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INTELLECTUAL PROPERTY IN THE TRANS-PACIFIC PARTNERSHIP: INCREASING THE BARRIERS FOR THE ACCESS TO AFFORDABLE MEDICINES

Carlos M. Correa



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I. INTRODUCTION¹

The pharmaceutical industry from the USA and Europe scored a major victory with the adoption, in 1994, of a binding agreement on intellectual property (Agreement on Trade Related Aspects of Intellectual Property Rights²) in the context of the nascent World Trade Organization (WTO). While some transitional periods were allowed, the TRIPS Agreement did not leave any space for a special and differential treatment based on the countries' levels of development. In particular, it imposed on all WTO members the obligation to grant patents in all fields of technology. The main objective of this obligation was to put an end to the policies applied in many developing countries that did not grant patent protection for pharmaceutical products. The lack of patent protection allowed these countries to promote price competition in the pharmaceutical market and, in some cases, to develop generic pharmaceutical industries. The most noticeable case is that of India, which developed a strong pharmaceutical industry – known today as 'the pharmacy of the developing world'³ – while patent protection in this field was not available.

The Trans-Pacific Partnership (TPP) is an ambitious trade agreement that the United States is negotiating, through its Trade Representative (USTR) with 11 other countries (Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam). Most of the countries negotiating the TPP fall under the category of developed countries; four of them are developing countries.⁴ Notably, there are major differences in the level of development of these countries (e.g., Vietnam's GDP per capita is approximately 43 times less than the US GDP per capita and 35 times less than Singapore's).⁵ Despite this, as discussed below, the USA seeks the application of the same standards of IP protection to all parties in the partnership.⁶

In fact, as noted by the Nobel Prize economist Paul Krugman, tariffs are already low among the TPP negotiating countries.⁷ There are very little gains to be obtained from the TPP in this regard.⁸ The International Trade Commission in their latest report 'put the cost of

¹ This paper is partially based on a chapter to be published in Thilo Rensmann (editor), *Mega-Regional Trade Agreements and the Future of International Trade and Investment Law*, OUP.

² Hereinafter 'the TRIPS Agreement'.

³ See, e.g., Sidonie Descheemaeker, 'India, Pharmacy of the Developing World IP, Trade and the Access to Medicine', *Jura Falconis* Jg. 49, 2012-2013, No. 3, available at <https://www.law.kuleuven.be/jura/art/49n3/descheemaeker.pdf>.

⁴ The North American Free Trade Agreement (NAFTA) is the only precedent where the US negotiated and concluded an agreement with these two categories of countries in a single FTA.

⁵ See <http://data.worldbank.org/indicator/NY.GDP.PCAP.KD>.

⁶ The negative implications of this 'one size fits all' approach have extensively been addressed in the literature and various reports. See, e.g., the Report of the UK Commission on Intellectual Property (CIPR), available at www.iprcommission.org/graphic/documents/final_report.htm.

⁷ Krugman, P (2014), "No Big Deal", *The New York Times*, 28 February, available at www.nytimes.com/2014/02/28/opinion/krugman-no-big-deal.html.

⁸ This is probably one of the reasons for the scepticism of Pascal Lamy, former director of the WTO, in relation to the TPP, in his view an 'old-fashioned agreement... the last of the big old-style agreements'. See Peter Martin, 'Ex-WTO chief tips pacts are on the way out', May 28, 2014, available at <http://www.smh.com.au/business/exwto-chief-tips-pacts-are-on-the-way-out-20140527-392fq.html#ixzz32w6hVKzt>.

In accordance with one study, even if tariffs for agricultural products were entirely eliminated (an unlikely outcome) the intraregional trade expansion would be modest and mainly benefit US exports. See Burfisher, Mary E., John Dyck, Birgit Meade, Lorraine Mitchell, John Wainio, Steven Zahniser, Shawn Arita, and Jayson Beckman. *Agriculture in the Trans-Pacific Partnership*, ERR-176, U.S. Department of

American import restraints at 0.01 per cent of GDP. What these agreements tend to be really about are issues such as intellectual property rights – with far less certain advantages...'⁹

The most important strategic reason of this initiative for the USA is likely to be to counter China's growing influence in the Asia-Pacific region, and to make the region less hospitable for the Chinese 'state capitalism'. In the last instance, the main objective seems to be to isolate or contain China.¹⁰ This country, however, has not entered into the TPP negotiation. The disciplines proposed in the TPP in various fields, including state enterprises, would require dramatic changes in the functioning of its economy. The intellectual property provisions sought by the USA – eventually with the support of other negotiating parties – may undermine China's capacity to continue its technological catching up with the Western countries¹¹ and to address the health needs of its vast population.

This paper briefly considers some of the intellectual property components of existing FTAs which may affect access to medicines, and focuses thereafter on those aspects being negotiated in the context of the TPP initiative.

II. THE TPP PRECEDENTS: US-FTAs

The USTR has signed a number of FTAs with developed and developing countries that systematically provide for TRIPS-plus protections for pharmaceutical products in relation to patents, test data and enforcement of the conferred rights. The enhanced protection of pharmaceutical products was a key concern for the USA in the GATT negotiations that led to the adoption of the TRIPS Agreement. Despite the significant enhancement of the international standards of intellectual property (IP) protection that that Agreement entailed, the pharmaceutical industry from the USA and the EU remain unsatisfied. They aimed at even higher standards of protection. However, it soon became evident that it would not be possible to obtain such higher standards within the relevant multilateral organizations, WTO and WIPO, where developing countries resisted further increases in IP protections.

Indeed, the pharmaceutical industry's expectations were frustrated by the adoption in 2001, by the 4th WTO Ministerial Conference, of the Doha Declaration on the TRIPS Agreement and Public Health,¹² which essentially confirmed the right that WTO members have to interpret and apply the TRIPS Agreement in a manner that ensures the protection of public health and, in particular, to use the 'flexibilities' allowed by that Agreement, such as parallel imports and compulsory licenses. While WTO became an unfriendly forum for an

Agriculture, Economic Research Service, October 2014, available at <http://www.ers.usda.gov/media/1692509/err176.pdf>.

⁹ Yves Smith, 'The Transatlantic Trade and Investment Partnership: Review of Economic Blogs', July 22, 2014, available at <http://www.nakedcapitalism.com/2014/07/transatlantic-trade-investment-partnership-review-economic-blogs.html>.

¹⁰ See, e.g. Peter Yu, 'TPP and Trans-Pacific Perplexities', *Fordham International Law Journal*, Vol. 37:1129, 2014, available at http://fordhamilj.org/files/2014/06/FILJ_Yu_TPPandTrans-PacificPerplexities.pdf; Shiro Armstrong, 'China's participation in the Trans-Pacific Partnership', EASTASIAFORUM, 11 December 2011, available at <http://www.eastasiaforum.org/2011/12/11/china-participation-in-the-trans-pacific-partnership/>.

¹¹ See Deepak Nayyar, *Catch up. Developing countries in the world economy*, Oxford University Press, 2013.

