

# WORKING PAPER

## The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-Plus Era: Implications for Treatment Access

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*These papers were written to inform the work of the Global Commission on HIV and the Law, which is convened by UNDP on behalf of UNAIDS. The content, analysis, opinions and recommendations in the papers do not necessarily reflect the views of the Commission, UNDP or UNAIDS. While the Commission's Technical Advisory group provided review and commentary, the authors accept responsibility for any errors and omissions.*

Citation: Baker, B. and Avafia, T., (2011), *The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-plus Era: Implications for Treatment Access*. Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011.

### Abstract

*Intellectual property and data protection rights on pharmaceutical products have become increasingly controversial as monopoly prices associated with these rights have made the cost of treatment for diseases, including Human Immunodeficiency Virus (HIV), unaffordable for many people in low and middle-income countries. Yet, a review of the historical evolution of intellectual property law reveals that there has been a deliberate erosion of the balance between right-holders to exclusive use of a patented invention and the rights of the consumer to use a patented invention. This paper outlines the historical evolution of intellectual property law and notes that from an early point in the development of intellectual property regulations, countries retained the flexibility to customise intellectual property policy and laws to meet specific national priorities including transfer of technology, developing certain industrial sectors and attracting foreign direct investment.*

*The paper examines the extent to which safeguards have historically been used in patent laws to safeguard public interest and how both developed and developing countries have made use of exceptions to patent rights to meet policy objectives. The paper then traces efforts by industry in developed countries to increase the level of intellectual property protection and enforcement in the 1970s and 1980s culminating in the inclusion of intellectual property to the Uruguay trade round and the creation of the Agreement on Trade Related Aspects of Intellectual Property rights (TRIPS) which made it a requirement for every World Trade Organisation (WTO) Member to apply minimum standards on intellectual property.*

*The paper then explores the impact of TRIPS on the balance of interests between pharmaceutical companies, governments, and the public. The paper traces the application of corporate pressure and the use of trade negotiations by wealthy nations to advance the pharmaceutical industry's interests with the emergence of an agenda to increase the level of intellectual property protection and enforcement beyond the minimum standards of the TRIPS Agreement and briefly explores the potential impact of access to essential medicines. In conclusion, the paper discusses the failure of the TRIPS Agreement to achieve its promised benefits and offers recommendations to developing countries to increase access to treatment.*

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# 1. Introduction: Historical Development of Intellectual Property Law

Intellectual property rights (IPRs) have a greater impact on the development of societies now than at any time in our history. Whether it is a discussion over the scope of copyrights and their impact on access to learning materials for students in low-income countries, limitations on peer-to-peer file sharing of music over the internet, the growth of open-source and free software movements, the exploration of ways to empower indigenous communities to benefit from traditional knowledge, or concerns about the impact of patenting plants, seeds, animals, genes, viruses or pathogens for profit, it is highly unlikely that debates around the utility, scope and enforcement of intellectual property have ever been more in the public eye than now. More importantly, however, for the purposes of this study, granting patents and data protection rights on pharmaceutical products<sup>2</sup> has become increasingly controversial, especially in low- and middle-income countries where monopoly prices associated with exclusive rights have made the cost of treatment for many diseases unaffordable for the majority of the world's people. While events of the past few decades<sup>3</sup> have provided some opportunities for low- and middle-income countries to exact development advantages, in almost all cases, the growth of intellectual property right protection in subject matter and territorial scope has disadvantaged those most in need.<sup>4</sup> While the impact of these developments in intellectual property on access to HIV treatment is discussed later in this paper and in companion papers, understanding the impact of intellectual property on low- and middle-income countries is enhanced by briefly exploring the historical development of patents and data protection and the original purpose behind the granting of periods of monopolies as an incentive to stimulate innovation.

## 1.1 The Origins of Intellectual Property Law

A number of scholars trace the history of IPRs back several centuries.<sup>5</sup> While the awarding of exclusive rights to authors and inventors in ancient times was unusual, rewards and incentives were granted in Persia and China as prizes in the arts and crafts. In ancient Greece, systematic awards were rarely given to scientists, but rather to artists.<sup>6</sup> This began to change when the first monopoly privileges began to appear after the dark ages. Initially, these privileges were exclusive rights of monarchs to grant economic benefits for various reasons completely at their discretion.<sup>7</sup> Alternatively, rulers awarded exclusive franchise rights as a form of political patronage to favoured subjects. Monopolies on inventions and artisan techniques were also granted, particularly to craft guilds to secure their continued presence and to preserve the secrets of their craft within a particular territory. This secrecy and monopoly gave territories advantages in trade for the duration of the period of exclusivity.<sup>8</sup>

The first formal intellectual property law, which signified the first legal and institutional framework developed to regulate the ownership of knowledge, can be traced back to a Venetian statute of 1474.<sup>9</sup> It contained key principles including the balancing of the rights of inventors with consumers, which formed the basis of modern intellectual property law. According to Mandich<sup>10</sup>:

*“Venice was the first to have continuously and constantly applied certain rules to patents of invention instead of granting an occasional isolated monopoly. Among these rules were these: the protection always was extended to an inventor, provided that his invention was recognized as useful; that the patent term was limited; that the right was transferrable inter vivos and mortis causa; and that it was subject to a compulsory license in favor of the state, that a patent was forfeited by failure to use it within certain term and that it failed in cases of prior knowledge within the territory of the Republic.”<sup>11</sup>*

2 The term “pharmaceutical products” applies to small molecule and biotech medicines, vaccines, and pharmaceutical diagnostics. The use of the term “medicine” in this paper should be considered to include all pharmaceutical products.

3 Report of UK Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property rights and Development Policy* (2002) Available at: [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf)

4 These developments in recent decades include the patenting of living things and materials found in nature as opposed to man-made inventions, the extension of the scope of patenting to include software and business methods and the widening of exclusive rights, extending the duration of patent rights and strengthening enforcement mechanism. These matters, insofar as they relate to access to treatment, are discussed in companion papers.

5 See for instance, P Drahos, (1996), *A Philosophy of Intellectual Property*, Aldershot and Brookfield, Dartmouth.

6 F Payer, *The early growth and influence of intellectual property*, (1950), *Journal of the Patent Office Society* 34 (2) 106-140 at p. 111.

7 *Ibid.* Payer at pp. 116-119.

8 *Ibid.* Payer at p. 121.

9 C May, *The Venetian Movement: new technologies, legal innovation and the institutional origins of intellectual property* (2002) in D Vaver, (2006), *Intellectual Property Rights: Critical Concepts in Law*, (2006) Volume 3, Routledge.

10 G Mandich, *Venetian patents (1450-1550)*, (2002) *Journal of the Patent Office Society* 30: 166-224.

11 The Venetian statute is a clear indication that at the outset, exclusive rights provided to the inventor were to be balanced by the requirements that the invention be worked locally, that it pass the test of utility or usefulness and the rights of the inventor were subject to compulsory licensing (whether to another private party or for purposes of government use).

## 1.2 The Motivation Behind the First Patent Laws

A review of even the earliest intellectual property policies, laws and practices over centuries shows how countries traditionally have retained the flexibility to advance their strategic interests, including transfer of technology, developing certain industrial sectors and attracting foreign direct investment. In Europe for instance, even before the first patent were used by governments as instruments to induce the transfer and disclosure of foreign technologies, there had been a practice of providing skilled artisans with periods of temporary monopoly as an incentive for them to move to less technologically advanced regions and countries.<sup>12</sup> In the mid 14<sup>th</sup> century at a time when England lagged behind several regions in continental Europe technologically, letters of patent were provided to incentivise the immigration of the Flemish weaver John Kempe to England by King Edward II,<sup>13</sup> followed by the conferring of letters of patent to two weavers from the Dutch area of Brabant.<sup>14</sup> While the letters of patent gave skilled artisans a period of exclusivity, it was expected that in exchange for the temporary monopoly that guaranteed protection against domestic competitors, the foreign artisans would introduce English apprentices to the skills and knowhow required to eventually operate their own businesses. The practice of issuing letters of patent was eventually replaced with a law more than a century later. MacLeod and others<sup>15</sup> note that the immigration of foreign skilled workers one of the motivating factors behind the enactment of the first English intellectual property law, the Monopolies Statute of 1623.<sup>16</sup> According to David, the logic behind providing a 14-year period of exclusivity under the Monopolies Statute (with the possibility of a further seven-year extension) was to provide artisans protection from two generations of apprentices given that the period of training at the time lasted seven years.<sup>17</sup>

This practice of disclosure through apprenticeship was supplemented in a later era with the requirement of disclosure as a condition of the patent being granted to allow it to be worked by those skilled in the art, at the end of the patent term.<sup>18</sup> In addition, disclosure would incentivise follow-on innovation by allowing subsequent inventors to understand and build upon the disclosed innovation.<sup>19</sup> Another example of how intellectual property was used to safeguard a country's strategic interests lies in the United States (US), which, as a net importer of technology, did not allow foreigners to file for patents from 1790 until 1836, when the *United States Patent Act* was passed.<sup>20</sup> When the restriction on foreigners was eventually lifted, patent fees for foreigners were approximately tenfold (with an additional 65% charge for British nationals) higher than those for American citizens.<sup>21</sup> The US government only lifted the restriction on copyright protection for foreigners in 1891.<sup>22</sup> Even after extending copyright protection to include foreigners, the US government maintained specific restrictions on copyright that delayed its ratification of the 1886 Berne Copyright Convention by 102 years.<sup>23</sup>

In addition to preserving flexibilities by not ratifying certain international Conventions and treaties, countries have applied intellectual property strategically to further national interests. When an American company filed a patent

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12 P David, *Intellectual property institutions and the panda's thumb: patents, copyrights, and trade secrets in economic theory and history*, in Wallerstein, Mogege and Schoen (eds.), *Global dimensions of Intellectual Property Protection in Science and Technology*, National Academy Press, Washington, D.C.

13 As also noted in E Wyndham Hulme, *The History of the Patent System under the Prerogative and at Common Law*, *Law Quarterly Review* (1896), Volume 46, 141-154.

14 P David, *Intellectual property institutions and the panda's thumb: patents, copyrights, and trade secrets in economic theory and history*, in Wallerstein, Mogege and Schoen (eds.), *Global dimensions of Intellectual Property Protection in Science and Technology*, National Academy Press, Washington, D.C. at p 45.

15 C MacLeod, (2002) *The paradoxes of patenting: Invention and its diffusion in the 18<sup>th</sup> and 19<sup>th</sup> century Britain, France and North America*, *Technology and Culture* 32 (4), 885-911. See also, W Cornish, (1999), *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 4<sup>th</sup> edition, London.

16 While the statute generally condemned monopolies, it provided the true and first inventor of a given item up to 14 years of exclusive rights provided that the rights were not contrary to the law, mischievous to the state by raising prices of commodities at home, did not result in the disruption of trade or were not generally inconvenient.

17 P David, *Intellectual property institutions and the panda's thumb: patents, copyrights, and trade secrets in economic theory and history*, in Wallerstein, Mogege and Schoen (eds.), *Global dimensions of Intellectual Property Protection in Science and Technology*, National Academy Press, Washington, D.C.

18 See for example, the following comments by Justice Buller in the case of *The King v. Arkwright*, *Dav. Pat. Cas.* 106 (1785) who noted that the disclosure requirement dated back to the Statute of Monopolies:

*If the specification be such that mechanical men of common understanding can comprehend it, to make a machine by it, it is sufficient; but then it must be such that persons skilled in the art or science to which the invention relates may be able to make the machine by following the directions of the specification, without making any experiments, and without any new invention or addition of their own.*

19 M Janis, (2000), *On Courts Herding Cats: Contending with the "Written Description" Requirement (and other unruly Patent disclosure Doctrines)*, *Washington University Journal of Law and Policy*, volume 2, page 56.

20 This is the first intellectual property law that contains elements of modern day legislation requiring for instance, applications to be examined by the government patent office to confirm the novelty and usefulness of the invention before a patent could be granted.

21 Report of UK Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property rights and Development Policy* (2002) Available at: [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfinal.pdf) at p. 18.

22 *Ibid.*

23 With the passing of the *Berne Convention Implementation Act* of 1988.

application in Japan on the integrated circuit, arguably one of the most important inventions of the second half of the 20<sup>th</sup>

century, the Japanese Patent office took an extraordinary 29 years to grant the patent. Bearing in mind that information on the specifications of a patent application were publically available (including to Japanese competitors) after 18 months, by the time the patent was granted, Japanese companies had acquired the technology, improved upon it and controlled 80% of the US market for computer semi-conductors.<sup>24</sup>

### 1.3 The Special Case of Pharmaceuticals in Intellectual Property Laws

As intellectual property law developed, countries retained the flexibility to customise intellectual property policy and laws to meet specific national priorities. The *German Patent Act* (Reichspatentgesetz) of 1877 was in line with several laws of the time in not allowing the patenting of inventions that were considered to be against public order or morality.<sup>25</sup> The Act also prohibited the patenting of luxury goods, medicines, articles of food and chemical products,<sup>26</sup> on the basis that they were essential goods, which should not be subject to a monopoly, and that more was to be gained by allowing access to foreign technology than relying on the domestic industry to stimulate innovation.<sup>27</sup> Countries such as Switzerland had only a patent system from 1799 to 1802 and did not re-establish it until 1888.<sup>28</sup> Switzerland was motivated to re-establish the patent system not because it believed that patent protection was beneficial to the economy, but because Swiss authorities had come under intense pressure from Germany to adopt a patent law and did not wish to face retaliation for failing to do so. Eventually, when a patent law was passed it included strong compulsory licencing and government use provisions and excluded chemicals and textile dyes from patent protection.<sup>29</sup> This policy choice favouring compulsory licences was also codified in Article 5 A(2) of the *Paris Convention for the Protection of Industrial Property* (Paris Convention).<sup>30</sup> Compulsory and government-use licences for medicines are expressly authorised in the patent laws of several industrialised countries and were granted extensively.<sup>31</sup> Canada for instance, granted 613 licences to import or manufacture pharmaceutical products between 1969 and 1992.<sup>32</sup>

In Africa, Asia and the Pacific, the formal introduction of intellectual property laws began in the late nineteenth century, initiated by European colonial powers after the 1884 Congress of Berlin.<sup>33</sup> The United Kingdom imposed versions of its 1911 *Copyright Act* through East Africa, Malaysia, and Nigeria.<sup>34</sup> France also applied its intellectual property laws to its colonies until the end of the colonial period.<sup>35</sup> Despite the imposition of colonial laws, some countries, particularly Asian countries, used the relative flexibility available to countries, to customise intellectual property laws to meet their development objectives. As was the case with many colonies, pharmaceutical patents were first introduced to India in the nineteenth century<sup>36</sup> Concerned by high prices and the domination of the pharmaceutical industry by foreign firms<sup>37</sup> post independence, the Indian government passed a *Patent Act* in 1970<sup>38</sup> which excluded pharmaceutical products from patent protection. Kapczynski<sup>39</sup> notes that until the passing of the 1970 Act, colonial style laws in India were used effectively by foreign companies to suppress competition by Indian generic companies. In fact, when Great Britain

24 C Johnson, *Japan: Who Governs? The Rise of the Developmental State*, (1995) New York and London: W.W. Norton & Co, at 74-5.

25 UNCTAD-ICTSD, *Intellectual Property rights and Development: A Policy Discussion Paper*, Project on IPRs and Sustainable Development (2002) at 34.

