GLOBAL COMMISSION ON
HIV and the LAW

WORKING PAPER

Access to Medicines: The Role of Intellectual Property Law and Policy

Mohammed El Said & Amy Kapczynski

Citation: El Said, M., and Kapczynski, A., (2011), Access to medicines: The role of intellectual property law and policy. 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.

Introduction

Intellectual property (IP) policy is an important structural determinant of health. Patent policy influences the rate and direction of innovation for health, playing a positive or negative role depending on how it is shaped and implemented.[1] Patent policy also has critical implications for access to existing medicines and medical technologies.[2] This has been illustrated most dramatically in the context of the global Acquired immunodeficiency syndrome (AIDS)/ Human immunodeficiency virus (HIV) pandemic. Prices for a three-drug combination of anti-retroviral (ARV) HIV therapy in 2000 from patent-holding companies exceeded USD $10,000 per person per year, ensuring that treatment could not be extended to the vast majority of those living with HIV around the world. Generic competition led to precipitous price reductions, so that today treatment can be provided for less than USD $75 per person per year.[3] This history has contributed to the growing recognition that strong patent law applied to pharmaceuticals in developing countries undermines access to medicines and compromises the human right to health.[4] While the relationship between IP and innovation is covered in a separate paper,[5] it is worth noting here that there is little reason to expect that stronger patent rights in developing countries will lead to any substantial offsetting gains in innovation for the affected countries. Developing countries represent a very small share of the world's pharmaceutical market, meaning that the marginal added value of stronger patent protection will be small, and is unlikely to outweigh the costs to access.[6]

1 See, e.g., World Health Organisation (2006), *Commission on Intellectual Property Rights, Innovation. and Public Health, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (hereinafter "CIPIH report").

2 Not only medicines, but also diagnostics, vaccines, and other medical technologies are essential for health, and IP has implications for the availability of all such technologies. For ease of use, we will refer to medicines in this report, but this should be understood to include the broader category of medical technologies as well.

3 For the most recent available worldwide prices, see World Health Organisation Global Price Reporting Mechanism, at http://www.who.int/hiv/amds/gprm/en/.

4 See, e.g., UK Commission on Intellectual Property Rights (2002), *Integrating Intellectual Property Rights and Development Policy* (hereinafter "UK CIPR"); CIPIH report.

5 See Working Paper on *Approaches to Intellectual Property and Innovation That Meet the Public Health Challenge of AIDS* by Anthony D. So & Cecilia Oh.

6 For an attempt to quantify the negative implications of extending patents to all low-income nations, taking into consideration both innovation and projected price increases, see Scherer FM (2004), *A Note on Global Welfare in Pharmaceutical Patenting*, 27 World Econ. 1127, 1128. He concludes that *"It is reasonably well established in the economics literature that, especially in a world of AIDS and resistant tuberculosis epidemics, low-income nations enjoy higher economic welfare when they can free-ride on pharmaceutical innovations made and patented in the first world than when they must pay monopolistic prices for the newest and most effective drugs." Ibid* at 1128–29. Patent-driven R&D is particularly unlikely where the condition in question

From both economic and human rights perspectives, the optimal patent policy in developing countries would likely be to exclude patents on medical products altogether, as many once did. In light of the contemporary framework of international agreements on IP, such a policy is no longer an available strategy for most developing countries, and is only a short-term option for least-developed countries.[7] The most important such agreement is the World Trade Organisation's (WTO) TRIPS (Trade-Related Aspects of Intellectual Property) Agreement (the Agreement)[8] TRIPS establishes a high floor for IP protection for all WTO members, and crucially, introduces the requirement that members grant patents on medicines. TRIPS also makes disputes about treaty application justiciable, and authorises trade retaliation for adjudicated violations of the Agreement. A series of other IP treaties, both multilateral and bilateral, add to national obligations (and will be discussed further below).

As has been recognised repeatedly in recent years, TRIPS permits countries to take advantage of numerous "flexibilities," which may be used to tailor IP protection to local circumstances. In accordance with Articles 7 and 8 of TRIPS, such flexibilities serve a variety of objectives, including the protection of public health and nutrition, the promotion of competition and curbing the monopolistic potential of patent rights, and the encouragement of technology transfer and dissemination of knowledge.

Many reports and policy guides over the years have described these flexibilities, and urged developing countries to implement them in order to protect access to medicines.[9] There have also been important successes in implementation over the past several years, some of which are identified below. But an honest assessment leads to the conclusion that TRIPS flexibilities have been little used and/or only minimally effective in the majority of developing countries.

The implications are grave, particularly in the context of an HIV epidemic that continues unabated. While many first-line HIV therapies are available at generic prices in many countries (the result of both the delayed phase-in of TRIPS and the judicious use of flexibilities like compulsory licensing), some countries continue to pay higher, patented prices. This puts additional strain on already overburdened healthcare budgets. The "treatment time-bomb" also awaits us,[10] in the form of exploding costs for second-line therapies. Most developing countries also have little hope of moving to improved first-line therapies (utilising newer drugs with fewer side effects – regimens that have become, or will become, standard in developed countries), because of their cost. IP policy is a critical component of substantial, continued price reductions for ARVs, and of the ability of national governments to extend the implications of lessons learned in HIV to other areas of health. The ultimate implications, of course, are measured not in technical prose, but in people's lives. Millions of people are on ARV treatment today because activists brought attention to the catastrophic consequences that patents can have. This fundamentally changed the dynamics of ARV pricing, and made extending HIV treatment around the world possible. But whether HIV/AIDS patients continue to have access to life-saving medicines, and whether those with other conditions will be able to do the same, depends critically on attention to IP policy, particularly in developing countries.

This paper identifies and describes the most critical TRIPS flexibilities and describes the barriers to their widespread use, as well as developments undermining their continued availability. We also offer conclusions and policy recommendations based upon our analysis. While TRIPS does formally offer certain flexibilities to developing countries, in practice, the complexity and administrative burdens associated with these flexibilities imposes a substantial toll on health in developing countries. More than 15 years after the adoption of the TRIPS Agreement, it is time for a reassessment of its impact, and for consideration of a binding amendment or instrument that could protect access to medicines for the global poor. At a minimum, much more must be done to support the use of TRIPS flexibilities in developing countries, as we describe in our conclusion.

Methodology

is suffered by the global poor. As the Nobel-prize winning economist Joseph Stiglitz and a co-author recently put it, *"as private incentives respond to the size of potential markets, several diseases that affect the poor, and thus have potentially limited markets, are not the focus of sufficient R&D investment. Here, the point is that 'private profitability' is not a good measure of social return."* Stiglitz, JE & Jayadev, A (2010), *Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals*, 3 J. Generic Meds. 217, 219.

7 Least developed countries still enjoy a transitional period exempting pharmaceutical patents from protection until 2016, but this is merely a short-term solution unless it is substantially extended. TRIPS Council's decision of 27 June 2002. See http://www.wto.org/english/news_e/pres02_e/pr301_e.htm#texts_decisions. Moreover, countries may be required in negotiations in free trade agreements or urged through unilateral pressure to forgo this exemption. *See infra*.

8 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (hereinafter "TRIPS")

9 Correa, C (2007), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 21 (ICTSD / UNCTAD 2007), available at http://www.iprsonline.org/resources/docs/Correa_Patentabilitypercent 20Guidelines.pdf; El Said, M (2010), *Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region* (WHO and ICTSD), available at http://www.emro.who.int/publications/Book_Details.asp?ID=1081; CIPIH report, at Ch. 2; Musungu, S & Oh, C (2006), *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* (South Centre and WHO, 2006); UNDP (2010), *Good Practice Guide: Improving Access To Treatment By Utilizing Public Health Flexibilities In The WTO TRIPS Agreement*.

10 See UK All-Party Parliamentary Group on HIV and AIDS (2009), *the Treatment Timebomb.*

This paper is based upon an analysis of the meaning and scope of legal obligations created by international IP law, as supported by the text of agreements, relevant interpretive decisions, and, where relevant, expert opinion. We also analyse local legal frameworks where relevant, using the same conventional legal tools. Finally, we relied upon secondary sources ranging from policy briefs to empirical quantitative work to in-depth qualitative analyses to develop an account of the effect of TRIPS and TRIPS-plus requirements in practice.

I. Key IP Policy Tools to Promote Access to Medicines

Much is now known about how developing countries would have to craft their IP laws in order to protect access to medicines within the confines of the TRIPS Agreement. The list of important flexibilities is long, and will be reviewed only in brief in this paper.[11] We focus most of our discussion on three domains of flexibility that are of particular, demonstrated, importance:

- appropriate criteria of patentability,
- strong procedures to protect patent quality, and
- effective safeguards after the granting of patents.

We then discuss the practical difficulties countries face in deploying these flexibilities in the context of resource limitations, continued unilateral pressure, and new trade agreements that seek to restrict their use.

A. Appropriate Criteria of Patentability

There is no such thing as an international patent; rather, companies must seek and enforce patents locally (although some systems exist, e.g. in Europe and Africa, that grant patents on a regional level).[12] All patent laws establish criteria of patentability, to ensure that the "strong medicine" of exclusive rights is limited to truly innovative inventions. As TRIPS reflects, patents may be granted only to inventors who show that their creation (1) is novel, (2) embodies an "inventive step", and (3) is "capable of industrial application."[13]

Countries often exclude some subject matter as such from the domain of patentability. In developing countries, such *per se* exclusions are particularly important policy tools. These exclusions are best understood as an application of the general standards of patentability, but resource-constrained patent offices may have difficulty applying broad requirements (for example of "inventive step") with consistency and accuracy.[14] Codified exclusions on patentability are thus important to the development of consistent and coherent legal standards in these settings.