¹² Available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

expansion of intellectual property protections, attempts to do so in WIPO also failed. The proposal of a Substantive Patent Law Treaty (SPLT)¹³ faced stiff resistance from developing countries and collapsed, even after the proponents drastically narrowed down their ambition and focused only on a few elements of patent law. Moreover, in 2004 developing countries obtained the adoption in WIPO of the ‘WIPO Development Agenda’ that required any new treaty initiative to be looked at under the lens of its likely development impact.¹⁴

In this scenario, developed countries opted to seek the enhanced protection demanded by the pharmaceutical industry and other constituencies through bilateral or plurilateral trade agreements, where the bargaining position of individual countries is weaker and the promises of market access, or other real or expected trade advantages, make agreements of intellectual property more viable.

Thus, while under the TRIPS Agreement patents must last for 20 years from the date of application, the FTAs promoted by the USA¹⁵ oblige the partner signatory countries to extend the patent term to compensate for “unreasonable” delays beyond a certain period in the procedures for the marketing approval of a medicine as well as in the examination and grant of patent applications. FTAs also oblige, *inter alia*, to grant patents based on ‘utility’ rather than industrial applicability¹⁶ and, importantly, to secure market exclusivity on the basis of the protection of test data required for the marketing approval of pharmaceuticals, generally for five years from the date of such approval in the country where protection is sought.¹⁷ FTAs also require partners to establish a ‘linkage’ between the marketing approval of medicines and patents, thereby granting pharmaceutical companies with rights that, under some FTAs, are also stronger than those available under the US law.¹⁸

Some studies have shown the negative impact of TRIPS plus provisions in FTAs. For instance, a study found that the patent term extension would generate in Colombia an increase in pharmaceutical expenditures of USD 329 million and a reduction in pharmaceutical consumption of 7 per cent by 2025.¹⁹ The application of ‘data exclusivity’ in the same

¹³ See, e.g., Jerome H. Reichman & Rochelle Cooper Dreyfus, ‘Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty’, 57 DUKE L.J. 85 (2007), available at <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1330&context=dj&sei-redir=1&referer=http%3A%2F%2Fwww.google.com%2Fsearch%3Fclient%3Dsafari%26rls%3Den%26q%3Dreichman%2Bsubstantive%2Bpatent%2Blaw%2Btreaty%26ie%3DUTF-8%26oe%3DUTF-8#search=%22reichman%20substantive%20patent%20law%20treaty%22>.

¹⁴ See, e.g., ‘Development Agenda for WIPO’, <http://www.wipo.int/ip-development/en/agenda/>.

¹⁵ With the exception of the FTAs signed with Peru, Colombia and Panama, which introduced lower standards for pharmaceuticals as a result of a bipartisan agreement reached in June 2007 between the Republican administration and Democratic leaders in the U.S. Congress. See <http://www.hktdc.com/info/mi/a/baus/en/1X0078EY/1/Business-Alert-%E2%80%93US/Congress--Administration-Announce-Trade-Policy-Agreement.htm>.

¹⁶ One implication of this obligation is that under the utility standard patents on the second use of a medicine (which would fail to comply with the industrial applicability standard) may be admissible.

¹⁷ This obligation is clearly TRIPS-plus. See, e.g., Carlos Correa, Test data protection: rights conferred under the TRIPS Agreement and some effects of TRIPS-plus standards, in *The law and theory of trade secrecy. A Handbook of Contemporary Research*, Edited by Rochelle C. Dreyfuss and Katherine J. Strandburg, Edward Elgar, 2011.

¹⁸ See, e.g., Carlos Correa, Expanding patent rights in pharmaceuticals: the linkage between patents and drug registration, in Neil Netanel (editor), *The Development Agenda; Global Intellectual Property and Developing Countries*, Oxford University Press, 2008.

¹⁹ See Fundación Misión Salud/IFARMA, Impacto de la Propuesta Europea en el Acuerdo de Asociación Can-Ue Sobre el acceso a Medicamentos en Colombia, Bogotá, 2009, p. 4, available at www.ifarma.org/.../impacto-ada-can-ue-sobre-medicamentos-en-colombia11.Pdf.

country increased expenditures on medicines in 2003-2011 by an estimate of U\$S 396 million.²⁰ Studies for other countries show similar results.²¹ With respect to the potential impact of the TPP, in particular, a study by Australian and US researchers estimated that, in Vietnam, the government would only be able to provide anti-retroviral therapy to 30 percent of people in living with HIV (down from its current rate of 68 per cent) since the cost per person per year of treatment would increase to \$501 under the U.S. proposal from its current level of \$127.²²

The negative impact of TRIPS-plus standards on access to medicines has been found even in developed countries that are not IPRs net exporters, such as in Canada²³ and Australia. In Australia – one of the parties in the TPP negotiations – a government's independent research and advisory body reported that 'there had been clear net costs to Australia in adopting IP requirements agreed to in the TRIPS and AUSFTA agreements and recommended that the Government avoid the inclusion of IP in future agreements unless overall net benefits could be demonstrated'.²⁴

The costs incurred by the smaller partners in FTAs are disproportionately high in relation to the benefits that accrue to pharmaceutical companies.²⁵ As noted in relation to Australia by the same report mentioned above, given the relative small size of the economy, the FTA locks-in the country 'into a number of inefficiencies which have clear costs to Australia and yet which confer benefits on other countries that are either small or negligible'.²⁶

The likely impact of the TPP will not be different: the provisions on intellectual property will enhance the market power of the so-called 'originator' pharmaceutical

²⁰ See Miguel Ernesto Cortés Gamba, Francisco Rossi Buenaventura and Mayra Damaris Vásquez Serrano, *Impacto de 10 años de protección de datos en medicamentos en Colombia*, IFARMA, Bogotá. 2012, available at http://web.ifarma.org/index.php?option=com_content&view=article&id=70:serie-buscando-remedio-qimpacto-de-10-anos-de-proteccion-de-datos-en-medicamentos-en-colombia&catid=22:buscando-remedio.

²¹ See, e.g., Kessomboon, N., Limpananont, J., Kulsomboon, V., Maleewong, U., Eksaengsri, A. & Paothong, P. 'Impact on Access to Medicines from TRIPS-PLUS: A Case Study of Thai-US FTA', *Southeast Asian J. Trop. Med. Publ. Health* 41, 667–677 (2010); IFARMA. Impact of the EU-Andean Trade Agreements on Access to Medicines in Peru, available at [http://www.haiweb.org/11112009/11Nov2009ReportIFARMAImpactStudyPeru\(EN\).pdf](http://www.haiweb.org/11112009/11Nov2009ReportIFARMAImpactStudyPeru(EN).pdf); Oxfam, *All Cost No Benefit : How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines*, Oxfam Briefing Paper, March 2007.

²² Hazel Moir, Brigitte Tenni, Deborah Gleeson and Ruth Lopert, *Assessing the impact of alternative patent systems on the cost of health care: The TPPA and HIV treatment in Vietnam*, Conference paper presented at the Nov. 27-29 Asia-Pacific Innovation Conference at the University of Technology, Sydney., available at researchgate.net/publication/270511439_Assessing_the_impact_of_alternative_patent_systems_on_the_cost_of_health_care_The_TPPA_and_HIV_treatment_in_Vietnam.

