Global Perspectives and Challenges for the Intellectual Property System

A CEIPI-ICTSD publications series

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The Emergence and Impact of Mega-Regionals

Edited by Pedro Roffe and Xavier Seuba

With contributions by
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ICTSD
International Centre for Trade and Sustainable Development

CEIPI

Issue Number 4
September 2017

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Published by

International Centre for Trade and Sustainable Development (ICTSD)
7 Chemin de Balexert, 1219 Geneva, Switzerland
Tel: +41 22 917 8492
Fax: +41 22 917 8093
Email: ictsd@ictsd.ch
Internet: www.ictsd.org

Center for International Intellectual Property Studies (CEIPI)
11 rue du Maréchal Juin - BP 68 - 67046 STRASBOURG
Email: ceipi@ceipi.edu
Internet: www.ceipi.edu

Series editors: Christophe Geiger and Xavier Seuba, Center for International Intellectual Property Studies (CEIPI), University of Strasbourg; Pedro Roffe, International Centre for Trade and Sustainable Development (ICTSD), Geneva; and Ahmed Abdel-Latif, International Renewable Energy Agency (IRENA).

Current Alliances in International Intellectual Property Lawmaking: The Emergence and Impact of Mega-Regionals, Global Perspectives for the Intellectual Property System, CEIPI-ICTSD, Issue Number 4, 2017.

The series editors acknowledge the assistance of Ann Bone for her careful copy-editing as well as Emily Bloom and Anna Sims, ICTSD, for their contribution in the production of this publication.

Citation: Pedro Roffe and Xavier Seuba (eds.), Current Alliances in International Intellectual Property Lawmaking: The Emergence and Impact of Mega-Regionals, Global Perspectives for the Intellectual Property System, CEIPI-ICTSD, Issue Number 4, 2017.

ISSN 2414-343X

The Evolution of Public Health Provisions in Preferential Trade and Investment Agreements of the United States

Frederick M. Abbott

1. Introduction

Bilateral, regional and plurilateral trade and investment agreements negotiated by the United States since the conclusion of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) limit public health regulatory autonomy. In negotiating plurilateral trade and investment agreements (PT&IAs), the immediate post-Uruguay Round negotiating objectives of the United States involved filling in perceived gaps left in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This included expanding the minimum scope of patent subject matter coverage, adding specificity regarding the criteria of patentability, requiring patent term extension, expanding the scope of obligations regarding protection of regulatory data through marketing exclusivity requirements, and bringing intellectual property (IP) disputes within the sphere of investor to state dispute settlement (ISDS). More recently, the PT&IA template advanced by the United States initiates a deeper intrusion into the public health regulatory arena. The new template provides for intervention by pharmaceutical originator companies into government decision-making regarding whether to include particular drugs in national health formularies, and into decisions regarding pricing. Such provisions appear in agreements concluded by the United States with Australia and South Korea, and are part of the Trans-Pacific Partnership (TPP) Agreement from which the United States withdrew its signature. The latest template extends a requirement of regulatory market exclusivity to the area of biologic drugs, effectively mandating delays in the introduction of biosimilar products whether or not they are protected by patent.

As a matter of US law and practice, the provisions of PT&IAs are not directly incorporated in national law. The US Congress must expressly implement relevant provisions, and private litigants are not authorised to initiate court claims based directly on PT&IA terms. Only legislatively implemented provisions are subject to enforcement through the courts. There is, however, a prospective caveat to this general rule. In a case currently pending before the US Supreme Court—involving the appropriate rule of exhaustion (national or international) with respect to patents—an argument is raised that the United States must adopt a rule that is incorporated in a few PT&IAs, or otherwise find itself in breach of its international obligations. A Supreme Court decision following that argument would create a new situation in US law bringing about a form of direct effect through an indirect mechanism.

President Trump has signalled an intention to negotiate, and renegotiate, trade deals in a way more favourable to the United States, suggesting that the USA has been unfairly taken advantage of in prior trade deals. This may come as a surprise to trade negotiators of other countries. At the same time, the President has expressed strong dissatisfaction with high pharmaceutical prices. It is unclear at this moment how these signals will be translated into future US trade negotiating positions. But, it would be surprising if the result is a relaxation of demands with respect to protection of intellectual property, including regulatory exclusivity, or a relaxation of the push towards regulatory intrusion. Countries negotiating and implementing PT&IAs with the United States should remain cautious in accepting obligations that may be directly effective in national law. The model of the United States requiring legislative transformation or implementation remains the prudent approach, allowing the legislature to do what it can to maintain a domestic balance that favours the interests of consumers and patients.

2. Evolution

2.1 Negotiations and Agreements Preceding Conclusion of the TRIPS Agreement

The United States was an architect of the WTO TRIPS Agreement, initiating its policy drive in the late 1970s, moving towards the GATT in the early 1980s, and completing the TRIPS framework by late 1993.[1] The provisions of the TRIPS Agreement and the effect of those provisions on public health are the subject of an extensive literature, not to be repeated here.[2]

Prior to the TRIPS Agreement, the United States had negotiated bilateral investment treaties that included intangible property as a form of investment, and that subjected unlawful takings to third-party dispute settlement.[3] The negotiation of such provisions generated little discussion or controversy within the United States.

The first US "free trade agreement" was negotiated with Israel and entered into force on 1 January 1985, but included only a cursory reference to intellectual property, and no provisions on investment or third-party dispute settlement related to that.[4] The Canada–US Free Trade Agreement, entering into force on 1 January 1989, currently suspended, did not contain provisions regarding intellectual property, and did not in its investment chapter expressly refer to intellectual property or intangible property. In addition, there was no formal mechanism for third-party dispute settlement.[5] However, the United States had long expressed concern regarding Canada's compulsory licensing system with respect to pharmaceutical patents that effectively provided licences of right. Canada initially amended its Patent Act in 1987, among other reasons, to address those concerns. It was in 1992, during the North American Free Trade Agreement (NAFTA) and TRIPS negotiations, that Canada enacted legislation that effectively eliminated this "alternative" compulsory licensing regime for pharmaceuticals.[6]

The United States, Canada and Mexico initiated negotiation of the NAFTA in 1991, the agreement was signed at the end of 1992, ratified in 1993, and entered into force on January 1, 1994.[7] The intellectual

1 Frederick M. Abbott, "Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework," *Vanderbilt Journal of Transnational Law* 22, no. 4 (1989): 689, https://ssrn.com/abstract=1918346; UNCTAD-ICTSD, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement*, last updated 1 June 2005, https://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm.

