaty

Patent linkage mechanisms create an unwarranted nexus between the grant of marketing approval for a generic medicine and the patent status of the originator, by preventing regulatory authorities from granting marketing authorization to a generic manufacturer while the originator is still patent protected — unless the patent holder is notified (and in some cases, unless permission is granted).²³ Such mechanisms can not only delay generic market entry, but can also interfere with the effective use of compulsory licensing.²⁴ Patent linkage is a U.S.-centric phenomenon that reflects perspectives underlying key provisions of the Hatch-Waxman Act;²⁵ in the E.U. patent linkage is not expressly prohibited, but there generic marketing authorization may only be refused on specific grounds, all of which are unrelated to the patent status of the originator.²⁶

The specification of a minimum five years for the protection of test data is also integral to the U.S. IP template,²⁷ and is usually accompanied by a provision specifying a further three years' protection for new uses of existing products. In the later FTAs this protection is extended to data already in the public domain, thereby becoming in effect a data exclusivity provision.²⁸ Where a generic marketing application relies on the safety and efficacy data submitted by the originator, it may not be evaluated by the regulatory agency until the end of the data protection period, irrespective of the originator's patent status. Where reflected in national law, such provisions can thus become a substantive impediment to compulsory licensing, since regulatory agencies cannot assess a generic marketing application for a

product still subject to data protection even where a compulsory license has been granted and thus patent infringement cannot be asserted.²⁹

U.S. FTAs have also included restrictions that limit the use of compulsory licensing to drugs for certain infectious diseases (such as HIV/AIDS, malaria and tuberculosis) or to circumstances of “extreme urgency” or “national emergency.”³⁰ TRIPS Art. 31 makes no mention of specific diseases, and references to “national emergency” and “other circumstances of extreme urgency” are relevant only to the capacity to waive the requirement for prior effort to obtain a voluntary license. Nevertheless, beginning with the U.S.-Morocco FTA signed in June 2004, U.S. FTAs have consistently sought to limit scope for compulsory licensing by narrowing the circumstances in which it can be applied.³¹

The impacts of these TRIPS-Plus provisions have been demonstrated in empirical studies and anticipated in modeled analyses.³² For example, following Jordan’s 2000 WTO accession, for which it was required to introduce both patents and data protection,³³ the Jordan–U.S. FTA added a prohibition on parallel importation³⁴ and a modified patent linkage provision,³⁵ as well as three additional years of data protection for new uses of known products, restrictions on the use of compulsory licensing, and patent term restoration.³⁶ Oxfam found that the introduction of these obligations resulted in a 20 percent overall increase in medicine prices between 2001 and 2006, and that data protection led to the delayed introduction of generic equivalents for 79 percent of new medicines produced by 21 pharmaceutical companies between 2002 and mid-2006.³⁷ Furthermore, putative benefits of these expanded IPRs were not seen the introduction of TRIPS-Plus provisions did not result in greater foreign direct investment in Jordan’s pharmaceutical industry, further investment in R&D or earlier introduction of “innovative” medicines, as had been claimed at the time of the agreement.³⁸

Box 2

Key IP Provisions of the May 2007 Bipartisan Agreement on Trade Policy

- Test data protection need not extend beyond the period of protection for the same product in the US
- Exceptions from test data protection possible where necessary to protect public health
- Flexibility in applying patent term extension (restoration), subject to expeditious processing of patent and marketing approval applications
- Flexibility in the application of patent linkage provisions
- Acknowledgement within IP chapters that provisions need not affect the ability to take necessary measures to protect public health by promoting access to medicines for all
- Inclusion of a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health

The only moderation to the rising trajectory of IP standards in U.S. FTAs occurred in 2007, with the advent of the New Trade Policy (NTP). Although the Peru Trade Promotion Agreement (Peru TPA) was signed in April 2006, Congress had not yet ratified it when the November 2006 mid-term elections delivered Democrat majorities in both the House and the Senate. In May 2007 Congress and the White House reached an agreement to moderate some of the TRIPS Plus provisions in bilateral FTAs with developing countries, beginning with Peru.³⁹ The NTP’s IP provisions specified certain conditions for congressional approval of

future FTAs⁴⁰ (see Box 2), which included allowing developing countries flexibility in the application of patent term extension, patent linkage, and data protection where necessary to protect public health.⁴¹ Flexibility with respect to data protection is particularly important for developing countries as it can represent an impediment to the effective use of compulsory licensing.

While these were not insubstantial concessions, Congress noted that the IP chapters of U.S. trade agreements would nevertheless (continue to) “represent an enhancement of IPR protection for pharmaceutical products in those markets” and would

- continue to protect pharmaceutical test data;
- require the establishment of procedures for patent holders to effectively enforce their rights against infringing products;
- limit grounds for patent revocation; and
- retain the option for patent term extension to be applied in cases of unreasonable delays.⁴²

While the NTP provisions are reflected in the final text of the Peru TPA, and subsequently in the U.S.-Colombia and U.S.-Panama FTAs, the concessions were limited to developing countries and so were not available to the Koreans when KORUS was concluded a month later, despite South Korean per capita GDP being little more than half that of the U.S.

From AUSFTA to KORUS

The progression of IPRs has been well described in reference to U.S. bilateral and regional trade agreements.⁴³ As such, we do not attempt an exhaustive description here but instead consider the provisions of the bilateral agreements with Australia and South Korea to illustrate both the IP and non-IP trajectory with respect to medicines, and to set the scene for the later discussion of the proposed TPPA.

AUSFTA: IPRs

While the U.S. made substantive gains in IPRs in the Australia-U.S. Free Trade Agreement (AUSFTA),⁴⁴ the outcome again fell short of its ambitions. The IP chapter of the 2004 agreement expanded the scope of patentability, limited grounds for revocation of patents, specified limitations on compulsory licensing, prohibited parallel importation, (nominally) extended test data protection, and imposed patent linkage and patent term extension provisions.⁴⁵ Australia conformed to high (including some TRIPS-Plus) standards of IP protection prior to the AUSFTA, and several of its provisions (e.g., patent term extension, data protection and prohibition of parallel importation) were already reflected in Australian law.⁴⁶ These IPRs were nonetheless “future-proofed” by the AUSFTA, precluding future domestic policy flexibility to reduce or remove them without U.S. consent.⁴⁷ Others appeared to introduce substantive changes but were either effectively nullified within the text itself (e.g., extension of test data protection)⁴⁸ or, while limiting Australia’s future options, have had no material impact to date (e.g., limitations on compulsory licensing).

Perhaps the most controversial provision was the requirement to introduce a form of patent linkage, intended to prevent the marketing approval of a generic medicine during the term of a patent on the originator. In part reflecting a rejection of the role of a drug regulatory agency as a patent “watchdog,” the patent linkage provision was implemented in the form of a requirement for “self-certification” by generic manufacturers. Prior to final approval of a marketing application and the addition of the product to the Australian Register of Therapeutic Goods, a generic manufacturer relying on the safety and efficacy data of an originator must certify either that it will not market its (generic) product in a manner that

would infringe a valid patent claim, or that if it intends to market the generic prior to the expiry of a patent on the originator, it has notified the patent holder of its application.⁴⁹ Arguments that this would encourage patent evergreening⁵⁰ prompted amendments to the AUSFTA implementing legislation to introduce complementary certification requirements for patent holders, to create putative safeguards against vexatious litigation and disincentives to evergreening.⁵¹ It might equally be argued, however, that the incentives for evergreening are such that neither the patent linkage provision nor the putative safeguards are likely to have had a substantive impact.