²³ Consuelo Ahumada, 'The Impact TRIPS and Free Trade Agreements Have on Access to Medicines: The Cases of Canada and Columbia', *Studies in Political Economy*, vol. 84, 2009, available at <http://spe.library.utoronto.ca/index.php/spe/issue/view/786>.

²⁴ Australian Government, *Pharmaceutical Patents Review*, Draft Report, April 2013, p. 20. available at <http://www.ip-watch.org/weblog/wp-content/uploads/2013/04/Pharmaceutical-Patent-Review-Draft-Report.pdf>. See also, e.g., Deborah H Gleeson, Hazel Moir and Ruth Lopert, 'Costs to Australian taxpayers of pharmaceutical monopolies and proposals to extend them in the Trans-Pacific Partnership Agreement', *MJA* 202 (6), 6 April 2015, available at <https://www.mja.com.au/system/files/issues/gle01682.pdf>.

²⁵ See, e.g., Carlos Correa, High costs, negligible benefits from intellectual property provisions in FTAs, *International Review of Intellectual Property and Competition Law*, Vol. 44, Issue 8, 2013.

²⁶ Australian Government, *op. cit.* p. 32.

companies, and reduce the policy space to implement policies promoting the use of cheaper generic versions.²⁷

III. TPP OBJECTIVES IN RESPECT OF IP

Given the previous involvement of the USA with FTAs covering, among other issues, intellectual property rights, there would seem to be nothing unique with the TPP. There are two important differences, however. On the one hand, the TPP involves a larger number of countries than any other previously negotiated FTA.²⁸ On the other, the enhanced protection sought by the USTR reaches in some respects, unprecedented levels.

The TPP is conceived by the USA as a means to protect jobs within the country in “IP-intensive” industries – which are deemed to drive approximately 60 percent of U.S. merchandise exports and a large share of services exports – and to promote such exports throughout the Asia-Pacific region.²⁹ However, the claims made with regard to the contribution of such industries to job creation ‘are unsupported by any evidence linking job creation to intellectual property’.³⁰ If there were a correlation between patents and growth, ‘one would expect the quadrupling of the annual rate of patents granted in the past 30 years to correlate with a speedup in economic growth. In fact, economic growth has significantly slowed in the past 30 years’.³¹ Boldrin and Levine observe in this regard that ‘[T]here is no empirical evidence that [patents] serve to increase innovation and productivity, unless productivity is identified with the number of patents awarded –which, as evidence shows, has no correlation with measured productivity’.³²

In accordance with the USTR, the ‘TPP will provide...a robust and balanced intellectual property rights framework’.³³ This is probably true with regard to robustness, but is far from credible in relation to ‘balance’. Like other FTAs, the TPP is not driven by ‘the common goal to achieve a mutually advantageous, balanced regulation of IP among the

²⁷ For a detailed analysis of the draft TPP provisions relating to access to medicines, see UNITAID, *The Trans-Pacific Partnership Agreement: Implications For Access To Medicines And Public Health*, Geneva, 2014, available at http://www.unitaid.eu/images/marketdynamics/publications/TPPA-Report_Final.pdf.

²⁸ The USA embarked before in a plurilateral negotiation on intellectual property, which concluded with the signature of the Anti-counterfeiting Trade Agreement (ACTA). This agreement, however, was limited to enforcement measures related to intellectual property rights. ACTA was not ratified by the European Union and other negotiating parties and failed to enter into force. See, e.g., Pedro Roffe and Xavier Seuba, *The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath*, Cambridge University Press, 2014.

²⁹ USTR, Trans-Pacific Partnership: Summary of U.S. Objectives, <http://www.ustr.gov/tpp/Summary-of-US-objectives>.

³⁰ Eli Dourado, Ian Robinson, How Many Jobs Does Intellectual Property Create?, MERCATUS CENTER AT GEORGE MASON UNIVERSITY,

<http://mercatus.org/publication/how-many-jobs-does-intellectual-property-create>, 6 August, 2014.

³¹ Ibid.

³² Michele Boldrin and David K. Levine, “The Case against Patents,” *Journal of Economic Perspectives* 27(2013), p. 3.

³³ USTR, Trans-Pacific Partnership (TPP), available at <http://www.ustr.gov/tpp>.

parties. While these agreements may pursue an overall balance of concessions, they usually do not lead to international IP rules that address the interests of all countries affected'.³⁴

The USTR is seeking an agreement that would require the implementation of broader rights than those available in the negotiating countries – including in some respects the United States, – which may particularly benefit the pharmaceutical industry. While USTR statements allude to the benefit that producers and consumers of those goods and services would obtain in all TPP countries, consumers' and patients' rights are ostensibly outside the agenda of the USTR,³⁵ whose tangible objective is to satisfy the demands of the so-called 'research-based' pharmaceutical industry. The USTR is advised by the Industry Trade Advisory Committee-15 (ITAC 15) composed of companies' representatives, business associations and pro-IP coalitions.³⁶

While the USTR has claimed that it 'is committed to providing the public with information on what we are working to achieve through TPP',³⁷ the draft text must be treated as confidential by all negotiating parties. The lack of transparency³⁸ limits the capacity of consumers' and patients organizations to monitor what is being proposed, but does not affect the participation of business organizations. The 18 members of the referred to Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15), can freely access TPP negotiation documents on intellectual property.³⁹

If the USTR stated objectives for the TPP were credible, the intellectual property provisions in the TPP would 'promote innovation and the development of new, lifesaving medicines, create opportunities for robust generic drug competition, and ensure affordable access to medicines, taking into account levels of development among the TPP countries and their existing laws and international commitments'.⁴⁰

However, the TPP is unlikely to promote the development of new medicines in the US partners or even in the USA, since it would do little to change the multiplicity of factors that influence investment in that area. Notably, the rate of innovation in new chemical entities for pharmaceuticals has drastically declined in the last 15 years despite the expansion of patent protection for pharmaceutical products on a global scale,⁴¹ the availability of massive financial resources and advances in science and technology. The TPP provisions, as discussed

³⁴ Max Planck Institute for Innovation and Competition, *Principles for intellectual property provisions in bilateral and regional agreements*, para. 1, available at www.ip.mpg.de/en/pub/news/fta_statement.cfm.

³⁵ See, e.g., Public Citizen, <http://www.citizen.org/more-about-trans-pacific-partnership-agreement>.

³⁶ See <http://ita.doc.gov/itac/committees/itac15.asp>.

³⁷ USTR, Trans-Pacific Partnership (TPP), available at <http://www.ustr.gov/tpp>.

³⁸ See Max Planck Institute for Innovation and Competition, op. cit.. In the context of the negotiations on a Trans-Atlantic Trade and Investment Partnership (TTIP), the European Commission has recommended, on 25 November 2014, that the EU's TTIP text proposals be released to the public, and that other information related to TTIP be shared more broadly with all Members of the European Parliament. See http://ec.europa.eu/news/2014/docs/c_2014_9052_en.pdf.