Overly permissive patent standards are particularly worrisome in the pharmaceutical context, because of their impact on both access to medicines and innovation. As the global pharmaceutical industry has become less innovative,[15] it has more aggressively sought to exploit so-called "secondary" patents (for example, patents on new uses of known substances, or new forms of known substances, such as polymorphs, enantiomers, salts, esters, prodrugs, and so forth).[16] Such patents are often considered less inventive than primary patents (that is, than patents on new active ingredients

---

11 For fuller accounts, see sources: Correa, C (2007), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 21 (ICTSD / UNCTAD 2007), available at http://www.iprsonline.org/resources/docs/Correa_Patentabilitypercent 20Guidelines.pdf; El Said, M (2010), *Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region* (WHO and ICTSD), available at http://www.emro.who.int/publications/Book_Details.asp?ID=1081; CIPIH report, at Ch. 2; Musungu, S & Oh, C (2006), *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* (South Centre and WHO, 2006); UNDP (2010), *Good Practice Guide: Improving Access To Treatment By Utilizing Public Health Flexibilities In The WTO TRIPS Agreement.*

12 The European system is governed by the European Patent Convention of 1973. The two African systems are the African Regional Intellectual Property Organization (ARIPO), covering 17 countries in East and Central Africa, and the African Intellectual Property Organization (commonly known as OAPI, by its French acronym), which covers 16 French-speaking states.

13 See TRIPS Article 27.1.

14 Kapczynski, A (2009), *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector,* 97 Cal. L. Rev. 1571, 1597.

15 For example, the CIPIH report explains that, *"there are studies which find that many new medicines offer little or no improvement over existing medicines. For instance, in a recent Canadian study, the conclusion was that in British Columbia, 80% of the increase in drug expenditure between 1996 and 2003 was explained by the use of new, patented drugs that did not offer substantial improvements over less expensive alternatives available before 1990."* CIPIH report at 131. See also United States Government Accountability Office (2006), *New Drug Development: Science, Business, Regulatory and Intellectual Property Issues Cited As Hampering Drug Development Efforts* (*"[O]ver the past several years it has become widely recognized throughout the industry that the productivity of its research and development expenditures has been declining; that is, the number of new drugs being produced has generally declined while research and development expenses have been steadily increasing. Similarly, FDA and analysts reported that pharmaceutical research and development investments were not producing the expected results and that innovation in the pharmaceutical industry had become stagnant."*).

16 See Sawicka M, & Bouchard, R (2009), *Empirical Analysis of Canadian Drug Approval Data 2001-2008: Are Pharmaceutical Players "Doing More with Less"?* 3 McGill J.L. & Health 85.

in medicines themselves), and are often successfully used by industry to generate or extend the life of exclusive control over medicines.[17]

To offer an illustration, consider the patent landscape for the important anti-HIV drug efavirenz in China.[18] It is covered by five different patents, only one of which claims the actual active ingredient. That primary patent is set to expire in 2013. But many additional years of exclusivity may be provided by secondary patents, such as a patent on "crystallised forms" of the drug (expiring in 2018), and certain solid dosage forms (expiring in 2019). A more extreme example may be found in another anti-HIV drug, darunavir. In this instance, there appears to be no patent on the active ingredient itself in China, yet a host of secondary patents covering new forms, formulations, and combinations of the drug could prevent generic competition in China until 2023.

TRIPS expressly authorises certain *per se* exclusions from patentability, such as for diagnostic, therapeutic, and surgical methods, recognising their importance to national innovation policy.[19] Other exclusions, while not explicitly protected in TRIPS, may be appropriate applications of the conventional criteria for the grant of a patent. While TRIPS does forbid discrimination by field of technology, it also permits *"bona fide exceptions to deal with problems that may exist only in certain product areas."*[20] *The Doha Declaration on the TRIPS Agreement and Public Health recognises that special concerns apply to pharmaceuticals, affirming that this is a legitimate area for such exceptions*.[21] Application of these standards in the context of developing countries suggests a series of exclusions that can help protect patent quality, appropriate use of patents, and access to medicines.

First, countries can – and some do – limit patents on new or second medical uses of known compounds.[22] These restrictions prevent drug companies, for example, from obtaining a new patent for an old cancer drug by claiming not the drug itself (which is no longer novel), but a "new use" of the drug as a heart disease medicine. Such exceptions are best understood as implementations of the novelty or industrial applicability requirements of patent law.[23] Many expert reports have recommended that developing countries embrace *per se* exceptions on new or second uses of known products.[24] Relatedly, developing countries may exclude patents on methods of treatment (for example, "the use of the medicine AZT to treat HIV"), which are very common in the pharmaceutical context.[25]

Second, patent laws may restrict patents on new forms of known substances. India's patent law offers an example. Section 3(d) of the Indian law restricts patents on *"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,"*[26] *and has served as a model for other countries.*[27] *Countries such as India also exclude patents on "mere admixtures" of known drugs, which may prevent patents that have caused concern in the context of HIV, such as patents on fixed dose combinations.*[28]

---

17 European Commission (2009), *Pharmaceutical Sector Inquiry: Final Report* at Annex B at 189 (hereinafter EC Report); Burdon M, and Sloper, K (2003), *The Art of Using Secondary Patents to Improve Protection*, 3 J. Medical Marketing 3, 226, 228.

18 All information taken from, I-MAK (2010), *HIV Drug Patents in China*, available at http://www.i-mak.org/publications/. We chose the example because such a mapping existed; as we will discuss, such information is very difficult to obtain in the absence of this laborious work.

19 See TRIPS Article 27.3.

20 WTO, *Canada—patent protection of pharmaceutical products*. Geneva, WTO, 2000. WTO Dispute Panel Report, WT/DS114/1. (Mar. 17, 2000).

21 WTO, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, Fourth Session, Doha, Nov. 9-14 2001, WT/MIN(01)/DEC/2 (20 Nov 2001).

22 Deere, C (2008), *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*; Correa, C (2007), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 21 (ICTSD / UNCTAD 2007), available at http://www.iprsonline.org/resources/docs/Correa_Patentabilitypercent 20Guidelines.pdf at p.21. As a report by World Bank and ARIPO recently recognised, *"Legally, member countries, according to paragraph 4 of the Declaration, have the opportunity and indeed the obligation to interpret and implement the provisions of article 27.1 with respect to the patentability of the 'new use' of medicines in a manner that seeks to protect public health and ensure access to medicines. It would thus be legally sound to interpret and implement the novelty requirement by exempting from patentability the new use of any known pharmaceutical product, including HIV/AIDS medicines."* See Osewe, P et al (2008), *Improving Access to HIV Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights Flexibilities*, World Bank.

23 Correa, C (2007), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 21 (ICTSD / UNCTAD 2007), available at http://www.iprsonline.org/resources/docs/Correa_Patentabilitypercent 20Guidelines.pdf at p. 21.

24 Ibid. See also UK Commission on Intellectual Property Rights (2002), *Integrating Intellectual Property Rights and Development Policy* (hereinafter "UK CIPR"); CIPIH report. at p. 45 andUNDP (2010), *Good Practice Guide: Improving Access To Treatment By Utilizing Public Health Flexibilities In The WTO TRIPS Agreement.* at pp. 20-21.

25 See TRIPS Article 27.3; Correa, C (2007), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 21 (ICTSD / UNCTAD 2007), available at http://www.iprsonline.org/resources/docs/Correa_Patentabilitypercent 20Guidelines.pdf at at p. 20.

26 Section 3(d), Indian *Patents Act, 1970* as amended by *The Patents (Amendment) Act, 2005*.

27 Section 3(v), Zanzibar *Industrial Property Act, 2008*, available at http://www.zanzibarassembly.go.tz/documents/acts.php, (excluding from patentability "new uses or forms of known product or process"); Sections 5–6, Philippines *Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic* Act No. 8293 (June 6, 2008), available at http://www.senate.gov.ph/republic_acts/ra%209502.pdf. Section 3 (d) of India's law further specifies that *"salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."*

28 Section 3 (e), Indian *Patents Act*; Correa, C (2007), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective*

Also important is the standard established for "inventive step" (in some countries called "obviousness"). This requirement plays a key role in preventing trivial patents that may interfere with innovation. As the United States (US) Supreme Court wrote recently, in a case that reintroduced a stricter obviousness requirement in the US, *"[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility."*[29] *They noted, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."*[30]

Because the TRIPS Agreement does not require a particular definition of inventive step, developing countries are free to adopt their own interpretation of the requirement. They should impose strict standards to reduce concerns about the patenting of substandard inventions.[31]

If applied faithfully, stricter patentability criteria may substantially diminish the scope of exclusivity in the pharmaceutical sector, and limit the grant of patents to the class of most significant and innovative inventions.[32] There is reason to doubt that developing country patent policy has much effect at all on the allocation of research and development (R&D) efforts in originator pharmaceutical firms, but to the extent that it does, such policies should channel inventive effort toward the most important breakthroughs – entirely novel chemical entities. Other salutary effects may be reduced workload for patent offices, and more scope for generic competition in local markets as well as for export.