2 See, including for references, Frederick Abbott, "Trade in Medicines," in *Trade and Health: Building a National Strategy*, ed. R. Smith et al. (pp. 117–140) (Geneva: World Health Organization, 2015), https://ssrn.com/abstract=2659277.

3 Lahra Liberti, "Intellectual Property Rights in International Investment Agreements: An Overview," *OECD Working Papers on International Investment*, 2010/01 (Paris: OECD, 2010), http://dx.doi.org/10.1787/5kmfq1njzl35-en.

4 Agreement on the Establishment of a Free Trade Area between the Government of Israel and the Government of the United States of America, signature 22 April 1985, entry into force 19 August 1985, http://www.sice.oas.org/Trade/US-Israel/index_e.asp.

5 Canada–US Free Trade Agreement: http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/us-eu.aspx?lang=eng; http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/us-eu.aspx?lang=eng.

6 See Kristen Douglas and Célia Jutras, "Patent Protection for Pharmaceutical Products in Canada—Chronology of Significant Events," Canadian Parliamentary Information and Research Service, PRB 99-46E (2008), http://www.lop.parl.gc.ca/content/lop/ResearchPublications/prb9946-e.pdf.

7 Frederick M. Abbott, *Law and Policy of Regional Integration: The NAFTA and Western Hemispheric Integration in the World Trade Organization System* (Dordrecht: M. Nijhoff, 1995), ch. 1; Frederick M. Abbott, "The North American Integration Regime and Its Implications for the World Trading System," in The EU, the WTO, and the NAFTA: *Towards a Common Law of International Trade*, ed. Joseph H. H. Weiler (pp. 169–200) (Oxford: Oxford University Press, 2000).

property chapter of the NAFTA was negotiated contemporaneously with the TRIPS Agreement, and the negotiators for each of the parties was well aware of the provisions under negotiation at the GATT. While NAFTA may have been negotiated for its own sake, it was also a US "bargaining chip" during the Uruguay Round as US negotiators pointed out that regional arrangements were an alternative should other countries not want to make concessions at the GATT. These concessions included the TRIPS Agreement.

The intellectual property chapter of the NAFTA introduced protection of regulatory data for pharmaceuticals as the subject of trade agreement.[8] While the initial form was softer than those later included in bilateral/regional PT&IAs, it was stronger than the provision in the TRIPS Agreement because it included an express requirement for market exclusivity, with a presumption regarding the appropriate duration. In addition, NAFTA included a commitment by Mexico to pharmaceutical product patent "pipeline" protection pursuant to which US and Canadian pharmaceutical patent owners were authorised to obtain corresponding patents in Mexico for the duration of the pending patent terms, provided that the subject pharmaceutical products had not previously been marketed in Mexico.[9] The regulatory exclusivity provision in the NAFTA did not appear to generate public controversy at the time it was concluded.[10] The pipeline provision raised concerns among other GATT Contracting Parties because there was no mechanism for extension to non-NAFTA countries. And, because Mexican nationals would not benefit from the pipeline provision in Mexico, this is cited as one of the reasons why the most favoured nation provision is included in the TRIPS Agreement (along with a US–China bilateral agreement that gave certain rights to US nationals that were better than those granted to Chinese nationals).

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8 Article 1711: Trade Secrets, NAFTA:

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

9 Article 1709: Patents, NAFTA:

4. If a Party has not made available product patent protection for pharmaceutical or agricultural chemicals commensurate with paragraph 1:

(a) as of January 1, 1992, for subject matter that relates to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, and

(b) as of July 1, 1991, for any other subject matter,

that Party shall provide to the inventor of any such product or its assignee the means to obtain product patent protection for such product for the unexpired term of the patent for such product granted in another Party, as long as the product has not been marketed in the Party providing protection under this paragraph and the person seeking such protection makes a timely request.

10 However, Canada did not initially implement the regulatory exclusivity requirement in a way preferred by the United States, giving rise to some follow-on controversy. See *Bayer Inc. v. The Attorney General of Canada and The Minister of Health and Apotex Inc and Novopharm Limited*, A-679-98, 19990519, para. 4.

It is worth noting that Mexico revised its national patent law to allow pharmaceutical product patenting in 1991, prior to conclusion of the NAFTA, but apparently at the urging of the US government, and as context for the NAFTA negotiations.[11]

In addition to the patent and regulatory data provisions, the NAFTA included an investment chapter and third-party investor to state dispute settlement either through the International Centre for Settlement of Investment Disputes or under the rules of the United Nations Commission on International Trade Law (UNCITRAL).[12] There is no direct link in the intellectual property chapter to the investment chapter. The definition of investment refers to "intangible property."[13] The investment chapter, in Article 1110(7), introduces language that purports to remove compulsory licensing from the subject matter of ISDS, though in a way that nevertheless permits arbitration regarding whether the licensing complied with IP chapter rules:

> This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).

In this specific way, the investment chapter expressly links to the intellectual property chapter.

A notable development regarding the NAFTA investment and intellectual property chapters is the claim brought by the US-based pharmaceutical company Eli Lilly against the government of Canada in 2012, which claim was rejected by a NAFTA-UNCITRAL arbitration panel in early 2017. Eli Lilly invoked the takings provisions in the NAFTA investment chapter as grounds for challenge of a determination of patent invalidity by Canadian federal courts regarding two Eli Lilly patents.[14] The Eli Lilly complaint and subsequent proceedings against the government of Canada provided a stark illustration of why governments and other stakeholders have become increasingly concerned about the potential scope of ISDS obligations in PT&IAs. Eli Lilly's complaint was nothing more than an attempt to appeal ordinary adverse patent determinations by Canadian federal courts to a non-Canadian arbitral body, accompanied by demands for an extraordinary level of compensation (US$500 million). It also represented an effort to pressure the Canadian government to modify Canadian patent law. Canada was in the fortunate position to have the financial and human resources

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11 Mexico, Industrial Property Law of 25 June 1991, subsequently amended, at http://www.wipo.int/edocs/lexdocs/laws/en/mx/mx113en.pdf. Kenneth C. Shadlen, "Intellectual Property for Development in Mexico," in *The Future of North American Trade Policy: Lessons from NAFTA*, Pardee Center Task Force Report, November 2009, at 53, 57; Edwin S. Flores Troy (Student Note), "The Development of Modern Frameworks for Patent Protection: Mexico, a Model for Reform," *Texas Intellectual Property Law Journal* 6, no. 2 (1998): 133.