KORUS: IPRs

Although concluded in June 2007, some three years after the AUSFTA, the Korea-U.S. Free Trade Agreement (KORUS) was not ratified until March 2012. The KORUS outcomes were substantially different, with some IPRs extending significantly beyond those in AUSFTA. Key comparisons are shown in Table 1. Patent term extensions, limited in AUSFTA to new pharmaceutical products, are broadened in KORUS to patents on methods of use and methods of manufacture. The KORUS text also specifies that any action to oppose a patent can only occur after it has been granted, effectively eliminating the capacity for pre-grant opposition (which is retained in AUSFTA). The capacity to challenge the validity of a patent before it is granted is important in preventing the approval of spurious or inappropriate patent applications, and may also play a role in enhancing the quality of patent applications overall, ultimately reducing the likelihood of costly and potentially harmful litigation.⁵²

The data protection provisions in KORUS are broader than those of AUSFTA both in duration and scope, with three years of additional data protection for new uses of an existing product and without the qualification limiting protection to *undisclosed* data. In this way the KORUS obligation effectively becomes a data exclusivity provision that precludes the evaluation of a generic marketing application even where it utilizes data in the public domain.⁵³

Curiously, KORUS also has some elements that are less restrictive than AUSFTA. Unlike AUSFTA there is no prohibition on parallel importation, no specific limitations are placed on compulsory licensing, and Art. 18.9.3 permits the waiving of data protection where a compulsory license has been granted. The patent linkage provision is present but requires notification to the patent holder only in circumstances where market entry is anticipated prior to the end of the patent term.

Beyond IPRs: Vertical Forum Shifting AUSFTA and KORUS

As noted above, the inclusion of provisions specifically addressing the conduct of domestic drug coverage programs in the U.S. FTA template is a relatively recent phenomenon. We describe below the U.S.'s attempts to undermine pharmaceutical coverage and reimbursement programs, firstly – but ultimately unsuccessfully – through the AUSFTA Annex 2C,⁵⁴ but by utilizing the Annex as a template, with greater impact in the Pharmaceutical Products and Medical Devices chapter in KORUS.

AUSFTA: Pharmaceuticals Annex

In 2003 USTR approached the AUSFTA negotiations with an explicit Trade Promotion Authority mandate to seek “the elimination of government measures such as price controls and reference pricing which deny full market access for United States products” in overseas markets.⁵⁵ Australia’s universal pharmaceutical subsidy program, the Pharmaceutical Benefits Scheme (PBS), was unambiguously in the sights of the U.S. pharmaceutical industry.⁵⁶ To the industry and its peak body, the Pharmaceutical Research and Manufacturers of America (PhRMA), “fourth hurdle” systems⁵⁷ like the PBS are considered

non-tariff barriers to overseas markets,⁵⁸ and characterized as “trade distorting” and “discriminatory.”⁵⁹ This was accompanied by rhetoric intended to deflect criticism over the high prices of medicines in the U.S. — claims that countries like Australia that regulate drug prices or utilize evidence-based priority setting are not only “free-riding” on U.S. R&D investment but also, by reducing revenues to the industry, are undermining future “innovation.”⁶⁰ In addition to fundamental changes to pricing mechanisms, through the AUSFTA the industry also sought to gain greater influence over national formulary decision-making processes, including the introduction of contestability mechanisms that would shift the final decision from the technical expert committee to a nontechnical appeal body.⁶¹

Despite assurances from the Australian government of the day that the AUSFTA would not adversely affect the PBS,⁶² there was widespread concern amongst academics and non-government organizations that the U.S. had made substantial inroads.⁶³ Some of this concern centered on references to ‘valuing innovative pharmaceuticals’ in the so-called ‘Agreed Principles’ of Annex 2C of AUSFTA. At the time it was argued that these, combined with procedural changes (the establishment of an independent review process, and opportunities for applicants to be heard by the expert formulary committee, the Pharmaceutical Benefits Advisory Committee (PBAC), while their applications were being considered) would allow industry greater influence in the decision-making process. This, it was claimed, would undermine the committee’s capacity to make independent, evidence-based assessments, and by eroding Australia’s capacity to ensure value for money in formulary listing decisions, drug prices would inevitably rise.⁶⁴ The concomitant establishment of a joint U.S.-Australian discussion forum, the Medicines Working Group, was seen as a means by which the U.S. would direct or influence future domestic policy-making around medicines.⁶⁵

The apparent concessions notwithstanding, U.S. gains were actually limited to matters of process and transparency in the formulary listing process; there is no evidence that the AUSFTA has had an impact on PBS decision-making, pricing mechanisms, or the actual prices of medicines.⁶⁶ Most of the obligatory provisions of the text reflected either existing practices with respect to the transparency and timeliness of PBAC processes, or process improvements that were already underway or proposed. As implemented, the independent review process cannot remake a decision of the PBAC, but serves as an independent quality assurance mechanism.⁶⁷ The Medicines Working Group is a discussion forum with limited terms of reference, chaired by health officials,⁶⁸ and with no decision-making, advisory or even reporting role; it has met only twice since the conclusion of the agreement.

The AUSFTA text also includes a provision ostensibly legalizing direct to consumer advertising (DTCA) via the internet:

Each Party shall permit a pharmaceutical manufacturer to disseminate...through the manufacturer’s Internet site...truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party’s territory ...

However, the intent is effectively obviated in Australia by the subsequent clause specifying

... as is permitted to be disseminated under the Party’s laws, regulations and procedures.

While DTCA continues to be prohibited in Australia, this nuance in the text is often either overlooked or misunderstood — internet DTCA was not legalized as a result of the AUSFTA.⁶⁹ This does, however, illustrate the U.S. rationale for retaining a provision within a negotiating template even where a carve-out is agreed — the perception that it has been

accepted allows it to appear normative, and legitimises its inclusion in future trade agreements.

Notably, the AUSFTA text excludes those U.S. programs (such as Medicaid) that would otherwise have been in scope, and which might also have benefitted from such “worthwhile improvements” in process and transparency.

Despite public concern in Australia, the PBS’ fundamental building blocks — those components most strongly criticized by the pharmaceutical industry — remained intact. Australia actually made a small but significant gain, through the inclusion in the Pharmaceuticals Annex of a specific obligation regarding transparency to the public. This effectively created a treaty-level obligation facilitating disclosure — of PBAC processes, evidence and outcomes — to an extent that the pharmaceutical industry had hitherto strongly resisted.⁷⁰

Thus, this initial attempt by the U.S. to test whether it could use a trade agreement to circumscribe another nation’s domestic policies for the provision of subsidized medicines was, to all intents and purposes, unsuccessful. However, by incorporating provisions addressing the conduct of another nation’s domestic drug coverage program within a bilateral trade agreement, the very existence of the Pharmaceuticals Annex nevertheless set an unfortunate precedent.

KORUS: Medicines and Medical Devices Chapter

The AUSFTA Pharmaceuticals Annex had established a new benchmark on which the U.S. could build in its approach to KORUS, and the lessons learnt from the AUSFTA negotiation would have been salutary. U.S. determination to succeed in KORUS where its efforts had been frustrated in AUSFTA can be understood in the context of health and pharmaceutical policy developments taking place in South Korea over the period 2001-2012.