B. Strong Procedures to Protect Patent Quality

Patent examination is intensive, demanding work, and patent offices all around the world experience challenges to their ability to carefully examine each patent application. In recent years, serious concerns have been raised about the ability of examiners even in the most well-resourced jurisdictions to discharge their duties effectively, and thus to safeguard patent quality.[33]

Developing countries face particularly acute challenges in this regard. In a few countries, examinations are not even required, and in many more, patent examiners are meant to scrutinise patents, but are unable effectively to do so. Limits on resources and shortages of examiners with appropriate technical expertise mean that examiners in developing country settings must often examine many more patents than their counterparts in the US and the European Union (EU). For example, in the 2008-2009 year, 36,812 patents were filed in India.[34] Only 75 patent examiners were employed in this same period.[35] This translates to a ratio of about 490 patents filed per examiner.[36] In comparison, the European Patent Office (EPO) in 2009 received 134,542 patents, and had 5234 examiners.[37] The corresponding ratio at the EPO is 26 patents filed per examiner. This only begins to illustrate the scale of the challenge to effective examination in developing country patent offices, because personnel shortages are exacerbated by other resource constraints (for example with respect to access to evidence of prior art or labour-saving information technology).

One policy tool that may be used to enhance the quality of examination is **pre-grant and post-grant patent oppositions, and patent revocation proceedings**.[38] These methods have been used at different times in a wide range of countries,

---

21 (ICTSD / UNCTAD 2007), available at http://www.iprsonline.org/resources/docs/Correa_Patentabilitypercent 20Guidelines.pdf at p. at 7. See also the submission made by Kajal Bhardwaj for the Asia-Pacific Regional Dialogue of the Global Commission on HIV and the Law.

29 *KSR International Co. v. Teleflex, Inc. et al*., 550 U.S. 398, 419 (2007).

30 *Ibid* at 421.

31 Correa, C (2007), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 21 (ICTSD / UNCTAD 2007), available at http://www.iprsonline.org/resources/docs/Correa_Patentabilitypercent 20Guidelines.pdf at at p. 4; see also TRIPS Article 1 (*"Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement."*). India's law (section 2(ja)) offers a possible model, defining inventive step as *"a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."*

32 In relation to this, Shashikant states that, *"…in January 2011, the Indian patent office rejected patent applications related to two AIDS medicines – lopinavir/ritonavir and atazanavir - on the basis that they did not merit patents under India's patents law. This decision leaves the door open for the production of more affordable generics that is relied on by patients around the world."* – see submission made by Sangeeta Shashikant, Third World Network, Switzerland for the High-Income Countries Dialogue of the Global Commission on HIV and the Law.

33 See, e.g., Noveck, BS (2006), *"Peer to Patent": Collective Intelligence, Open Review, and Patent Reform*, 20 Harv. J.L. & Tech. 123, 124-25; Bessen J, & Meurer, MJ (2008), *Patent Failure: How Judges, Bureaucrats, and Lawyers put Innovators at Risk*.

34 Indian Patent Office, Annual Report 2008-2009 at 7.

35 *Ibid* at 23.

36 Not every patent will be examined, however, because applicants must request examination in India.

37 European Patent Office Annual Report 2009 at 15, 47.

38 The period to initiate post-grant opposition applications may vary. For instance, under section 25(2) of the Indian *Patents Act, 1970*, the post-grant opposition can be filed against any granted Indian patent within twelve months from the date of publication of grant. Patent revocation proceedings permit a patent to be revoked anytime after its grant, for example because it is shown that the patentee is not entitled to the patent, or the patent was obtained by fraud or misrepresentation. See Section 64, Indian *Patents Act 1970* (amended 2005).

and are employed today in developed and developing countries alike. They allow interested parties to bring evidence and arguments before the patent office that a particular patent does not meet local requirements. The rationale behind them is the safeguarding of the quality of granted patents and the prevention of patent "evergreening".[39]

The first example of the use of oppositions to address access to medicines in the context of HIV was the successful opposition that Thai activists brought to the didanosine patent in 2001.[40] But the most extensive use of opposition proceedings has been more recently in India, which provided for both pre-grant and post-grant oppositions when it amended its law to come into compliance with TRIPS in 2005.[41] In India, companies and non-governmental organisations (NGOs) have launched dozens of oppositions to pending patents, and achieved a substantial success rate. The importance of oppositions, and in particular of NGO participation, is illustrated by the now well-known case involving the Novartis anti-cancer drug Glivec/Gleevec. There, a cancer aid organisation represented by the Lawyers Collective HIV/AIDS Unit challenged a secondary patent on the drug, citing Section 3(d) among others.[42] The patent was invalidated, paving the way for generic competition of the drug, and substantial price reductions.[43]

The Indian example also shows two other salutary implications of oppositions. Simply filing an opposition may induce companies to lower prices and/or to grant voluntary licences (as Gilead did for tenofovir after an opposition was filed in India), or may induce companies to withdraw patent applications (as GlaxoSmithKline did in the case of the Combivir patent).[44]

Patent oppositions can play an important role in bringing relevant evidence and arguments before examiners and appeals boards. They are likely to be of particular importance in countries with serious resource constraints. Notably, however, they are also an important part of quality assurance in some developed country patent offices, including in Europe and Australia. The US Patent and Trademark Office has also sought to better harness outside information for patent quality in recent years with a "peer to patent" project that allows outsiders to comment on applications and introduce prior art.

Patent revocation proceedings have been less explored by advocates for access to medicines, but can play a similar role, and have the advantage of being available throughout the life of a patent. To be effective in resource-poor settings, such proceedings must permit participation from companies, NGOs, and third parties, and avoid limits on types of challenges or evidence presented or presumptions of patent validity (which can only be supported where one has a high degree of confidence in the reliability of the initial patent examination).

C. Effective Safeguards after the Granting of a Patent

After the grant of a patent, governments retain many policy tools to address problems that may arise. The following is a brief overview of some of these flexibilities and the impact of their use.

The first and the most critical of these in the context of access to medicines are the tools of **compulsory licencing and government use**. These tools were in widespread use in European countries in the nineteenth century, and thus were explicitly protected in the Paris Convention of 1883. Developed and developing countries alike both recognised the importance of these mechanisms during the TRIPS negotiations. As a result, TRIPS explicitly authorises them, but circumscribes their use with certain procedural requirements.[45] Typically patent holders must be remunerated and engaged in prior negotiations, although there are exceptions for the latter in cases of emergency and government non-commercial use.[46] (Government use refers to instances of compulsory licensing when the government itself uses or authorises a third party to use a granted patent in order to address the needs of government, for example to supply

39 See Drahos, P (2010), *The Global Governance Of Knowledge: Patent Offices And Their Clients*. Evergreening is a term used to describe the use of trivial secondary patents to extend the effective exclusivity over a drug beyond the initial 20 years provided.

40 UNDP (2010), *Good Practice Guide: Improving Access To Treatment By Utilizing Public Health Flexibilities In The WTO TRIPS Agreement at p.* 23; see Médecins Sans Frontières (2003), *Drug Patents under the Spotlight: Sharing Practical Knowledge about Pharmaceutical Patents*, available at http://apps.who.int/medicinedocs/pdf/s4913e/s4913e.pdf. at 20; see *AIDS Access Foundation et al.* v. *Bristol Myers-Squibb Company and Department of Intellectual Property*, Central Intellectual Property & International Trade Court, Black Case No. Tor Por 34/2544, Red Case No. 92/2545 (2002).

41 Sections 25.1, 25.2, Indian *Patents Act, 1970.*

42 Park, C & Menghaney, L (2010), *TRIPS Flexibilities: The Scope of Patentability and Oppositions to Patents in India*, in Access to Knowledge in the Age of Intellectual Property (Krikorian, G & Kapczynski, A eds. 2010), available at http://mitpress.mit.edu/books/chapters/189095196Xchap18.pdf

43 *Ibid.*

44 Both examples are discussed in Amin, T (2010), *Re-visiting the Patents and Access to Medicines Dichotomy: An Evaluation of TRIPs Implementation and Public Health Safeguards in Developing Countries*, in Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines (Aginam, O, Harrington J & Yu PK eds., 2010).

45 See TRIPS Article 31.

46 In cases of public non-commercial use or emergency or other extreme urgency, governments need not first negotiate with patent holders, but instead must only inform them promptly or as soon as reasonably practicable. TRIPS Article 31(b).

medicines in government programmes and hospitals.[47])

There is a common misperception (promoted by advocates for the patent-based pharmaceutical industry)[48] that compulsory licensing is limited to "emergencies." This is emphatically, and clearly, not the case. TRIPS does not limit the grounds on which states may grant compulsory licences, as the 2001 Doha Declaration of the TRIPS Agreement and Public Health (adopted unanimously by all WTO Members) reaffirmed.[49] States may thus use compulsory licences to circumvent anti-competitive behaviour and encourage the transfer of technology, or simply to address excessive pricing of medicines.

Compulsory licensing remains one of the most effective tools in reducing the price of medicines, and has been deployed with particular success in the context of ARVs. As TRIPS came to be implemented in developing countries, and the AIDS pandemic exploded, a growing number of developing countries have successfully used the policy tool of compulsory licensing to lower the price of AIDS (and other) medicines.