12 Frederick M. Abbott, "The North American Free Trade Agreement (NAFTA): Structure, Dispute Settlement and Case Law" (1 June 2014), in *Max Planck Encyclopedia of Public International Law*, gen. ed. Rüdiger Wolfrum (Oxford: Oxford University Press, 2012; updated 2014), vol. 7, p. 776, https://ssrn.com/abstract=2080209.

13 Article 1139(g), NAFTA, includes among defined investments "(g) real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes." Regarding the standard of protection to be provided by the host country, Article 1105(1) provides: "Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security."

14 Frederick M. Abbott, "Introductory Remarks by Frederick M. Abbott," *Proceedings of the ASIL Annual Meeting* 108 (2014): 311–313, doi:10.5305/procannmeetasil.108.0311; Jerome H. Reichman, "Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection," *Proceedings of the ASIL Annual Meeting* 108 (2014): 313–317, doi:10.5305/procannmeetasil.108.0313.

available to defend itself properly. For developing countries, taking on a well-capitalised originator pharmaceutical company in an international arbitration will place strain on government resources, regardless of the merits of the case.

The process of approval of the NAFTA in the United States was politically controversial. However, at the relevant time, neither the investment chapter nor ISDS provisions were the substantial subject matter of that controversy. The main focus was on labour rights and environmental protection, in addition to the general question whether NAFTA would result in a transfer of US jobs to Mexico.[15] Notably, H. Ross Perot, a successful Texas businessman, ran a third-party presidential campaign against George H. W. Bush and Bill Clinton principally on the argument that approval of NAFTA would create "a giant sucking sound going south" in terms of American jobs.[16]

At the time the GATT Tokyo Round (1979) was concluded, the US Congress began to incorporate in its trade agreement approval legislation provisions expressly barring the agreements from "self-executing" or direct effect in the law of the United States, and precluding individuals from initiating court actions on the basis of the relevant trade agreement. Such a provision was included in the legislation approving and implementing the NAFTA,[17] along with a so-called "Statement of Administrative Action" which is a formal document transmitted by the Executive Branch along with the proposed approval legislation that states the Executive's interpretation of the agreement and is binding on the Executive.[18]

2.2 The WTO TRIPS Agreement

The US pharmaceutical industry was a major force behind TRIPS Agreement demands, and the industry accomplished several of its principal objectives in the TRIPS Agreement. Foremost was establishing the obligation on all WTO members to provide pharmaceutical product patent protection, albeit with transition arrangements. The minimum patent term of 20 years from the date of filing substantially extended duration for many countries. However, various compromises were required to bring along the most important developing countries (from an economic standpoint), such as Brazil and India. Probably the most important from the industry standpoint was the relatively soft nature of the commitment in Article 39.3 regarding protection of regulatory data. The United States and European Union (then European Community) had sought a requirement for regulatory market exclusivity, including a minimum duration, but were unable to secure this concession.[19] The provisions regarding exceptions and compulsory licensing were less strict than the United States

15 See Abbott, *Law and Policy of Regional Integration*, ch. 1.

16 Ross Perot "Giant Sucking Sound," 15 October 1992, C-SPAN clip of presidential candidates' debate, https://www.c-span.org/video/?c4554632/ross-perot-giant-sucking-sound.

17 A "light" form of the preclusion of direct effect was used to approve the US–Israel Free Trade Agreement in 1985. Description of implementing procedure in Approval of United States-Israel Trade Agreement, Report of the Senate Finance Committee, Senate Report 99-55, May 15, 1985, p. 6 https://www.finance.senate.gov/imo/media/doc/srpt99-55.pdf.

18 The inclusion of the Statement of Administrative Action is a practice that grew out of a dispute between the US Senate and President Reagan regarding interpretation of the US–Russia Anti-Ballistic Missile (ABM) Treaty of 1972. President Reagan asserted an interpretation of the treaty that had been specifically disclaimed before the Senate by the US Department of State when it was initially approved and ratified. Congress thereafter insisted upon a formal binding record of agency interpretations. The Statement of Administrative Action of the Executive with respect to approval of the Uruguay Round agreements in the United States played a role in the decision of the WTO panel in the US-Section 301 case; *United States – Sections 301-310 of the Trade Act of 1974*, Report of the Panel, WT/DS152/R, 22 December 1999.

19 See UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, 525–526.

would have preferred. While the TRIPS Agreement referred to the basic criteria of patenting, it did not incorporate express definitions of those criteria. The US pharmaceutical industry was opposed to international exhaustion and potential parallel importation of patented pharmaceuticals, and the TRIPS Agreement left that matter open.[20] While the US pharmaceutical industry had accomplished its fundamental objectives with the TRIPS Agreement, it was an incomplete success.

The TRIPS Agreement entered into force on 1 January 1995. The originator pharmaceutical industry may have initially envisaged progressive tightening of IP rules at the new WTO, but the prospect to secure additional concessions at the WTO was surrendered when the industry initiated a lawsuit against Nelson Mandela following adoption by South Africa of the Medicines and Related Substances Controls Amendment Act of 1997 (including the provision authorising the Minister of Health to approve parallel importation of patented medicines).