26 *Ibid.* at 34.

27 Report of UK Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property rights and Development Policy* (2002) Available at: [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf)

28 F Dessemontet, (2000), *Intellectual Property Law in Switzerland*, The Hague, London and Bern: Kluwer Law International, AT 23.

29 Report of UK Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property rights and Development Policy* (2002) Available at: [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf) at p. 19.

30 For the complete text of the 1883 Paris Convention, refer: [http://www.wipo.int/treaties/en/ip/paris/trtdocs\\_wo020.html](http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html).

31 J H Reichman and C Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* (2003).

32 *Ibid.* at p.4.

33 C Deere, (2009) *The Implementation Game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries*, Oxford University Press at p. 35.

34 Gana, *Two Steps forward: reconciling Nigeria's Accession to the Berne Convention and the TRIPS Agreement*, *International Review of Industrial Property and Copyright Law*, 27, 4: 446-489.

35 C Deere, (2009) *The Implementation Game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries*, Oxford University Press at p. 35-36.

36 India's first patent law was passed in 1856 just before the beginning for the British Raj. See P Nayaranan, *PATENT LAW* 3<sup>rd</sup> edition (1998) at 541.

37 See for instance S Chaudhuri, (2005) *The WTO and India's Pharmaceutical Industry: Patent Protection, TRIPS and Developing Countries*, 1, 29 which suggests that foreign market share was as high as 68% of the total Indian market.

38 Act 39 of 1970.

39 A Kapczynski, (2009), *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector* *California Law Review*, Vol. 97 p. 1571).

enacted the first *Indian Patent Act* in 1856, it was specifically designed to enable British patent holders to acquire control over Indian markets. However, with the passing of the 1970 Act which eliminated patent rights for pharmaceutical and agricultural products, the number of patents declined by as much as 75% according to some estimates.<sup>40</sup> This, together with other important measures implemented by the government<sup>42</sup> led to Indian pharmaceutical companies increasing in manufacturing sophistication over a short period of time<sup>43</sup> and eventually becoming so skilled at reverse-engineering that some firms were able to launch generic products in the Indian market even before the originator companies did.<sup>44</sup> By the 1990s, Indian generic manufacturers were able to offer some of the lowest prices globally.<sup>45</sup> However, with India having to pass a new *Patent Act* by 2005 in order to comply with the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS or TRIPS Agreement),<sup>46</sup> some of the effects of this extraordinary phase of growth have begun to be reversed, with the increased consolidation of the generic industry through the acquisition of several generic pharmaceutical manufacturers by multinational originators.

Aside from India, a number of countries in east Asia including Taiwan and South Korea grew their indigenous innovation capacity benefitting from having the policy space to adopt Intellectual Property (IP) systems which allowed imitation and reverse engineering.<sup>47</sup> When South Korea adopted a *Patent Act* in 1961, it excluded foodstuffs, chemicals and pharmaceuticals and only allowed for 12 years of patent protection.<sup>48</sup> While historically, intellectual property was used by countries meet specific industrial policy objectives, as discussed in a companion paper<sup>49</sup>, the modern day patent system has not adapted to reflect modern day problems concerning the innovation of medicines, diagnostics and prevention technologies required to treat people living with HIV or neglected tropical diseases.

## 2. The Contested Move Towards International Standards

### 2.1 The First International Treaties

Attempts to expand the scope and subject matter of intellectual property commenced in the second half of the 19<sup>th</sup> century. Initiated in part, by unions who were interested in the protection of industrial property as well as literary and artistic works, the push for IP protection has grown to the extent that very few countries have remained outside the scope of one international intellectual property treaty or another. The *1883 Paris Convention* and the *1886 Berne Convention for the Protection of Literary and Artistic Works* (Berne Convention)<sup>50</sup> embodied the first results of efforts to co-ordinate an international IP agreement to which states would be bound.<sup>51</sup> Despite the success of developed countries in creating the first international treaties on IP, many newly independent countries were reluctant to sign and ratify the Paris Convention,<sup>52</sup> because of philosophical differences over the role of IP in stimulating innovation and the impact on development. Although developed economies codified some of their industries' international IP objectives in early treaties, many IP protection goals were not realised and emerging technologies sought new forms of protection or inclusion in older forms. Countries were interested in extending the scope of IP beyond the Paris and Berne Conventions because of a lack of strong enforcement provisions for national judicial and administrative entities as well as a perceived lack of an effective and binding dispute settlement mechanism to which countries could resort to in the event of a dispute.<sup>53</sup> This push conflicted with the growing assertiveness of a few of the larger developing countries

40 While process patents for pharmaceuticals were still obtainable under the 1970 Act, they were limited in scope and rarely granted.

41 J O Lanjouw, (1998), *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?* 3 (National Bureau of Economic Research, Working Paper No. 6366.

42 Chaudhuri suggests that other supportive government policies included the requirement that many drugs could only be produced by government companies or private companies with at least 60% Indian equity. He also suggests that price controls reduced the interest of foreign firms in the Indian market. Lanjouw notes that tariffs and import restrictions on formulations played an important role in stimulating the growth of the Indian pharmaceutical industry.

43 A Kapczynski, 'Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' *California Law Review*, Vol. 97 at p. 1578.

44 S Chaudhuri, (2005), *The WTO and India's Pharmaceutical Industry: Patent Protection, TRIPS and Developing Countries*, at p. 54.

45 *Ibid.*

46 *Marrakesh Agreement Establishing the World Trade Organization*, art. 8(1), annex 1C, 33 I.L.M. 81 (1994), available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

47 Report of UK Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property rights and Development Policy* (2002) Available at: [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfinal.pdf) at p. 20.

48 *Ibid.*

49 See M El Said and A Kapczynski, (2011), *Access to Medicines: The Role of Intellectual Property Law and Policy*, authored for *The Global Commission on HIV and the Law*.

50 The text of the Berne Convention is electronically available at: [http://www.wipo.int/treaties/en/ip/berne/trtdocs\\_wo001.html](http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html)

51 D Matthews, (2002), *Globalizing intellectual property rights – the TRIPS Agreement*, Routledge/Warwick Studies in Globalisation, at p. 11.

52 In the 1960s and 1970s, only some 33 developing countries became signatory to the Paris Convention.

53 As indicated for example, in S Scotchmer, (2001), *The Political Economy of Intellectual Property Treaties* Institute of Economic and Business Research, Working Paper E01-304, University of California, Berkley at 5-6.

who were interested in maintaining the policy space to tailor their laws to suit their national interests<sup>54</sup> and led to some tense debates on the role of IP in fostering development from the 1960s.

## 2.2 UN Debates on IP and Development: The Role of UN Agencies

In 1961, Brazil tabled a draft resolution before the United Nations General Assembly (UNGA) calling on the Secretary General to conduct an analysis of the effects of patents on developing countries and upon completion of the research, to organise a conference on patents and the special needs of developing countries.<sup>55</sup> According to Deere, Brazil had planned to use the subsequent UN report to push for the revision of the *Paris Convention*, which it felt did not sufficiently address the needs of developing countries.<sup>56</sup> While the UN Secretariat eventually responded to the request by Brazil in 1964 by highlighting some of the challenges facing developing countries in implementing IP policies and laws, the international conference was never held.<sup>57</sup> Around the same time in the early 1960s, certain developing countries and newly independent states primarily but not exclusively from the global south also began advocating for the establishment of a trade body beyond the General Agreement on Tariffs and Trade (GATT), which, it was argued, did not sufficiently address the needs of developing and newly independent countries. A political event of importance was the Conference on the Problems of Developing Countries held in Cairo in 1962, which led to the adoption of a Declaration calling for an international conference on all vital questions relating to international trade, primary commodity trade, and economic relations between developing and developed countries. This, together with concerted efforts by developing countries and the Non-Aligned Movement led to the establishment of the United Nations Conference on Trade and Development (UNCTAD) in 1964, despite opposition from developed countries.<sup>58</sup>

Meanwhile, the counter-movement by developed countries to deepen commitments on intellectual property, initiated through the *Paris* and *Berne Conventions*, led to the establishment of the World Intellectual Property Organisation (WIPO) in 1967, to administer the *Paris* and *Berne Conventions* and to promote the harmonisation of intellectual property legislation.<sup>59</sup> Within WIPO, developed countries conducted a protracted campaign to deepen, strengthen, and extend the scope and application of IP, but a resilient coalition of developing countries, led by Brazil and India, was steadfast in opposing such measures. Indeed, in continuing their efforts to revise the *Paris Convention*, developing countries in 1970, were able to pass a resolution in the UN General Assembly on an 'International Development Strategy for the Second UN Development Decade calling for, among other things, a review of the international convention relating to patents.<sup>60</sup>

## 2.3 Inclusion of Intellectual Property into the Uruguay Round, and the Establishment of TRIPS

Meanwhile in the US and the European Community, by the end of the 1970s a movement among businesses to make a stronger case for IP protection had taken hold. In the US, the Association of American Publishers<sup>61</sup> (AAP) for instance, began activities to redress copyright infringements at a global level by sending a delegation to Harvey Bale, then the Deputy United States Trade Representative (USTR), arguing that the US should take action against copyright infringement worldwide.<sup>62</sup> The 1980s brought with it increased industry collaboration against copyright infringement with organisations as diverse as the agricultural chemicals producers, the Anti-counterfeiting Coalition and the Copyright Alliance co-coordinating their efforts to lobby for changes in US trade policy.<sup>63</sup> The pharmaceutical industry played a particularly active role in initiating and consolidating a robust coalition of IP industries that persuaded trade negotiators, first in the US and then in Europe and Japan to champion a comprehensive and enforceable international IP regime, and

54 India and Brazil passed laws to exclude pharmaceuticals from patentability. India, with the passing of the *Patent Act* of 1970, excluded pharmaceutical products from patent protection while Brazil amended its Industrial Property Code of 1971 to exclude from patentability, both pharmaceutical manufacturing processes and products.

55 C Deere, (2009), *Developing Country Perspectives On Intellectual Property in the WTO: Setting the Pre-TRIPS Context* Research Handbook on Intellectual Property Law and the WTO, E Elgar, Oxford, available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1405430](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1405430)

56 *Ibid* at p. 8.

57 *Ibid*.

58 J and R Toye, (2004), *The UN and Global Political Economy: Trade, Finance and Development*, United Nations Intellectual History Project Series, 187-203 for a thorough discussion of the positions taken by various blocs of countries including developing countries, newly independent countries and the Non aligned movement on the one hand, and the reactions by developed countries to the proposal to establish UNCTAD.

59 Although created in 1967, the Convention establishing the World Intellectual Property Organization entered into force in 1970. WIPO officially became a specialized Agency of the United Nations in December 1974.

60 See Resolution 2626, adopted during the 25<sup>th</sup> Session of the UN General Assembly dated 24 October 1970. According to paragraph 64: *Developed and developing countries and competent international organizations will draw up and implement a program for promoting the transfer of technology to developing countries which, will include, inter alia, the review of international conventions on patents, the identification and reduction of obstacles to the transfer of technology to developing countries, facilitating access to patented and non-patented technologies to developing countries under fair terms and conditions...*

61 The AAP is the principal trade association of US book publishing industry.

62 D Matthews, (2002), *Globalizing Intellectual Property Rights – the Trips Agreement*, Routledge/Warwick Studies in Globalisation, at p. 13.

63 See S Sell, (1998), *Power and Ideas: The North-South politics of intellectual property and anti-trust*, State University of New York.

to do so within the context of GATT negotiations.<sup>64</sup> Pfizer in particular played a leading role ideologically throughout the 1970s and 1980s, especially in forging the Intellectual Property Committee, an international business coalition whose paper became the blueprint for IP demands by high-income countries in the GATT negotiations.<sup>65</sup> The pharmaceutical industry was primarily interested in eliminating what it felt was unfair discrimination against the patenting of medicines, but it was also motivated to try to gain control over uses of its clinical and regulatory data to delay registration of generic equivalents, in essence seeking another form of exclusive rights.

Until this stage, the US government had taken an ad hoc approach to claims of IP protections and infringement. However, industry pressure, a lack of progress in the Tokyo Round of the GATT<sup>66</sup> as well as a lack of progress in attempts to introduce enforcement and dispute settlement provisions into the *Paris* and *Berne Conventions*, prompted it to introduce amendments to Section 301 of the *Trade Act* of 1974. These amendments allowed the US to place strong bilateral pressure on countries to meet its demands for IP protection, drawing a clearer nexus between IP protection and trading rules.<sup>67</sup> The newly-amended Section 301 was used for the first time against the Republic of Korea after US companies complained about the limited scope of Korean IP laws in 1985, which were promptly amended to comply with US demands.<sup>68</sup> Other examples of the US using Section 301 to pressure countries for a perceived lack of adequate IP protection continued throughout the 1980s and 1990s.<sup>69</sup>

When the Uruguay Round of trade negotiations began in 1986, more than 40 of the then 90 GATT Members did not grant patents for pharmaceutical products<sup>70</sup> while others granted process patents rather than product patents, which, in a number of countries, facilitated the growth of domestic generic pharmaceutical manufacturing industries.<sup>71</sup> Likewise, few if any countries, except in North America and Europe, explicitly protected pharmaceutical regulatory data. Initially, the US and other developed countries proposed including IP within the scope of the Uruguay round of negotiations mainly as a means of combating trade in counterfeit goods.<sup>72</sup> However, by the time the Uruguay Round of negotiations had commenced, corporate networking had been achieved on a global scale through the formation of some key relationships between individuals, companies and business groups in the US, Europe and Japan. This had proved to be so effective in uniting stakeholders over issues of common concern that there was a great sense of optimism and determination to adopt an IP agreement supportive of the business agenda.<sup>73</sup>

This effective new grouping of IP industries, advocating for the continued and strategic use of Section 301 of the *Trade Act*, enabled rich-country negotiators to impose pressure on developing countries to increase the level of IP protection.<sup>74</sup> Together with negotiation fatigue and the belief by some countries that concessions in IP would result in greater market access for agricultural products and textiles,<sup>75</sup> by the final stages of the Uruguay Round negotiations in the first few years of the 1990s, the majority of developing countries had stopped opposing the inclusion of the TRIPS Agreement under the umbrella of the soon to be established WTO. The TRIPS Agreement was duly adopted as one of the three primary Agreements of the newly established WTO making it a requirement for every Member to apply minimum standards on

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64 See P Drahos and J Braithwaite, (2003), *Information Feudalism: Who Owns the Knowledge Economy* (2003) for a detailed history of the political and strategic genesis of the TRIPS Agreement as engineered by US knowledge industries.

65 On 14 June 1988, a text codifying the IPC's consensus position was released in Washington, Brussels and Tokyo, Bearing the title *Basic Framework of GATT Provisions on Intellectual Property: Statement of Views of the European, Japanese and United States Business Communities*. For a more complete history of the leadership role of Pfizer in the TRIPS negotiations, see P Drahos, (2004), *Who Owns the Knowledge Economy: Political Organizing Behind TRIPS*, The Corner House: Briefing 32 available at <http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy>.

66 The Tokyo Trade Round of the GATT took place from 1973 to 1979, involved, at its height, negotiations between 102 countries and is remembered for being the first round where non-tariff barriers were the subject of negotiation between GATT contracting states.