South Korea was one of the first Asian countries to introduce the use of economic evaluation in drug reimbursement and pricing decision-making.⁷¹ This was prompted not only by rising National Health Insurance (NHI) system expenditure and concerns about its long term financial sustainability, but also by a desire to allocate health care resources in a more rational manner.⁷² By 2002, pharmaceutical expenditure accounted for more than a quarter of the total NHI expenditure and costs were rapidly rising.⁷³

The reforms began in 2001 with an amendment to the NHI Act permitting economic evaluation for decisions related to health insurance coverage and reimbursement.⁷⁴ Subsequently, further pharmaceutical policy reforms were announced in May 2006, including the adoption of economic evaluation and conversion from a negative list to a positive list system (PLS) for pharmaceutical reimbursement.⁷⁵ Prior to this, South Korea had been required, by virtue of its 1999 ‘A-7’ agreement with the U.S., to use external reference pricing for new medicines based on prices in seven developed countries.⁷⁶

The 2006 reforms were to be introduced in an incremental fashion, and were highly controversial.⁷⁷ Soon after the announcement however, negotiations for KORUS began, and the USTR objected to South Korea’s proposed changes,⁷⁸ reportedly demanding “the cancellation of economic evaluation policy as a prerequisite for further FTA talks.”⁷⁹ Nonetheless, despite U.S. objections South Korea proceeded with introducing the PLS and the use of cost-effectiveness as a consideration in listing drugs for reimbursement.⁸⁰ A drug reimbursement evaluation committee was established to make listing recommendations, with final reimbursement decisions made by the Health Insurance Review Agency (HIRA), and price negotiations by the National Health Insurance Corporation.⁸¹ These reforms reduced the number of new drug listings, particularly of expensive new drugs.⁸²

It is perhaps South Korea's determination to introduce economic evaluation, and its potential as a model for other Asian countries considering the adoption of similar reforms, that explains the U.S. determination to use KORUS to place restrictions on the operation of the NHI. While the KORUS IP chapter is an amalgam of provisions both more and less onerous than those in AUSFTA (see Table 1), the obligations with respect to domestic health programs are substantially more ambitious, and are not limited to drug coverage, but for the first time extend also to medical devices (see Table 2).⁸³

Here references to “patented” rather than “innovative” products appear intended to preclude assessments of innovation based on therapeutic impact or value.⁸⁴ Whereas the AUSFTA text articulates that “the value of innovative pharmaceuticals” may be based either on “the operation of competitive markets” or “the objectively demonstrated therapeutic significance of a pharmaceutical” (Annex 2-C Art. 1(d)) – reflecting the existing evidence-based decision-making processes of the PBS – the KORUS text requires reimbursement amounts to be “based on competitive market-derived prices” or to “appropriately recognize the value of the patented pharmaceutical product or medical device” (Art. 5.2(b)). Given that in industry parlance, every new molecular entity that is patented is deemed to be innovative, this supplants an assessment of therapeutic benefit or value for money with an assertion of patent status as the basis for determining price and value.

KORUS also establishes some substantial obligations with respect to rulemaking within drug coverage programs and appears to create significant opportunities for industry to exert undue influence in the listing and pricing processes. An obligation to establish a review process in AUSFTA becomes a broader obligation within KORUS, covering not only drugs and devices, but also both listing and pricing determinations. While in AUSFTA the right to review is limited to decisions to decline formulary listing, in KORUS there is no similar limitation, implying that any decision at variance with the outcome sought by the applicant could be subject to appeal – a situation that could rapidly become unworkable. Moreover, a side letter requires the establishment of a review *body* rather than a review *process*, implying that such a body would have the capacity to overturn the original decision.⁸⁵

Other features of KORUS include the establishment of a Medicines and Medical Devices Committee with a far more extensive and influential remit than the Medicines Working Group (MWG) established under the AUSFTA. The committee established by KORUS will be co-chaired by health and trade officials (unlike the AUSFTA MWG which is chaired by health officials only), has a specific mandate for monitoring and supporting implementation of the KORUS pharmaceutical products and medical devices chapter, is required to meet at least once a year and reports to the Joint Committee.⁸⁶ These arrangements potentially create scope for ongoing US influence in health policy making in South Korea.

KORUS also introduces a requirement to permit DTCA via the internet, but without the textual qualification that prevented its introduction in Australia. Evidence suggests that DTCA – among OECD countries permitted only in the U.S. and New Zealand can adversely affect demand, undermine rational prescribing, over-medicalise well populations, and increase overall expenditure on health care.⁸⁷ These risks would appear to substantially outweigh any putative benefits, particularly in contexts where regulatory enforcement is less than ideal.⁸⁸

While South Korea has been required to make substantial changes to its domestic programs for medicines and medical devices, the KORUS provisions, like those in the AUSFTA, carefully exclude most U.S. programs, with a clarifying footnote explicitly carving out state Medicaid programs.

Although the KORUS was signed in June 2007, neither party ratified it until late 2011, and the agreement did not enter into force until March 2012. Nevertheless in February 2012 the Pharmaceutical Research and Manufacturers of America (PhRMA) registered a number of complaints about the extent to which South Korea had implemented its obligations.⁸⁹ In fact many of the obligatory changes had been put in place prior to ratification, including various procedures to increase transparency (e.g., public release of listing decision criteria, opportunities for manufacturers to be heard at drug reimbursement evaluation committee meetings, an appeals process, and requirements for notifying decisions within a certain period of time).⁹⁰

“Free” Trade in a Brave New World: The Trans Pacific Partnership Agreement

The objectives pursued by the US in the AUSFTA and KORUS agreements were unarguably ambitious, but the proposed Trans Pacific Partnership Agreement (TPPA) marks a distinctly new phase in the US trade agenda. While the TPPA countries currently negotiating are Australia, Brunei Darussalam, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, U.S., and Vietnam, the TPPA’s potential impact will extend well beyond these eleven. Should Japan (which has expressed interest but has not yet been formally invited) also join the negotiations, the combined economies of the TPPA countries will represent 40 percent of global GDP.⁹¹ The TPPA text will likely become the template for future agreements between the U.S. and other developing and developed countries, and the agreement itself could form the genesis of a broader trade bloc across the Asia-Pacific region, and with the capacity to set de facto global standards.⁹² Reports suggest that countries which join the negotiations after consensus has already been reached on parts of the text may be required to accept that text – sight unseen – when making the commitment to join, thus also potentially committing to changes to their domestic laws without any clarity as to their scope or effect.⁹³

Described by the leaders of the TPPA countries as a “next-generation” and “landmark” agreement that addresses “21st-century challenges,”⁹⁴ it is clear that the TPPA is intended to break new ground in reaching beyond traditional trade issues. It is likely to extend further into domestic policy space than any FTA to date,⁹⁵ through a complex web of rules and obligations designed to streamline and harmonize regulatory frameworks and procedures across many areas such as investment, cross-border services, state-owned enterprises, and government procurement.⁹⁶

TPPA: IPRs

Consistent with this ambitious agenda, leaked U.S. TPPA negotiating texts demonstrate TRIPS-Plus ambitions with respect to IPRs for drugs and medical devices.⁹⁷ This is not surprising considering that PhRMA, along with many other U.S. associations with interests in strengthening IPRs, has lobbied aggressively for “high standards for the protection and enforcement of IP rights,” citing their importance to productivity, economic growth, job creation, and living standards.⁹⁸

The U.S. TPPA IP proposals go further than both AUSFTA and KORUS (see Table 1) and include provisions that would require changes to patent law in each of the parties to the agreement, including the U.S.⁹⁹ Although essentially based on the principles of U.S. IP law, as with earlier U.S. FTAs they are stricter in the sense that they leave out important checks and balances that mitigate their effects in the U.S.¹⁰⁰

The leaked U.S. IP text¹⁰¹ requires parties to make patents available for new forms of existing products, even without improvements in efficacy or performance.¹⁰² This would enable, for example, patenting of variations to methods of administration, in addition to less significant modifications.¹⁰³ The TPPA provision would also eliminate the exclusion from

patentability (preserved in both the AUSFTA and KORUS) for diagnostic, therapeutic, and surgical methods — potentially leading to license fees and royalty payments for the use of diagnostics and treatment methods.¹⁰⁴

The same leaked U.S. text also requires the granting of extensions to patent terms to compensate for delays in both in the granting of patents and in marketing approval processes. This is a mandatory requirement that represents a significant step back from the NTP, under which patent term extension was optional. The text goes further than KORUS in that the definition of unreasonable delay is only two years from request for patent examination (cf three years in KORUS). In addition, patent term extension is required not just for molecule patents but also for methods and use patents.¹⁰⁵