³⁹ Even members of the US Congress have limited access to negotiating texts, as they 'must visit the offices of the United States Trade Representative to review the provisions. They are not allowed to bring anyone with them, nor can they make copies of any documents pertaining to the working agreement' (Industry powers with access to TPP plans lavish money on Congress, January 18, 2014, <http://rt.com/usa/congress-tpp-corporate-donations-802/>); see also William New, 'WikiLeaks? Release of TPP Chapter on IP Blows Open Secret Trade Negotiation, 2013, available at <http://www.ip-watch.org/2013/11/13/wikileaks-release-of-tpp-chapter-on-ip-blows-open-secret-trade-negotiation/>.

⁴⁰ USTR, Trans-Pacific Partnership (TPP), available at <http://www.ustr.gov/tpp>.

⁴¹ Least Developed Countries (LDCs) are still exempted from granting such protection under the TRIPS Agreement (in accordance with article 66.1), but many of them allow for such protection.

below, would reduce generic competition, *inter alia*, by requiring the grant of patents on minor improvements, extending patent terms and preventing the use of test data to obtain marketing approval of generics under ‘data exclusivity’ provisions. Finally, the known draft of TPP provisions would not allow for a differential treatment in accordance with the level of development of partner countries. At the maximum, as discussed below, some transitional periods would apparently be included, which will only help to delay for some time the negative effects on access to medicines of such provisions.

IV. SOME PUBLIC HEALTH-RELATED PROVISIONS IN THE DRAFT TPP

Patentable subject matter

Like the chapters on intellectual property of other FTAs, the draft TPP quotes some of the provisions of the TRIPS Agreement and introduces TRIPS-plus elements. While some of these elements are common to previous FTAs (with textual variants), the draft also contains provisions that have no precedents in previous FTAs. The following analysis is based on the draft texts of May 2014⁴² and May 2015.⁴³

One of such provisions was contained in article QQ.E.1 of the May 2014 draft regarding patentable subject matter. The USA and Australia proposed a specific provision that would have required patent offices and courts to admit what has been termed ‘evergreening’ patents, that is, patents covering minor – often trivial – developments around an existing medicine, such as salts, formulations, polymorphs and the like.⁴⁴ In accordance with the proposed text (opposed by other negotiating countries),

A Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application.

The proposed provision was clearly aimed at countering section 3(d) of the Indian Patent Act, which stipulates that the new form or some derivatives of known medicines are not ‘inventions’ unless a significant increase in efficacy⁴⁵ can be demonstrated. The U.S. Trade Representative (USTR) has regularly cited section 3(d) among the reasons to keep India on the USTR list of countries whose intellectual property regimes are of concern for the USA, on the argument that it imposes an additional criterion of patentability, beyond those provided for by the TRIPS Agreement.⁴⁶ While neither the USA nor any other WTO member has filed a complaint against India on this subject, other countries are adopting the concept introduced by

⁴² See <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>.

⁴³ See <http://keionline.org/tpp/11may2015-ip-text>.

⁴⁴ See, e.g., Carlos Correa, *Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain*, in *Droit, économie et valeurs. Le droit économique, maître ou esclave de l'économie? Hommage au Professeur Bernard Remiche*, Larcier, Brussels, 2014.

⁴⁵ This test has been interpreted as requiring an increase in *therapeutic* efficacy. See, e.g., various articles in the special issue of *Economic and Political Weekly*, Vol - XLVIII No. 32, August 10, 2013.

⁴⁶ See, e.g., Sampat B, K Shadlen and T Amin (2012): ‘Challenges to India’s Pharmaceutical Patent Laws’, *Science*, 27 July, vol. 337, p. 414. See also USTR Special 301 Report 2013, p. 38.

the referred to section 3(d). For instance, Philippines incorporated it in its patent law and Thailand introduced a similar standard in recently adopted guidelines for the examination of pharmaceutical patents.⁴⁷ Hence, the US concern probably is not only that India may refuse patents filed by US companies, but that the model introduced by section 3(d) may be replicated in other countries with the same effect.

Evergreening is one of the main strategies used by pharmaceutical companies to block generic competition, which is essential to bring the prices of medicines down and to increase access by the population. Having many patents on secondary developments can provide such companies marketplace power in a scenario ‘where individual patents become increasingly less certain in scope and validity’.⁴⁸ The proposed TPP provision, if adopted, would have deprived TPP parties of the possibility of refusing patents that do not entail a real technical contribution, thereby limiting the policy space currently available under the TRIPS Agreement. The deletion of this provision in the draft of May 2015 is a positive step indeed.

Footnote 58 of the May 2015 draft provides that ‘[i]n determinations regarding inventive step (or nonobviousness), each Party shall consider whether the claimed invention would have been obvious to a person skilled or having ordinary skill in the art having regard to the prior art’. This text attempts to establish a standard to assess inventive step/nonobviousness⁴⁹ that is absent in the TRIPS Agreement.⁵⁰

In addition, the US and Australia proposed ‘to confirm’ that ‘patents shall be available for any new uses or methods of using a known product’. This provision aimed at making it mandatory to grant patents on the second use of a known medicine, for instance, in cases where a medicine was administered to treat disease X and it is claimed that it can be applied to disease Y. This is another common form of evergreening that, if accepted, would have allowed companies to obtain a new monopoly for at least 20 additional years. For instance, the US pharmaceutical company Eli Lilly obtained a patent – which was subsequently revoked by Canadian and US courts – claiming that olanzapine had a marked superiority in the treatment of schizophrenia, and filed at least 29 other Canadian patent applications relating to the same drug, arguing that it had ‘invented’ at least 16 distinct new and surprising uses for the compound, ranging from sexual dysfunction to autism.⁵¹

The referred to provision was also deleted in the May 2015 draft, but a new text was introduced according to which:

Article QQ.E.1(2). [US/NZ/SG/AU/JP/CA/PE/MX/BN/VN propose; CL oppose: Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms

⁴⁷ See Chapter 5 ‘Examination of Applications for Patents of Invention and Petty Patents on Chemical and Pharmaceutical products’, 2014.

⁴⁸ R. Polk Wagner, Understanding Patent-Quality Mechanisms, *University of Pennsylvania Law Review*, Vol. 157: 2135, p. 2155.

⁴⁹ This was one of the main objectives of the failed SPLT initiative, mentioned above.

⁵⁰ While the reference to ‘a person skilled’ may give TPP parties certain flexibility, it would have been desirable to refer to an *expert* in the field. As stated by the US Supreme Court in in *KSR v. Teleflex*, parties may consider that ‘[a] person of ordinary skill is also a person of ordinary creativity, not an automaton’. (*KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) available at <http://www.supremecourt.gov/opinions/06pdf/04-1350.pdf>). The Indian Revised Draft Guidelines For Examination Of Patent Applications In The Field Of Pharmaceuticals, state in this regard that ‘the person skilled in the art ‘is not a dullard and has certain modicum of creativity’ (available at http://ipindia.nic.in/iponew/draft_Pharma_Guidelines_12August2014.pdf).

⁵¹ See, e.g., Carlos Correa, *Modelling Patent Law through Investment Agreements*, Policy Brief, South Centre (forthcoming).

that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit such processes to those that do not claim the use of the product as such.]