67 E Henderson, (1997), *TRIPS and the Third World: The Example of Pharmaceutical Patents in India*, *European Intellectual Property Review*, 11, 651-663.

68 D Matthews, (2002), *Globalizing Intellectual Property Rights – the Trips Agreement*, Routledge/Warwick Studies in Globalisation, at p. 16.

69 For instance, in response to a petition by the Pharmaceutical Manufacturers' Association, the US increased tariffs by 100% on \$39 million worth of Brazilian imports in retaliation for Brazil's perceived inadequate patent protection for pharmaceutical products.

70 WHO, Network for monitoring the impact of globalisation and TRIPS on access to medicines, Health Economics and Drugs, EDM Series no 11, WHO/EDM/PAR/2002, 1.

71 Indian companies have demonstrated an impressive cost-effective production process and have established pharmaceutical manufacturing facilities that easily comply with international quality standards. India has as a result, received worldwide recognition as a low-cost producer of high-quality medicines.

72 C Wadlow. (2007), *Including Trade in Counterfeit Goods: The origins of TRIPS as a GATT anti-counterfeiting code* *Intellectual Property Quarterly* 3, at pp. 350-402

73 D Matthews, (2002), *Globalizing Intellectual Property Rights – the Trips Agreement*, Routledge/Warwick Studies in Globalisation, at p. 28.

74 In total between 1985 and 1994 (during the Uruguay round), the USTR brought Section 301 actions dealing with intellectual property against Brazil (1985, 1987 and 1993), Korea (1985), Argentina (1988), Thailand (1990 and 1991), India (1991), China (1991 and 1994) and Taiwan (1992). At times, these Section 301 actions managed to quell opposition to the US agenda on intellectual property. In 1992 for instance, the US acting on the basis of Section 301, revoked tariff concessions that India had for pharmaceutical products, resulting in an estimated \$ 60 million loss. After the revocation of concessions by the US, India's opposition to the US agenda on intellectual property decreased considerably.

75 C Michalopoulos, (2002), *Special and Differential Treatment of Developing Countries in TRIPS* Quaker United Nations Office (QUONO), at p. 11.

IP with far reaching implications. In the words of Edmund Pratt of Pfizer, “Our combined strength enabled us to establish a global private sector-government network which laid the groundwork for what became TRIPS.”<sup>76</sup> Standards relevant to pharmaceuticals will be discussed below.

The impact of the TRIPS Agreement’s provisions on the ability of low- and middle-income countries to formulate IP law to meet specific development objectives cannot be overstated. Its creation constituted a major coup for several corporate interests as it prescribed minimum standards across various aspects of IP including copyrights and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits and protection of undisclosed regulatory data. TRIPS constituted a significant erosion of much of the policy space in the *Paris Convention* such as the freedom of WTO Members to determine the duration of patents in national legislation and to restrict the patentability of pharmaceutical products. The TRIPS Agreement has had a largely negative impact on the ability of low- and middle-income countries to access affordable pharmaceutical products especially in light of the explosion of the HIV epidemic in the 1990s.

### 3. An Increase in Patent and Data Protection From TRIPS to TRIPS-Plus

The preceding sections have outlined the historical evolution of patent protections and the eventual consolidation of a patent-based pharmaceutical industry that engineered an international coalition of IP-based industries that was the driving force behind the adoption of a harmonised global minimum of intellectual property protections. Having first convinced the US and later the European Union (EU) and Japan to act on their behalf, these industry groups have continued to work in official and unofficial coalitions to advance unachieved corporate interests through the widening and deepening of IP protections. The pharmaceutical industry, in particular, has considered the provisions of TRIPS as a floor – and as a launching pad for ever-expanding patent and data protections.<sup>77</sup> This section first explores the impact of TRIPS on the balance of interests between originators, users of medicine, and the broader public interest in innovation and technology transfer. Thereafter, it examines the direct application of corporate power to achieve TRIPS-Plus<sup>78</sup> goals, as well as the use of trade negotiations and other state mechanisms by the US, Europe, and Japan to advance their pharmaceutical industries’ interests. Finally, the section readdresses whether developing countries are achieving promised benefits from the escalation of IP protections, concluding that they certainly have not.

#### 3.1 How TRIPS Restricted Policy Space by Focusing on Protecting Right Holders

The TRIPS Agreement established minimum substantive protections and enforcement standards for a set of IPRs, including those most relevant to access to medicines – patents<sup>79</sup> and registration-related data.<sup>80</sup> The TRIPS Agreement greatly limited the pre-existing policy space of Members to enact IP standards more closely tailored to their national interests and did little or nothing to advance their interests with respect to innovation, technology transfer, and user access. Nonetheless, countries did retain certain flexibilities concerning interpretation, application, and implementation of TRIPS.<sup>81</sup>

In order to join the WTO at its inception or thereafter, Members were required take on TRIPS in its entirety (no reservations) and, depending on the length of relevant transition periods<sup>82</sup> and waivers for “least-developed countries” (LDCs), to implement TRIPS through national legislation.<sup>83</sup> Because of its “national treatment” provisions,<sup>84</sup> Members not previously bound by the *Paris Convention* or other binding treaties were no longer permitted to treat their own nationals differently than those from other WTO Members in order to pursue industrial development or other policies. Likewise, because of “most-favoured nation” provisions,<sup>85</sup> any IP-related trade benefit given to one WTO Member must be extended to all others.

Pursuant to TRIPS, Members are obligated to grant patents to all comers on an equal basis permitting patent holders to

76 E T Pratt, Jr., Intellectual Property Rights and International Trade available at <http://www.tradeobservatory.org/library.cfm?refID=24157>.

77 Data protection refers to provisions that restrict or prevent the use of regulatory data (clinical trials, stability studies, proof of built-in quality) by drug regulatory companies to facilitate the registration (marketing approval) of equivalent generic medicines. It also refers to provisions restricting the disclosure of such information.

78 TRIPS-plus refers to substantive intellectual property protections and enforcement measures that are greater than the minimums specified by the TRIPS Agreement and to the elimination or reduction of flexibilities granted in TRIPS.

79 TRIPS Agreement Part II, Section 5, Arts. 27-34 available at [www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm3\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm3_e.htm)

80 *Ibid.* Art. 39.

81 *Ibid.*

82 See *Ibid.* Arts. 65 and 66 for relevant transition periods.

83 *Ibid.* Art. 1.1.

84 *Ibid.* Arts. 1.3, 3, 27.1.

85 *Ibid.* Art. 4.

exclude competitors for a uniform 20 years (from the date of filing a patent application)<sup>86</sup> from making, using, offering for sale, selling, or importing patent-infringing products or products made through a patent infringing process.<sup>87</sup> By incorporating anti-discrimination provisions, patent-holders and developed countries are now able to enforce patent rights regardless of the place of innovation, to control the site of production and work the patent via importation rather than via domestic production, and to prevent discrimination against particular fields of technology.<sup>88</sup> Preventing discrimination against imports was a key objective of the IP industry because of the history of import substitution and industrialisation pursued by developing countries whereby they tried to require local inputs in terms of materials and/or value-added manufacturing and to require technology transfer of advanced pharmaceutical manufacturing capacity. Likewise preventing discrimination against a particular field of technology meant that countries could no longer, as high-income countries had done previously, treat pharmaceutical or agricultural innovations as special areas where broader use and more affordable access could be pursued by excluding patents on pharmaceuticals.<sup>89</sup>

In addition to protecting patents, the TRIPS Agreement also provided limited protection for pharmaceutical regulatory data that is submitted for the purpose of obtaining marketing approval. Pursuant to Article 39.3:

*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*

Although Article 39.3 only protects data from disclosure and unfair commercial use, the pharmaceutical industry and upper-income country trade representatives have engaged in a concerted campaign to turn its minimal protections into an ironclad form of exclusivity and thus monopoly. However, Article 39.3 contains several terms that seem to defeat a claim that it mandates so-called data exclusivity<sup>90</sup> instead of mere data protection.<sup>91</sup> First, Article 39.3 only applies when countries require the submission of data as a condition of marketing approval. For example, if a country simply relies on the fact of registration of a medicine by another drug regulatory authority, rather than requiring the submission of new, comparable data, Article 39.3 would not apply.<sup>92</sup> Second, protection is limited to “new chemical entities,”<sup>93</sup> which either have not been granted regulatory approval in the WTO Member country or perhaps anywhere in the world.<sup>94</sup> Third, the data must be undisclosed, meaning that if the information is already in the public domain,<sup>95</sup> there is no need for data protection.<sup>96</sup> Fourth, there is a requirement that there be “considerable effort” – presumably effort and investment – in collecting the data.<sup>97</sup> Fifth, the most disputed element requires protection against “unfair commercial use,” not any use whatsoever, for example use for the purpose of registering an “equivalent” product. Here, the main controversy is whether drug regulatory authorities can rely on an earlier registrant’s data, or the fact of prior registration, to assess and certify the safety and efficacy of an equivalent generic product. The negotiating history of Article 39.3, during which US and European Community (EC) proposals for data exclusivity were rejected, “proves that negotiators did not agree upon an unalloyed obligation to ensure data exclusivity under any of the proposed terms.”<sup>98</sup> Despite this, both the US and the

86 *Ibid.* Art. 33.

87 *Ibid.* 28.1.

88 *Ibid.* Art. 27.1.

89 UNCTAD-ICTSD, *Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement* (2005).

90 Data exclusivity is a TRIPS-Plus form of data protection strongly pursued by the pharmaceutical industry and vigorously promoted by the US and EU. Data exclusivity bars the right of drug regulatory authorities to refer to or rely upon data previously supplied by earlier registrant (or the fact of earlier registration itself) in order to assess the safety and efficacy of a biologically equivalent generic medicine. In its strongest form, data exclusivity could bar the registration of a generic medicine produced pursuant to a compulsory licence. Data exclusivity in the US last a minimum of five years and can be extended for additional three year periods based on submission of new clinical data. In Europe, data exclusivity now lasts ten years and can be extended for an additional one year upon a showing of a significant therapeutic advantage over existing medicines. See Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity And Patent/Registration Linkage*, 34 *AM. J. LAW & MED.* 303-344 (2008).

91 C Correa, (2002), *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement 6*, available at <http://www.southcentre.org/publications/protection/protection.pdf>

92 C Correa, (2002), *Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 *CHI. J. INT'L L.* 69, 73.

93 New chemical entity is a term of art generally applying to a small-molecule chemical that has not previously been registered for medical use.

94 C Correa, (2002). *Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 *CHI. J. INT'L L.* 74, 75

95 Information can enter the public domain by publication in a journal or in some instances by prior use.

96 C Correa, *Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 *CHI. J. INT'L L.* 73, 74.

97 *Ibid.* at 75-76.

98 A X Fellmeth, (2004), *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPS Agreement*, 45 *HARV. INT'L L.J.* 443, 455. See also C Correa, *Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 *CHI. J. INT'L L.* at pp. 53-56.

EC have continued to assert that Article 39.3 requires data exclusivity. Without recounting the competing arguments at length, “the most compelling assertion is that the ‘unfair commercial use’ term prevents dishonest commercial practices, but not governmental performance of its duty to ensure safety and efficacy of follow-on products.”<sup>99</sup>

Although the TRIPS Agreement undoubtedly reduced the discretionary powers of WTO Members to customise national legislation to fulfill national interests with respect to medicines, WTO Members retained key flexibilities and safeguards that could be used to increase access to medicines, as discussed further in a companion paper. These include:

the right to strictly define baseline patentability rules<sup>100</sup> (novelty, inventive step, and industrial applicability)<sup>101</sup> and disclosure standards;<sup>102</sup>

- to issue compulsory licences and government use orders;<sup>103</sup><sup>104</sup>
- to parallel import;<sup>105</sup><sup>106</sup>
- to exclude patents for certain subjects, such as patents on surgical, diagnostic and therapeutic methods;<sup>107</sup>
- to apply general exceptions including early-working<sup>108</sup> and experimental use;<sup>109</sup> and
- to make use of transitional arrangements<sup>110</sup> and waivers.<sup>111</sup>

In addition, Members retained rights to prevent abusive practices that unreasonably restrain trade or adversely affect

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99 B K Baker, (2008), *Ending Drug Registration Apartheid: Taming Data Exclusivity And Patent/Registration Linkage*, 34 AM. J. LAW & MED. 303-344, 317; *Bayer, Inc. v. Canada* (Attorney Gen.), [1999] 87 C.P.R.3d 293 (Fed. Ct. of Appeal); C Correa, (2002), *Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69, 76-82; J H Reichman, *The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods*, in *Negotiating Health: Intellectual Property and Access to Medicines*, at pp. 133, 142 (P Roffe, G Tansey and DVivas-Eugui eds., 2006); U.K. Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Right* 50 (2002) [hereinafter U.K. COMM'N ON IPRs], available at [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfinal.pdf).

100 The most famous case involving this flexibility involves India, which, when amending its Patent Act in 2005 at the end of its transition period, adopted important exemptions to patents and stringent standards for patentability. *Patents Amendment Act 2005* (The *India Patent Act*) (2005), available at <http://patentoffice.nic.in/ipr/patent/patents.htm>.

Section 3d provides that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of a new property or new use for a known substance ...” is not considered an invention; likewise compositions of known substances are not considered patentable. This provision was unsuccessfully challenged by Novartis with respect to its cancer medicine Glivec with an appeal pending before the Supreme Court.

101 TRIPS Agreement, Arts. 1.1, 27.1..

102 *Ibid.* Art. 29.

103 When authorized in national legislation, compulsory licences are issued by governments to authorize use of the patent-protected invention by the government or third parties without the consent of the patent holder. Patent-holders retain their right to compete and are given adequate compensation in the form of a royalty. WTO Members are free to determine the grounds upon which compulsory licences may be granted. Practice shows that they may be issued on various grounds of general interest, such as public health and to redress anti-competitive practices, and are a common feature of patent law in both developed and developing countries. More pro-development compulsory licensing policies allow licences to stimulate local production.

104 TRIPS Agreement, Art. 31.

105 Innovators often charge lower prices for a medicine in one country than in another because of market conditions. Parallel importation permits a country to buy a patented medicine that has been sold more cheaply in another market and to import it rather than pay a premium in the domestic market.

106 TRIPS Agreement Art. 6.

107 *Ibid.* Art. 27.2.

108 The early-working exception permits the use of a patented invention without authorization from the patent owner in order to facilitate regulatory approval of an equivalent generic product before the patent expires. This preliminary approval allows a generic product to enter the market more quickly after patent expiry, which in turn expedites generic competition and reduces prices.