Brazil's efforts and initiatives are illustrative. In 1996, Brazil adopted a policy of universal access for ARVs, a policy made possible by reliance on the production and importation of generic HIV treatments. When Brazil came into compliance with TRIPS, older "first-line" HIV treatments remained generic because Brazil did not extend patents retroactively. But newer "second-line" ARVs were patented, and paying for them imposed a substantial burden on the national health budget. To address the challenge, Brazil first engaged in intensive price negotiations against the background threat of compulsory licenses.[50] But the strategy reached its limits. In 2007, after lengthy negotiations, a compulsory licence was issued for efavirenz, an important ARV used by a third of Brazilians in the national HIV treatment programme. The licence led to a substantial drop in price, from USD$1.60 per dose to USD$0.45 per dose for the imported generic version of the drug. Some estimates indicate that these policies saved approximately USD$1.2 billion on ARV purchasing costs between 2001 and 2005.[51] The results in terms of lives saved or prolonged are striking and self-evident.

Thailand has made perhaps the most energetic use of compulsory licensing among developing countries. Between 2005 and 2006, the Thai government exercised its right to issue multiple compulsory licences.[52] Two of the licences covered ARVs (efavirenz, marketed as Stocrin by Merck, and lopinavir/ritonavir, marketed as Kaletra by Abbott). These licences resulted in substantial price decreases and improvement of accessibility to drugs. For instance, the immediate result of issuing the efavirenz licence was the acquisition by the Thai health authorities of its generic version from the Indian producer Ranbaxy for USD$216 per patient/year, over a 50% decrease from Merck's price of USD$468, and by early 2008 the number of patients using lopinavir/ritonavir had tripled in Thailand.[53]

More recently, in April 2010, the Ecuadorean intellectual property office granted its first compulsory licence, also for the important ARV combination of lopinavir/ritonavir. The licence again led to substantial price savings. It was reported that Ecuador's compulsory licence *"immediately reduced the cost of a major public HIV drug purchase . . . by 27 percent,"* and it is expected that prices will fall further, reaching a reduction of over 50%.[54] As these three examples show, compulsory licensing can result in substantial reduction of prices.

Countries without manufacturing capacity must source generic medicines abroad, and are thus impacted not only by their own patent law and policy, but also by the patent law and policy of exporting countries. If a medicine is under patent in an exporting country, a compulsory licence must first be issued so that it can be produced there. TRIPS creates a substantial obstacle, in the form of Article 31(f). That provision requires compulsory licensing be "predominantly for the supply of the domestic market," so undermines the ability of the poorest countries to use compulsory licensing by limiting their ability to find a supplier. The 2001 Doha Declaration on the TRIPS Agreement and Public Health instructed the WTO Council for TRIPS to address the problem, leading to the TRIPS General Council Decision of August 2003.[55]

---

47 Because government use is a form of compulsory licensing, we will simply refer to it as compulsory licensing hereafter.

48 See USA For Innovation Launches Thai Myth #6, at http://www.prnewswire.com/news-releases/usa-for-innovation-launches-thai-myth-6-58148707.html (wrongly stating as "fact" that "countries instituting compulsory licenses should do so at a time of "national emergency.").

49 The 2001 Doha Declaration on the TRIPS Agreement and Public Health, Article 5(b) provides: *"Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."*

50 UNDP (2010), *Good Practice Guide: Improving Access To Treatment By Utilizing Public Health Flexibilities In The WTO TRIPS Agreement at p.*6.

51 Nunn AS et al (2007), *Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment*, 4 PLoS Med e305. For more on Brazil see the submission made by Contectas Direitos Humanos, Brazil, for the Latin America Regional Dialogue of the Global Commission on HIV and the Law.

52 Open Society Institute (2008), *Playing by the Rules: Using Intellectual Property Law and Policy to Improve Access to Essential Medicines*, available at http://www.soros.org/initiatives/health/focus/access/articles_publications/publications/playing_20080731/playing_20080818.pdf.

53 't Hoen, E (2009), *The Global Politics of Pharmaceutical Monopoly Power*; see Ford N, et al (2007), *Sustaining Access to Antiretroviral Therapy in the Less-Developed World: Lessons from Brazil and Thailand*, 21 AIDS S21–S29.

54 Public Citizen, *By Authorizing Generic Competition, Ecuador Cuts Cost of Key HIV/AIDS Drug*, Press Release, Apr. 22, 2010, at http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3116.

55 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of August

This waiver enables compulsory licensing for export to countries without sufficient manufacturing capacity, if parties otherwise comply with specified conditions of registration and packaging. However, this solution has been of limited use because its procedures are cumbersome.[56]

There are several other flexibilities that, if applied, may also improve access to medicines. Countries may adopt rules to facilitate "**parallel importation**," whereby countries import medicines that were legally put on the market in another country by the patent holder (or its licencee) in order to take advantage of price differences across national borders.[57]

TRIPS also provides that members *"may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"*.[58] However, the agreement does not define the scope or nature of the permissible exceptions thus awarding member countries some discretion to operate in this regard. It is widely understood that this provision of TRIPS gives countries the ability to incorporate a series of important post-grant flexibilities in their local law, including (but not limited to) so-called **"Bolar" exceptions** (which permit parties seeking to prepare for drug regulatory approval to work a patent) and **research and experimental use exceptions**.[59]

Another important tool that is yet to be systematically utilised by the majority of developing countries is **competition law**. TRIPS acknowledges this tool, providing member states with special powers to curb abuses of IP through the use of competition law and policy.[60] Because TRIPS does not define the concept of anti-competitive practices, countries have latitude to develop locally responsive interpretations. One successful example of creative use of this flexibility comes from a 2003 decision of the South African Competition Commission. As a result of the complaint filed by the Treatment Action Campaign, the Commission found that the pharmaceutical firms GlaxoSmithKline South Africa (Pty) Ltd and Boehringer Ingelheim had contravened the South African *Competition Act* of 1998 by abusing their prominent positions in their respective ARV markets through excessive pricing and "denying a competitor access to an essential facility." Although the Commission decided to refer the matter to the Competition Tribunal for determination, the case was later settled as the firms agreed to grant voluntary licences.[61]

Finally, it is important to note a post-grant flexibility that has only recently been recognised: the flexibility afforded to national judiciaries in granting **remedies**. When a patent is adjudged valid and infringed, a judge must determine the appropriate penalty. One possible penalty is an order to a generic competitor to cease any present or future production, leaving the market to the patent holder alone. But a recent US Supreme Court case, *eBay v. MercExchange*, has brought attention to the importance of judicious deployment of the alternative remedy, a continuing damage award.[62] Where factors including the "public interest" instruct, courts may decline an injunction, and instead assign an appropriate royalty.

An important example of the possible scope of this remedial flexibility was offered by the recent New Delhi High Court in the case of *Roche v. Cipla*.[63] Recognising that a preliminary injunction would have led to price increases that would have had fatal implications for patients, the court, citing *eBay*, declined an injunction. As the court noted, the traditional standard for injunctive relief requires a consideration of the harm to third parties, and courts cannot *"be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted."*[64]

Many of the above examples, including this last one, show that countries can apply IP policy in a creative manner, exploring forms of flexibility that are appropriate to national context, even if not well-known or explicitly demarcated in TRIPS. This kind of creative implementation is vital to ensure that countries are able to adapt their IP law to local conditions and needs.

30, 2003 (WT/L/540 and Corr.1) at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

56 Médecins Sans Frontières (2006), *Neither Expeditious, Nor a Solution: The WTO 30 August Decision is Unworkable*, available at http://www.doctorswithoutborders.org/news/hiv-aids/WTO_chretien.pdf. See also the submission made by Patricia Allard, Canadian HIV/AIDS Legal Network, Canada for the High-Income Countries Dialogue of the Global Commission on HIV and the Law.

57 The TRIPS Agreement grants member states freedom in devising their own exhaustion regime. See TRIPS Article 6.

58 See TRIPS Article 30.

59 It must be stated that these are not an exhaustive list of exceptions. Member states have the discretion to introduce other limited exceptions provided that such exceptions do not 'unreasonably conflict with a normal exploitation of the patent', and 'do not unreasonably prejudice the legitimate interests of the patent owner'. See TRIPS Article 30.

60 See TRIPS Articles. 8.2, 31, and 40.

61 Correa, C (2007), *Intellectual Property and Competition Law: Exploration of Some Issues of Relevance to Developing Countries*, International Centre for Trade and Sustainable Development.

62 547 U.S. 388 (2006).

63 *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*, (2008) 642 I.A, available at http://i-mak.squarespace.com/indian-pharmaceutical-patent-d/

64 *Ibid*. at para 85.

II. Scaling Up Implementation: What are the Barriers?

While there have been notable successes deploying each of these flexibilities, they have yet to be systematically implemented in developing countries.[65] Many countries, and often the poorest, offer IP protection that far exceeds what is required by TRIPS. The number of countries that have effectively used compulsory licences is still relatively small. In still fewer countries have rigorous patent opposition proceedings, or the possible limits on scope of patentability, been deployed.

Fundamental challenges exist to the systematic adoption of TRIPS flexibilities in developing countries. Four are key: (A) lack of supportive legal frameworks, (B) resource constraints and limited coordination, (C) continued unilateral pressure, and (D) new international agreements that reduce the scope of TRIPS flexibilities.