This provision would leave TPP parties the option to choose whether to grant patents on ‘new uses’, ‘new methods’ or ‘new processes’ of using a known product. However, unless it is clarified that such methods or processes should be of a *technical* nature, they may be understood as encompassing patent claims describing how a medicine may be used to address a particular disease. This is the interpretation that will probably be given by the USA, where the new use of a medicine is not patentable as such, but admissible as process-of-use-claims. This means that as long as the claim is on a process for use rather than use, it is admissible as subject matter of a patent.⁵² This is precisely what the USA aims at with the proposed text.

In accordance with article QQ.E1(3) of the draft TPP, parties may exclude from patentability therapeutic methods for the treatment of humans and animals. It may be argued that a claim on the use of a medicine is equivalent to a therapeutic method and that, therefore, that exception would allow TPP parties to exclude patents on the new use of a medicine. This reading, however, may be deemed unviable under the interpretation principle of ‘effectiveness’ (‘effet utile’), which means that amongst several possible interpretations the one will prevail which best guarantees the practical effect of all provisions in the treaty, including article QQ.E.1(2).⁵³

It should also be noted that the carefully worded article QQ.E.1(2) refers to ‘inventions claimed as’ a new use, method or process. This seems to exclude the possibility of considering that, in essence, the claimed invention is a therapeutic method, *if the claim is drafted in the form of a method or process*.⁵⁴ In other words, the current text does not seem to indicate that the USA has abandoned the target of forcing all TPP parties to grant patents in respect of the new use of a medicine. The intention to achieve that target is evident in the proposed article QQ.E.17.1(b)(ii) which refers to ‘a product for an approved use, during the term of a *patent identified as claiming that approved use*’, (emphasis added).

Many countries – such as India, Argentina, Andean Community members – refuse to grant second use patents, as they have no industrial applicability and are equivalent to methods of treatment. If TPP Parties were forced to accept such claims, Peru (a member of the Andean Community) would be bound not only to introduce legislation in violation of the applicable regional law,⁵⁵ but to abandon a sound policy that prevents one popular form of evergreening.

⁵² See, e.g. Carlos Correa (editor), *A guide to pharmaceutical patents*, South Centre, Geneva, 2102, p. 143

⁵³ For the application of this principle in WTO jurisprudence see, e.g., *Repertory Of Appellate Body Reports. Interpretation* (para. 1.3.7) available at https://www.wto.org/english/tratop_e/dispu_e/repertory_e/i3_e.htm.

⁵⁴ Typically claims on the new use of a medicine are drafted in the USA as “a method of treating X in a patient, comprising administration of a therapeutically effective amount of compound Y.” The proposed provision would oblige to grant a patent if a new use is claimed in this form; alternatively, TPP parties may accept what are known as ‘Swiss claims’ (“Use of substance or composition X for the treatment of disease Y’), but would not escape from the obligation to grant patents relating to new uses of a medicine.

⁵⁵ See article 21 of Decision 486 ‘Common Regime on Industrial Property’, which stipulates that “[p]roducts or processes that are already patented and included in the state of the art within the meaning of Article 16 of this Decision may not form the subject matter of a new patent owing to the fact of having a use ascribed to them different from that originally provided for in the first patent’.

The admissibility of second use patents would be facilitated if another current proposal of the USA, joined by Australia and Singapore, is accepted. In article QQ.E.10 they propose – with the opposition of other negotiating parties – to require that a patent should be granted if the claimed invention is ‘useful’. A new use of a known medicine would not meet the standard of industrial applicability since it lacks technical effect, while it may be deemed useful or having a ‘specific, substantial and credible utility’ (as also proposed by the USA).⁵⁶

Another controversial area in TPP negotiations has been the patentability of diagnostic, therapeutic, and surgical methods for the treatment of humans or animals. These methods can be excluded from patentability in accordance with the TRIPS Agreement and, in fact, most countries in the world (including the TPP negotiating parties, except the USA and Australia) do so.⁵⁷ There are certainly good public health reasons for that exclusion, as the monopolization of such methods may prevent or increase the cost of the application of needed treatments, even if no patented products are involved.

The leaked draft text of May 2014 showed that the positions on this subject had evolved. Notably the USA shifted in that text from an earlier proposal requiring absolute protection to one conditional upon the use as part of the method ‘a machine, manufacture, or composition of matter’. Interestingly, the opposition by other negotiating parties to this proposal was quite compact. The suggested condition was not tied to the use of a *patented* machine or material; hence, patentability would have to be secured if any object, whether or not in the public domain, was used to implement the method. Doctors and surgeons could have been deemed liable of patent infringement unless they treated patients with their bare hands, what is clearly impossible in the case of surgery. Under the US law, infringement can only be established if the patented method requires the use of a patented object. The draft TPP, hence, was more restrictive in this respect than US law.⁵⁸

The draft of May 2015, as noted, shows another substantial change in the negotiating positions as article QQ.E.1(3) would allow TPP parties to exclude altogether diagnostic, therapeutic, and surgical methods from patentability, in line with the exclusion permissible under the TRIPS Agreement.

Opposition and revocation

Initially, the US sought to prevent TPP Parties from allowing for procedures of pre-grant opposition in patent procedures. The elimination of a provision to that effect⁵⁹ is one of the few successes of the negotiating countries that oppose a drastic increase in intellectual

⁵⁶ The relationship between article QQ.E.10 and article QQ.E.1 (and its footnote 58) is unclear. While the latter seems to leave open the possibility of applying a standard of industrial applicability, the former (as proposed by the US and other countries) would seem to require *each party* to grant patents when the claimed invention is merely ‘useful’, provided that it has a specific substantial and credible utility.

⁵⁷ Existing FTAs, including NAFTA, permit parties to exclude the patentability of such methods.

⁵⁸ See Public Citizen, Medical Procedure Patents in the TPP: A Comparative Perspective on the Highly Unpopular U.S. Proposal, November 13, 2013, available at http://www.citizen.org/documents/MedicalProceduresMemo_final%20draft.pdf.

⁵⁹ Article QQ.E.4 ‘Opposition to Grant of Patent’ -as proposed by New Zealand, Canada, Singapore, Chile and Malaysia- states that ‘Each Party shall provide a procedure for third persons to oppose the grant of a patent, either before or after the grant of a patent, or both’.

property protection through the TPP. The attempt to ban pre-grant oppositions was another example of an obligation beyond US law, which provides for such opposition.⁶⁰

The US proposed in the initial draft TPP to limit the grounds that may be invoked to invalidate or revoke a patent.⁶¹ This represented ‘an attempt to overturn a specific issue negotiated and rejected in the TRIPS negotiations’.⁶² The TRIPS Agreement does not determine, in effect, what grounds can or cannot be articulated. It only requires that an opportunity be given for a judicial review of a decision in that respect.

Patent applicants may use fraudulent and other inequitable practices to obtain patents. The USA seems to admit that a TPP Party could provide that fraud, misrepresentation, or inequitable conduct may be the basis for cancelling, revoking, or nullifying a patent, or for holding a patent unenforceable⁶³ – in line, in the latter circumstances, with the US legislation.