109 TRIPS Agreement Art. 30; see generally C Garrison, *Exceptions to Patent Rights in Developing Countries* (2006), available at [http://www.unctad.org/en/docs/iteipc200612\\_en.pdf](http://www.unctad.org/en/docs/iteipc200612_en.pdf); E Misati and K Adachi, *The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda*, (2010), available at [http://ictsd.org/downloads/2010/04/evans\\_paper-v2.pdf](http://ictsd.org/downloads/2010/04/evans_paper-v2.pdf). through of several industrializlogy: *The Origins and Aftermath of the United Nations Negotiations on a Draft Codedaectua Baker'*

110 TRIPS Agreement Arts. 65, 66.

111 In November 2005, before the WTO Hong Kong Ministerial, a decision was reached to grant a waiver exempting LDCs from having to comply with the TRIPS Agreement, other than the provisions providing for non-discriminatory treatment, until July 2013. Even earlier, paragraph 7 of the Doha Declaration, as implemented by a TRIPS Council Decision of June 2002, waives the obligation of Least Developed Countries, with respect to pharmaceutical products, from having to grant patents and from providing for the protection of undisclosed information until 1 January 2016. These waivers could also be extended, though no such applications have yet been made.

the international transfer of technology<sup>112 113</sup> and to regulate the terms of licencing agreements to promote trade, competition, and technology transfer.<sup>114</sup> Collectively, these flexibilities, if effectively utilised, should enable low- and middle-income countries to better achieve a degree of balance between IP protection and development priorities, including the pursuit of public health objectives. However, as discussed further below, even with its best interpretations and flexibilities, the TRIPS framework, despite being often cited as an important incentive for innovation, provides insufficient incentives for research and development into so-called neglected diseases that primarily affect poor people in developing countries; it has failed to promote technology transfer, and it needlessly restricts easy and affordable access to new life-saving pharmaceutical technologies.

### 3.2 TRIPS-Plus Through Bilateral Pressure, FTAs, WTO Accession, and the New IP Enforcement Agenda

Although many developing countries may have believed that they were signing a multilateral agreement that would eliminate unilateral pressures to adopt even more stringent IP protections such as those historically pursued by the United States, the first Article of TRIPS made it clear that countries “may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement.” (Emphasis added.)<sup>115</sup> This floor-not-ceiling provision in TRIPS has opened countries to relentless pressures to strengthen patent and data protections and to increase IP enforcement activities. These pressures come from pharmaceutical companies, pharmaceutical trade associations,<sup>116</sup> and chambers of commerce, as well as from various US and EU trade negotiators, ambassadors, and governmental agencies.

Early attempts by low- and middle-income countries to use TRIPS-compliant flexibilities were strenuously rebuffed by host nations of major pharmaceutical companies. A number of countries, including Brazil, were pressured to ignore their transition periods and to adopt TRIPS-compliant legislation prematurely.<sup>117</sup> When Thailand first considered issuing a compulsory licence on an AIDS medicine, the US applied trade and diplomatic pressure to force it to drop its effort.<sup>118</sup> Similarly, after the South African Parliament passed the *Medicines and Related Substances Control Amendment Act of 1997*,<sup>119</sup> which – amongst other provisions – authorised parallel importation of cheaper medicines,<sup>120</sup> thirty-nine pharmaceutical companies and a trade association took legal action against the Mandela government to block the coming into force of the amended Act, claiming that it violated TRIPS and the South African Constitution.<sup>121</sup> Acting in tandem, the USTR placed South Africa on its 301 Special Watch List, suspended certain trade advantages, and employed persistent diplomatic pressure urging South Africa to repeal the Act.<sup>122</sup> Fortunately, as a result of activist pressure and legal intervention by the AIDS Law Project, the lawsuit was dropped,<sup>123</sup> and President Clinton eventually adopted an Executive Order preventing the USTR from interfering with African countries TRIPS-compliant efforts to ensure access to AIDS medicines.<sup>124</sup>

During this same timeframe, the US initiated a WTO trade dispute against Brazil, later withdrawn, over legislation

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112 The most famous example of using these provisions thus far is the case of *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, where the South Africa Competition Commission found both companies guilty of excessive pricing and refusal to license an essential facility. Before referral to the Competition Tribunal, both companies entered into separate sets of settlement agreements with the Commission and the complainants respectively granting licences to multiple generic companies on reasonable terms. T Avafia, J Berger, and T Hartzenberg, *The Ability of Select sub-Saharan African Countries to Utilize TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries*, Tralac Working Paper No. 12 (2006).

113 S Flynn, *Using Competition Policy Law to Promote Access to Knowledge*, in *Access to Knowledge in the Age of Intellectual Property* 451-475 (G Krikorian and Kapczynski eds.) (2010).

114 TRIPS Agreement Arts. 8.2, 40.

115 *Ibid.*

116 Major trade pharmaceutical trade associations include: Pharmaceutical Researchers and Manufacturers of America, European Association of Euro-Pharmaceutical Companies, and the International Federation of Pharmaceutical Manufacturers and Associations.

117 Brazil adopted patent protection for pharmaceutical products in 1996. Amendments to Brazil's patent law became effective on May 15, 1997. Law No. 9.279, 14 May 1996, Regulating Rights and Obligations Regarding Industrial Property, D.O., 15.05.96, notified to WTO Council on Trade-Related Aspects of Intellectual Property Rights, WTO Doc. IP/N/1/BRA/1/1 (Sept. 19, 2000).

118 W Wisarksakul, (2004), *Civil Society Movement to Revoke the Thai Patent on DDI*.

119 Act 90 of 1997.

120 See J Watal, (1999), *TRIPS and the 1999 WTO Millennium Round*, 3 *Journal of World Intellectual Property* 1.

121 *Pharm. Mfrs. Ass'n of S. Africa v. President of the Republic of S. Africa*, Case No. 4193/98 (filed Feb. 18, 1998).

122 See, e.g., *Omnibus Consolidated and Emergency Supplemental Appropriations Act*, Pub. L. No. 105-277, 112 Stat. 2681 (1999); P D Siplon, (2002) *AIDS and the Policy Struggle in the United States* 120-21; P Bond, (1999), *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, 29 *INT'L J. HEALTH SERV.* 765, 768.

123 See S Tickell, *Cutting the Cost of Drugs*, *Managing Intellectual Property* (3 March 2001). One can only imagine that the PMA would be on the losing end of a campaign which involved a court case billed by treatment activists as “the Pharmaceutical Manufacturer's Association v Nelson Mandela” in a country where the adult HIV prevalence hovers around 20%.”

124 Executive Order 13155 (10 May 2000).

allowing Brazil to issue compulsory licences when patented medicines were not produced locally.<sup>125</sup> Although the provision had not yet been utilised, the US and its industry believed that the provision allowed discrimination against imports, whereas Brazil thought it was a legitimate measure to promote technology transfer and to stimulate local production. The dispute was settled in 2001 with an agreement to consult about utilisation of the provision. Earlier, in 1999, the US filed a WTO complaint against Argentina<sup>126</sup> relating to its TRIPS-compliant decision to limit protection for drug registration-related data.<sup>127</sup> The USTR used Argentina as a test case to establish a global standard that would require data exclusivity rather than mere data protection, but settled its claim in 2002, presumably because of uncertainty over whether a WTO Dispute Settlement Panel would decide on its behalf given the negotiation history and the language of Article 39.3. Despite their outcomes, these WTO complaints signaled US intentions to pursue enhanced data protection as well as strong patent protections.

Because developing countries were being denied the benefits of flexibilities previously negotiated in TRIPS, the Africa Group undertook to reaffirm those flexibilities and Members' rights to address public health concerns.<sup>128</sup> The Africa Group sought clarifications of existing patent and data flexibilities and of countries' rights to use such flexibilities. It also argued that Article 30's provision authorising "limited exceptions" to exclusive patent rights is a basis for an exception to the restriction in Article 31(f)<sup>129</sup> on using compulsory licences for export to countries without sufficient manufacturing capacity.<sup>130</sup> These efforts, combined with activist pressure by civil society, and a spate of anthrax attacks in the US in late 2001<sup>132</sup>, re-emphasised the importance of using TRIPS flexibilities for public health purposes and resulted in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001,<sup>133</sup> which clarified patent-related flexibilities in the TRIPS Agreement and reemphasised Members' freedom to take measures to promote public health and in particular to ensure access to medicines for all.<sup>134</sup> In other words, governments would not be prevented from taking measures to limit exclusive patent and data rights, where public health interests and access to affordable medicines so require. One issue left open by the Doha Declaration, despite the Africa Group's Article 30 limited exception proposal, was the problem facing countries with insufficient pharmaceutical manufacturing capacity to utilise compulsory licencing mechanisms to produce medicines locally. These countries would have to import, but exporters were limited in the quantity of CL medicines they could export. Although Paragraph 6 of the Doha Declaration mandated an expeditious solution to this production-for-export problem, because of US opposition and the position taken by the pharmaceutical industry it took nearly 21 months to come up with a temporary waiver, the 30 August 2003 Decision,<sup>135</sup> that was procedurally labyrinthine<sup>136</sup> and that has only been used once in seven-plus years.<sup>137</sup> Furthermore,

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125 US-Brazil – Measures Affecting Patent Protections, Dispute DS199 (2001), available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds199\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm).

126 Dispute Settlement: Dispute DS171 Argentina — Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals, available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds171\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds171_e.htm)

127 Argentinian law allowed a follow-on company to rely on registration in Argentina or the US to register an "equivalent" product.

128 See F M Abbott, (2002), *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L ECON. L. 469, 480-90.

129 Article 31(f) of the TRIPS Agreement requires that medicines produced pursuant to compulsory licences be "predominantly for the supply of the domestic market."

130 The Article 30 limited exception proposal would have resulted in an easy-to-use exception authorizing compulsory licences permitting export of unrestricted quantities of medicine to countries lacking pharmaceutical capacity – exportation that is otherwise restricted by Article 31(f). It would have granted non-producing countries the same ability to utilize compulsory licensing to access generics that is available to big market countries in the US and EU that are not negatively impacted by the Article 31(f) rule.

131 B K Baker, (2004), *Arthritic Flexibilities for Accessing Medicines, Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 Ind. Int'l & Comp. L. Rev. at pp. 613-715.

132 In October 2001, a few US government buildings were contaminated with an anthrax-laced powder, which resulted in deaths and several cases of illness. In response to the possibility that bioterrorism would need a broader public health response, the US Secretary of Health and Human Services threatened R&D based company Bayer with a compulsory licence for its patented product ciprofloxacin, if the company did not meet the government's demand for a reduced price.

133 Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, Doha, Nov. 9-14 2001, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/min01\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm).

134 *Ibid.* Para. 4.

135 WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Sept. 1, 2004) WT/L/540, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)

136 B K Baker, (2004), *Arthritic Flexibilities for Accessing Medicines, Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 Ind. Int'l & Comp. L. Rev. at pp. 613-715; F Abbott, (2005), *The WTO Medicines Decision: World Pharmaceutical Trade and Public Health*, 99 Am. J. Int'l L. 317-358.

137 Canada and Rwanda are the only two countries that have cooperated thus far to use the complex 30 August 2003 Decision, via Canada's legislation implementing that decision, and all accounts of that effort suggest that further use of "Canada's Access to Medicines Regime" is unlikely absent some key reforms. R Elliott, Delivery past due: global precedent set under Canada's Access to Medicines Regime, 13 HIV/AIDS Policy & Law Rev. 1-9 (2008), available at <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=864>. This calls into question whether it is the effective and expeditious solution that is needed. The practicability and effectiveness of the mechanism is the subject of a continuing debate at the WTO Council for TRIPS. K Mara, Efficacy of TRIPS Public Health Amendment in Question at WTO, Intellectual Property Watch (March 1, 2010), available at <http://www.ip-watch.org/weblog/2010/03/01/efficacy-of-trips-public-health-amendment-in-question-at-wto/>.

the fact that to date, only 43 countries plus the EU have ratified the corresponding proposed amendment to TRIPS, Article 31bis,<sup>138</sup> can serve to show a general lack of belief that this is an effective solution.<sup>139</sup>

Perhaps because of these developments at the WTO, EC and US trade negotiators have more recently shifted forums and now seek TRIPS-Plus measures primarily in non-multilateral venues. In particular, as multilateral trade negotiations at the WTO stalled, major powers turned to negotiating and concluding bilateral and regional free trade agreements (FTAs) and economic partnership agreements (EPAs). A worrying number of these FTAs/EPAs, especially those negotiated by the US, EU, EFTA countries<sup>140</sup> and Japan, contain numerous TRIPS-Plus provisions. Acquiescence to these provisions is obtained via multiple carrot-and-stick pressures described further below. In essence, developing countries are asked to take on TRIPS-Plus IP protections in exchange for long-delayed concessions on textiles<sup>141</sup> and agricultural products<sup>142</sup> or for favourable treatment of select export-oriented industries. Through promises of trade concessions (increased market access, quotas and lowered tariffs), technical assistance, and increased foreign aid, countries often trade long-term and costly obligations with respect to heightened IPRs for short-term and often illusory advantages.<sup>143</sup> When such tactics don't work, unilateral trade and diplomatic pressures are brought to bear in the form of threats to withdraw or not renew trade preferences, threats concerning direct foreign investment and foreign aid, and even threats to be labelled as enemies of trade liberalisation or on the wrong side of the war against terror.<sup>144</sup>

The types of provisions that have recently been included in FTAs/EPAs that may have an impact on public health and/or may hamper the use of flexibilities include the following:

- Requiring countries to ease standards of patentability (for example requiring patents for new forms and new uses or methods of use of existing chemical entities),<sup>145</sup> resulting in “ever-greening”;
- Eliminating certain patent exclusions (for example for plants and animals and diagnostic, therapeutic and surgical methods) and restricting the use of limited exceptions;
- Providing extensions of patent terms beyond the TRIPS-required 20 years, ostensibly to compensate for regulatory delays in granting patents or marketing approvals;
- Limiting the grounds upon which compulsory licences may be issued (e.g., for public, non-commercial use and emergencies only) or changing the terms of licences (e.g., higher levels of remuneration to patent-holders);
- Requiring data exclusivity instead of mere data protection;<sup>146</sup>
- Requiring drug regulatory authorities to link marketing approval to the absence of any claimed patents;
- Restricting availability of pre-grant opposition procedures and the grounds for post-grant oppositions and revocations;
- Limiting the use of price controls and therapeutic formularies;<sup>147</sup>

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138 Members accepting amendment of the TRIPS Agreement (updated March 15, 2011) available at [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm).

139 It is important to note that the 30 August Decision waiver system will stay in effect even without passage of Article 31bis.

140 Norway, Switzerland, Iceland, and Liechtenstein.

141 Concessions on textiles were finally implemented in 2005, but by that time China had a huge comparative advantage in the sector.

142 Agricultural access and elimination of agricultural subsidies, especially export subsidies, has been long pursued, especially within the so-called Doha development round, but these negotiations have been stalled for over a decade.

143 Although developing countries often seek to gain access to lucrative US markets, the US's ability to maintain let alone expand its trade deficit is in serious doubt. Instead of gaining privileged access to a growing market, developing countries may be competing for a shrinking pie of US imports, especially where China is such a dominant exporter across a broad range of products. See D Baker and M Weisbrot, *Fool's Gold: Projections of the US Import Market* (2004), available at [http://www.cepr.net/documents/publications/trade\\_2004\\_01\\_08.htm#\\_ftn1](http://www.cepr.net/documents/publications/trade_2004_01_08.htm#_ftn1).

144 A Kwa, *Power Politics at the WTO* (2<sup>nd</sup> ed. 2003) (discussing similar pressures in the WTO).

145 The most far-reaching proposal to date is found in the recently disclosed US draft IP chapter in the Transpacific Partnership Agreement negotiations. There, Article 8.1 goes further than preceding proposals by not only requiring patentability of new uses and new methods of use, but patenting of new forms as well. The “new forms” language will cover variations on existing chemical entities, variations in formulation, method of delivery, dosage, combinations, and the like, but only so long as the new form satisfies the basic, minimum standards of patentability in the first sentence of subsection 1. However, the proposed language specifically repudiates the language adopted by India in 3(d) of its *Amended Patent Act* (2005) that requires a showing of significant impact on efficacy in order to patent a new form (interpreted by India to mean more than enhanced bioavailability or stability).