A. Lack of Supportive Legal Framework

The flexibilities identified above must be incorporated into local law before they can be deployed. But few countries have adopted the comprehensive range of flexibilities discussed above. For example, while most sub-Saharan African countries have legislation permitting compulsory licensing, these laws do not always incorporate the full range of grounds to authorise such licences.[66] The same is true in Latin American countries,[67] and in at least some countries in Asia.[68] Perhaps more importantly, many developing countries lack clear local guidelines for the issuance of compulsory licences, and have no mechanism to work out adequate remuneration or even appeal periods against the issuance or rejection of the licences. The Eastern Mediterranean Region [69] countries offer a clear demonstration of such a case. Despite some prevalence of disease epidemics in the region,[70] none of the region's member states – comprising over 22 developing and least developed states – have any guidelines for the issuance of compulsory licences, and unsurprisingly, none has thus far issued any such licence.[71]

Less information is available about the legal frameworks for proceedings opposing or revoking patents, but it is likely that legal frameworks here too are often insufficient. The majority of countries in Southern Africa lack legislation forbidding patents on second medical uses, for example.[72] A recent study that considered legislative frameworks in India, the Philippines, Mexico, Brazil, and Thailand concluded that the latter three countries had taken almost no advantage of limits on the scope of patentability.[73] While all but Mexico permitted pre-grant oppositions or observations, without limits on the scope of what is patentable, it will be difficult to deploy patent oppositions to good effect for public health. Similarly, if countries do not facilitate oppositions to patents, it will also be difficult to effectively enforce limits on the scope patents.

The lack of supportive legal framework in so many countries can itself be attributed to further challenges. Some of these include the lack of coordination at the national level between ministries, or conflict between ministries of finance and trade (stemming, for example, from fear of loss of revenues) and ministries of health. Another important influence

---

65 Deere, C (2008), *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*

66 See Avafia, T et al (2006), *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; WIPO, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, CDIP/5/4. (2010).

67 ICTSD, *Has the Implementation of TRIPS Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation that Favors Public Health?* 82 Bulletin of the World Health Org. No. 11 (Nov. 2004). For more on efforts to use compulsory licensing in Columbia see the submission made by Germán Humberto Rincón Perfetti, Columbia for the Latin America Regional Dialogue of the Global Commission on HIV and the Law.

68 See, e.g., Deere, C (2008), *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* at p. 82.

69 The EMRO region encompasses the following countries: Afghanistan, Bahrain, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Pakistan, occupied Palestinian territory, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates, and Yemen.

70 Egypt provides an example in this regard. According to WHO, *"Egypt has a very high prevalence of hepatitis C virus (HCV) and a high morbidity and mortality from chronic liver disease, cirrhosis, and hepatocellular carcinoma. Approximately 20% of Egyptian blood donors are anti-HCV positive. Egypt has higher rates of HCV than neighbouring countries as well as other countries in the world with comparable socioeconomic conditions and hygienic standards for invasive medical, dental, or paramedical procedures. The strong homogeneity of HCV subtypes found in Egypt (mostly 4a) suggests an epidemic spread of HCV."* See http://www.who.int/csr/disease/hepatitis/whocdscsrlyo2003/en/index4.html.

71 El Said, M (2010), *Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region* (WHO and ICTSD), available at http://www.emro.who.int/publications/Book_Details.asp?ID=1081;

72 See Osewe, P ET AL (2008), *Improving Access to HIV Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights Flexibilities*, World Bank. at p. 12. While this report concluded that no sub-Saharan African country implemented restrictions of this sort, as of 2008, at least one has done so. See Section 3(1)(v) Zanzibar *Industrial Property Act* of 2008 (forbidding patents on new uses or forms of products), available at http://www.zanzibarassembly.go.tz/documents/acts.php.

73 Amin, T (2010), *Re-visiting the Patents and Access to Medicines Dichotomy: An Evaluation of TRIPs Implementation and Public Health Safeguards in Developing Countries*, in Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines (Aginam, O, Harrington J & Yu PK eds., 2010).

on local legal frameworks is resource limitations and continued pressure from information-exporting countries to limit the use of flexibilities.[74]

B. Resource Constraints and Limited Coordination

The use of TRIPS flexibilities requires not only a supportive and coherent legal framework but also administrative and technical resources and expertise. Compulsory licensing is the simplest flexibility – although often also the most politically contentious – to deploy in an administrative sense, requiring only an assessment of relevant patent status, negotiations with patent holders, and a decision regarding remuneration. Nonetheless, many countries have had difficulties managing the process. For example, Malawi invoked the Doha Declaration when it sought to use the combination ARV Triomune (stavudine, lamivudine and nevirapine), but did not take legal action to override the local patents before importing the drug. While the patent holder did not in that case use its legal power to prevent the importation, these situations are precarious for self-evident reasons.[75] The use of the judicial remedies flexibility requires sensitisation of the judiciary, a matter that has received almost no attention, except from industry groups which have supported judicial training programmes that are likely supportive of the private interests of these parties.

The challenges of resources and technical expertise are much more acute where patent offices are involved. Few patent offices in developing countries have the resources to consistently and accurately scrutinise patent applications, (particularly if countries join the Patent Cooperation Treaty,[76] because this tends to dramatically increase the number of patent applications received).[77] For example, Ghana did not permit patent protection for pharmaceuticals before 1992, yet did not object when African Regional Intellectual Property Organisation (ARIPO) granted a patent to Pfizer for azithromycin. As a result, the patent holder and third parties *"erroneously believed that there was a valid patent in force in Ghana, although the grant was void from the beginning."*[78]

Limits on the scope of patentability are difficult to apply with accuracy. For example, there is evidence that even in India, which enjoys relatively high levels of scientific training and patent expertise, patents are being granted that do not meet the requirements of Section 3(d) of its Patents Act.[79] Patent opposition proceedings can help matters, but require sophisticated and technically skilled participants. Few countries have the kind of vibrant generic industry that India enjoys, and few NGOs currently have the capacity or resources to engage in patent oppositions. It is also typically very expensive, difficult, and time-consuming to simply identify relevant patent applications or patents at the country level, and thus to identify where oppositions may be needed.[80] Some cooperation across borders has occurred, as when activists in Brazil worked with Indian activists to launch a successful opposition to a patent on the important ARV tenofovir.

More South-South cooperation, between not only public health advocates but also patent examiners, is needed before flexibilities related to patent quality can be deployed more broadly. A welcome example of the latter is the International Policy Centre for Inclusive Growth's dialogue bringing together specialists, policy makers, researchers and civil society groups from India, Brazil, and South Africa (IBSA) to discuss key issues for the promotion of inclusive growth. The process produced several recommendations in the area of health innovation, IP and access to essential medicines including co-operation between the patent offices in the IBSA countries to stop awarding frivolous patents; consultation between IBSA countries on bilateral processes including free-trade agreements; sharing information on cost effectiveness analyses undertaken by the three countries; and collaboration in R&D especially on priority and neglected diseases.[81]

South-South coordination is also important as a counter-weight to technical assistance that has historically produced programmes and model laws that do not encourage the use of TRIPS flexibilities. Important efforts led by NGOs,

---

74 For a description of attempts to issue compulsory licences in Columbia see the submission made by David Alba, Comunicación Positiva, Columbia for the Latin American Regional Dialogue of the Global Commission on HIV and the Law."

75 Osewe, P ET AL (2008), *Improving Access to HIV Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights Flexibilities*, World Bank at p. 14; see also Lewis-Lettington R, & Munyi, P, *Willingness and Ability to use TRIPs Flexibilities: Kenya Case Study*, DFID Issue Paper 39 (September 2004) (discussing the need for resources and technical assistance before effective use of compulsory licensing and government use can be made in Kenya).

76 The PCT is an international patent treaty, concluded in 1970. It facilitates applications for patents around the world by providing applicants with a process to preserve their right to file patents in all PCT countries by filing a single PCT application in a receiving office, and by diminishing the administrative requirements of local filing in other ways.

77 Kapczynski, A (2009), *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. at 1621.

78 Osewe, P ET AL (2008), *Improving Access to HIV Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights Flexibilities*, World Bank at p. 14

79 Sampat, BN (2010), *Institutional Innovation or Institutional Imitation? The Impacts of TRIPs on India's Patent Law and Practice*, available at http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_6_10/wipo_ip_econ_ge_6_10_ref_sampat.pdf

80 As a result, such tools may not be sufficient in themselves, highlighting the need for other complementary tools, including post-grant remedies and unfair competition law and policy.

81 For more see http://www.ipc-undp.org/ipc/PageIBSA.do?id=208

developing and least-developed states have been made in recent years at several international organisations including the World Intellectual Property Organisation to change the tenor of technical assistance so that it is country-driven and development oriented.[82] A shift in the culture of technical assistance is important, but more integrated South-South coordination and exchanges would also be needed in order to generate and develop a culture of sophisticated patent examiners who can accurately apply patent laws that would, if full flexibilities were adopted, be different in letter and orientation than those in the countries that currently provide the bulk of technical assistance.