Like KORUS, the U.S. text precludes pre-grant opposition and imposes data exclusivity (i.e., data protection not limited to undisclosed data) for five years for new pharmaceutical products and three years for new uses or new indications.¹⁰⁶ In addition, there is a placeholder for a separate data exclusivity provision for biologics. In the U.S. biologics currently receive four years of data exclusivity and a total 12 years of market exclusivity.¹⁰⁷ Despite U.S. domestic controversy and President Obama's own 2012 Budget proposal seeking a reduction in market exclusivity to seven years,¹⁰⁸ reports indicate that the pharmaceutical industry is still pursuing up to 12 years in the TPPA.¹⁰⁹

The patent linkage provision proposed for the TPPA by the U.S. is both AUSFTA-Plus and KORUS-Plus. It includes a requirement for regulatory authorities to actively scan for existing patents, provide notification to patent holders, and delay granting marketing approval until any dispute is settled.¹¹⁰ This reflects further elements of U.S. domestic law (as laid out in the Hatch-Waxman Act) being exported via a preferential trade agreement.

While the inappropriateness of developed countries imposing TRIPS-Plus standards on developing countries through FTAs has been widely recognized,¹¹¹ particular concerns have been voiced by major NGOs including Médecins Sans Frontières¹¹² and Oxfam International¹¹³ (as well as various national and regional fair trade, medical, public health and HIV/ AIDs organizations) over the likely effects of the U.S.' proposed IP provisions on the developing countries in the TPPA. ¹¹⁴ The U.S. consumer advocacy organization Public Citizen has also observed that the proposals would require extensive changes to domestic patent law in many of the TPPA developing countries.¹¹⁵ For example, Vietnam currently has no patent protection for new forms, uses, or methods of using a known product; no patent term extension or patent linkage mechanism; and data protection is not automatic.¹¹⁶ Increasing IPRs in each of these areas would be likely to have a significant impact on access to generic medicines in a country where drugs are already unaffordable for much of the population,¹¹⁷ over 48 percent of whom were living on less than U.S. \$2 per day in 2002-2007.¹¹⁸ In 2009 an estimated 280,000 people were living with HIV in Vietnam,¹¹⁹ of whom only a third had access to anti-retroviral therapy (ART).¹²⁰ Moreover, the U.S. is the largest contributor to global HIV programs, committing \$5.5 billion in 2010, and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program is heavily dependent on the deployment of generic anti-retrovirals.¹²¹ Measures that would raise the price of ARTs or delay the availability of generics would seem to be antithetical to the US' own interests in this sphere — at best they suggest a lack of policy coherence.

Importantly, the leaked TPPA IP proposals suggest the U.S. is largely resiling from the 2007 New Trade Policy, which attempted to achieve a more balanced approach by taking into account the need for developing countries to retain flexibilities to protect public health.¹²² This is of concern not only because there are several developing countries involved in the TPPA negotiations, but because of the scope for TPPA standards of IP protection to eventually become de facto global standards — in part through the effect of a growing number

of countries adopting these, together with the Most Favored Nation provision of TRIPS, which requires WTO members to extend any enhanced IPRs agreed in preferential trade agreements to all other WTO members.¹²³

TPPA: Beyond IPRs

In addition to expanding IP protections, for the first time the U.S. is pursuing non-IP objectives with respect to pharmaceuticals in trade negotiations with developing countries. Leaked U.S. negotiating texts include a proposed annex to the “Transparency” chapter (“the TPPA Annex”), which applies to healthcare technologies (pharmaceutical products and medical devices).¹²⁴ The TPPA Annex articulates a number of proposals likely to constrain TPPA countries’ domestic policy flexibilities in developing and operating therapeutic formularies, setting coverage and reimbursement policies, and applying and enforcing other price moderating mechanisms.¹²⁵ While several TPPA countries do not yet have such programs in place, the draft provisions have the capacity to seriously circumscribe the ways in which they might develop these in future, thereby limiting their scope to respond to market failure, regulate drug prices and promote affordable access.

In some respects, the 2011 draft TPPA Annex resembles that of KORUS (see Table 2) in extending its reach beyond medicines to also capture medical devices. It also mirrors KORUS in abandoning references to “valuing innovation” and “objectively demonstrated therapeutic significance,” adopting instead references to the value of “patented and generic pharmaceutical products and medical devices.” It includes a broadly comparable set of disclosure and transparency requirements and a similar clause requiring member countries to legalize internet-based DTCA.

However, Art. X.3(d) of the TPPA Annex¹²⁶ specifies that the determination of reimbursement amounts must have:

a transparent and verifiable basis consisting of competitive market–derived prices in the Party’s territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue.

While the full implications of this wording are not yet entirely clear, concerns have been expressed that references to “in the Party’s territory” could prevent countries from using external (international) reference pricing — the setting of a drug’s price based on the price(s) paid in one or more reference countries (noting that this is a pricing mechanism which can be highly disadvantageous where the reference countries have higher GDPs, and can lead to prices that reflect neither opportunity cost nor therapeutic value).¹²⁷ Of far greater concern, however, are references to “competitive market–derived prices” and “benchmarks that appropriately recognize” the value of patented products. (A market-derived price for a product protected by a monopoly is simply a price set by the rights holder. Who will set the benchmarks and what will be deemed “appropriate”?). These are intended to undermine both the use of therapeutic reference pricing (by which the price of a drug is referenced to that of another conferring similar therapeutic benefit, irrespective of patent status — a practice which is argued by industry as undermining the value of patents) and the application of value for money assessment, thereby undermining any rational calculus of opportunity cost through the use of evidence-based formulary listing and pricing processes.

Moreover, the conjunction of this clause with an independent appeal process as specified in Art. X.3(i) is particularly concerning, as this would facilitate challenges to formulary decision-making, particularly if a decision to decline listing were made on the grounds of inadequate cost effectiveness or lack of evidence of value for money.¹²⁸ In addition, several placeholders remaining in the leaked TPPA Annex appear likely to foreshadow potentially

controversial provisions, such as a reference to “possible cooperative mechanisms” [Paragraph X.6.2] which could become a forum similar to the Medicines and Medical Devices Committee established under KORUS, and with ongoing capacity to influence domestic policy-making in ways that may favour commercial interests to the detriment of public health.

Presumably intending to deflect criticism, the USTR published a “White Paper” in September 2011 in which it claimed its TPPA proposals would remove rather than enhance barriers to access to medicines.¹²⁹ The document is substantially lacking in detail but appears focused on mechanisms for promoting rapid market access for patented medicines. The White Paper articulates the concept of an “Access Window,” a limited period measured from the date of first registration in the U.S. within which pharmaceutical companies would be required to register new medicines in other TPP countries in order to take full advantage of data exclusivity provisions. However, this does little to promote affordable access, instead coercing early registration in return for maximum protection from competition for originator manufacturers, and the text retains or extends many highly problematic TRIPS-Plus provisions. Moreover, the U.S. pharmaceutical industry is currently lobbying for an “Access Window” of six years essentially reflecting the status quo.¹³⁰

The provisions of the TPPA Annex also appear likely to interact with provisions of other chapters such as those concerning regulatory coherence and transparency — in ways that may be difficult to anticipate, but may reduce domestic regulatory flexibility and promote deregulation or industry selfregulation.¹³¹ The Technical Barriers to Trade (TBT) chapter (for which text is unavailable to date) is also likely to have implications for the labeling of pharmaceuticals and other therapeutic goods. The stated aim of the proposed annexes on medical devices, pharmaceuticals and cosmetic products is “better alignment of regulatory approaches”,¹³² by closely specifying regulatory requirements pertaining to marketing authorization.¹³³