146 Alternatively, generic manufacturers must abuse the rights of human subjects by repeating clinical trials where the health benefits and costs have already been established.

147 The US has imposed limits on price control mechanisms in FTAs with Australia and South Korea.

- Adopting investment clause rules that allow investor-state claims.<sup>148149</sup>

A recent study undertaken by academics, pharmaceutical manufacturers and civil society groups in Thailand that forms the basis of a submission to the Global Commission, highlights the potential impact of a TRIPS-Plus FTA on access to treatment in Thailand.<sup>150</sup> One particularly important and dangerous FTA is the pending India- EU Free Trade Agreement. Given India's global status as the pharmacy of the poor, proposed TRIPS-Plus provisions limiting India's flexibility to produce generic medicines for domestic use and export are especially unsettling.<sup>151</sup> An even broader regional trade agreement is being negotiated by the United States, the Trans-Pacific Partnership (TPP) Agreement that also threatens to reverse the temporary stand-down in US policy of escalating IPRs that was codified in the 2007 New Trade Policy.<sup>152, 153</sup> In fact, the US IP proposal for the TPP contains numerous new provisions, including relaxed standards of patentability, that are even more onerous than in past agreements.<sup>154</sup> The Joint United Nations Programme on HIV/AIDS (UNAIDS) / United Nations Development Programme (UNDP) / World Health Organisation (WHO) are now on record that "The decision on whether a new form of a known substance can be patented has major implications for many drugs used in HIV care, now and in the future"<sup>155</sup> and civil society organisations have filed a complaint to the UN Special Rapporteur for Health challenging the US TPP proposal because of its predictable impact on access to medicines.<sup>156</sup> In addition to the inclusion of TRIPS-Plus terms in FTAs/EPAs, countries often face additional FTA-Plus demands during the process of implementing those agreements.<sup>157</sup>

Furthermore, some high-income countries have developed additional ways to pressure developing countries into increasing IP protections beyond those in the TRIPS Agreement. For instance, the *US Omnibus Trade and Tariff Act of 1988* established a Special 301 Watch List that threatens countries with trade sanctions and/or withdrawals of trade preferences if they fail to comply with US standards of TRIPS-IP protections.<sup>158</sup> Accordingly, in response to Thailand having issued compulsory licences on AIDS, heart disease, and cancer medicine in 2006-2008, the USTR placed Thailand on successive Special 301 Priority Watch Lists.<sup>159</sup> For the 2010 Special 301 report, the USTR reviewed 77 trading partners and placed a total of 29 on the Watch List and an additional 11 on the Priority Watch List,<sup>160</sup> both of which require degrees of bilateral engagement to address alleged IP problems.<sup>161</sup> Civil society activists in the US have recently ramped up pressure against the USTR's unilateral use of the Special 301 list claiming that it illegally evades the WTO multilateral dispute resolution mechanisms, undermines the Doha Declaration, and violates the *Administrative Procedure*

148 Ordinarily, TRIPS violations are prosecuted by Member States deciding to pursue dispute resolution within the WTO. Investment clauses in BITS and FTAs frequently allow investors, including IP investors, to bring claims directly against states when their expected rates of return are impaired.

149 E T Biadgleng, *IP Rights Under Investment Agreements: The TRIPS-Plus implications for enforcement and Protection of Public Interest* (Aug. 2006) available at <http://www.southcentre.org/publications/researchpapers/ResearchPapers8.pdf>; Cr Gibson, (2009), *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1428419](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1428419)

150 J Limpananont, N Kessomboon, et al., Specialised Submission to the Global Commission on HIV and the Law.

151 J Love, (2011), *The Production of Generic Drugs in India*, 342 Brit. Med. J. 1694 (2011), available at <http://www.bmj.com/content/342/bmj.d1694.full?keytype=ref&ijkey=2XAgzJiAkbaCptX>; A Grover, *On EU-India FTA's Threat to Generic Medicines* (2010), available at <http://www.msfaaccess.org/main/access-patents/free-trade-agreements/india/un-special-rapporteur-anand-grover-on-eu-india-fta-s-threat-to-generic-medicines/>; C M Correa, (2009), *Negotiation of a Free Trade Agreement European Union-India: Will India Accept TRIPS-plus Protection?*, available at [http://www.oxfam.de/download/correa\\_eu\\_india\\_fta.pdf](http://www.oxfam.de/download/correa_eu_india_fta.pdf)

152 In the New Trade Policy, the US allowed public health exceptions to data exclusivity and removed demands for patent term extensions and patent-registration linkage.

153 Office of the United States Trade Representative, *Bipartisan Agreement on Trade Policy: Intellectual Property Provisions*, May 11, 2007, available at [http://www.ustr.gov/assets/Document\\_Library/Fact\\_Sheets/2007/asset\\_upload\\_file312\\_11283.pdf](http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2007/asset_upload_file312_11283.pdf).

154 U.S. TPP Proposal Broadens Patent Rights, But Secondary Liability Unclear, Inside US Trade (March 18, 2011).

155 UNAIDS, UNDP, WHO Policy brief: *Using TRIPS flexibilities to improve access to HIV treatment* (2011), available at <http://content.undp.org/go/newsroom/2011/march/unaids-undp-who-concerned-over-sustainability-of-hiv-treatment.en>

156 Knowledge Ecology International Staff, *UN Rapporteur for the Right to Health asked to intervene in the TPP negotiation* (2011) available at <http://keionline.org/node/1099>.

157 P Roffe, (2007), *Intellectual Property, Bilateral Agreements and Sustainable Development: The Challenges of Implementation* available at [http://www.ciel.org/Publications/IP\\_StrategyNote\\_Apr07.pdf](http://www.ciel.org/Publications/IP_StrategyNote_Apr07.pdf).

158 The Section 301 trade sanction threat was clarified in the 1998 House of Representatives Conference Report on legislation in congress. See H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 580 (1988) (stating that "as a complement to US objectives on intellectual property rights protection in the Uruguay Round of trade negotiations, the conferees intend that the President should ensure wherever possible, that the US intellectual property rights are respected and market access provided in international trade with all our trading partners").

159 J Limpananont and K Kijitwathakul, *TRIPS Flexibilities in Thailand: Between Law and Politics, in the Age of Intellectual Property* at pp. 435-450 (G Krikorian and A Kapczynski eds., 2010).

160 Press Release, Office of the United States Trade Representative, *USTR Releases Special 301 Report on Intellectual Property Rights* (April 30, 2010), available at: <http://www.ustr.gov/about-us/press-office/press-releases/2010/april/ustr-releases-2010-special-301-report-intellectual-p> (noting that the 11 countries on the Priority Watch List are: China, Russia, Algeria, Argentina, Canada, Chile, India, Indonesia, Pakistan, Thailand, and Venezuela).

161 Office of the United States Trade Representative, *The 2010 Section 301 Report on Intellectual Property Rights* (2010), available at <http://www.ustr.gov/about-us/press-office/reports-and-publications/2010-3>.

Act.<sup>162</sup> Outside of the Special 301 context, TRIPS-Plus pressures are also asserted during the process of non-members negotiating their accession to the WTO<sup>163</sup> or their integration into the EU.<sup>164</sup>

In addition to long-standing efforts to increase substantive IP protections, another threat to access to medicines comes from longstanding demands by the US and EU for heightened IP enforcement. Multiple multilateral institutions have set policies and norms on IP enforcement in recent years including the World Customs Organisation, WIPO, the WHO, the WTO and Interpol.<sup>165</sup> A prime example of TRIPS-Plus enforcement provisions can be found in the pending plurilateral Anti-Counterfeiting Trade Agreement (ACTA), which risks setting new norms for increased IP enforcement obligations even for non-signatory countries.<sup>166</sup> The final ACTA text contains provisions affecting access to medicines that exceed the minimum standards of IP enforcement contained in the TRIPS Agreement, though some of its worst features were rejected following a protracted campaign and response by certain countries.<sup>167</sup> A practical example of how increased IP enforcement can impede treatment access is the seizure of essential medicines from India and elsewhere to various developing countries by European customs authorities on multiple occasions while in transit through the EU in 2008-2009.<sup>168</sup> These seizures, initiated both at the insistence of putative right holders and customs agents, were based on the suspicion that intercepted medicines violated fictional patent and/or trademark rights even though the medicines had been lawfully produced in India and would be lawfully sold and consumed in destination countries. There were no patents in either the country of production or of import. One shipment unlawfully detained was a consignment of AIDS medicines purchased by UNITAID and destined for Nigeria.<sup>169</sup> These seizures resulted in a WTO complaint against the EU by India and Brazil.<sup>170</sup>

Pursuant to this same enforcement agenda, confusing anti-counterfeiting legislation has been passed in Kenya<sup>171</sup> and proposed in Uganda, Tanzania, and the entire East Africa Community (EAC), usually through clandestine efforts of Pharma and pro-IP technical advisors.<sup>172</sup> Over-broad definitions of counterfeit medicines that conflate trademark violations with safety, efficacy, and quality concerns are quite troubling. Following a resolution at the 2010 World Health Assembly, the WHO is currently investigating ways to separate IP concerns from the problem of unsafe, substandard, and unregistered medicines<sup>173</sup> mainly because IP enforcement provides the wrong tools to address medicines that threaten public health. Adopting so-called IP-focused anti-counterfeiting policies and laws could hinder generic competition, foster high prices of medicines, and compromise not only affordability, but also make the criminal trade in spurious medicines more lucrative.

Research-based pharmaceutical companies have also found ways of pressuring countries to unilaterally increase IP

162 S M Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicines*, J. Generic Med. (forthcoming 2011); see Allegation Letter to the UN Special Rapporteur on the Right to Health In the Matter of the Use of the Special 301 Program, Section 182 of the *Trade Act of 1974*, to Limit Access to Medicines in Violation of the International Right to Health (2010), available at [www.healthgap.org/documents/ComplainttoSpecialRapporteur-1.pdf](http://www.healthgap.org/documents/ComplainttoSpecialRapporteur-1.pdf); Submission of Global Health Organizations In the Matter of 2011 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974 (2011), available at <http://infojustice.org/resource-library/bilateral-trade-pressures/special-301/2011-special301comments>.

163 F Abbott and C Correa, (2007), *World Trade Organization Accession Agreements: Intellectual Property Issues*, available at <http://www.quono.org/geneva/pdf/economic/Issues/WTO-IP-English.pdf>.

164 See EC Enlargement: *How Does A Country Join the EU?*, available at [http://ec.europa.eu/enlargement/enlargement\\_process/accesion\\_process/how\\_does\\_a\\_country\\_join\\_the\\_eu/negotiations\\_croatia\\_turkey/index\\_en.htm](http://ec.europa.eu/enlargement/enlargement_process/accesion_process/how_does_a_country_join_the_eu/negotiations_croatia_turkey/index_en.htm).

165 S K Sell, (June 9, 2008), *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play*, [http://www.ipsensato.org/wp-content/uploads/Sell\\_IP\\_Enforcement\\_State\\_of\\_Play-OPs\\_1\\_June\\_2008.pdf](http://www.ipsensato.org/wp-content/uploads/Sell_IP_Enforcement_State_of_Play-OPs_1_June_2008.pdf).

166 A copy of the final text and documentation concerning the negotiation history can be found at <http://www.ustr.gov/acta> and <http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/anti-counterfeiting/>.

167 B K Baker, *ACTA: Risks of Third-Party Enforcement to Access to Medicines*, PUJIP Research Paper no. 1 (2010), available at <http://digitalcommons.wcl.american.edu/research/1/>.

168 X Seuba, (2010), *Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border*, Programme on IPRs and Sustainable Development Series • Issue Paper 27, available at <http://ictsd.org/i/publications/74589/>.

169 A statement by UNITAID condemning the seizure of the medicines in transit by the Dutch authorities is available at: <http://www.unitaid.eu/en/20090304156/News/UNITAID-statement-on-Dutch-confiscation-of-medicines-shipment.html>.

170 European Union and a Member State [India] – Seizure of Generic Drugs in Transit, WTO Dispute Settlement DS408, available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds408\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm) and European Union and a Member State [Brazil] – Seizure of Generic Drugs in Transit, WTO Dispute Settlement DS409, available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds409\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm); see generally Third World Network, *India, Brazil raise dispute over EU drug seizures*, 6924 SUNS (May 17, 2010), available at <http://www.twinside.org.sg/title2/wto.info/2010/twninfo100509.htm>; Intellectual Property Watch, *Consultations on WTO Drug Transit Case Continue* (September 16, 2010), available at <http://www.ip-watch.org/weblog/2010/09/16/consultations-on-wto-case-on-drugs-in-transit-continue/>; C.H. Unnikrishan, *India may move WTO as it seeks to resolve EU dispute*, *livemint.com* (October 10, 2010), available at <http://www.livemint.com/2010/10/11225420/India-may-move-WTO-as-it-seeks.html>.

171 The Kenyan Bill has been suspended pending the outcome of a court challenge on the constitutionality of the Bill.

172 Wi Michel, *I have never opposed generics* – British Ex-Politician, *AllAfrica News* (June 24, 2010), available at <http://allafrica.com/stories/201006241046.html>.

173 World Health Organization (WHO), *Report of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products*, A/SSFFC/WG/5 (2011).

protections and of expressing their displeasure at countries that utilise TRIPS flexibilities. As an example of lobbying, the US India Business Council directly advocates with the government of India for enhanced IP protections and against compulsory licences.<sup>174</sup> As an example of retaliation, in 2007, Abbott responded to Thailand's issuing of compulsory licences for the anti-retrovirals (ARVs) lopinavir/ritonavir by withdrawing seven medicines, including heat-stable lopinavir/ritonavir, from the drug registration process.<sup>175</sup> Similarly, drug companies in India have challenged, unsuccessfully thus far, the legality of Section 3(d)'s strict patent standards<sup>176</sup> and India's refusal to provide regulatory linkage between registration rights and alleged patent rights.<sup>177</sup> What major pharmaceutical companies cannot accomplish by lobbying or retaliation, they may now be trying to achieve via buy-outs and acquisition agreements with generic companies.<sup>178</sup> There has been significant consolidation of the pharmaceutical industry in India, with several of the most successful generics, including Ranbaxy, being purchased by multinational pharmaceutical companies. Indeed, the government of India has expressed concerns about the potential impact of this take-over and its implications for access to affordable medicines and it is considering measures to limit foreign ownership of Indian generics.

### 3.3 The False Promises of Heightened IPRS: Innovation, Technology Transfer and Market Access

A logical question in response to this history of ever increasing IP protections is what have developing countries gotten in return, both with respect to the promises in TRIPS itself and with respect to the larger-scale balance of interests involved in the IP social contract. TRIPS referenced matters of central importance to developing countries, namely (1) technological innovation, (2) technology transfer<sup>179</sup> and (3) the interests of users of technological knowledge (e.g., patients needing medicines), but has not produced much in these areas. Nonetheless, developing countries have continued to pursue these interests through the WIPO Development Agenda at the<sup>180</sup> and through the WHO Global Strategy and Plan of Action on Public Health Innovations and Intellectual Property.<sup>181</sup>

According to Article 7 of the TRIPS Agreement:

*"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."*

Article 8 also authorises Members to promote public health in manners consistent with the TRIPS Agreement. Despite these interpretive provisions, TRIPS has done little to promote medical innovation on diseases primarily affecting developing countries, to accelerate technology transfer, or to assure wider access to affordable medicines.