Conferred patents are often abused, for instance, through strategic litigation aiming at delaying the market entry of generic products. Despite the fact that such behaviour has been found and condemned in the USA,⁶⁴ the USTR opposes a draft provision in the TPP that would allow Parties to cancel, revoke or nullify a patent on the basis that it is used in a manner determined to be anti-competitive.

Interestingly, some of the negotiating parties are attempting to reconfirm the right recognized under article 5(A)(3) of the Paris Convention for the Protection of Industrial Property, which stipulates that a patent may be revoked in cases of abuses, such as lack of working of the protected invention, where the grant of compulsory licenses has not been sufficient to prevent the said abuses and the proceedings for the forfeiture or revocation are instituted after the expiration of two years from the grant of the first compulsory license.

Exceptions

Articles 30 and 31 of the TRIPS Agreement allow for some important ‘flexibilities’ regarding patent protection, as they allow WTO members to provide for exceptions to the exclusive rights and for the grant of compulsory licenses, respectively.

The known draft text of the TPP reproduces article 30 of the said Agreement without

⁶⁰ The patent opposition procedures were reinforced in the USA by the ‘America Invents Act’ in 2011. Other examples of proposed obligations inconsistent with the US law are the lack of limitation for damages in case of infringement of patents on biologicals not disclosed to competitors, and in the case of use of patent and other intellectual property rights by or for the US government.

⁶¹ Article QQ.E.3: [US: Without prejudice to Article 5A (3) of the Paris Convention,] Each Party shall provide that a patent may be cancelled, revoked or nullified only on grounds that would have justified a refusal to grant the patent...’.

⁶² Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, The U.S. Proposal For An Intellectual Property Chapter In The Trans-Pacific Partnership Agreement, *AM. U. INT’L L. REV.* [28:1, 2012, available at <http://ssrn.com/abstract=2185402>, p. 162.

⁶³ See draft Article QQ.E.3.

⁶⁴ See, e.g. the case brought by the US Federal Trade Commission against Bristol Myers Squibb (information available at <http://www.ftc.gov/opa/2003/03/bms.htm>) . See also Federal Trade Commission. “*Generic Drug Entry Prior to Patent Expiration*”. FTC Study. July 2002. <http://www.ftc.gov>. See also European Commission, *Pharmaceutical Sector Inquiry Report* -2009 (http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_1.pdf).

too much apparent contention; hence it does not seem to be an attempt to narrow down the available exceptions. Some negotiating countries (New Zealand, Canada, Singapore, Chile and Malaysia) have proposed, however, to specify some admissible exceptions (not expressly mentioned but clearly allowable under the TRIPS Agreement)⁶⁵ regarding the so-called ‘regulatory review exception’ (which allows generic companies to request the marketing approval of a medicine before the expiry of the relevant patent)⁶⁶, and the ‘experimentation exception’.⁶⁷ Although specific provisions on these exceptions may not be strictly necessary, they may help to confirm the policy space available under national laws.

The draft of May 2015 does not refer to the ‘experimentation exception’ but contains two options and several formulations regarding the ‘regulatory review exception’. This seems to indicate a general acceptance of the inclusion of a clause on the matter. This should not be a major problem for the USA, which introduced this latter exception in 1984.

Australia is proposing (in the draft of May 2015) to introduce a provision (Article QQ.E.4.2) stating that

Nothing in this Chapter shall limit a Party's rights and obligations under Article 31 of the TRIPS Agreement or any amendment thereto.

Concerns have been raised regarding whether the TPP would subject compulsory licenses to the three-step test of article 30 of the TRIPS Agreement, if the proposed provision confirming the application of article 31 were not adopted.⁶⁸ These concerns are grounded on the notion that compulsory licenses constitute one type of exception⁶⁹ and that attempts could be made to subject such licenses to the application of those tests. The key question in this regard is whether the lack of reference to said article 31 may restrain rather than expand the policy space to use compulsory licenses, one of the critical ‘flexibilities’ in that Agreement.⁷⁰

Exhaustion of rights

A similar question may be raised in relation to the right recognized in article 6 of the TRIPS Agreement to decide whether and how to apply the doctrine of exhaustion of rights, under which parallel imports may be allowed. It may be argued that the lack of any reference to the subject in the TPP leaves the applicability of that article untouched. Chile, however, suggested to include a provision – apparently not supported by other negotiating parties – stating that

⁶⁵ See *Canada-Patent Protection of Pharmaceuticals*, WT/DS114/R of 17 March 2000; Carlos Correa, International Dimension of the Research Exception, SIPPI Project, AAAS, Washington D. C., available at <http://sippi.aaas.org/intlexemptionpaper.shtml>, 2005.

⁶⁶ This exception is generally known as ‘Bolar exception’.

⁶⁷ The proponents of this clause suggest to clarify that ‘[F]or the purposes of this Article, experimental purposes may include, but need not be limited to, determining how the invention works, determining the scope of the invention, determining the validity of the claims, or seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention)’.

⁶⁸ See James Love, New leak of TPP consolidated text on intellectual property provides details of pandering to drug companies and publishers, KEI, 16 October 2014, available at <http://www.keionline.org/node/2108>.

⁶⁹ See the footnote (no. 7) to article 31 of the TRIPS Agreement.

⁷⁰ In fact, it is unclear why certain provisions of the TRIPS Agreement – which is generally applicable to the TPP negotiating parties – are reproduced in the draft TPP (as well as in many existing FTAs), and other provisions are not.

The Parties are encouraged to establish international exhaustion of patent rights. For this purpose, the registration of a patent shall not entitle its holder to prevent third parties from making, using, offering for sale, selling or importing a product protected by that patent, which has been put in the market in any country by the patent holder or with his consent.

If accepted, this provision would have explicitly legitimized the principle of international exhaustion under the TPP, which is fully admissible under the TRIPS Agreement. The draft text of May 2015, however, does not contain any longer this proposal.

Data exclusivity

Like other FTAs promoted by the USA, the draft TPP includes provisions that will submit test data (that is, the results of pre-clinical and clinical studies) to a regime of exclusivity.⁷¹ As examined elsewhere⁷², data exclusivity is not mandated by the TRIPS Agreement, whose article 39.3 only requires the protection of such data against unfair competition. While most TPP negotiating countries have already introduced data exclusivity as a result of US unilateral actions⁷³ or participation in prior FTAs, the USTR aims at ensuring that such a regime is fully recognized in the TPP. Its proposals go beyond, however, what has been introduced in prior FTAs, as it attempts to export to other negotiating countries a special regime of data exclusivity for biologicals⁷⁴ that would exclude the use of those data for 12 years,⁷⁵ that is, 7 years more than in the case of non-biological medicines. While these terms would apply in the case of new chemical entities, the US also seeks to ensure a three years period of data exclusivity in cases where new clinical information for known medicines are submitted.⁷⁶

It is worth noting that the 12 years term – introduced by the US Affordable Care Act – has been criticized by the US Administration, which has proposed to reduce it to 7 years in order to substantially diminish the cost of biologics for the health programmes. The ‘Fiscal Year 2014 Budget of the U.S. Government’ refers as follows to the impact of high-cost biologics and patent evergreening practices:

The Budget also proposes to accelerate access to affordable generic biologics by modifying the length of exclusivity on brand name biologics. Beginning in 2014, this proposal would award brand biologic manufacturers seven years of exclusivity, rather than 12 years under current law, and prohibit additional periods of exclusivity

⁷¹ Significantly, eight other negotiating countries seem to oppose the US proposal.