During the multi-year battle with South Africa and the international community of non-governmental organisations (NGOs), the pharmaceutical industry turned its attention to bilateral and regional agreements. The Doha Declaration on the TRIPS Agreement and Public Health was adopted in November 2001 as a direct response to the litigation in South Africa and would play an ongoing role in respect to bilateral and regional agreements.[21]

2.3 First Generation Post-TRIPS PT&IAs

The first major success from the industry standpoint was negotiation of the Central America Free Trade Agreement (CAFTA)–Dominican Republic–US (DR-US),[22] concluded in 2004, entering into force 2006–2009.[23] These negotiations were quite interesting from a political standpoint. Between the conclusion of the TRIPS Agreement in 1993 and the negotiating timeframe of the CAFTA-DR a powerful coalition of NGOs, academic experts and developing country governments had turned their attention to the IP provisions in trade agreements as potential obstacles to the accomplishment of important public health objectives. Central American governments received expert external advice regarding the potential impact of the IP chapter, especially, on public health in that region. NGOs were successful in generating political opposition to rules that would inhibit access to medicines. Yet, despite these "headwinds," the trade and investment benefits of entering into the agreement persuaded the governments of the CAFTA-DR countries to largely accept US pharmaceutical industry-backed demands. A new "template" was now in evidence that secured substantial concessions for the US pharmaceutical industry. That template has continued to evolve through the TPP text, though its foundations can be directly traced to the CAFTA-DR.

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20 Compare Frederick M. Abbott, "First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation," *Journal of International Economic Law* 1, no. 4 (1998): 607–636, https://ssrn.com/abstract=915046, and Harvey E. Bale, Jr, "The Conflicts between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals," *Journal of International Economic Law* 1, no. 4 (1999): 637.

21 Frederick M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO," *Journal of International Economic Law* 5 (2002): 469, https://ssrn.com/abstract=1493725.

22 Central America–Dominican Republic–United States Free Trade Agreement (CAFTA-DR), http://www.sice.oas.org/Trade/CAFTA/CAFTADR_e/CAFTADRin_e.asp.

23 Frederick 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 No. 14, Quaker United Nations Office (Geneva), April 2004, https://ssrn.com/abstract=1977300.

The CAFTA-DR also was the first US-negotiated PT&IA to include a side letter referencing the Doha Declaration on the TRIPS Agreement and Public Health, though in a less well articulated form than subsequent such side letters.[24]

Twists and turns were navigated on the US-led PT&IA road during and following the negotiation of CAFTA-DR. From the standpoint of the pharmaceutical industry, the US–Morocco text represented a zenith in the sense that the Kingdom appeared to have little interest in making demands, so the then industry wish list was largely incorporated into the text.[25] On the other side, among the earlier agreements, Chile and Jordan actively resisted demands affecting the pharmaceutical sector, perhaps because each country had a large and successful generics industry which pressured their respective governments.[26] Chile and Jordan accepted TRIPS-plus pharmaceutical-related commitments, but each with some concessions from the United States regarding its preferred template. Colombia, Peru and Panama were each pressured by US negotiators to accept restrictive templates, but were then the beneficiaries of objections by the US Democratic Party, and a bipartisan congressional agreement regarding modifications.[27] The terms were amended in favour of relaxing the restrictive rules prior to entry into force of the agreements.[28]

2.4 Second Generation Preferential Trade and Investment Agreements

2.4.1 Australia and South Korea

A new template began to emerge in negotiations between the United States, on one side, and higher income countries, notably Australia[29] and South Korea.[30] In these cases, the US pharmaceutical

24 CAFTA-DR, "Understanding Regarding Certain Public Health Measures," 5 August 2004.

25 United States–Morocco Free Trade Agreement, entry into force, 1 January 2006, https://ustr.gov/sites/default/files/uploads/agreements/fta/morocco/asset_upload_file118_3819.pdf.

26 Regarding Chile, see Pedro Roffe, "Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement," *TRIPS Issues Papers* No. 4, Quaker United Nations Office, Geneva (2004), http://www.quno.org/sites/default/files/resources/Bilateral%2BAgreements%2Band%2BTRIPS%2Bplus%2BEnglish.pdf.

27 Binyamin Appelbaum and Jennifer Steinhauer, "Congress Ends 5-Year Standoff on Trade Deals in Rare Accord," *New York Times*, 12 October 2011.

28 See Tove Iren S. Gerhardsen, "Observers Watchful of US Trade Impact on Medicines Access," *IP-Watch*, 24 July 2007, http://www.ip-watch.org/2007/07/24/observers-watchful-of-us-trade-impact-on-medicines-access/.

29 US–Australia, Annex 2-C and Side Letter, http://sice.oas.org/Trade/US-AusFTAFinal/chapter1_13.asp#ANNEX_2C:

Annex 2-C, Pharmaceuticals

2. Transparency

To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:

(a) ensure that consideration of all formal proposals for listing are completed within a specified time;
(b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;
(c) afford applicants timely opportunities to provide comments at relevant points in the process;
(d) 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;
(e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and
(f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

30 US–South Korea, Chapter Five: Pharmaceutical Products and Medical Devices, http://sice.oas.org/TPD/USA_KOR/Draft_text_0607_e/asset_upload_file899_12703.pdf.

industry became more aggressive with respect to demands regarding the broader regulatory structure surrounding pharmaceuticals, including determinations by public health authorities regarding insurance reimbursement and pricing issues. This was an important set of developments representing a deeper intrusion into international public health regulatory structure and decision-making. This new form of intrusion was introduced as a template for the TPP negotiations.

The new template with Australia and South Korea requires that pharmaceutical companies have a right to challenge determinations regarding whether purchases of particular drugs will be reimbursed by national health schemes. The public health authorities make these determinations on the basis of comparative efficacy and cost, among other factors, and these determinations are now subject to challenge. The companies may ultimately be able to force the Australian and South Korean governments to reimburse for expensive new drugs, notwithstanding the initial decisions of the public health authority.[31]

The pharmaceutical companies argue that these measures are important to promote transparency and fairness. However, it should be apparent that the prospects of facing time-consuming litigation involving pharmaceutical industry lawyers will pressure public health authorities to lean towards approval so as to avoid it. Because the industry uses advertising and promotion to stimulate physician prescribing, once a drug is approved there is a substantial possibility that it will be prescribed, typically without great attention to the ultimate budgetary imposition on the government (or private patients). Given that sovereign governments would typically guard the regulatory discretion of their public health authorities, it is naturally surprising that Australia and South Korea would accept these provisions, and it shows the extent of the pressure that can be brought to bear.