The justification for increased IP protections has been that they are important drivers of innovation. According to Grabowski,<sup>182</sup> because the costs of innovation in the pharmaceutical industry are so high and the costs of imitation so low, the exposure of the originator pharmaceutical industry to free-riding highlights the importance of patents in the pharmaceutical industry. Evidence to date does not clearly suggest that heightened IP protections are incentivising more pharmaceutical innovation within developing countries or innovation addressing neglected diseases.<sup>183</sup> According to the CIPIH report:

174 See USIBC, 2010 Advocacy Objectives, available at <http://www.usibc.com/advocacy/objectives>; USIBC, Intellectual Property Rights Initiative, available at <http://www.usibc.com/advocacy/initiatives/ip>; USIBC, Comments of the U.S.-India Business Council in Response to the Department of Industrial Policy and Promotion's Discussion Paper on Compulsory Licensing (Sept. 29, 2010), available at [www.dipp.nic.in/ipr-feedback/Feedback\\_USIBC\\_29September2010.pdf](http://www.dipp.nic.in/ipr-feedback/Feedback_USIBC_29September2010.pdf)

175 J Limpananont and K Kijitwathakul, *TRIPS Flexibilities in Thailand: Between Law and Politics, in the Age of Intellectual Property* at pp. 435-450 (G Krikorian and A Kapczynski eds., 2010).

176 *Novartis Patent Challenge Dismissed in India*, 11 BRIDGES WEEKLY TRADE NEWS DIGEST 1-3 (Sept. 5, 2007) <http://www.ictsd.org/weekly/07-09-05/story3.htm>.

177 PT Jyothi Datta, Apex court dismisses Bayer's appeal in patent-linkage case, *The Hindu Business Line* (Dec. 1, 2010), available at <http://www.thehindubusinessline.in/2010/12/02/stories/2010120251140500.htm>.

178 TV Padma, *Action urged on foreign takeovers of Indian drugmakers*, 17 *Nature* 141 (Feb. 4, 2011), available at <http://www.nature.com/nm/journal/v17/n2/full/nm0211-141a.html>.

179 Art. 66.1 of TRIPS creates some affirmative duties concerning technology transfer to Least Developed Countries: "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."

180 World Intellectual Property Organization (WIPO), *The 45 Adopted Recommendations under the WIPO Development Agenda* (2007), available at <http://www.wipo.int/ip-development/en/agenda/recommendations.html>.

181 World Health Organization (WHO), *Global strategy and plan of action on public health, innovation and intellectual property*, World Health Assembly Resolution 61.21 (2008), available at [http://who.int/gb/ebwha/pdf\\_files/A61/A6w\\_R21-en.pdf](http://who.int/gb/ebwha/pdf_files/A61/A6w_R21-en.pdf).

182 H Grabowski, (2002) *Patents, innovation and access to new pharmaceuticals*, *Journal of International Economic Law* 2002 5(4): at pp. 849-860, Oxford University Press.

183 Y Qian, (Aug. 2007), *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment?: A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978-2002*, 89 *REV. ECON. & STAT.* At pp. 436-453.

*It is also assumed that society at large will be able to benefit from present and future innovation. But where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding. Thus the overall effect of intellectual property regimes is context-specific – the impact in a country such as India may differ from that in Thailand or in Ghana.*<sup>184</sup>

In a new study, UNDP has comprehensively analysed the impact of the new product patent regime in India and its impact on innovation activity, concluding that TRIPS has not yet delivered either in accelerating domestic research and development (R&D) capacity more broadly or in intensifying R&D more suited to local needs.<sup>185</sup> Multiple studies have catalogued how the existing IP regime and R&D financing mechanisms fail to incentivise the development and sale of medicines that focus on neglected diseases primarily affecting developing countries.<sup>186</sup> Critics of the current patent system claim that it focuses pharmaceutical research and development towards market rewards arising from supra-competitive pricing on medicines for chronic diseases affecting rich people in high-income markets. The patent system has been criticised as steering research not towards medicines with important therapeutic applications for underserved needs, but instead encourages ever-greening of existing block-buster medicines,<sup>187</sup> pursuit of “me-too” drugs,<sup>188</sup> disease mongering,<sup>189</sup> buy-outs of patent challenges<sup>190</sup> and other patent abuses. Even when concentrating on diseases of the rich, major pharmaceutical R&D activities are producing diminishing returns while the costliness of such research is greatly exaggerated.<sup>191</sup> Although chronic, type III diseases such as hypertension, diabetes, cancer, and chronic respiratory diseases increasingly affect patients in poor countries,<sup>192</sup> type I and type II diseases primarily affecting poor people are still largely neglected.<sup>193</sup> The World Health Organisation and others continue to struggle to find new financing mechanisms to incentivise research into neglected diseases.

Similarly, the chimera of **technology transfer**, long pursued<sup>194</sup> but rarely realised, has not been incentivised by higher IP protections in most developing countries, especially those that lack absorptive capacity.<sup>195</sup> Indeed, heightened IPRs may instead have led to deindustrialisation in the pharmaceutical sector in countries where importation was more economical than supporting small-scale local production.<sup>196</sup> Similarly, there is little evidence that increases in IP protections result in higher levels of direct foreign investment.<sup>197</sup> A full discussion of the interactions between IP and

184 See Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), World Health Organization, Geneva, available at: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>

185 S Chaudhuri, C Park and K M Gopakumar, (2010), *Five Years into the Product Patent Regime: India's Response* available at <http://apps.who.int/medicinedocs/documents/s17761en/s17761en.pdf>

186 *Ibid.*; See also *Global Funding for Innovation for Neglected Diseases, Neglected Disease Research and Development: Is the Global Financing Crisis Changing R&D* (2010), available at [http://www.policycures.org/downloads/g-finder\\_2010.pdf](http://www.policycures.org/downloads/g-finder_2010.pdf); World Health Organization (WHO), *Working to overcome the global impact of neglected tropical diseases* (2010), available at <http://bit.ly/b6LcUX>; P Chirac, (2010), *Different Methodology, Some Mistakes*, PLoSOne, available at <http://ow.ly/26usp>; J Lexchin, (2010), *One Step Forward, One Step Sideways? Expanding Research Capacity for Neglected Diseases*, 10 BMC J. Int'l Health & Human Rights 1-10, available at <http://www.biomedcentral.com/content/pdf/1472-698X-10-20.pdf>.

187 World Health Organization (WHO), *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, (2006), available at <http://www.who.int/intellectualproperty/report/en/index.html>.

188 A Hollis, (2004), *Me Too Drugs, Is There a Problem*, available at [http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs\\_Hollis1.pdf](http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf).

189 PLoS Medicine, (2006), *Disease Mongering Collection*, available at <http://www.ploscollections.org/article/browse/issue.action?issue=info:doi/10.1371/issue.pcol.v07.i02>.

190 J Leibowitz, (2009), *Pay for Delay Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The \$35 Billion Solution)*, available at <http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf>.

191 D Light and R Warburton, (2011), *Demythologizing the high cost of pharmaceutical research*, 6 BioSocieties 34-50, available at [http://www.pharmamyths.net/files/Biosocieties\\_2011\\_Myths\\_of\\_High\\_Drug\\_Research\\_Costs.pdf](http://www.pharmamyths.net/files/Biosocieties_2011_Myths_of_High_Drug_Research_Costs.pdf).

192 World Health Organization (WHO), *2008-2013 Action plan for the global strategy for the prevention and control of non-communicable diseases* (2009), available at [http://whqlibdoc.who.int/publications/2009/9789241597418\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241597418_eng.pdf).

193 The WHO has created a typology of diseases: Type I (widespread in rich countries – ample incentives for private R&D), Type II (occurring primarily in poor countries but present in rich countries as well – moderate incentives for private R&D), and Type III (occurring almost exclusively in poor countries – virtually no incentives for private R&D).

194 See UNCTAD, *Proposed International Code of Conduct on Transfer of Technology*, UNCTAD Doc. TD/COT/TOT/47 (1985); *International Transfer of Technology: The Origins and Aftermath of the United Nations Negotiations on a Draft Code* (S. Patel et al., eds., 2001).

195 E Hassan, O Yaqub and S Diepeveen, (2010), *Intellectual Property and Developing Countries*, available at [http://www.rand.org/pubs/technical\\_reports/2010/RAND\\_TR804.pdf](http://www.rand.org/pubs/technical_reports/2010/RAND_TR804.pdf); C Saez, *Patent System Mainly Serves Select Developed Country Industries, Study Says*, IP-Watch (Dec. 2, 2010), available at <http://www.ip-watch.org/weblog/2010/12/02/patent-system-mainly-serves-select-developed-country-industries-study-says/>; S Moon, *Does TRIPS Art. 66.2 Encourage Technology Transfer to Least Developed Countries?*, UNCTAD-ICTSC Policy Brief No. 2 (2008), available at [http://www.unctad.org/en/docs/iprs\\_pb20092\\_en.pdf](http://www.unctad.org/en/docs/iprs_pb20092_en.pdf); D Foray, *Technology Transfer in the TRIPS Age: The Need for New Kinds of Partnerships Between Least Developed and Most Developed Economies*, ICTSD Issue Paper No. 23 (2009), available at [www.iprsonline.org/New%202009/foray\\_may2009.pdf](http://www.iprsonline.org/New%202009/foray_may2009.pdf).

196 See J Amuasi, (2009), *Technology Transfer and Local Manufacturing of Pharmaceuticals: The South African Case*, available at <http://ictsd.org/downloads/2009/12/amuasi-paper-edited.pdf>.

197 LBrantetter, R Fisman, et al. (April 2007), *Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence*, NBER Working Paper Series 13033, available at [http://www.nber.org/papers/w13033.pdf?new\\_window=1](http://www.nber.org/papers/w13033.pdf?new_window=1)

technology transfer are well beyond the scope of this paper, but evidence to date, on a theoretical and empirical level, is that technology transfer in the pharmaceutical sector is much more dependent on market size, technological capacity, economic infrastructure, and expert human resources than it is on riding to the top floor on IP protections.<sup>198</sup> Indeed, by creating patent thickets, heightened IPRs can in fact impede technology transfer especially into countries where market benefits are smaller and less certain.<sup>199</sup> This relatively intractable problem of meager technology transfer is still being addressed within WTO via the establishment of The Working Group on the Relationship Between Trade and Transfer of Technology, established to promote and monitor transfer of technology to LDCs.<sup>200</sup> It is hard to identify any concrete outcomes of the WTO Working Group.

Finally, **access to affordable medicines** for end users in poor countries remains elusive except with respect to first-generation AIDS medicines. To date, major pharmaceutical companies have reluctantly agreed to tiered or discount pricing mainly in response to AIDS activism and competition from generic producers and mainly with respect to low-income or sub-Saharan African countries. Without generic competition from fully capacitated producers in India, who were not barred by patented pre-1995 innovations, it is doubtful that even AIDS medicines would have been so steeply discounted.

### 3.4 Opportunities Available to Push for a More 'Pro Development' IP Agenda

Developing countries continue to struggle with how to guarantee the right to health, to incentivise the development of medicines for neglected diseases, to ensure access to affordable medicines, and more broadly to reap the benefits of a knowledge-based economy and thus to promote economic and human development. Developing countries need a virtuous knowledge ecology that simultaneously activates efficient collaborative research on medicines addressing unmet therapeutic needs and that ensures the availability of good quality medicines at an affordable price. At present, globalised and escalating standards of IP protection stand in the way and are not delivering desired results on either front – innovation or access.

Despite this seemingly intractable problem, many developing countries have not yet taken full advantage of the TRIPS-compliant flexibilities available to them either by amending their IP legislation and regulatory regimes or by implementing access measures. Similarly, they have not actively supported some of the existing initiatives that lower prices for AIDS medicines, such as undertaking pooled procurement, expediting the timely registration of newer ARVs, and supporting alternative innovation models such as the Medicines Patent Pool. Furthermore, they have not systematically explored the benefits and risks of various proposals to incentivise research on AIDS medicines and improved formulations, including prize mechanisms,<sup>201</sup> a binding R&D treaty, advanced market commitments<sup>202</sup> and/or the Health Impact Fund<sup>203</sup> (all discussed in a companion paper). These unilateral measures are the first order of business.

Even then, however, the question arises what can be done to push for a more “pro-development” IP agenda, something clearly critical to an effective global response to HIV. Given correlative concerns about the pace of industrial development, including an increase in local and regional pharmaceutical capacity, there are also questions about how to balance the tension between building local capacity for the future against the need for immediate efficiency and affordability in the present. Finally, there are questions about how to increase south-south dialogue on a coherent, but hopefully more flexible international IP regime that advances access to AIDS treatment and prevention technologies and to medical technologies more broadly.

Although developing countries have both right-to-health obligations and multiple options for using legal flexibilities and policy initiatives to increase access to more affordable pharmaceutical products, now and in the future, their willingness to do so is undermined if developed countries do not allow them to act. Instead of pursuing heightened

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198 See X Li, (2008), *The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement—A Comparative Study of China and India*, 31 *World Economy* 1367–1386; C Correa, *Can the TRIPS Agreement Foster Technology Transfer in Developing Countries* in *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* at pp. 227-256 (K E Maskus and J H Reichman eds., 2005); P Roffe, *Comment: Technology Transfer on the International Agenda* in *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* at pp. 257-264 (K E Maskus and Jerome H Reichman eds., 2005); K E Maskus, K Saggi, and T Puttitanum, *Patent Rights and International Technology Transfer Through Direct Investment and Licensing* in *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* at pp. 265-281 (K E Maskus and J H Reichman eds., 2005); S Kortum, *Comment: II: TRIPS and Technology Transfer – Evidence from Patent Data* in *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* at pp. 282-287 (K E Maskus and J H Reichman eds., 2005).

199 A K Rai, *Proprietary Rights and Collective Action: The Case of Biotechnology Research with Low Market Value* in *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* at pp. 288-306 (K E Maskus and J H Reichman eds., 2005).

200 Decision by the Council for TRIPS of February 2003, WTO Doc. IP/C/28; see WTO TRIPS Issues: Technology Transfer, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/techtransfer\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm).

201 J Love and T Hubbard, (2008), *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 *Chicago-Kent L.R.*

202 M Scudellari, (2011), *Are Advanced Market Commitments for Medicines a Real Advance?*, 17 *Nature Medicine* 139 available at <http://www.nature.com/nm/journal/v17/n2/full/nm0211-139.html>.

203 A Banerjee, A Hollis, T Pogge, (2010), *The Health Impact Fund, Incentives for improving access to medicines*, 375 *Lancet* at pp. 166-169 (2010).

IP protections, especially with respect to patents and data, and a more stringent IPR enforcement regime, developed countries should respect their human rights obligations not just to avoid interfering with the achievement of access to medicine and universal access goals in developing countries, but also to actively promote those objectives both by their own policies and by their regulation of the pharmaceutical industry.