⁷² See, e.g. Carlos Correa, ‘Test data protection: rights conferred under the TRIPS Agreement and some effects of TRIPS-plus standards’, in *The law and theory of trade secrecy. A Handbook of Contemporary Research*, Edited by Rochelle C. Dreyfuss and Katherine J. Strandburg, Edward Elgar, 2011.

⁷³ As it was the case of Australia in 1998, following a threat of trade sanctions under the Special section 301 of the US Trade Act.

⁷⁴ On the potential scope and implications of the protection sought by the USA, see Sanya Smith, TWN, *Preliminary analysis of biologics exclusivity*, 21 August 2015, available at <http://www.twn.my/title2/wto.info/2015/ti150808.htm>.

⁷⁵ See US Office of Management and Budget, *Fiscal Year 2014 Budget of the U.S. Government*, Executive Office of the President of the United States. Available at: <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/budget.pdf>.

⁷⁶ The case of colchicine, a drug known in the USA since the 19th century on which new clinical trials were conducted – for just one week – led to a 50-fold increase in the price from US\$ 0.09 to US\$ 4.85. See, e.g., Kesselheim AS, Solomon DH. Incentive for drug development—the curious case of colchicine *N Engl J Med*. 2010; 362:2045-2047, available at <http://www.nejm.org/doi/full/10.1056/NEJMp1003126>.

for brand biologics due to minor changes in product formulations, a practice often referred to as “evergreening.” The proposal will result in \$3 billion in savings over 10 years to Federal health programmes including Medicare and Medicaid.

Paradoxically, in the TPP negotiations the USTR – an agency also belonging to the Executive Office of the US President – is pursuing a 12 year term of protection in the TPP. One possible explanation is the fact that the USA does not consider itself bound to introduce any legislative change in its national law to implement obligations in the FTAs that go beyond such law, such as the administrative linkage system introduced by Article 15.10.2 of the FTA with the Central American countries and the Dominican Republic (DR-CAFTA).⁷⁷

Although test data are required to be protected under the TRIPS Agreement and some prior FTAs to the extent that the data are *undisclosed*, the draft TPP of May 2014 would have required to create exclusive rights even when such data have been disclosed. In the May 2015 text (article QQ.E.16), a reference is made, however, to ‘undisclosed test or other data’.

In accordance with the proposed data exclusivity provision, pharmaceutical companies would be able to claim data exclusivity not only in respect of a ‘new pharmaceutical product’, but also in respect of a ‘similar’ product, an ambiguous concept that, if accepted, would further expand the reach of the protection sought. The different options contained in the draft of May 2015 suggest that this is an area where getting consensus is becoming very problematic.

The US proposal contains language that seems to be aimed at tempering the impact of data exclusivity. It states that

- ...a Party may take measures to protect public health in accordance with:
- (a) the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”);
 - (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and
 - (c) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.

However, this language has little or no practical effect. It would not limit in any manner the obligations imposed by the agreement. The referred to Declaration only confirms the flexibilities allowed by the TRIPS Agreement in relation to public health matters (such as compulsory licenses and parallel imports), but it is unlikely to provide a sufficient legal basis to derogate from the obligations established by the TPP.

It is worth noting that although some TPP negotiating countries such as Canada, Singapore and Chile have already introduced some form data exclusivity, they sponsored with other negotiating parties an alternative (contained in article QQ.E.XX.4 of the draft of May 2014) to the US proposal based on the TRIPS standard, that is, the protection of such data against unfair competition only, without recognition of exclusive rights. This option does not seem to be any longer on the table. New wording has been proposed by a number of

⁷⁷ See, e.g., Carlos Correa, ‘Expanding patent rights in pharmaceuticals: the linkage between patents and drug registration’, in Neil Netanel (editor), *The Development Agenda; Global Intellectual Property and Developing Countries*, Oxford University Press, 2008.

negotiating countries (opposed by the USA and Japan) to the effect of making data protection conditional upon submission of an application for marketing approval within a period (12 or 18 months) from the date of the marketing approval in any country. If adopted, this would be a logical limitation to the acquisition of rights under a data exclusivity provision.

Linkage

Like in other FTAs, the US is seeking to introduce in the TPP an additional measure of protection for pharmaceutical companies: a ban for drug regulatory agencies to grant the marketing approval of a drug in case there are patents in force in relation to that drug.

The USTR and the U.S. pharmaceutical industry's justification for seeking linkage provisions is the prevention of the infringement that may occur if generic versions of a patented product were approved for commercialization. This argument overlooks the fact that most patents do not cover the drugs, as such, but different forms thereof, including pharmaceutical formulations and combinations, and that the role of drug regulatory agencies is to protect public health, not to take part in private disputes about intellectual property protection. The development implications of linkage provisions may be substantial, as they may unduly⁷⁸ restrain generic competition that reduces drug prices and increases access to medicines.

The linkage system proposed in the May 2014 draft of the TPP mirrored the US system whereby an 'automatic' delay for the grant of marketing approval of a generic product could be sought by the patent owner (article QQ.E.17(a)(i)). Unlike the US system, however, there was no requirement on the patent owners to register the patents they intended to assert (as is the case with the 'Orange Book' in the USA) nor any limitation on the subject matter covered by such patents.⁷⁹ The negotiating text in the draft of May 2015 shows significant divergences amongst the negotiating parties, and a shift towards an administrative form of 'linkage' under which the drug regulatory authority would be bound to reject an application for marketing approval when a product is subject to a patent.⁸⁰ This should be an issue of particular concern since, if evergreening of pharmaceutical patents through the protection of new forms or uses of known medicines takes place, patent owners may block the marketing approval of a generic product well beyond the expiry of the basic patent on the active ingredient.

In comparison with other provisions on linkage, such as those contained in the referred to DR-CAFTA, the draft TPP does not mandate a purely administrative linkage regime, under which the drug regulatory authority is required to refuse a marketing approval even in the absence of a judicial decision or a request by a patent owner. In any case, the impact on the affordability of drugs – even if off-patent – may be substantial.

⁷⁸ See, e.g., Carlos Correa, 'Expanding patent rights...', op. cit.

⁷⁹ For instance, in 2003 a requirement was introduced in the US law to ensure that only relevant polymorphs are listed in the Orange Book. See Mark Pohl, "Orange Book Patent Listing: The Rationale and Economic Impact of the New Rule," 1 *Journal of Generic Medicines* 224 (issue 3, 2004).

⁸⁰ Footnotes 126 and 128 to the proposed text may be interpreted –despite the reference to 'measures in its marketing approval process'- as allowing a party to satisfy its 'linkage' obligation by making available judicial provisional injunctions, and to consider that the 'consent or acquiescence of the patent owner' has been given when he has failed to avail itself of the opportunities afforded by administrative or judicial measures to prevent the marketing approval of a generic product. If this is the intention of the negotiators, a clarification of the nature and scope of that obligation would be called for..