2.4.2 The Trans-Pacific Partnership

The TPP was projected to initially encompass 12 countries, making it a substantially wider arrangement than previous PT&IAs of the United States. In this regard, the TPP is sometimes referred to as a

31 US–South Korea provides:

ARTICLE 5.2: ACCESS TO INNOVATION

To the extent that health care authorities at a Party's central level of government operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or medical devices, under health care programs operated by its central level of government, the Party shall:

(a) ensure that the procedures, rules, criteria, and guidelines that apply to the listing of pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or medical devices are fair, reasonable, and non-discriminatory;

(b) ensure that the Party's determination, if any, of the reimbursement amount for a pharmaceutical product or medical device, once approved by the appropriate regulatory authority as safe and effective, is based on competitive market-derived prices; or if its determination is not based on competitive market-derived prices, then that Party shall:

(i) appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides;

(ii) permit a manufacturer of the pharmaceutical product or medical device to apply, based on evidence of safety or efficacy, for an increased amount of reimbursement over that provided for comparator products, if any, used to determine the amount of reimbursement; and

(iii) permit a manufacturer of the pharmaceutical product or medical device, after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for the product based on evidence the manufacturer provides on the product's safety or efficacy; and

(c) permit a manufacturer of the pharmaceutical product or medical device to apply for reimbursement of additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy.

"mega-regional." With respect to pharmaceuticals and IP, the TPP text incorporated new template elements, though more in the nature of an evolution than a sharp break from the prior template.

For the first time the text of an PT&IA would explicitly extend regulatory marketing exclusivity to biologic pharmaceuticals.[32] The extension to biologic pharmaceuticals would entail a substantially longer duration than prior PT&IAs with respect to pharmaceuticals created through synthetic organic chemistry. The extension to biologic pharmaceuticals is important on several counts. First, Article 39.3 of the TRIPS Agreement imposes a requirement for pharmaceutical regulatory data protection with respect to "new chemical entities."[33] On its face, this language does not encompass biologic drugs which are outside the ordinary definition of chemical entities. In this regard, the TPP extension addresses what to the pharmaceutical industry is a significant gap in the TRIPS Agreement. At the same time, of course, for countries that may wish to allow accelerated follow-on introduction of biologics, this extension creates a genuine obstacle.

Second, negotiation of the duration of the biologics exclusivity period was perhaps the most controversial part of the TPP negotiations, or at least among the top few. Ultimately, the parties agreed upon an eight-year period of market exclusivity that, in response to demands from Australia regarding the way its regulatory system operates, include an alternative "5+3" formulation that is understood to effectively correspond to an eight-year term.[34] The situation in the United States was "peculiar" at best in that the Obama Administration under industry pressure lobbied for a 12-year exclusivity period, which corresponds to the internal US legislation, while domestically the same

32 TPP, Article 18.52: Biologics:

1. With regard to protecting new biologics, a Party shall either:

(a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, mutatis mutandis, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,

(b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:

(i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, mutatis mutandis, for a period of at least five years from the date of first marketing approval of that product in that Party,

(ii) through other measures, and

(iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.

2. For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

3. Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely availability of follow-on biosimilars, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.

33 Article 39.3, TRIPS Agreement: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize *new chemical entities*" (emphasis added).

34 The provision embodying the 5+3 alternative is not a model of clarity, and foreseeably might lead to disputes among governments and/or other stakeholders.

Obama Administration was pressing to reduce the exclusivity duration to seven years.[35] Basically, the Executive was negotiating internationally for an agreement that would contradict its own internal legislative preference.

In other matters regarding the template, TPP parties would need to provide patents for new uses of known products, or new methods of use of previously known compounds.[36] This is consistent with prior US PT&IAs. A provision that would have effectively negated the type of provision that India adopted as section 3(d) of its Patent Act—requiring new forms of known pharmaceutical substances to evidence a significant enhancement in efficacy from known use[37] —was not part of the final text.

The TPP requires parties to link registered patents with drug regulatory approval, providing at least a notice and opportunity to seek a preliminary injunction, or alternatively simply to block approval based on a patent.[38] Though the drafting of this requirement may include somewhat more extensive obligations than earlier template versions, this is not a new development. Linkage presents the largest scale problem for the countries with the least well developed legal systems: countries where preliminary injunctions may last for a decade because there is no one that can effectively challenge them.

There is a requirement that customs authorities will have ex officio power to seize goods in transit based on suspicion of trademark infringement. Patents are not specifically covered in this provision in the TPP.[39]

There is a criminal trademark provision that makes it illegal to repackage and relabel using a registered trademark of a party.[40] This provision, not much mentioned, could raise substantial obstacles to parallel trade worldwide. There is, for example, US jurisprudence to the effect that reusing an existing "non-original" trademark may, in fact, constitute trademark infringement.[41]

The TPP investment chapter enumerates intellectual property as protected investment, authorises investor to state dispute settlement, and includes a now-standard compulsory licensing exemption that is contingent on TRIPS Agreement compliance.[42]

There is a "Transparency and Anti-Corruption" chapter of the TPP, which includes an annex which gives private third parties the right to challenge decisions by national health authorities about the drugs

35 Peter Gosselin, "Obama Pushes Trade Partners for Drug Rules He Opposes in U.S.," *Pharmaceutical Law & Industry Report* (Bloomberg BNA), 10 July 2015.

36 TPP, Article 18.37.2.

37 Trans-Pacific Partnership Intellectual Property Rights Chapter, Draft, 10 February 2011, ARTICLE 8:

PATENTS

1. Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. In addition, the Parties confirm that: patents shall be available or any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, **even if such invention does not result in the enhancement of the known efficacy of that product. [bold added]**

38 TPP, Article 18.51: Measures Relating to the Marketing of Certain Pharmaceutical Products.

39 TPP, Article 18.76.5.

40 TPP, Article 18.77.3.

41 See Lever Brothers v. United States, 981 F.2d 1330 (D.C. Cir. 1993).

42 TPP, Article 9.1: Definitions, "investment," para. f.

that are listed on their reimbursement formularies, burdening health ministers in determinations regarding what drugs should and should not be on their formularies.[43] This is modelled on the Australia/South Korea template discussed earlier, although it includes less precise reference (i.e. ambiguous) regarding challenging of prices than was included in the US–Australia and US–South Korea FTAs. This provision is further discussed below.