#### 4. Using TRIPS- Flexibilities to Increase Access to Affordable AIDS Medicines

The TRIPS Agreement has been in force for 17 years, and developing countries have increasingly become aware of its negative impacts on access to medicines. Nonetheless, recent studies conducted by UNDP and WIPO have catalogued that most countries have not yet amended their legislation to take full advantage of TRIPS-compliant flexibilities, such as options for streamlined compulsory and government use licences (for domestic production or importation, as appropriate), parallel importation, adoption of patent exemptions and exclusions, strict definitions of patentability, data protection rather than data exclusivity, etc.<sup>204</sup> As a result, UNAIDS, UNDP and WHO have recommended that “Low- and middle-income governments should consider revising national IP legislation in order to ensure that TRIPS flexibilities specifically geared to promote access to medicines are incorporated into national law and regulations without delay.”<sup>205</sup> These UN Agencies have also recommended that countries should not enter into trade agreements that are contradictory to the Doha Declaration,<sup>206</sup> meaning that countries should not trade away the right to health. Delay in adopting TRIPS-compliant flexibilities is ordinarily traceable either to the lack of political leadership and technical capacity or to concern about retaliation from major economic powers. Low- and middle-income countries need to convene stakeholder coalitions that include parliamentarians, civil society representatives, and technical experts to draft country-specific amended legislation and to plan the political campaign that will win passage. However, even when flexibilities are eventually on the books, countries will need to use them or facilitate their use by others, preferably in a coordinated manner, promote generic competition and lower the price of medicines. They also need to stand firm and support each other in the face of pressure such as that which has previously been focused on Brazil, Thailand, and India when they utilised TRIPS flexibilities.

One of the more promising existing opportunities for decreasing the costs of AIDS medicines and for promoting the development of improved paediatric formulations and new fixed-dose combinations is the UNITAID-affiliated Medicines Patent Pool. The newly established Pool is currently negotiating licence agreements with multiple patent holders of ARVs.<sup>207</sup> Once licences are received from right holders, the Pool will grant licences to qualified generic producers who can thereafter compete at efficient economies of scale to sell existing and improved formulations and combinations throughout the developing world. Current controversies centre around whether a sufficient number of pharmaceutical companies will participate, whether Pool generic licences will be able to sell not just in low-income and sub-Saharan African countries but in HIV-affected middle-income countries as well and whether there has been and will be sufficient transparency regarding the transactions of the Medicines Patent Pool. To date, developing countries have done little to publicly support the Patent Pool, but it is anticipated that their concerted support could help it get off the ground. Additional opportunities to incentivise needed product development and to reduce the costs of AIDS medicines may be found in well-designed prize funds and advance market commitments, especially those that target truly new medicines that are well-suited and affordable in poorer countries. Another proposal that has been discussed is the Health Impact Fund, an optional mechanism that offers pharmaceutical innovators a supplementary reward based on the health impact of their products, if they agree to sell those products at cost. The proposed Fund is to be financed mainly by governments.<sup>208</sup>

In addition to IPR-related law reform, support for alternative innovation models, countries can also streamline and rationalise regulatory and procurement mechanisms to increase the availability and affordability of medicines.<sup>209</sup>

204 United Nations Development Programme (UNDP), *Access to ART and other essential medicines in sub-Saharan Africa: Intellectual property and relevant legislations* (2007); World Intellectual Property Organization (WIPO), *Patent related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels*, CDIP/5/4 (2010), available at [http://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=153559](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=153559).

205 UNAIDS, UNDP, WHO Policy brief: *Using TRIPS flexibilities to improve access to HIV treatment* (2011), available at <http://content.undp.org/go/newsroom/2011/march/unaid-undp-who-concerned-over-sustainability-of-hiv-treatment.en>

206 *Ibid.*

207 Medicines Patent Pool, *The Medicines Patent Pool: Stimulating Innovation, Improving Access* (2011), available at <http://www.medicinespatentpool.org/content/download/311/2031/version/1/file/FACTSHEET+FINAL+EB.pdf>; J Bermudez & E t’Hoen, (2010), *The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good*, 4 Open AIDS J. 37-40 (2010), available at <http://www.medicinespatentpool.org/content/download/216/1235/version/1/file/The+UNITAID+Patent+Pool+Initiative.pdf>.

208 See, A Banerjee, A Hollis, T Pogge, (2010), *The Health Impact Fund: incentives for improving access to medicines*, 375 Lancet at pp. 166-169 (2010). Sceptics are concerned that the HIF maintains patent hegemony and undermines generic competition. J Love, (2011), *HIF in the European Parliament* available at <http://keionline.org/node/1112>.

209 See, generally, WHO, *Procurement and Supply Systems*, available at <http://www.afro.who.int/en/clusters-a-programmes/hss/essential-medicines/programme-components/procurement-and-supply-systems.html>.

Countries can amend their drug regulatory procedures to expedite the registration of priority medicines, including AIDS medicines in two ways. First, they can fast-track registration of priority medicines that have been pre-qualified by the World Health Organisation Prequalification Programme or approved by a stringent regulatory authority.<sup>210</sup> Second, they can coordinate and harmonise registration standards and procedures on a regional basis (thereby lowering registration costs) and expedite the processing of registration requests both by originators and generics.<sup>211</sup> Similarly, it is extremely unfortunate that developing countries are not using existing pricing information<sup>212</sup> and/or pooled procurement to purchase medicines and are instead often paying vastly different prices for the same medicines.<sup>213</sup> Coordinated bulk and third-party procurement<sup>214</sup> methods can provide cost savings,<sup>215</sup> though the impact of bulk purchasing on the price of ARVs has been minimal.<sup>216</sup> Use of therapeutic formularies and pharmaco-economic analysis to achieve value for price<sup>217</sup> and even external reference pricing<sup>218</sup> can help control costs of medicines. Efficiencies in access-to-medicines can also be enhanced by regulating wholesale and retail mark-ups.<sup>219</sup> Similarly, reducing tariffs and value-added taxes on medicines, can significantly lower consumer prices.<sup>220</sup> Finally, countries can use competition policy to control abusive and collusive pricing and availability policy that adversely affect access to medicines as well as to enact other pro-competition policies.<sup>221</sup>

#### 4.1 WIPO Development Agenda, WHO, TRIPS Council

As outlined briefly above, developing countries and health advocates have been engaged in multiple multilateral forums to try to increase attention to the defects in the TRIPS and TRIPS-Plus IP regime and to promote a more comprehensive innovation/access-to-medicines policy. Some of the most strident battles have been waged within the WTO, first to adopt the 2001 Doha Declaration and then new August 30 2003 Decision (on implementing Paragraph 6 of the Doha Declaration on compulsory licensing for export/import), but more recently to review the pace of progress on technology transfer and the efficacy of proposed Article 31bis.<sup>222</sup> For many analysts, the evidence is already in that the Article 31bis production-for-export system is too cumbersome to be used effectively and that a simplified Article 30

210 Countries could either rely directly on WHO pre-qualification or registration by a stringent drug regulatory authority or adopt priority fast-track procedures that would address quickly locally significant questions concerning safety or efficacy, taking into account epidemiology and population-specific responses to the medicines.

211 B K Baker, (2008), *Ending Drug Registration Apartheid: Taming Data Exclusivity And Patent/Registration Linkage*, 34 *AM. J. LAW & MED.* 303-344, 317;; M Moran, N Strub-Wourgaft, et al., (2010), *Registering New Medicines for Low-Income Countries: The African Challenge*, 8 *PLoS Medicine* e1000411), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000411>. African countries are taking steps to harmonize regional registrations standards. See WHO, *African Medicines Registration Harmonization*, available at [http://www.afro.who.int/index.php?option=com\\_content&view=article&id=2514:african-medicines-registration-harmonization-amrh&catid=1963&Itemid=2697](http://www.afro.who.int/index.php?option=com_content&view=article&id=2514:african-medicines-registration-harmonization-amrh&catid=1963&Itemid=2697).

212 See WHO global price report mechanism report (May 2010), available at <http://who.int/hiv/amds/en/>; *Medecins Sans Frontières, Untangling the Web of Antiretroviral Price Reductions* (13<sup>th</sup> ed. 2010) available at <http://utw.msfaaccess.org/downloads>; Clinton Health Access Initiative – Antiretroviral (ARV) Price List (May 2011), available at [http://www.clintonfoundation.org/files/chai\\_arv\\_ceilingPriceList\\_201105\\_english.pdf](http://www.clintonfoundation.org/files/chai_arv_ceilingPriceList_201105_english.pdf).

213 B Waning, W Kaplan, M P. Fox, et al., (2010), *Temporal trends in generic and brand prices of antiretroviral medicines procured with donors funds in developing countries*, 7 *J. Generic Medicines* 159-175 (2010), available at <http://www.palgrave-journals.com/jgm/journal/v7/n2/full/jgm20106a.html#bib12>.

214 Bulk procurement involves large-scale purchases and often requires buyers to pool their orders. Third-party procurement involves an agent, such as Clinton Health Access Initiative, to negotiate prices with raw materials producers, generic manufacturers and distributors.

215 V Bradford Kerry and K Lee, (2007), *TRIPS, the Doha Declaration and Paragraph 6 Decision: what are the remaining steps for protecting access to medicines*, 3 *Globalization & Health*, available at <http://www.globalizationandhealth.com/content/pdf/1744-8603-3-3.pdf>.

216 B Waning et al., (2009), *Global strategies to reduce the price of antiretroviral medicines: evidence from transactional databases*, 87 *Bull World Health Org.* at pp. 520-528.

217 E Walkom, J Robertson et al. (2006), *The role of pharmacoeconomics in formulary decision making*, 41 *Formulary* at pp. 374-386 (; WHO & Management Sciences for Health, *Drug and Therapeutics Committees: A Practical Guide* (2003).

218 WHO & Health Action International, *WHO/HAI Project on Medicine Prices and Availability: Review Series on Pharmaceutical Pricing Policies and Interventions – Working Paper 1: External Reference Pricing* (2011), available at <http://www.haiweb.org/medicineprices/05062011/ERP%20final%20May2011.pdf>.

219 WHO & Health Action International, *WHO/HAI Project on Medicine Prices and Availability: Review Series on Pharmaceutical Pricing Policies and Interventions – Working Paper 3: The Regulation of Mark-ups in the Pharmaceutical Supply Chain* (2011), available at <http://www.haiweb.org/medicineprices/05062011/Mark-ups%20final%20May2011.pdf>. P Yadav, (2010), *Differential Pricing for Pharmaceuticals: Review of current knowledge, new findings and ideas for action*, available at [www.dfd.gov.uk/Documents/publications1/prd/diff-pcing-pharma.pdf](http://www.dfd.gov.uk/Documents/publications1/prd/diff-pcing-pharma.pdf).

220 M Okay and R Laing, (2005), *Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation?*, available at <http://www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf>; WHO & Health Action International, *WHO/HAI Project on Medicine Prices and Availability: Review Series on Pharmaceutical Pricing Policies and Interventions – Working Paper 5: Sales Taxes on Medicines* (2011), available at <http://www.haiweb.org/medicineprices/05062011/Taxes%20final%20May2011.pdf>.

221 WHO & Health Action International, *WHO/HAI Project on Medicine Prices and Availability: Review Series on Pharmaceutical Pricing Policies and Interventions – Working Paper 4: Competition Policy* (2011), available at <http://www.haiweb.org/medicineprices/05062011/Competition%20final%20May%202011.pdf>.

222 The August 30 2003 Decision remains as a waiver even after the proposal to codify it as an amendment to TRIPS was passed in 2005. The proposed Article 31bis requires acceptance by 2/3rds of WTO Member States to replace the August 30 2003 Decision has been ratified by 34 Member States countries as of June 2011.

“limited exception” would be a preferred approach.<sup>223</sup> In addition to the complexities of the August 30 Decision, some exporting countries have adopted conservative interpretations of national legislation to give effect to the Decision. The sole example where the Decision was used did not prove to be an expeditious solution<sup>224</sup>, has not encouraged other countries to use the mechanism and is the source of continued discussion at the WTO Council for TRIPS. Many developing countries are also beginning to question the so-called enforcement agenda and its conflation of trademark “counterfeits” with unsafe medicines and the seizure of medicines-on-transit. More broadly developing countries are concerned about the proliferation of bilateral, regional, and plurilateral trade agreements and of unilateral trade pressures that undermine multilateral norm-setting, support the ratcheting up of IPRs, and use divide-and-conquer strategies to create lose-lose outcomes for developing countries.

Although some productive collaborations between developing countries and their allies might still be forthcoming within the WTO, powerful Members are unlikely to allow significant changes in the global IP architecture unless a strong political consensus develops in other settings as well. Clearly, the WHO is now a premiere venue for such efforts given its Global Strategy and Plan of Action on Public Health Innovations and Intellectual Property and its disassociation from the “counterfeit”-medicines/IP-enforcement agenda. In response to Resolution WHA 59.24, the Director General established the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property to devise a plan of action for “securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries.” The resulting Global Strategy and Plan of Action, WHA 61.21, focuses on the following elements: (1) prioritising R&D needs; (2) promoting research and development; (3) building and improving innovative capacity; (4) transfer of technology; (5) application and management of IP to contribute to innovation and promote public health; (6) improving delivery and access; (7) promoting sustainable financing mechanisms; and (8) establishing and monitoring reporting systems. Because of the importance of innovative sources of financing, the WHO established a Consultative Expert Working Group on Research and Development: Financing and Coordination, which recently released a report assessing various proposals to stimulate innovation for HIV and neglected diseases.<sup>225</sup> Developing countries should continue to engage in the Global Strategy and Plan of Action and carefully monitor and contribute to its implementation. Likewise, developing countries can contribute positively to the WHO Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products. The WHO has been asked to distance itself or to withdraw completely from the International Medical Products Anti-Counterfeiting Taskforce (IMPACT),<sup>226</sup> which primarily advances an IP-related approach to the problem of unsafe medicines and instead to take greater leadership in stopping the global flow and consumption of unsafe and untested medicines whether they are trademark infringing or not.

Developing countries can also continue to pursue the WIPO Development Agenda. Out of the 45 Adopted Recommendations, there are clearly many that are directly relevant to the IP challenges discussed in this paper.<sup>227</sup> Within the framework of policy setting and requesting technical assistance, legislation assistance, norm setting, and technology transfer, the Development Agenda offers multiple opportunities for developing country participation and leadership.<sup>228</sup>

## 4.2 Increasing Domestic Coherence Between Relevant Country Stakeholders

Domestic norm setting on IP is often left to IP departments and the department of trade and industry. Because of the technical nature of IP legislation and the need to abide by relevant trade and investment agreements, even within these few departments IP is often considered to be the domain of select experts. Domestic capacity is concentrated and fractured further because specialists are dispatched to Geneva to oversee trade and IP interests in multilateral forums, often creating disjuncture on key issues. Historically, technical assistance on IP from has tended to favour IP protection and enforcement instead of being tailored to the needs of low- and middle-income countries. Again, because domestic IP policy setting has been concentrated, multinational and domestic corporate lobbying and pressure from developed-country trade representatives more easily results in regulatory capture by these interests.