The investment chapter of the TPPA could present further challenges. A draft of the investment chapter leaked in June 2012 includes an investor-state dispute settlement (ISDS) mechanism that could be invoked to challenge other efforts to introduce or implement public health policies.¹³⁴ ISDS provisions in bilateral investment treaties are currently being utilized by the tobacco industry to challenge restrictions on tobacco marketing and labeling in both Australia and Uruguay.¹³⁵ The costs of arbitration can be very high even where a challenge is ultimately unsuccessful,¹³⁶ and thus even the threat of legal action can be sufficient to influence health policy-making,¹³⁷ particularly in developing countries. Beyond tobacco control, there are several ISDS cases that have involved other areas of health policy, including medicines.¹³⁸ Depending on regulatory and judicial frameworks, it is conceivable that an ISDS mechanism could be used to challenge unfavorable formulary listing and pricing decisions, thereby creating another avenue for commercial interests to undermine TPPA partners’ mechanisms for facilitating affordable access. Even the threat of ISDS proceedings may be sufficient to dissuade even strongly evidence-based formulary decision-making, with developing country partners particularly vulnerable in this regard.¹³⁹

Furthermore, although compulsory licensing appears to be specifically excluded in the draft text of the investment chapter, it is imperative that this exclusion is maintained. In countries that already face significant obstacles in utilizing compulsory licensing, the fear of breaching the investment obligations and initiating trade disputes with trading partners or of challenges by U.S. companies could have a substantial chilling effect.¹⁴⁰

Finally, a key concern regarding the TPPA stems from the absence of transparency and public input to the development of the U.S. position, despite a high degree of pharmaceutical and other industry participation in the process through USTR’s various Industry Trade

Advisory Committees, particularly ITAC3 (Chemicals, Pharmaceuticals, Health Science Products and Services) and ITAC15 (Intellectual Property Rights), the latter chaired by a representative of the PhRMA.¹⁴¹ Not surprisingly, neither committee includes representation from NGO or public health interests. Informed public comment on the intent and progress of US ambitions within the TPPA has thus been limited to the few leaked draft texts, and the TPPA countries have undertaken to keep negotiating documents confidential until four years after the conclusion of the Agreement or the failure of the negotiations.¹⁴² Various analyses of the leaked drafts have highlighted significant shifts in domestic policy settings that the U.S. proposals would require in the TPPA countries to give effect to the U.S. proposals, policy changes that should be developed through democratic processes, preferably with meaningful public consultation.¹⁴³ Instead the TPPA has been described as reflecting “a major and consequential shift in international standards for domestic regulation with scant public process, on the one side, and a highly structured and consultative relationship with a limited range of commercial interests on the other.”¹⁴⁴ Almost three years into the negotiations, it remains unclear how successful the U.S will ultimately be in its objectives in relation to medicines and medical devices.

While it has been widely reported that the draft text of the Transparency Annex leaked in 2011 has been superseded, it has also been reported that key issues of concern in the earlier draft continue to be prominent in the later text. To date the TPPA parties appear united in their opposition to the U.S. proposals, but this unity could be undermined by political compromises made in pursuit of market access. In December 2012, for example, New Zealand’s Trade Minister was reported as being prepared to be “flexible” in response to U.S objectives regarding the operation of New Zealand’s Pharmaceutical Management Agency, presumably a reference to possible concessions on US market access for dairy products.¹⁴⁵ What is clear is that these high sensitive issues are unlikely to be resolved until the final stages of the negotiations, when pressure to secure a deal may be resolved in the form of trade-offs between different sectors.

The Broader Agenda

In this paper we have attempted to highlight how the U.S., by pursuing an aggressive “trade” agenda, has sought to influence the laws and policies of other countries in two important ways. These include first, pushing trading partners to enact laws that create IP protections for pharmaceuticals well above and beyond those required by TRIPS, and second, by exporting

U.S. policy settings, driving changes to trading partners’ efforts to establish normative standards for programs to promote pharmaceutical access and coverage. These changes are antithetical to public health, because they prioritize the profits of the pharmaceutical industry over the universally relevant public health goal of affordable access to medicines. Moreover, the conjunction of IP provisions that facilitate monopolies and inhibit and delay competition, with those that prioritize price-setting according to “market value” (where “market value” is an artificial construct distorted by those same monopoly protections) in drug coverage programs can be seen as multiplicative in their effects.

The pharmaceutical industry has persistently justified the extension of IPRs as essential to reward research and promote “innovation.”¹⁴⁶ The argument that patent protection is necessary to stimulate innovation, and that such innovation invariably leads to better health outcomes, has been widely overemphasized, however.¹⁴⁷ Increased spending on R&D does not necessarily result in genuine innovation; many new molecular entities (NMEs) promoted by the industry as innovations are considered “me-too’s” — later entrants in existing therapeutic classes offering little or no additional benefit over earlier ones, or minor modifications to

existing drugs or their methods of administration.¹⁴⁸ This lends support to claims that patent protection can actually crowd-out true innovation by creating lucrative incentives for clinically unimportant changes to existing drugs.¹⁴⁹

Moreover, while there is some association between patent protection and research and development for diseases that are prevalent in wealthy countries, empirical research has shown that this relationship does not hold true for the development of drugs to treat diseases that overwhelmingly affect the developing world (the so-called “neglected diseases”).¹⁵⁰ This calls into question arguments that developing countries will ultimately benefit from strengthened IPRs. The WHO Consultative Expert Working Group (CEWG) on Research and Development recently recommended a fundamental overhaul of the financing systems for research and development in recognition of the inability of IPRs to correct for market failure in developing countries.¹⁵¹

U.S. health care exhibits many characteristics of market failure, with the result that expenditure is now approaching 18 percent of GDP, health insurance premiums are projected to exceed median household income by 2030, millions of Americans are without (or without adequate) health insurance, and the U.S. continues to distinguish itself as the global leader (if not the sole exponent) of medical bankruptcy.¹⁵² And while it may rightly boast some of the finest and most technologically advanced healthcare facilities in the world, it nevertheless lags behind many far poorer nations in key health and population indices, such as life expectancy (ranking 27th among the 34 OECD countries in 2009) and infant mortality (ranking 31st of 34 OECD countries in 2008).¹⁵³

Unlike the U.S., many developed and developing countries have recognized that addressing market failure is critical to the provision of affordable access to medicines. To do this they have introduced systems that refuse to accept sellers’ assertions of the value of medicines, or the possession of a patent as evidence of medical innovation, but attempt instead to moderate prices and drive efficiency either by direct price regulation, value-based purchasing or evidence-based, “fourth hurdle” mechanisms. The response of the pharmaceutical industry, and by virtue of intense lobbying, U.S. politicians and policymakers,¹⁵⁴ has been to label these countries as “free-riders,” failing to “reward innovation” and “devaluing patents.”¹⁵⁵ Such mechanisms, they argue, shortchange industry revenues, and countries that utilize them are not contributing their “fair share” to pharmaceutical research and development; by reducing the overall pool of funds available for research, it is argued, they undermine the development of the next generation of “miracle” drugs.¹⁵⁶ These arguments are then used to justify increasingly intrusive efforts to constrain the conduct and scope of programs introduced by other countries to facilitate access, promote efficient resource allocation and support rational priority setting,

Taken together, the pursuit of increasing standards of IP protection with provisions that constrain domestic drug coverage programs may be viewed not only as advancing the interests of a powerful global industry, but also as an attempt to export and impose U.S. values abroad. They reflect the U.S.’ enduring adherence to market-based solutions, coupled with a profound conviction that government intervention in market failure is not just unnecessary, but unhelpful. This perspective appears not only increasingly counter-productive in light of current health expenditure trends, but also suggests that those political interests that staunchly resist such government intervention domestically are, perhaps not surprisingly, committed to undermining, if not eliminating them elsewhere.¹⁵⁷

Irrespective of the motivation, if through the TPPA the U.S. is ultimately successful in the pursuit of its broader agenda, this will lead to higher prices, increased expenditure, poorer access to medicines, and — ultimately — poorer health outcomes among its trading partners. This highlights apparent conflicts between trade ambitions — pursued through the

negotiation of legal instruments to promote economic “health” — and public health goals — the development of treatments for neglected diseases, the pursuit of efficiency and equity in priority setting, and the procurement of medicines and other health technologies at prices that reflect their therapeutic value and promote affordable access. Experience to date suggests these goals are often not sufficiently taken into account — or are neglected altogether — in the negotiation of trade agreements. At the very least these conflicts should be recognized and subjected to open debate and structured balancing of goals and interests.