The value of pharmaceutical patents

In addition to the substantive standards on intellectual property contained in the draft TPP that may affect access to medicines, a proposed chapter was leaked in 2011 that would mandate TPP countries to ensure pharmaceutical companies the right to appeal decisions on the reimbursement prices of medicines, if they consider that the prices paid do not ‘appropriately recognize the value’ of particular pharmaceutical patents.⁸¹ The proposed text would also require TPP governments to recognize an ‘increased amount’ of reimbursement based on evidence of ‘superior safety, efficacy or quality’. These provisions, if accepted,⁸² would narrow down the policy space that governments have to set limits to the prices of patented drugs. They would clearly run counter to the principle enshrined in article 8.1 of the TRIPS Agreement, which allows WTO members to adopt measures necessary to protect public health.⁸³

Extension of the patent term

The draft TPP contains another worrying element, which is generally present in FTAs: the extension of the patent term in order to compensate for ‘unreasonable’ delays in the grant of a patent or in the marketing approval of a pharmaceutical product. Such extensions represent an essentially unfair and dysfunctional mechanism, as it penalizes the public with a longer monopoly for the failure of the administration to process patent and marketing approval applications within a reasonable time, and put pressure on the authorities to make decisions without sufficient consideration of the reasons that may lead to the refusal of an application. The applicability of the extension based on marketing approval delays to pharmaceuticals only, is an indicator of the influence that the large pharmaceutical industry has in this negotiating process.

Significantly, the extension of the patent term required under the draft is not subject to the limitations that can be found, for instance, under US law where the extension to compensate for delays in the marketing approval procedures should not exceed five years and, in no case, should exclusivity exceed fourteen years from the date of approval by the Food and Drug Administration; in addition, the extension applies to only one patent per product (35 U.S.C. § 156). In the case of extensions due to delays by the patent office, the term of a patent has to be adjusted for each day beyond a period of three years.⁸⁴

While article QQ.E.14 (draft of May 2015) on ‘Patent term adjustment/marketing approval’ states that ‘in implementing the obligations of this Article, each Party may provide for conditions and limitations provided that the Party continues to give effect to this Article’, this clause fails to establish concrete limits as provided for under US law. In addition, the

⁸¹ Similar provisions can be found in the US FTAs with Australia and South Korea.

⁸² The draft TPP adds other obligations, such as making public the composition of the reimbursement committees and to justify any decision made on reimbursement prices.

⁸³ Intellectual property rights would also be protected, under the leaked TPP investment chapter Article II.1 <https://wikileaks.org/tpp-investment/>, as ‘investments’ including, in particular, the possibility for a right-owner to direct sue a State in case of an alleged violation of such rights, Section B. An example is the Eli Lilly claim against Canada under the investment chapter in NAFTA. See, e.g. Carlos Correa, *Modeling Patent Law...*, op. cit.

⁸⁴ See, e.g. Joseph Drexel and Nari Lee (editors), *Pharmaceutical Innovation, Competition and Patent Law*, Edward Elgar, 2013, p. 124.

extension in the case of delays in processing a patent application is not subject to the same flexibility regarding implementation.

V. TRANSITIONAL PERIODS

In view of the resistance by many TPP negotiating parties to some of the US proposals that may have a direct impact on public health, the USA has apparently opted to explore a strategy that succeeded in the TRIPS negotiations: to introduce transitional periods for countries with lower per capita income. The proposal, however, would provide for a lower standard in relation to some issues only, such as data exclusivity, patent term extension, and patent linkage. Such a standard would be based on the so-called ‘May 10’ agreement between the House Democrats and the Bush Administration reached in 2007, which allowed Peru, Colombia and Panama to consider patent term extension for pharmaceuticals as optional, and to replace the ‘linkage’ mechanism by one offering patent owners the means to defend against infringement expeditiously. However, this special treatment would only apply during the transition period in the case of the TPP parties.

Initially, the USA has apparently proposed to establish a threshold based on the GNI per capita as used by the World Bank to classify countries, which would have benefitted countries with a per capita GNI below US\$12.736. As a result, Peru, Mexico, Vietnam and Malaysia would be eligible for the transition period,⁸⁵ while Chile would be excluded. This proposal could be replaced – in accordance with some reports – by fixed transition periods, an option that would seem preferable to the pharmaceutical industry, as it would provide more certainty about the date in which the obligations would enter into force. This is what is suggested by the draft of May 2015, where four categories of countries are mentioned but not characterized. The applicable terms are not defined either.

As illustrated by the experience with the transition periods under the TRIPS Agreement, the relief they may bring is insufficient. At the end of those periods – which are arbitrarily fixed – the conditions in the beneficiary countries may have not changed at all or to the extent necessary to make the application of the required standards of protection more tolerable. The case of the Least Developed Countries (LDCs), for instance, shows that their economic conditions deteriorated after the WTO agreements were adopted, and it is uncertain whether they will sufficiently improve at the time the new extension of the transition period expires on 1st July 2021.

⁸⁵ However, given the current level of the per capita GNI of some of these countries, such as Malaysia and Mexico, any transition period may have already expired for them by the time the TPP comes into force.

VI. CONCLUSIONS

The TPP follows the tradition of previous FTAs signed by the USA, but with even higher levels of protection for pharmaceuticals. Despite the enormous differences in the economic wealth of the negotiating parties, the USA is seeking a ‘one-size-fits-all’ approach (that may be only temporarily tempered by transition periods) that is likely to aggravate the problems of access to medicines that those countries face, especially for highly priced biologicals. The resistance by most negotiating parties to the maximalist protections sought by some of such parties, point to concerns about the impact that those protections may have in terms of medicines’ costs and access by patients.

The TPP provides a paradigmatic example of international law making led by the interests of a business group, adopted by a government as an essential component of its own agenda. The rights of patients to get access to needed treatments⁸⁶ are systematically overlooked by the proponents of levels of protection that are TRIPS-plus and that would most probably be rejected in multilateral fora, such as in the WTO. Like in previous FTAs, the asymmetric bargaining position of the negotiating parties, and unjustified expectations about *other* trade benefits that the TPP may bring about, would remain the only explanations for the acceptance – if such were the case – of intellectual property protections aimed at satisfying the pharmaceutical industry’s relentless demands of broader and longer monopolistic rights.

While in the course of the negotiations some of the TRIPS-plus provisions that may have a negative impact on access to medicines have been deleted or amended, many highly problematic provisions remain. Given the asymmetries in the negotiating power of the parties involved in the TPP, the agreement, if finally adopted, will represent another step in the process of ratcheting up intellectual property protection for the benefit of a small (but powerful) group of pharmaceutical companies, to the detriment of millions of patients in need of treatment in the TPP would-be parties.

⁸⁶ There is a vast literature on the implications on intellectual property on the fundamental right to health and on ways of realizing the latter through balanced regimes. See, e.g., Germán Velásquez, Carlos Correa and Xavier Seuba, *IPR, R&D, Human Rights and Access to Medicines – An Annotated and Selected Bibliography*, South Centre, Geneva, 2012.

SOUTH CENTRE RESEARCH PAPERS

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