The TPP IP chapter recognises the importance of the Doha Declaration and that nothing in the agreement will prevent governments from addressing public health,[44] but it does not indicate how conflicts with the Doha Declaration will be resolved. There is no specific mechanism to do that.

3. Relationship to Domestic Law

3.1 The International Plane

When an international trade agreement enters into force it has legal effects in terms of relations between the contracting parties, that is, rights and obligations on the international plane.[45] Typically disputes between the parties regarding the interpretation and application of the agreement will be settled by some form of arbitration involving a panel of experts appointed through a process prescribed in the agreement.[46] Upon a finding that a party has acted contrary to the terms of the agreement, there will usually be a directive to that party to bring its measures into conformity. If the defaulting party does not remedy its measures, there may be a further mechanism allowing for adjustment of obligations through the withdrawal of trade concessions or compensation.[47] This type of state to state dispute settlement mechanism is incorporated in the PT&IAs negotiated by the United States.

A PT&IA may include additional specific forms of state to state mechanisms for settling disputes, such as making specific provision for experts on a particular subject matter to issue some type of report around which the parties can pursue discussion prior to more formal dispute settlement.[48]

The PT&IAs negotiated by the United States in recent years also include investor to state dispute settlement mechanisms that allow private actors to initiate claims against host governments for interference with property rights, including expropriation.[49] These ISDS mechanisms typically do not require a state party that is found to have violated private rights to modify any governmental measures. Rather, the remedy is payment of compensation.

43 TPP, ANNEX 26-A. TRANSPARENCY AND PROCEDURAL FAIRNESS FOR PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES.

44 Article 18.6: Understandings Regarding Certain Public Health Measures.

45 See Vienna Convention on the Law of Treaties, Article 26 ("Every treaty in force is binding upon the parties to it and must be performed by them in good faith").

46 While treaties relating to public international law are often subject to dispute settlement by the International Court of Justice, international agreements in the sphere of trade are traditionally subject to an internally defined dispute settlement mechanism, including for the WTO the arrangement established by the Dispute Settlement Understanding (DSU) (Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the Agreement Establishing the World Trade Organization).

47 See, e.g., WTO DSU, Articles 19–22.

48 See, e.g., North American Agreement on Labor Cooperation, Supplemental Agreement to the NAFTA, entry into force 1 January 1994, http://www.sice.oas.org/trade/nafta/Labor1.asp.

49 See Abbott, "The North American Free Trade Agreement (NAFTA)."

3.2 The Domestic Plane

Whether and how the terms of an international trade agreement become part of the domestic law of a contracting party is a matter of constitutional law in each state.[50] The national constitution essentially mediates the relationship between international and domestic law. Some countries follow a "monist" tradition in which international agreements become part of national law without additional action on the part of a legislative or parliamentary body. Some countries follow a "dualist" tradition in which the terms of the international agreement must be incorporated by a legislative act into domestic law, so-called "transformation." Some countries, including the United States and the European Union follow a quasi-dualist approach in which the courts decide whether a particular international agreement is directly effective in national/regional law, or whether legislative action is required to transform its provisions into domestic law. This may entail examining the terms, structure and spirit of the agreement, including any express indications regarding the intent of the parties with respect to direct effect.

Though seemingly esoteric, the question whether an international trade agreement is directly effective in national law may entail very significant practical consequences. For example, the doctrines surrounding direct effect played a central role in the 2017 decision by the United Kingdom Supreme Court holding that an Act of Parliament was required to authorise the Prime Minister to provide notice under Article 50 of the Treaty on the Functioning of the European Union that the UK would exit the European Union.[51] It is particularly important in the area of public health where national laws and policies are carefully constructed to address the interests of citizens, and where changes based on trade negotiations may reflect different interest constellations than internal stakeholder discussions.

To illustrate the important role that direct effect may have, the pharmaceutical firm Novartis brought suit against the Indian government alleging that section 3(d) of the amended Patent Act (2005) contravened India's obligations under TRIPS. Because India follows a dualist model, as does the United Kingdom, the High Court in India rejected the allegation of TRIPS inconsistency on grounds that the TRIPS Agreement is not directly effective in Indian law.[52]

In a 2006 Issue Paper for ICTSD, this author described the relationship between trade agreements and domestic law from the perspective of the United States.[53] The US Constitution has a general provision regarding the relationship between treaties and domestic law (i.e., treaties are the supreme law of the land).[54] The Supreme Court has generally interpreted that to establish the possibility of direct effect, but determining the matter on a case-by-case basis. In terms of trade

50 See generally, *Parliamentary Participation in the Making and Operation of Treaties*, ed. Stefan A. Riesenfeld and Frederick M. Abbott (Dordrecht: M. Nijhoff, 1991).

51 R v. Secretary of State for Exiting the European Union, [2017] UKSC 5, 24 January 2017.

52 *Novartis v. Union of India*, High Court at Madras, dated 06.08.2007, W.P. Nos. 24759 and 24760 of 2006.

53 Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of US Federal Law*, Issue Paper No. 12, UNCTAD-ICTSD Project on IPRs and Sustainable Development, February 2006, https://ssrn.com/abstract=1912621.

54 US Constitution, Article VI:

This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

agreements, the US Congress has a special role because Article 1, section 8 of the Constitution provides that Congress has the power to regulate commerce with foreign nations.[55] For trade agreements, the President requires congressional assent to bring these agreements into force, and the Congress has the power to determine whether or not a trade agreement will have direct effect in the law of the United States. As noted earlier, since the conclusion of the GATT Tokyo Round, the Congress has legislated against the direct effect of trade agreements, including the PT&IAs. As a corollary, the Congress has legislated that decisions of dispute settlement bodies within such trade agreements do not have direct effect in US law.

In principle, this would suggest that changes to domestic law in the United States would come about only through congressional legislation amending federal law. This premise, however, does not reflect the complete picture. As this contribution is written, the US Supreme Court has before it a case regarding exhaustion of patent rights, asking whether the US follows a doctrine of international or national exhaustion with respect to patents.[56] The Supreme Court has decided in favour of international exhaustion regarding copyright[57] and trademark (for commonly controlled enterprises),[58] but the Court of Appeals for the Federal Circuit held in favour of national exhaustion for patents in 2001,[59] and recently affirmed that decision in *Lexmark International v. Impression Products*.[60] The Supreme Court granted certiorari and will decide the case later in 2017. The Supreme Court will decide whether the United States follows a doctrine of international or national exhaustion with respect to patents.