In some respects the TPPA could be viewed as a test bed where these tensions will be played out — albeit one with ramifications at the global level. It is, therefore, vital that TPPA countries recognize U.S. objectives and the potential trade-offs associated with them. They may ultimately choose to accept these not because they believe such changes reflect intrinsically sound public policy, but because of the economic imperative of gaining access to U.S. markets. Nevertheless, the notion that a free trade deal can be positive and beneficial for any nation — where the price of entrée to markets overseas is impaired access to essential medicines at home — at best reflects an absence of policy coherence between trade and health¹⁵⁸ or a lack of appreciation of the risks of disregarding “health in all policies.”¹⁵⁹ At worst, it represents a belief that maximizing corporate returns in the expectation of access to tomorrow’s therapeutic advances will ultimately yield greater public good than fair and accountable public policy today. Either way it makes the price of “free” trade seem very high indeed.

Table 1
Comparison of Key Pharmaceutical Intellectual Property Provisions in TRIPS, AUSFTA, KORUS, and U.S.TPPA Proposals

Provision	TRIPS	AUSFTA Chapter 17	KORUS Chapter 18	U.S. 2011 TPPA Proposal
Scope of patentability: Patents for new forms, uses, or methods of using a known product	No reference	Requires patents to be made available for new uses or methods of using a known product [Art. 17.9.1]	Requires patents to be made available for new uses or methods of using a known product [Art. 18.8.1]	Requires patents to be made available for new forms, uses or methods of using a known product [Art. 8.1]
Patents for diagnostic, therapeutic and surgical methods	Allows exclusion from patentability of diagnostic, therapeutic and surgical methods [Art. 27.3]	Allows exclusion [Art. 17.9.2]	Allows exclusion [Art. 18.8.2]	Requires patents to be made available for (a)plants and animals, and (b)diagnostic, therapeutic, and surgical methods for the treatment of humans or animals. [Art. 8.2]
Scope of patentability: Extent of exclusions	Allows exclusion from patentability of diagnostic, therapeutic and surgical methods [Art. 27.3]	<i>Limited to:</i> (a)inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect <i>ordre public</i> or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; and (b)diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.	<i>Limited to:</i> (a) inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect <i>ordre public</i> or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by its law; and (b)diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals.	<i>Limited to:</i> inventions, the prevention within its territory of the commercial exploitation of which is necessary to protect <i>ordre public</i> or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.
Patent term extension (adjustment)	No reference	Requires patent term adjustment to compensate for ‘unreasonable delays’ in the issuing of patents [Art.17.9.8[a]] and to compensate for ‘unreasonable curtailment of the effective patent term’ resulting from delays in marketing approval [Art. 17.9.8[b]].	Requires patent term adjustment for <i>all patents</i> [including those for new products*, methods of use and methods of manufacture]. May be limited to single patent, and to 5 years, and may be based on date of first marketing approval [MA]. May also be made contingent on application for MA within fixed period of MA in another Party* [Art. 18.8.6[b]]	Extends patent term adjustment to compensate for delays in marketing approval for new pharmaceutical products to patents covering methods of making or using pharmaceutical products [Art. 8.6[c]] May be limited to a single patent term adjustment for each new pharmaceutical product; the basis for the adjustment may be the first marketing approval granted to the new pharmaceutical product; and the period of the adjustment may be limited to 5 years.

Provision	TRIPS	AUSFTA Chapter 17	KORUS Chapter 18	U.S. 2011 TPPA Proposal
Pre-grant opposition	No reference	No reference	... proceedings that permit a third party to oppose the grant of a patent, .. shall not (be made) available before the grant of the patent. <i>Effectively eliminates pre-grant opposition</i> [Art. 18.8.4]	Explicitly eliminates pre-grant opposition [Art. 8.7]
Basis for patent revocation	No reference	May only be revoked on grounds that would have justified a refusal to grant the patent, or on the basis of fraud, misrepresentation, or inequitable conduct.	May only be revoked on grounds that would have justified a refusal to grant the patent...fraud, misrepresentation, or inequitable conduct may (also) be the basis for revoking a patent or holding a patent unenforceable.	May only be revoked on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation or inequitable conduct may be the basis for revoking a patent or holding a patent unenforceable.
Data protection for a new pharmaceutical product	Requires protection of <i>undisclosed</i> data from unfair commercial use; no duration specified [Art. 39.3]	<i>At least five years</i> of protection of <i>undisclosed</i> data from date of marketing approval [Art. 17.10.01]	<i>At least five years</i> of protection, <i>not limited to undisclosed data</i> [Art. 18.9.1]	<i>At least five years</i> of protection from the date of marketing approval, <i>not limited to undisclosed data</i> [Art. 9.2]
Definition of new pharmaceutical product	Not defined	Not defined	With respect to data protection “(a) <i>new pharmaceutical product is one that does not contain a chemical entity...previously approved in the territory of the Party</i> ” However with respect to patent term extension “ <i>a new pharmaceutical product... means a product that at least contains a new chemical entity...not ...previously approved as a pharmaceutical product in the territory of the Party.</i> ” which is much broader in scope. The latter would apply to combination products where at least one of the constituents is new; the former requires all constituent products to be new.	With respect to patent term extension a new pharmaceutical product means a product that at least contains a new chemical entity that has not been previously approved.
Extension of data protection for new uses of an existing product	No provision	<i>At least 3 years of additional data protection</i> for new uses or indications of an existing pharmaceutical product [Art. 17.10.2] [However Footnote 17.19 permits Australia to maintain its existing system which does not require this]	<i>At least 3 years of additional data protection</i> for new uses or indications of an existing pharmaceutical product; protection extends to <i>disclosed and undisclosed</i> data (data exclusivity provision). [Art.18.9.2]	<i>At least 3 years of additional data protection</i> for new uses or indications of an existing pharmaceutical product; protection extends to <i>disclosed and undisclosed</i> data (data exclusivity provision). [Art. 9.9] Also contains placeholder for specific provisions applying to biologics, likely to specify up to 12 years’ data exclusivity. [Art. 9.9]