One successful example of South-South coordination that has helped address the resource and technical barriers to effective use of flexibilities is pooled procurement.[83] By creating a regional body to share the work of identifying needed medicines, assessing patent status, negotiating price, and facilitating compulsory licences if needed, countries can pool administrative and technical resources, and significantly reduce the price of medicines. In 2002, for example, the Organisation of Eastern Caribbean States saved approximately 44% through joint procurement compared with the prices that individual countries paid.[84] The Gulf Cooperation Council Group Purchasing Programme which has been in place since 1978 has also provided its member states with more than 30% cost savings.[85]

C. Continued Unilateral Pressure

Countries may also be reluctant to fully deploy the flexibilities allowed to them under TRIPS because of pressure from countries with big IP industries. The US Special 301 process offers the most salient example. It was established by the 1988 *Omnibus Trade and Tariffs Act*, and under it, the US Trade Representative (USTR) must identify "priority countries," namely those that *"have the most onerous or egregious acts, policies, or practices"* that *"deny adequate and effective intellectual property rights,"* or *"deny fair and equitable market access to United States persons that rely upon intellectual property protection."*[86] *The USTR is permitted, by statute, to retaliate against such countries by imposing tariff or import restrictions, by suspending certain preferential trade agreements, or through other measures within the President's power.*

The WTO's Dispute Settlement Understanding (DSU) forbids retaliation outside of the WTO process,[87] *and the consistency of the Special 301 process with the DSU is a matter of dispute.*[88] *Notably, since joining the WTO, the US has only rarely used the Special 301 process to retaliate against any WTO member on the basis of purported failures of IP protection.*[89] *However, the US has regularly deployed its "watch list" to monitor other countries' intellectual property activities*, and to signal to countries its displeasure, as well as the possibility that trade sanctions or withdrawal of preferences may follow.

In 2010, for example, the US placed Thailand on the priority watch list of the Special 301 Report, for Thailand's reluctance to amend both its intellectual property regulations and customs law in line with the US demand to require customs officials to seize medicines if they bear a "confusingly similar" trademark to a medicine marketed by a multinational drug company in the country, and also to introduce *ex officio* enforcement measures.[90] In 2007, the difficulty pharmaceutical

---

82 In October 2007, the WIPO General Assembly adopted a set of 45 recommendations to enhance the development dimension of the Organisation's activities, initiating a process referred to as the "WIPO Development Agenda." The recommendations are divided into six clusters aimed towards placing development at the heart of WIPO's activities. For more on the Development Agenda see http://www.wipo.int/ip-development/en/agenda/background.html. In accordance with the Agenda, WIPO initiated an independent External Review in 2010 of WIPO's Technical Assistance in the Area of Cooperation for Development (led by Carolyn Deere and Santiago Roca). The Review seeks input from relevant stakeholders regarding their experience and views on the impact, orientation, cost-efficiency, management and coordination of WIPO technical assistance between 2008-2010.

83 The Eastern Caribbean Drug Service (ECDS)—now called the "Pharmaceutical Procurement Service"— was set up in 1996. Before its establishment, individual countries managed their own procurement processes, with wide price differentials. ECDS set up a system to pool needs, selectively and competitively manage the bidding process, guarantee payment, and (most importantly) monitor supply and quality. In the first year of its operation, ECDS managed to lower pharmaceutical expenditure by an impressive 44 % on average. Quick JD ed. 2nd ed., (1997), Management Sciences for Health & WHO, Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals.

84 Kerry VB & Lee K (2007), *TRIPS, The Doha Declaration and Paragraph 6 Decision: What Are The Remaining Steps for Protecting Access to Medicines?* 3 Global Health 3.

85 See DeRoeck D et al (2006), *Regional Group Purchasing of Vaccines: Review of the Pan American Health Organization EPI Revolving Fund and the Gulf Cooperation Council Group Purchasing Programme*, 21 Int'l J. Health Planning & Mgmt. 23; Khoja T & Bawazir, S (2005), *Group Purchasing of Pharmaceuticals and Medical Supplies by the Gulf Cooperation Council States*, 11 Eastern Mediterranean Health J.; see also WHO, Multi-Country Regional Pooled Procurement of Medicines, 2007, Meeting Report, Geneva, WHO/TCMMPM/2007.1.

86 Section 2242(b)(1)(A), 19. U.S.C.

87 According to Article 23.1 of the DSU, *"[w]hen Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements . . . they shall have recourse to, and abide by, the rules and procedures of this Understanding."* Understanding on Rules and Procedures Governing the Settlement of Disputes Article 23.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994); see also Panel Report, United States—Sections 301–310 of the *Trade Act of 1974*, ¶ 7.96, WT/DS152/R (Dec. 22, 1999).

88 Kapczynski, A (2009), *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector,* 97 Cal. L. Rev.at 1629-30; Panel Report, *United States—Sections 301–310 of the Trade Act of 1974*, WT/DS152/R (Dec. 22, 1999).

89 For example, in 1998, the US withheld benefits under the Generalized System of Preferences to South Africa in retaliation for the law on parallel importation that it passed. See Sell, S (2003), *Private Power, Public Law: The Globalisation of Intellectual Property Rights*.

90 Oxfam (2011), *Eye on the Ball: Medicines Regulation – Not IP Enforcement – Can Best Deliver Quality Medicines*, 143 Oxfam Briefing Paper, *available*

companies had in obtaining patents on "methods of treatment or diagnosis" in China was cited in USTR's Special 301 Report, as part of the reason China remained on the priority watch list.[91] Such threats, as well as warnings issued by the US and EU that the use of flexibilities will undermine investment in a country (which are unsubstantiated by evidence) seem to have significant influence in some ministries of trade and finance, leading them to advocate against the use of flexibilities at the local level.

Pressure from national governments has been supplemented by pressures directly from drug companies. For example, when Thailand issued a compulsory licence in 2007 on lopinavir/ritonavir (marketed as Kaletra), the holder of the licenced patent, Abbott announced that it was withdrawing multiple applications to obtain marketing approval for new drugs in Thailand, including a heat-stable version of Kaletra, as a response.[92]

III. Post-TRIPS Legal Threats

Finally, the use of all of the flexibilities stressed here is threatened by the push for higher standards and strengthened levels of intellectual property protection that continued after the signing of TRIPS in 1994. Here, we focus on two post-TRIPS legal threats: those emanating from bilateral or regional Free Trade Agreements (FTAs) between the US or Europe and developing countries,[93] and the recent "IP enforcement agenda," as represented by seizures of legitimate generic medicines that were in transit through Europe, and the negotiations of the Anti-Counterfeiting Trade Agreement.

A. Free Trade Agreements as a Barrier to Deployment of TRIPS Flexibilities

Under the guise of free trade and economic cooperation, the United States and European Union have actively negotiated and signed comprehensive bilateral trading arrangements with developing countries with chapters containing standards and commitments that go beyond those stipulated under TRIPS. The demand for these agreements, which generates so-called "TRIPS-plus" obligations, comes from multinational industries that depend heavily on intellectual property, such as big pharma and Hollywood, which strongly influence the trade policies of their host countries. In the area of public health, TRIPS-plus obligations restrict the aforementioned flexibilities and may severely impair access to medicines.[94]

Some existing and proposed FTAs put sharp restrictions on the use of flexibilities related to patent scope and quality. FTAs may forbid countries, for example, from excluding patents on new uses or methods of treatment.[95] More broadly, they may be forbidden from imposing *any* limits on the scope of patentability unless those limits derive from the need to prevent commercial exploitation of inventions, where such commercial exploitation is a threat to *"ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment."*[96]

FTA negotiations have also been used to restrict flexibilities used to promote patent quality. For example, the US-Morocco and US-South Korea FTAs both forbid pre-grant patent oppositions.[97] FTAs have been less aggressive with respect to the flexibilities inherent in countries' abilities to define inventive step and utility for themselves, though some have sought to establish constraints here too.[98]

Existing FTAs also restrict the grounds on which countries may grant compulsory licences. While TRIPS leaves countries discretion to decide when and why to grant such licences, FTAs may restrict the grounds, for example to public non-

at http://www.oxfam.org/en/policy/eye-ball. For a detailed discussion about the use of USTR's Section 301 in relation to Thailand see the submission made by Nimit Tienudom, AIDS Access Foundation, Thailand, for the Asia-Pacific Regional Dialogue of the Global Commission on HIV and the Law.

91 For a general description of the Chinese IP structure see the submission made by Hu Yuanqiong, China Access to Medicines Research Group, China for the Asia-Pacific Regional Dialogue of the Global Commission on HIV and the Law.

92 *Abbott to Stop Launching New Drugs in Thailand in Response to Country's Compulsory License for Antiretroviral Kaletra*, Medical News Today, Mar. 16, 2007, *available at* http://www.medicalnewstoday.com/articles/65274.php.

93 Such arrangements have taken various shapes under a variety of names, including association agreements (AAs), free trade agreements (FTAs), European Countries Free Trade Agreements (EFTAs), economic partnership agreements (EPAs), etc. We will call all of these "FTAs" for ease of reference.

94 Gustav describes the strong objections to these agreements, stating that *"The impacts of such trade agreement not just [in] India and other developing countries cannot be underestimated. As such, protests against the agreement have risen in different regions in India and the world. The Indians called the agreement 'trading away our lives'; the Nepalese condemned the EU effort to take benefit[s] from developing countries and enrich their pharmaceutical company; the Indonesians called the agreement 'a genocide'; the Latvians marched and critics their leaders for agreeing to such agreements; the Thais stood up and shouted 'EU! go away!' to stop EU to take their medicines away"*. See submission made by Rico Gustav, APN+ for the Asia-Pacific Regional Dialogue of the Global Commission on HIV and the Law.

95 See, e.g., US-Morocco FTA, Article 15.9(2); draft US proposed TPP chapter (leaked, available at http://keionline.org/node/1091).