The US Congress has not expressly addressed the exhaustion question with respect to patents. There is case-law precedent in US law favouring international exhaustion, prior to the 2001 decision of the Federal Circuit.[61] As a practical matter, in light of the lack of congressional direction the Supreme Court will essentially be deciding the question as a matter of policy, though it will certainly couch its decision in legal terms.

In its decision affirming national exhaustion, the Federal Circuit said that three free trade agreements (FTAs) entered into by the United States (US–Morocco, US–Australia and US–Singapore) obligate the United States to enforce a rule of national exhaustion of patents. The Federal Circuit did not say that the agreements are directly effective in the law of the United States, which clearly is precluded by the legislative acts approving the agreements. However, the Federal Circuit said that the United States would be in breach of its obligations under the agreements if it followed a rule of international exhaustion of patents.

To begin with, the three PT&IAs in question do not obligate any of the contracting parties to forgo international patent exhaustion.[62] They provide that the parties must have a mechanism to prevent

55 US Constitution, Article I, §8, cl. 3: "The Congress shall have power … To regulate commerce with foreign nations."

56 *Impression Products v. Lexmark International*, S. Ct. No. 15-1189, cert. granted 2016.

57 Kirtsaeng v. John Wiley & Sons, Inc., U.S._, 133 S.Ct. 1351 (2013).

58 Kmart v. Cartier, 486 U.S. 281 (1988).

59 Jazz Photo Corp. v. International Trade Commission, 264 F.3d 1094 (Fed. Cir. 2001).

60 Lexmark International, Inc. v. Impression Products, Inc., 816 F.3d 721 (Fed. Cir. 2016).

61 See Fuji Photo Film Co. v. Jazz Photo Corp., 249 F.Supp.2d 434, 452 (D.N.J.2003).

62 See Brief of Amicus Curiae (Frederick M. Abbott) in Support of Petitioner in *Impression Products v. Lexmark International*, US Supreme Court, No. 15-1189, filed 20 January 2017, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2906967.

importation of patented products put on the market outside their countries, but they expressly authorise the enforcement of contractual restrictions as a means of accomplishing this objective. So, even if the Supreme Court decides that US law should be compatible with the three trade agreements, this does not mean that it must adopt a rule of international exhaustion.

In addition, subsequent to congressional approval and entry into force of these three trade agreements, Congress began to preclude the Executive from incorporating similar language in subsequent free trade agreements. In that regard, these three agreements can be considered "outliers" and inconsistent with current congressional policy preferences.

Mainly because of the factor that the agreements do not mandate international exhaustion, it is doubtful that the Supreme Court will decide that they control the outcome of this case. But, reliance by the Federal Circuit on the terms of the PT&IAs in reaching its decision illustrates the risk that is inherent in public-health related provisions in international trade agreements. In other words, there is not only a risk that Congress will transform an obligation in the PT&IA into federal law, but a further risk that the federal courts will consider the provisions of such an agreement to obligate a particular decision, even if the relevant rule is not directly effective.

Another important constitutional doctrine in the United States is the "last in time rule" between congressional legislation and international agreements. The latter of the two rules governs. This means that even after the United States has entered into a trade agreement, the Congress may adopt legislation inconsistent with that agreement, and the congressional legislation will prevail as a matter of constitutional interpretation. The United States may then be in breach of the trade agreement in relation to other state parties to the agreement, but that is a distinct matter. In other words, Congress may choose to adopt legislation inconsistent with an existing trade agreement, and the congressional action will prevail.

4. The Political Dynamics of Modifying Domestic Law Through Trade Agreements

The interests taken into account by trade negotiators in reaching an international agreement are different than those taken into account by national legislators acting in the domestic context. In trade negotiations, each government is bargaining for concessions. The fundamental idea behind a comprehensive free trade agreement is that governments will concede preferences in some areas to obtain benefits in other areas. The GATT Uruguay Round negotiations were premised on the idea that bargaining for cross-concessions (e.g., agriculture for intellectual property) would facilitate a successful conclusion.

The trade bargaining arena gives particular industry groups an avenue for achieving objectives that might not otherwise be achievable if directly approaching a foreign national legislature through lobbying or otherwise. As an example, it is doubtful that Australia or South Korea would have agreed to permit foreign pharmaceutical companies to challenge administrative decisions regarding insurance reimbursement had such a demand been placed outside their PT&IA negotiations with the United States.

By the same token, however, industry groups that might find it difficult to achieve certain domestic objectives directly may find it useful to approach those objectives through the "backdoor" of free trade agreement negotiations. In some cases, an impact on domestic law might be an unforeseen or "surplus" benefit from the negotiations with foreign trading partners.

The 2006 Issue Paper regarding PT&IAs in US domestic law pointed to a number of differences between the terms of the trade agreements and US federal law. Of interest regarding public health these included provisions with respect to:

- patent term extension
- regulatory review exception
- patent–regulatory review linkage
- compulsory transfer of trade secret
- parallel importation
- enforcement, including damages calculations

There is not a conflict between the provisions of the TPP providing for a minimum eight-year term of market exclusivity for biologic products and current US law. US federal law provides for a 12-year exclusivity term.[63] However, the fact that the TPP would lock in an eight-year marketing exclusivity term for biologics—bearing in mind that the United States has withdrawn its signature—would act as a substantial constraint on the United States with respect to future modifications of that term. To be clear, the United States follows a "last in time" rule in respect to the relationship between international agreements and legislation. Congress may adopt legislation that is inconsistent with an existing international agreement, and the congressional legislation prevails as a matter of constitutional interpretation. No doubt, if there was a move in the Congress to reduce the exclusivity term, the biologics industry would assert that it was precluded from doing so by the terms of the agreement, and would suggest broader potential harm to US economic relations. But, as a practical matter it seems unlikely that other parties to the TPP, with the possible exception of Japan, would be concerned about this since the other countries were essentially pressured into accepting the exclusivity commitment.