223 See, e.g., B K Baker, (2004), *Arthritic Flexibilities for Accessing Medicines, Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 *Ind. Int'l & Comp. L. Rev.* at pp. 613-715 (2004);

224 For an extensive list of efforts undertaken by the Canadian HIV/AIDS Legal Network and other civil society organisations to reform various versions of legislation aimed at facilitating the export of medicines produced under compulsory licence from Canada, refer to a webpage on Canada's Access to Medicines Regime at: <http://www.aidslaw.ca/camr>

225 WHO (2012) Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*. Geneva, Switzerland: available at: [http://www.who.int/phi/CEWG\\_Report\\_5\\_April\\_2012.pdf](http://www.who.int/phi/CEWG_Report_5_April_2012.pdf)

226 WHO, IMPACT, available at <http://www.who.int/impact/en/>.

227 World Intellectual Property Organization (WIPO), *The 45 Adopted Recommendations under the WIPO Development Agenda*, available at <http://www.wipo.int/ip-development/en/agenda/recommendations.html>.

228 *Ibid.*, e.g., Recommendations 1, 7, 13, 14, 17, 19, 22, 23, 25, 28, 29, 37, 45.

Ultimately, the concentration of input and decision-making has severely disadvantaged low- and middle-income countries. Instead of having relevant and diverse inputs from other important departments, including health, education, agriculture, and labour, government policy on IP issues has been controlled by departments of trade and industry with perhaps limited input from departments of foreign affairs and finance. Likewise, interested civil society organisations and local business interests have often been excluded or marginalised, as well as experts from academic institutions. This non-consultative policy-making must become more inclusive if countries are to pursue a developmental IP policy that is responsive to broader social needs and in particular to the need to increase access to affordable medicines. In particular, countries need greater policy coherence in trade, IP policy, health, and development if they are to achieve progressive realisation of the human right to health.

Although it is clearly necessary to increase multi-stakeholder inputs on IP policy, sporadic consultations will not suffice: deliberative and participatory forums should be created for policy debates and eventual decision-making. Throughout, processes should be transparent and participatory – open to inputs from interested parties not in attendance but with priority given to those representing national interests rather than foreign corporate interests. The entire process must be guided, at least with respect to medicines, by a philosophy that prioritises access to medicine for all. Once the relevant IP policy frameworks are established, they must be communicated widely and rigorously implemented so as to create policy coherence across the broad spectrum of government activities, including most specifically trade.

### **4.3 Making Technology Transfer Real: Building Local/Regional Pharmaceutical Capacity**

Countries, and at least some of their development partners, are keen to build local/regional capacity to manufacture pharmaceutical products,<sup>229</sup> especially in Africa.<sup>230</sup> Doing so could help develop industry, have positive spill-over effects for suppliers and other technically oriented industries, help rebalance trade and reverse brain drain, and create self-sufficiency with respect to affordability and uninterrupted supply of important health commodities. However, developing local or even regional pharmaceutical capacity is difficult for at least five reasons: (1) IP rights can stand in the way;<sup>231</sup> (2) producing to required quality standards and doing so in a cost competitive manner depends on many industrial and infrastructure factors and expert human capital resources; (3) the economies of pharmaceutical manufacturing usually require internal or aggregated markets of sufficient size so that manufacturers can produce at efficient economies of scale; (4) given the size of required markets, there is likely to be competition between countries within a region with respect to where pharmaceutical capacity will be developed, making cooperation difficult; and (5) local and regional producers can face cost competition from even more efficient and low-cost-structure producers, especially from major Indian companies.

When IP rights stand in the way, one of the few policy options for technology transfer and local production is to promote voluntary licencing agreements. Some such licences could be truly transformational if they permit and capacitate local production from the manufacture of active pharmaceutical ingredients to final formulation and distribution. Such capacity building would ordinarily not only involve licencing of patent and data rights, but also licencing or transfer of technical know-how both with respect to manufacturing efficiencies and regulatory and marketing/distribution systems. However, many pharmaceutical licencing agreements are much “thinner” than this, either allowing limited local inputs like packaging and labeling or primarily relying on the licensee’s established regulatory expertise and distribution systems to gain marketing approval and to reach public and private sector buyers. Unfortunately, given the size of patent-owning pharmaceutical companies and the bargaining power they derive from their exclusive IP rights, potential generic licensees have little bargaining power to demand “thicker” licences with broad geographical scope. Fortunately, governments have some power under TRIPS Article 40 to regulate the terms of voluntary licences, though overly strenuous regulation might deter voluntary action.

When voluntary licences are not forthcoming or refused or when the licences involve minimal technology transfer and capacity building, government and private entities can consider compulsory licensing alternatives,<sup>232</sup> especially if there is an access/affordability issue. If the government has adopted easy-to-use compulsory licensing procedures, then

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229 At the outset, it is important to emphasize that local capacity can consist of local facilities of transnational pharmaceutical companies where spillover effects and local reinvestment are often thwarted by the business model. Conversely, indigenous pharmaceutical manufacturers, intent on servicing and focusing on local markets and adapting technologies to local needs are more likely to have positive spillover effects not only with respect to industrial development but also with respect to health. A hybrid form is true joint venture, like that involving the Indian generic pharmaceutical company CIPLA with a manufacturer in Uganda.

230 See UNCTAD, *Investment in Pharmaceutical Production in Least Developed Countries - A Guide for Policymakers and Investment Promotion Agencies* (2011), available at [http://www.unctad.org/en/docs//diaepcb2011d5\\_en.pdf](http://www.unctad.org/en/docs//diaepcb2011d5_en.pdf); Anderson, *The tide turns for drug manufacturing in Africa*, 375 *Lancet* at pp. 1597-1598 (2010).

231 IP rights should not stand in the way of manufacture by least developed countries since they have until 2016 under TRIPS to provide patents and data protection for pharmaceutical products. Moreover, many medicines are not patented in these small and poor markets. However, as discussed in the preceding section many LDCs have not amended their national legislation to take advantage of their TRIPS transition period.

232 B K Baker, (2004), *Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilize TRIPS Flexibilities in Non-Producing Countries*, U.K. Dept. for Int'l Development, Health Systems Resource Centre, available at <http://www.dfidhealthrc.org/publications/atm/Baker.pdf>.

private interests, including but not limited to generic producers, can take the initiative to promote competition. Here the licencing of local production would serve two purposes – access to the licensed technology and capacity building for the local industry. For the later purpose to succeed, the manufacturer might need some assurances concerning the potential market so that up-front investments in pharmaceutical capacity, product development, and registration costs could be recouped.

However, in many instances and for many developing countries, the major barrier to local production is not IP rights, it is technical capacity, access to financing, and supportive infrastructure, human and otherwise, across the broad spectrum involved in pharmaceutical manufacturing. Most critical in this regard is whether countries have, or can quickly develop, capacity to produce medicines to global quality standards (Good Manufacturing Practices) and thereby be eligible for WHO prequalification or purchase by U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund, and multilateral purchasing agencies. India has shown that incentives for quality in the form working capital credits, interest subsidies and export incentives can be sufficient to capacitate quality while maintaining competitiveness.<sup>233</sup> Some African manufacturers are beginning to receive pre-qualification with respect to GMP standards, including companies in South Africa and Uganda. Nonetheless, meeting global quality standards is only part of the equation. Other key variables include: availability of technical know-how and trained human resources, costs of capital, availability and cost of base ingredients, utility costs and transportation systems, and local regulatory capacity and coordination among relevant governmental authorities. Perhaps the most vexing problem is whether the local market is big enough to support cost-competitive manufacturing or whether an aggregated domestic and export market can be put together. Kaplan and Laing conducted a major study of the economics of local production, concluding that many countries may not qualify either because of market size or weaknesses in domestic capacity and infrastructure.<sup>234</sup> Despite this seminal study and because of recent more positive developments, African governments<sup>235</sup> remain interested in capacitating local pharmaceutical capacity and are receiving coordination assistance from the Interagency Pharmaceutical Coordination Group,<sup>236</sup> direct firm-level support from the United Nations Industrial Development Organisation,<sup>237</sup> WHO,<sup>238</sup> and World Bank, and indirect policy advice, capacity building, institutional work, and analytical work from many of these same entities plus the EU, Germany, the United Kingdom and the US.<sup>239</sup>

Since a central problem for local production is aggregating markets of sufficient size, there is inevitably competition between countries about where productive capacity should be sited. Regional groupings in sub-Saharan Africa have begun to strategise about the desirability of regional capacity. However, progress is slow to date on true regional cooperation because most countries would like to be chosen as the favoured site. Some countries have taken the initiative to strengthen domestic capacity, but it is hard to conclude at this point that this has been supported by true regional cooperation and decision-making.

However, even when African countries do develop good quality local capacity with regional export markets, there is still the problem of competition from highly efficient Indian manufacturers that often have lower cost structures and the legacy of governmental incentives. Aspen Pharmacare won the bulk of South Africa's first ARV tender in part because of a preference for local production in the procurement process. In the third tender, completed in 2010, international competitive prices were more aggressively pursued and foreign producers were more ardently courted, and thus the eventual prices were two times lower.<sup>240</sup> This example raises the policy dilemma of whether countries should give a bidding advantage to local producers and what "premium" is warranted and who should pay it (the Department of Health or the Department of Trade and Industries). This decision can have stark consequences when health budgets and donor aid are capped – 10% higher prices can result in fewer patients on treatment.

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233 UNIDO, *Report by the Director General, support in fostering local pharmaceutical industry in developing countries with special regard to essential health products*, para. 25, IDB.38/15 (Sept. 29, 2010).

234 W Kaplan and R Laing, (2005), *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicine – An Overview of Key Concepts, Issues, and Opportunities for Future Research*, World Bank HNP Discussion Paper .

235 See African Union Pharmaceutical Manufacturing Plan (2007), available at [http://www.pambazuka.org/actionalerts/images/uploads/Pharmaceutical\\_Plan-CAMH\\_MIN\\_8\(III\).pdf](http://www.pambazuka.org/actionalerts/images/uploads/Pharmaceutical_Plan-CAMH_MIN_8(III).pdf); Southern African Development Community's (SADC) Pharmaceutical Business Plan (2007-2013).

236 IPC is comprised by WHO, World Bank, UNAIDS, UNFPA & UNICEF, and has a Local Production Sub-group consisting of UNIDO, UNDP, UNDTAC, African Development Bank, and the Global Fund.

237 UNIDO, *Report by the Director General, support in fostering local pharmaceutical industry in developing countries with special regard to essential health products*, para. 25, IDB.38/15 (Sept. 29, 2010).

238 The WHO Global strategy and plan of action on public health, innovation and intellectual property, *supra*, highlights the need to build and improve innovative capacity in developing countries (element 3) and to facilitate the transfer of health-related technology (element 4). WHO, in partnership with the United Nations Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD), and with funding by the European Union, is undertaking a project on improving access to medical products in developing countries through local production and related technology transfer.

239 See, S Moon, (2010), *Presentation: Landscape of North-South and South-South Initiatives for Local Pharmaceutical Production of Drugs and Vaccines*, available at <http://ictsd.org/downloads/2010/03/moon-presentation.pdf>.

240 L Lopez Gonzalez, (Jan. 21, 2011), *How Better ARV Prices Were Won*, Inter Press Service, available at <http://ipsnews.net/news.asp?idnews=54199>.

#### 4.4 Increasing South-South dialogue: Increasing Coherent Behavior Between Developing Countries

South-South dialogue on IP and access to medicines is crucial to policy coherence and positive market dynamics for life saving medicines. If countries coordinate their adoption of TRIPS-compliant flexibilities and their utilisation, access-to-medicines initiatives will face less opposition. Similarly, if low- and middle-income countries increase policy dialogue, they can strategise harmonised positions at WHO, WIPO, and WTO, including initiatives to increase technology transfer<sup>241</sup> and to finance innovations addressing neglected diseases. Likewise, should compulsory licences become necessary for particular medicines, incentivising generic entry by multiple competing producers will be aided if several countries act in concert. Clearly, cooperating to harmonise regional registration standards and to expedite the registration of priority medicines is highly important. Similarly, countries can increase regional cooperation to address the scourge of unsafe medicines through properly-directed pharmacovigilance measures, rather than succumb to pressure for IP anti-counterfeiting agenda that falsely suggests IP is the best route for securing medicine safety, efficacy and quality.

Low- and middle-income countries have turned a corner in terms of seeking a more proactive policy on IP and access to medicines. They have gained a toehold for developmental issues in key multilateral institutions and have begun the arduous process of regional consultations. However, they face formidable challenges both in the form of an extremely powerful industry and the upper-income countries that support it. If low- and middle-income countries are going to achieve their developmental IP policy objectives and create more space for needed innovation, increased access to affordable medicines, and development of indigenous pharmaceutical manufacturing capacity, they will need to increase their own strategies for coordinated action. There will be inevitable conflicts and uncertainties within developing country IP coalitions but they will be less destructive if countries undertake to strive for policy coherence in good faith, invest in informed exchange, and prioritise key interventions.

#### 4.5 Human Rights Obligations of Developed Countries

General Comment No. 14 issued by the Committee on Economic, Social and Cultural Rights (CESCR) emphasises the obligations of powerful States “to take steps, individually and through international assistance and cooperation, especially economic and technical, towards the full realisation of ... the right to health.”<sup>242</sup> Not only are high-income countries obligated to share their technical and financial resources, but they also have a duty “to respect the right to health in other countries” by preventing third parties, including pharmaceutical companies, from violating the right of health in other countries and by ensuring that their own international agreements do not adversely impact on the right to health.<sup>243</sup> More specifically, revised Guideline 6 instructs that developed countries must avoid taking measures that would undermine access to HIV/AIDS treatment, including medicines, and to ensure that bilateral, regional and international agreements involving IP issues do not impede access to treatment including ARVs and other pharmaceutical products.<sup>244</sup>

The pattern of seeking increased protections for patent and data monopolies and enhanced enforcement beyond what is required by TRIPS arguably violates these right-to-health norms. Certain developed countries have exerted enormous pressures on developing countries to forego adoption and utilisation of TRIPS-complaint flexibilities, have sought to ratchet IPRs higher and higher through FTAs/EPAs and otherwise, and have retaliated when developing countries have used lawful means to increase access to more affordable medicines. Most recently, some high-income countries have reserved their right to oppose further extensions beyond 2013 of the transition period for LDCs to accede to TRIPS as well as further extensions to the 2016 transition period for the pharmaceutical patent and data protection provisions in TRIPS.<sup>245</sup>

Instead of imposing IP-maximising policies that threaten generic competition and access to lower cost medicines, developed countries should instead assist developing countries in their efforts ensure access to life-saving AIDS medicines and diagnostics. It is paradoxical, that developed countries have significantly increased their investments in HIV/AIDS programming at the same time that their trade negotiators are pursuing policies that will inevitably increase the costs of AIDS medicines in the future.

241 Technological Network on AIDS, *Technological Network on AIDS* (2007) (describing an initiative by Argentina, Brazil, China, Cuba, Nigeria, Russia, Ukraine and Thailand, to promote technology transfer), available at <http://www.aidstechnet.org>.

242 United Nations Committee on Economic, Social, and Cultural Rights, *General Comment 14: The right to the highest attainable standard of health* (Art. 12) Para 38, U.N. Doc. E/C.12/2000/4 (2000).

243 *Ibid.* at Para 39.

244 United Nations Office of the United Nations High Commissioner for Human Rights and Joint United Nations Programme on HIV/AIDS, *HIV/AIDS and Human Rights: International Guidelines: Third International Consultation on HIV/AIDS and Human Rights (revised Guideline 6)* Paras y & z, UNAIDS/02.49E (2003).

245 J Love, (2011), White House and European Commission trade official oppose waiver of drug patent for Least Developed Countries, KEI Policy Brief 2011:1 available at <http://keionline.org/node/1154>.