96 US-Morocco FTA, Article 15.9(1).

97 FTA between U.S. and Republic of Korea, Article 18.8 § 4, p. 18-17; FTA between U.S. and Morocco, Article 15.9(5).

98 For example, Article 15.9 (11) of the US–Morocco FTA states: *"Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility."*

commercial use, anti-competitive practices and national emergencies.[99] The impact of such restrictions may be severe. For example, a World Bank research projected that if the US and Thailand had signed the proposed FTA between the two states, the use of compulsory licensing that could have reduced the cost of second-line ARVs by 90% in Thailand would have been severely restricted. The World Bank concludes that issuing compulsory licences for second-line ARVs would represent a saving of USD$3.2 billion for the Thai national health budget over 20 years.[100]

Another important obstacle that FTAs present comes in the guise of data exclusivity requirements. TRIPS does not oblige member states to provide exclusive rights specifically to the originator of data but rather calls for the protection of "undisclosed data" against "unfair" and "non-commercial use" of these data. US and EU bilateral agreements are demanding data exclusivity protection that restricts the use of clinical test data on pharmaceutical products by national drug regulatory authorities for the approval of generic medicines for a certain period of time (ranging between five to eight years under US FTAs and reaching up to 11 years under the EU FTAs). Data exclusivity protection prevents generic producers from relying on such data in the course of establishing the efficacy and safety of their products, in some cases effectively requiring unethical and expensive repetition of clinical trials hence delaying the entry of generics into the market. Data exclusivity may apply even if no patent protection exists and may also curb the exercise of compulsory licensing.[101]

For instance, an Oxfam report found that data exclusivity provisions in the US–Jordan FTA resulted in delaying the introduction of generic drugs into the Jordanian market, increasing the costs of medicines as a result. This was a key factor behind the increase in the prices of medicines that the country experienced in recent years.[102] More recently, it has been reported that, *"when Guatemala introduced data exclusivity due to its USFTA, instead of paying $0.01 for the generic version of [a] medicine, the data exclusivity monopoly allowed the IP owner to charge $84.56 for the same medicine."*[103] *Fears are also expressed about the negative impact that the proposed FTA between the EU and India may have on the supply of generics and medicines worldwide if the agreement includes provisions on data exclusivity.*[104] *The USTR has also repeatedly listed under the Special Section 301 of the Trade Act* countries that do not recognise test data protection under their national law.

Finally, FTAs also include a host of other TRIPS-plus measures that can substantially threaten access to medicines. Such agreements often trade away health considerations in exchange for market access and tariff benefits, and they are often negotiated behind closed doors and lack transparency. Some FTAs relinquished the transition periods available to some developing countries,[105] while other FTAs require, for example, that patent terms be extended to compensate the owner for *"unreasonable curtailment of the patent term as a result of the marketing approval process."*[106] *A recent study in Thailand projected that if a 10-*year patent extension had been granted, as proposed under the Thai-US FTA, medicine prices would have increased in Thailand by 32%.[107]

B. A Growing Danger: Conflicts Between IP "Enforcement" and Health

A new threat to access to medicines has emerged over the past few years: a push for forms of "IP enforcement" that conflate IP enforcement and drug quality control and thereby threaten the integrity of the generic supply chain.

The IP enforcement agenda is complex, and emerging in a variety of contexts, including the World Health Organisation, the World Customs Union, Interpol, economic partnership agreements (EPAs), FTAs, EU regulations, and at the national level, for example, in recent East African "anti-counterfeiting" bills. Given the limited scope of this paper, we focus on three trends that are of particular relevance for those concerned with access to medicines.

C. Border Measures: A New Threat to the Generic Supply Chain

99 See US-Jordan FTA, Article 4.20.

100 See Revenga A, et al (2006), *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*, World Bank.

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

102 The report also found that TRIPS-plus rules, particularly data exclusivity, independently prevent generic competition for 79% of medicines launched by 21 multinational pharmaceutical companies since 2001. Additional expenditures for medicines with no generic competitor, as a result of enforcement of data exclusivity, were between USD$6.3 million and USD$22.04 million. Oxfam International (2007), *All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines*, Oxfam Briefing Note, *available at* http://www.oxfam.org/en/policy/bp102_jordan_us_fta

103 See submission made by Sangeeta Shashikant, Third World Network, Switzerland for the High- Income Countries Dialogue of the Global Commission on HIV and the Law.

104 Love, J (2011), *The Production of Generic Drugs in India: A New Trade Agreement with the EU Would Hinder Access to Drugs in Developing Countries*, 342 BMJ 1694. See the submission made by DNP+, India for the Asia-Pacific Regional Dialogue of the Global Commission on HIV and the Law.

105 See for instance the EU-Jordan Association Agreement.

106 See for example the US–Jordan FTA, Article 4.23(a) and the US–Morocco FTA, Article 15.10.3

107 See Kessomboon N et al (2010), *Impact on Access to Medicines From TRIPS-Plus: A Case Study of Thai-US FTA*, 41 Southeast Asian J. Tropical Meds. & Pub. Health 667.

Generic medicines often must cross national borders in order to reach those who need them, so what happens at the border is important to the integrity of generic supply chains. Under TRIPS, there was little cause for concern about the potential conflict between border measures and access to medicines, because TRIPS only requires border measures apply to "pirated" copyright and counterfeit trademark goods (the latter applying effectively only to deliberate fakes).[108] TRIPS also only requires that border measures be applied to imports, and does not require "ex officio" action (i.e. action on the sole initiative of customs officials, without first receiving an accusation from a rights-holder).[109] TRIPS also reflects a concern that border measures can be abused, codifying a requirement that enforcement measures *"be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."*[110] *The Agreement also includes specific safeguards at the border, such as the entitlement to quick evaluation or release of seized goods, and the requirement that officials have the authority to require that accusers post a "security or equivalent assurance" to compensate defendants and prevent abuse.*[111]

The potential of border measures to pose a threat to access to medicines came to light only recently, most prominently in 2008, when European customs authorities seized or temporarily detained at least 19 sizable shipments of Indian and Chinese generic medicines (including medicines to treat cardiovascular disease and HIV/AIDS) en route to other developing countries. These medicines were allegedly seized because they infringed intellectual property rights, under the recently adopted *EU Customs Regulation 1383/2003*.[112] This regulation has very broad scope, applying not only to trademark "counterfeiting," but also to patents and simple trademark infringement (e.g. where a product is not a deliberate fake, but may bear a confusingly similar mark to a registered mark, e.g. "Amoxyl" and "Limoxyl"). It has also been interpreted to authorise the application of European law not only to imports, but also to goods that are merely in transit (that is, not intended for use in Europe but merely passing through its airports or other ports). The generic shipments mentioned were thus seized on the grounds that they violated patents and trademarks in Europe, despite the fact that they were destined for developing countries where they infringed no IP rights. The result was a disruption in the supply chain of legitimate generics, including HIV/AIDS medicines, and likely increased cost due to changes in shipping patterns.[113]

International criticism of the EU customs regulations placed pressure on the EU Commission to consider revising them. In 2010, the Commission initiated a public consultation with the aim of submitting a proposal that would replace *Council Regulation No 1383/2003*.[114] In 2010, India and Brazil also initiated a WTO dispute against the EU measure.[115] Recently, they announced that an agreement had been reached that would satisfy India's concerns and enable it to withdraw its WTO complaint, although the agreement would require approval of the European Parliament. Brazil has yet to reach an agreement with the EU and has indicated that it is determined to press the dispute until the EU withdraws such regulations.

The expansion of border measures beyond what is required in TRIPS is, however, already well-established in FTAs, EPAs, and within international initiatives such as the World Customs Organisation's "Secure" project. In each of these domains, we have seen a push to extend border measures not only to imports, but also to exports and in-transit goods.[116] Some such initiatives also expand the scope of border measures, for example to include simple trademark infringement, and sometimes patents.[117] The final draft of the recently negotiated Anti-Counterfeiting Trade Agreement (ACTA) requires signatories to extend border measures to exports, and earlier drafts required application to in-transit goods.[118] ACTA drafts also included the requirement that border measures be applied to patents, and the completed draft appears to

---

108 TRIPS Article 51 & Kapczynski, A (2009), *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector,* 97 Cal. L. Rev. 1571, 1597.

109 *Ibid*. at Articles 51 & 58.

110 *Ibid.* at Articles 41.1.

111 *Ibid*. at Articles 53 & 55.

112 EU Regulation 1383/2003, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:196:0007:0014:EN:PDF.

113 In its request for consultation under the WTO Dispute Settlement, India stated that the EU's measures where inconsistent with a number of provisions of the GATT 1994 and of the TRIPS Agreement including *"Articles 41 and 42 of the TRIPS Agreement because the measures at issue, inter alia, create barriers to legitimate trade, permit abuse of the rights conferred on the owner of a patent, are unfair and inequitable, unnecessarily burdensome and complicated and create unwarranted delays."* Request for consolation by India, *EU and a Member State: Seizure of Generic Drugs in Transit*, WT/DS408/1G/L/921IP/D/28, May 19, 2010.

114 Consultation Paper Review of EU legislation on Customs Enforcement of Intellectual Property Rights, available at http://ec.europa.eu/taxation_customs/common/consultations/customs/ipr_2010_03_en.htm

115 WTO, India- European Union and a Member State Dispute — Seizure of Generic Drugs in Transit, WTO, DISPUTE DS408, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm

116 World Customs Organisation, Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE), Standard 1; see also Economic Partnership Agreement Between The Cariforum States, Of The One Part, And The European Community Article 163, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:289:0003:1955:EN:PDF, US - South Korea FTA, Article 18.1(22).