One of the second generation provisions in the TPP regarding pharmaceuticals is found in the Transparency and Anti-Corruption Chapter 26, Annex 26-A, "Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices." This provision requires that when a party's national healthcare authorities "operate or maintain procedures for listing new pharmaceutical products or medical devices for reimbursement purposes, or setting the amount of such reimbursement," government shall:[64]

(a) ensure that consideration of all formal and duly formulated proposals for such listing of pharmaceutical products or medical devices for reimbursement is completed within a specified period of time;

(b) disclose procedural rules, methodologies, principles, and guidelines used to assess such proposals;

63 42 U.S. Code § 262—Regulation of biological products, at subsection (k)(7).

64 This provision does not apply to government procurement as such (see footnote 11 in TPP text).

(c) afford applicants, and where appropriate, the public, timely opportunities to provide comments at relevant points in the decision-making process;

(d) provide applicants with written information sufficient to comprehend the basis for recommendations or determinations regarding the listing of new pharmaceutical products or medical devices for reimbursement by national health care authorities;

(e) make available:

(i) an independent review process; or

(ii) an internal review process, such as by the same expert or group of experts that made the recommendation or determination, provided that such a review process includes, at a minimum, a substantive reconsideration of the application and that may be invoked at the request of an applicant directly affected by such recommendation or determination by a Party's national health care authorities not to list a pharmaceutical or medical device for reimbursement; and

(f) provide written information to the public regarding such recommendations or determinations, while protecting information considered to be confidential under the Party's law. (Paragraph 26-A.2: Procedural Fairness; emphasis added, footnotes omitted)

The annex provides a mechanism for "consultation" regarding issues that may arise in the context of implementing its requirements. The annex is specifically exempted from the general dispute settlement chapter 28 of the TPP.[65]

The national healthcare authorities of the parties are specifically identified.[66] For the United States, it is the Centers for Medicare & Medicaid Services (CMS), with respect to CMS's role in making Medicare national coverage determinations. For Australia, as an example, it is the Pharmaceutical Benefits Advisory Committee, with respect to listing of products for reimbursement under the Pharmaceutical Benefits Scheme.

Annex 26-A, as quoted above, delineates a new level of regulatory intrusion in PT&IAs, although similar models already were used in the US–Australia and US–South Korea FTAs.[67] The US Medicare pharmaceutical benefits system is complex. The vast majority of determinations regarding what drugs are available under the large Part D government-subsidised system are made by private insurance companies.[68] However, the plans offered by the private insurance companies must meet

65 TPP, Paragraph 26-A.6: Disputes

The dispute settlement procedures provided for in Chapter 28 (Dispute Settlement) shall not apply to this Annex.

66 TPP, Schedule to Annex 26-A.

67 In describing the obligations of the United States under the FTA with Australia, the United States Trade Representative (USTR) notes that the Pharmaceutical Annex expressly excludes procurement by the US Veterans Administration and the Department of Defense, and suggests that Medicare procurement should not be affected because this is done by state officials, not the federal government. But, it notes that the transparency obligations may be applicable. USTR, US–Australia Free Trade Agreement—Questions and Answers about Pharmaceuticals, July 2004, https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/archives/2004/july/us-australia-free-trade-agreement-questions-and. There is no similar statement regarding the US–South Korea FTA.

68 *Medicare Prescription Drug Benefit Manual*, Chapter 6—Part D Drugs and Formulary Requirements (Rev. 18, 01-15-16), at 30.2—Provision of an Adequate Formulary, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

guidelines established by the CMS. It is not entirely clear how the requirement established by the TPP to provide regulatory access to government decision-making regarding reimbursement will function. Conceptually, pharmaceutical companies could use the TPP obligation as a mechanism for challenging CMS approvals of pharmaceutical benefit plans offered by private insurance companies. Medicare also provides under Part B coverage of drugs that are administered in doctors' offices, including many of the more expensive cancer treatments,[69] as to which CMS makes determinations regarding coverage, and as to which it has proposed to limit prices.[70] The pharmaceutical industry in the United States would appreciate a strong avenue to challenge CMS, which could come through the TPP obligation.

The pharmaceutical industry has managed to cross a threshold by inserting into PT&IAs provisions that obligate governments to provide them access to challenge national government benefit plan determinations regarding listings on formularies and prices. Since the inception of bilateral and regional negotiations to supplement the rules of the TRIPS Agreement and other multilateral rules there has been a progressive encroachment into national regulatory space in the field of public health. This continues a trend of viewing national government regulation as a part of reciprocal bargaining subject matter in trade negotiations. This began in the context of second-generation trade barriers at the GATT when the organisation began to seriously tackle barriers to market penetration posed by technical regulations and sanitary and phytosanitary regulations. It progressed through more detailed rules adopted during the Uruguay Round, and the third generation of alleged trade barriers posed by inadequate protection of intellectual property rights. Now, with challenges to legislation regulating tobacco packaging and national court decisions regarding patentability, the focus has more intensively turned to challenging national rules that may restrict market penetration on the basis of legitimate regulatory concerns. What is the alternative? If governments are allowed to pursue regulation solely to favour national goods and services providers, the basic concept underlying a liberal trading order breaks down. On the other hand, deep foreign intrusion into decision-making directed towards protecting the public has adverse consequences. Ultimately the system must be balanced if it is going to allow for economic efficiency gains while protecting public interests.

For the individual government that is a party to a PT&IA with the United States, it is essential to adopt a formula in approving the agreement that is similar to the one adopted by the US Congress to prevent the direct effect of the agreement in national law. The national legislature must act to transform the PT&IA in the interests of the nation. Otherwise, foreign companies can directly tie up the government in litigation based on claims under their own interpretations of the agreement. Even if the government ultimately prevails, or a private counterparty, the litigation may drain resources. In addition, the national government must retain the right to override the terms of the treaty within the national legislation, regardless of the consequences on the international plane as between the PT&IA parties. Otherwise, the country risks being run by foreign trade negotiators and the private interests that drive them.

69 Medicare.gov, "What Part B Covers," https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html.

70 Sarah Karlin-Smith and Brett Norman, "Pharma Unleashes on Part B Demo," Politico Prescription Pulse, 9 May 2016.