Provision	TRIPS	AUSFTA Chapter 17	KORUS Chapter 18	U.S. 2011 TPPA Proposal
Patent Linkage	No provision	Patent linkage provision linking marketing approval of generic drugs to patent status. Applies only to generic applications that rely on originator data. Required to provide measures to prevent the marketing of product subject to patent (on the product or its approved use); notification to patent holder required if market entry before end of patent term. [Art. 17.10.4]	Patent linkage provision requiring notification to patent holders of generic marketing applications requesting marketing approval during the term of patent on a product or its approved use, and implementation of measures to prevent marketing of a generic product without consent of the patent owner during the term of a patent covering that product or its approved method of use <i>notified to the approving authority</i> [Art. 18.9.5]	Patent linkage provision requiring regulatory authorities to actively scan for existing patents, provide notification to patent holders, and delay granting marketing approval until disputes are settled. Not limited to patent on a product or its approved use. [Art. 9.5]
Parallel importation	Not addressed in TRIPS	Prohibited without consent of patent holder [Art. 17.9.4]	No reference	No reference
Compulsory licensing	TRIPS specifies conditions for granting a compulsory license: In general, efforts should first be made to obtain a voluntary license (VL), on reasonable terms. A compulsory license must be predominantly for the supply of the domestic market. Requirement to seek VL may be waived if CL is issued to remedy anti-competitive practices	Compulsory licensing limited to circumstances of: (a)remedying anticompetitive practices, or (b)in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency. Requires reasonable compensation for the patent owner; patent owner may not be required to provide undisclosed information or technical know-how.	No specific reference but constrained by virtue of data protection provisions	No specific reference but constrained by virtue of data protection provisions

Table 2

Comparison of Pharmaceutical Provisions in AUSFTA Annex 2-C, KORUS Chapter 5, and TPPA Transparency Annex (2011 Draft)

Provision	AUSFTA Annex 2-C Pharmaceuticals	KORUS Chapter 5: Pharmaceutical Products & Medical Devices	TPPA (2011 Draft) Annex on Transparency and Procedural Fairness for Healthcare Technologies
Scope of annex/chapter	Pharmaceutical products only	Pharmaceutical products and medical devices	Pharmaceutical products and medical devices
Language referring to pharmaceuticals [in the Agreed principles (AUSFTA/TPPA)/general provisions (KORUS)]	Text referring to recognition of innovation (“the important role played by innovative pharmaceutical products”) reflects existing mechanisms [Annex 2-C Art. 1(a)]	Shift in language from “innovative pharmaceutical products” to “patented and generic pharmaceutical products and medical devices [Art. 5.5.1 (b)]	Similar language to KORUS: “high-quality patented and generic pharmaceutical products and medical devices” [Art. X.1.(b)]
Basis for determining reimbursement amount	“the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that <i>appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical</i> ” [Annex 2-C Art. 1 (d)]	Requirement for reimbursement amounts to be “based on competitive market-derived prices” or to “appropriately recognize the value of the patented pharmaceutical product or medical device” [Art. 5.5.2(b)]	“ensure that the Party’s determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of competitive market derived prices in the Party’s territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue” [Art. X.3 (d)]
Procedures allowing manufacturers to apply for increased reimbursement	Side letter states that “Australia shall provide opportunities to apply for an adjustment to the price of a pharmaceutical under the PBS”; no criteria specified.	Requirement to permit a manufacturer to apply for an increased amount of reimbursement: a) over comparator, b) after decision on reimbursement amount, c) for additional indications [Art. 5.5.2 (b) and (c)]	Requirement to permit a manufacturer to apply for an increased amount of reimbursement: a) over comparator, b) for additional medical indications [Art. X.3 (e) and (f)]
Requirement to publish regulations	No reference	Requirement to publish proposed regulations and provide opportunities for “interested persons and the other Party” to comment [Art. 5.3] Very onerous obligations likely to frustrate policy making and allow undue influence in process by industry Significant delays in rule making and obligations to allow comment periods, reasons in writing and allow time before implementation will be difficult to operationalize.	Refers to Articles XX.2 (Transparency-Publication) – no text available But requires each Party to “allow reasonable time between publication of final regulations of general application at the central level of government respecting any matter related to the reimbursement of pharmaceutical products or medical devices and the effective date of such regulations” [Art. X.2.2]

Provision	AUSFTA Annex 2-C Pharmaceuticals	KORUS Chapter 5: Pharmaceutical Products & Medical Devices	TPPA (2011 Draft) Annex on Transparency and Procedural Fairness for Healthcare Technologies
Timeliness of listing and pricing processes	“ensure that consideration of all formal proposals for listing are completed within a specified time” [Art. 2.2(a)]	“ensure that consideration of all formal requests for the <i>pricing or approval</i> of pharmaceutical products or medical devices for reimbursement is completed within a <i>reasonable, specified period</i> [Art. 5.3.5(a)]	“ensure that consideration of all formal applications for the approval of pharmaceutical products or medical devices for reimbursement or for setting the amount of reimbursement of such products is completed within a reasonable, specified period” [Art. X.3 (b)]
Transparency in decision making	Requirement to “disclose procedural rules, methodologies, principles and guidelines used to assess a proposal” [Annex 2-C Art. 2.2(b)] No requirement to disclose decision criteria for reimbursement	Requirement to “disclose...all procedural rules, methodologies, principles, <i>criteria (including those used, if any, to determine comparator products)</i> , and guidelines used to determine pricing and reimbursement of pharmaceutical products or medical devices” [Art. 5.5 (b)] (<i>emphasis added</i>)	“disclose...all procedural rules, methodologies, principles, criteria (including those used, if any, to determine comparator products) and guidelines used to determine the eligibility for, and amount of, reimbursement for pharmaceutical products or medical devices” [Art. X.3 (b)]
Transparency to applicants	“provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities” [Art. 2.2 (d)]	Requirement to cite expert opinion/studies (impact unclear) [Art. 5.3.5(d)]	Requirement to cite expert opinion/studies (impact unclear) [Art. X.3 (g)]
Transparency to public	Requirement to “provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party’s law” [Art. 5.5(e)]	No requirement for transparency to the public Requirement to: “make all reimbursement decision-making bodies open to all stakeholders, including innovative and generic companies” [Art. 5.3.5(f)] and “make publicly available the membership list of all committees related to pricing or reimbursement of pharmaceutical products or medical devices” [Art. 5.3.5(g)]	Requirement to “make available to the public written information regarding its recommendations and determinations relating to the reimbursement of pharmaceutical products or medical devices, subject to any requirements under the Party’s law to protect information considered to be confidential” [Art. X.3 (h)] No requirement to make reimbursement decision-making bodies open to all stakeholders. Requirement to: “make publicly available the membership list of all committees involved in determinations related to the reimbursement of pharmaceutical products or medical devices” [Art. X.3 (k)]

Provision	AUSFTA Annex 2-C Pharmaceuticals	KORUS Chapter 5: Pharmaceutical Products & Medical Devices	TPPA (2011 Draft) Annex on Transparency and Procedural Fairness for Healthcare Technologies
Contestability mechanisms	<p>“make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination” [Art. 5.5(d)]</p> <p>Obligation narrowed by side letter; refers only to listing recommendations; no role with respect to pricing</p>	<p>“make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination” [Art. 5.3.5(e)]</p> <p>Broader obligation covering drugs and <i>devices</i>, listing and <i>pricing</i></p> <p>Side letter specifies that in implementing Art. 5.3.5(e), South Korea must establish and maintain a body (independent of health care authorities) to conduct such reviews</p>	<p>“make available an opportunity for independent appeal or review of recommendations or determinations relating to reimbursement for pharmaceutical products or medical devices”</p> <p>Obligation similar to KORUS, covering drugs and <i>devices</i>, listing and <i>pricing</i></p>
Direct to Consumer Advertising (DTCA) via the Internet	<p>Only as permitted to be disseminated under the Party’s laws, regulations and procedures (effectively preserves pre-existing prohibition on internet advertising or DTCA in any form) [Art. 5]</p>	<p>Requires South Korea to DTCA permit internet advertising [Art. 5.4]</p>	<p>Similar to KORUS [Art. X.4]</p>
Ongoing engagement	<p>“Medicines Working Group” Forum for discussion only</p> <p>No obligation WRT frequency of meetings</p> <p>Chaired by Health officials [Art. 3]</p> <p>Confined to discussion of issues arising from Annex 2-C</p> <p>No recommendatory or decision-making role and no requirement to report to joint committee</p>	<p>“Medicines and Medical Devices Committee” Forum to monitor and support implementation and explore collaboration</p> <p>Required to meet at least once a year</p> <p>Co-chaired by Health and Trade officials</p> <p>Required to report to Joint Committee [Art. 5.7]</p>	<p><i>Placeholder for possible cooperative mechanisms</i> [Art. X.6.2]</p>
U.S. carve-out	<p>Most US programs, <i>including Medicaid</i> (although considered by some to be ambiguous) carved out.</p> <p>May be argued that text does not exclude Medicare Part B.</p>	<p>Most US programs subject to carve-out; with footnote explicitly excluding Medicaid</p>	<p>Use of explicit references to reimbursement programs where decisions are made at central level of government effectively carves out many US programs, including Medicaid.</p> <p>May be argued that leaked text does not adequately exclude parts of Medicare (esp. Part B), the 340B program, or Medicare National Coverage Determinations (NCDs)</p>

Acknowledgements

We wish to record our grateful thanks to the following for their helpful comments on earlier versions of the manuscript: Rebecca de Boer, Colleen Flood, Katie Kirk, David Legge, Marcelo Rodriguez Ferrere, Sara Rosenbaum, and an anonymous reviewer.

The views presented are entirely the authors' and do not represent those of the Australian Government, or any institution with which the authors are affiliated.

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7. See Mitchell and Voon, *supra* note 6, at 188.
8. See WTO, *supra* note 1.
9. See Drahos, *supra* note 2, at 16.
10. S. Reid Smith, "Introduction to Intellectual Property, Trade and Access to Medicines," in "Our Health, Our Right: The Roles and Experiences of PLHIV Networks in Securing Access to Generic ARV Medicines in Asia," *Asia Pacific Network of People Living with HIV/AIDS*, 2010, APN+, 9-22, at 12 et seq.
11. This provision is frequently misrepresented by the pharmaceutical industry as representing the only circumstances in which TRIPS permits compulsory licensing as opposed to the circumstances in which the requirement to seek a voluntary license may be waived.
12. See Smith et al., *supra* note 5, at 686.
13. Subsequent to the November 2001 Declaration on the TRIPS Agreement and Public Health, WTO Members adopted instruments on TRIPS and public health in 2002 extending until 2016 the deadline for LDCs to provide patent protection for pharmaceuticals; in 2003 introducing a "waiver" removing limitations on exports under compulsory license to countries without domestic manufacturing capacity; in 2005 – the related Protocol Amendment giving effect to the waiver and replacing the August 2003 decision; and in 2007, 2009 and 2011, extending the deadline for the adoption of the amendment.
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17. Oxfam International, *All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA affect Access to Medicines*, Oxfam Briefing Paper, 2007, at 2; see Drahos, *supra* note 2, at 33.
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19. E. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (The Netherlands: AMB Publishers, 2009): at 70

et seq; see Reid Smith, *supra* note 10, at 16 *et seq*; G. P. Krikorian and D. M. Szymkowiak, "Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine," *Journal of World Intellectual Property* 10, no. 5 (2007): 388-418, at 393.

20. Evergreening refers to the variety of strategies employed by patent holders to prolong monopolies by securing additional patent protection for minor and arguably trivial product variations, thereby delaying generic competition, and facilitating maintenance of monopoly pricing.

21. Despite referring specifically to delay in the "marketing approval process," this is generally interpreted as the delay between the granting of the patent and the entry to market, rather than within the regulatory evaluation process *per se*. Delays in generic market entry are usually taken to refer to the period of time between the discovery and patenting of the molecular entity and its entry to market, which because of the long lead times required for clinical trials can be 10-15 years. However, in reality the marketing approval process only begins with the submission of an application dossier to the regulatory agency.

22. See Sell, *supra* note 3, at 61.

23. See Sell, *supra* note 3, at 62. Patent linkage mechanism fundamentally alter the role and remit of the regulatory agency, forcing them to take into account factors not relevant to the safety, efficacy or quality of the product for which marketing approval is being sought, and requiring them to adjudicate the existence and/or relevance of patents on reference products.

24. F. M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements. Occasional Paper 14," (Geneva: Quaker United Nations Office, 2004), at 8, *available at* <<http://www.quno.org/geneva/pdf/economic/Occasional/TRIPS-Public-Health-FTAs.pdf>> (last visited February 19, 2013).

25. The Drug Price Competition and Patent Term Restoration Act 1984, Public Law 98-417 a.k.a. the Hatch-Waxman Act.

26. See Article 126 of Directive (EC) No 2001/83, and Article 81(2) of Regulation (EC) No. 726/2004. See also A. Kumar, "Patent or Patient, Link Them Properly: 'Patent Linkage and Competition' (A Comparative Study)," *ExpressO*, 2012, *available at*

<http://works.bepress.com/ashutosh_kumar/1> (last visited February 19, 2013). Where individual EU member states have introduced forms of patent linkage, they have been instructed to desist.

27. See Sell, *supra* note 3, at 60.

28. In some jurisdictions, it is possible for a generic manufacturer to submit a literature-based application, relying on efficacy and safety data already in the public domain rather than on the dossier submitted by the originator. A literature-based submission is not possible unless protection is limited to undisclosed data. This distinguishes a data "protection" from a data "exclusivity" regime.

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33. See Oxfam International, *supra* note 17, at 5.

34. See 't Hoen, *supra* note 19, at 72.

35. The provision requires notification of generic application to patent holder only.

36. See Oxfam International, *supra* note 17, at 7.

37. *Id.*, at 2.

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39. See 't Hoen, *supra* note 19, at 72.

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42. See Office of the U.S. Trade Representative, *supra* note 40.
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- "Evaluation on the First 2 Years of the Positive List System in South Korea," *Health Policy* 104, no. 1 (2012): 32-39, at 34.
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138. A current example is a \$300 million action by French pharmaceutical company Servier against the Polish government – while details of the case are scant, it appears to relate to the review of medicines by regulatory bodies in the process of Poland’s accession to the EU. See L. E. Peterson, “France’s Second Largest Pharmaceutical Company Quietly Pursues Arbitration against Republic of Poland,” *Investment Arbitration Reporter*, August 19, 2011, available at <http://www.iareporter.com/articles/20110819_9> (last visited April 30, 2012; subscribers only). Other health-related ISDS cases have involved pharmaceutical regulation and drug patents (e.g., *Signa v. Canada*, *Apotex v. USA*), health care services (e.g., *Centurion Health v Canada*) and a range of environmental health issues such as potable water, food contamination, pesticides, and other environmental health contaminants. See International Investment Arbitration and Public Policy website, available at <<http://www.iiapp.org/>> (last visited February 20, 2013). Eli Lilly has also indicated its intention to commence investor-state action against the Canadian Government for invalidating a drug patent see Public Citizen, *Fact Sheet: U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada’s Medicine Patent Policy, Demand \$100 Million for Denial of a Patent* (Washington, D.C.: Public Citizen, 2013).
139. The South Korean Supreme Court apparently recommended renegotiation of the KORUS ISDS provision as early as June 2006, citing concerns over the capacity for such a mechanism to infringe national and judicial sovereignty and the potential distortion of state public policy that could result from administrative bodies assessing and reviewing government policies. The South Korean government recently announced that it would be seeking to renegotiate the investment-related provisions in the KORUS FTA with the US within 90 days of its effective date of March 15, 2012. See “Supreme Court recommends renegotiation of ISD clause,” *The Hanyoreh*, April 26, 2012, available at <<http://www.bilaterals.org/spip.php?article21397>> (last visited February 20, 2013).
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142. See <<http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/TransPacific/1-TPP-Talk/0-TPP-talk-29-Nov-2011.php>> (last visited February 20, 2013).
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149. See ‘t Hoen, *supra* note 19, at 81.
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