117 See WCO SECURE, *ibid.* Standards 1 & 3 (urging customs enforcement to incorporate not only copyright and trademark, but other areas of IP too); US - South Korea FTA, Article 18.1(19) (incorporating simple trademark infringement).

118 *Anti-Counterfeiting Trade Agreement* (Dec. 3 Draft), Article 16(1); ACTA, Public Predecisional/Deliberative Draft: April 2010, Article 2.6.

require that they be extended to trademark infringement.

The expanding domain of border measures presents a substantial risk to supply chains for generic medicines. The application of border measures to goods in transit is troubling because it threatens the principle of national determination of IP law, by reaching out to affix the law of the nation of transit to goods that are destined for another country. The EU cases provide evidence that this risk is real, and the risk becomes more acute as more countries sign on to agreements that require the application of in transit measures. *Ex officio* authority for customs agents presents the risk of excessive discretion and selective enforcement; this too could lead to supply disruptions of legitimate essential medicines. Customs officials do not have the training to adequately apply patent law or the law of trademark infringement. The introduction of more authority for border agents will lead to a shift in the cost of IP enforcement from rights-holders to the state, with undesirable budgetary implications for developing countries. Initiatives like ACTA that require more intrusive border measures do not require the same safeguards that are incorporated into TRIPS, raising the risk the rights-holders will come to see border measures as a convenient, rapid means to disrupt the legitimate business activities of their generic competitors.

As countries address the potential threat of IP enforcement measures to public health, current experience suggests that several principles are of particular importance:

- Border measures should not be applied beyond willful trademark counterfeiting and copyright piracy. Customs officials lack the expertise to evaluate claims of patent infringement and "confusingly similar" trademark infringement.
- Border measures should be applied to imports, but not to in transit measures, because the latter generates conflicts with national autonomy over IP law.
- Countries should reject international agreements that require ex officio authority for customs, and consider carefully the implications of applying such measures at the national level.
- Countries should implement the affirmative safeguards against abuse outlined in the TRIPS Agreement, such as measures for securities to indemnify the accused.

Where countries make resisting the enforcement agenda's implications for medicines a priority, they have had success. Public outcry and opposition to ACTA drafts by many developing countries and civil society groups resulted in the removal of patents and in-transit measures from the border measures section. The Andean countries successfully refused to include additional border measures in their proposed FTA with the EU. India has declared that it will not accept any border measures in its FTA currently under discussion with the EU, although negotiations are still underway.

D. Constraints on Remedies

The enforcement agenda has also taken aim at the remedial flexibilities that countries enjoy under TRIPS. For example, TRIPS is quite permissive with respect to whether courts must issue injunctions or can adopt other remedies in the event of patent infringement (as discussed above), and also includes no specific commitments about how countries must calculate awards for damages. The ACTA negotiations brought attention to the importance of such remedial flexibilities, because early drafts targeted these kinds of flexibilities specifically. The final draft of ACTA's "civil enforcement" chapter expands requirements for heightened damages and injunctive authority for courts, but excludes patents from this section of the Agreement.[119] Should such provisions reappear, for example in Trans-Pacific Partnership Agreement[120] or FTA negotiations, they will raise a substantial concern. It is finally worth noting here that TRIPS does not require that criminal liability be applied to either patents or simple trademark infringement, and this too is a form of flexibility that countries may wish to preserve, in light of the potential chilling effects of such threatened liability for legitimate generic manufacturers.

E. Conflation of IP Enforcement and Quality Assurance

The enforcement agenda has also been characterised by a dangerous tendency to equate IP enforcement with drug quality assurance. IP enforcement itself cannot be understood as a measure that enhances public health. Indeed, some of the measures that are imposed under the enforcement agenda are an affirmative threat to access to medicines, as described above. While some counterfeit medicines are of substandard quality, the same is true of branded and patented products. To ensure the integrity and coherence of the oversight of drug quality, safety, and efficacy, these

119 See ACTA (Dec. 3 draft) Article 9.

120 There have been several formal rounds of Trans-Pacific Partnership Agreement negotiations since 2010. They have involved officials from Australia, the United States, New Zealand, Chile, Singapore, Brunei, Peru, Vietnam and Malaysia. For a discussion of the TRIPS-Plus provisions and Malaysia's participation in the TPP discussion see the submission made by Meena Raman, Consumers Association of Penang, Malaysia for the Asia-Pacific Regional Dialogue of the Global Commission on HIV and the Law. Also see the submission made by Low Cheap Fod (Edward), MTAAG+, Malaysia for the Asia-Pacific Regional Dialogue of the Global Commission on HIV and the Law.

issues must be separated from issues of IP enforcement. Attempts to address substandard medicines should be led by well-resourced and trained drug regulatory agencies, not IP enforcement officials.

Although this understanding is well accepted in public health communities, it has not been reflected in recent domestic attempts to increase IP enforcement. Particularly notable here are the "anti-counterfeiting" bills that have been adopted or proposed in East Africa. In 2008, with support and applause from the multinational pharmaceutical industry, Kenya enacted a law that purported to address drug counterfeiting, but in fact dramatically expanded IP protection. The most extreme measure in the bill obliged local enforcement authorities to take measures against generic medicines that are lawful in the Kenyan market on the basis that they infringe patents in *other* countries. This presents an evident threat to the local availability of legitimate generic medicines. As Nyachae explains, *"the enforcement and application of the Anti-Counterfeit Act (No. 13 of 2008), particularly sections 2, 32 and 34, will endanger the lives of Kenyan citizens afflicted with HIV and AIDS, as they will be arbitrarily denied access to affordable and essential drugs and medication necessary for the fulfillment of the rights to life and human dignity that are enshrined in Articles 26, 28 and 43 of the Constitution of the Republic of Kenya"*.[121] Similar laws have been promoted in a number of other African and Asian countries including Tanzania, Uganda,[122] Malawi, Zambia and Thailand, and if successful would have far reaching implications for these countries' national public health and access to medicines regimes.[123]

Emerging attempts to resist the conflation of drug quality and IP enforcement and to turn back the provisions of these so-called "anti-counterfeiting" bills have met with some success. A 2009 challenge against the Kenyan law submitted by people living with HIV/AIDS before Kenya's Constitutional Court argues that the law undermines access to affordable generic ARVs, and therefore infringes upon their constitutional right to life. In April 2010, the Court suspended the law's application to medicines, pending its final decision. In its decision, the Court acknowledged that the application of the law to medicines could lead to irreparable harm, including loss of life. More recently, the close collaboration between Thai civil society groups and health authorities thwarted the attempt of industry to pressure the ministry of commerce to amend its customs law to introduce anti-counterfeiting measures that would impose restrictions on the use of generic drugs in the country.[124]

Again, where countries act in concerted fashion, they have been able to deflect this new threat to existing TRIPS flexibilities, but more remains to be done. The conflation of IP enforcement and drug quality assurance, in particular, will be difficult to resist until more comprehensive and better-resourced efforts to ensure drug quality, safety, and efficacy in developing countries, led by drug regulatory agencies, are in place.

IV. Conclusions and Recommendations

After more than 15 years of experience with TRIPS, and in the shadow of the growing number of TRIPS-plus agreements, it is clear that the existing international IP regime undermines access to medicines in developing countries. Tremendous effort has been devoted by governments, advocacy organisations, AIDS activists, and UN agencies, over the years, to creating strategies to protect access to medicines in the context of TRIPS. Much can be done in that regard, as the preceding pages show. But this should not blind us to a simple reality: There is no doubt that a different international regime, one that did not require or encourage developing countries to provide patents for medicines, would result in access to affordable medicines for many more people.

The need to attend to IP barriers drains resources and technical expertise from other priorities, in the context of health systems that are already critically under-resourced. And although developing countries expected both innovation and an end to unilateral pressure in exchange for their acquiescence to TRIPS, neither has materialised in sufficient measure to compensate for the ill effects of strong IP standards.

The time has come for a reassessment of the overall structure of the system, and for new thinking about avenues for change. But we should not be naïve about the difficulty involved in changing the existing system, and therefore must at the same time, work to ensure that the conditions for robust use of TRIPS flexibilities are in place in developing countries. Chronic shortages of capacity and technical expertise must be addressed, via technical assistance that is directed from the South rather than the North. Even with more expertise, flexibilities cannot be effective unless the tide of TRIPS-plus

121 See submission made by Jacinta Nyachae, AIDS and Law Project, Kenya for the Africa Regional Dialogue of the Global Commission on HIV and the Law.

122 In relation to the Ugandan Anti-counterfeiting Bill, Kentutsi states that, *"the Bill contains various ambiguities, which if misinterpreted or abused, would be detrimental to the ongoing local and international efforts to ensure access to essential medicines for all Ugandans. This is because the Bill greatly undermines access to low-cost generic medicines by branding them counterfeits."* See the submission made by Stella Kentutsi, National Forum of People Living with HIV/AIDS Networks in Uganda (NAFOPHANU), Uganda for the Africa Regional Dialogue of the Global Commission on HIV and the Law.

123 Oxfam (2011), *Eye on the Ball: Medicines Regulation – Not IP Enforcement – Can Best Deliver Quality Medicines*, 143 Oxfam Briefing Paper, *available at* http://www.oxfam.org/en/policy/eye-ball. at p. 90.

124 *Ibid*.

agreements and unilateral pressure is stemmed.

As such, we make the following recommendations:

1. **An independent commission should be convened that proposes amendments to the TRIPS Agreement.**

   Such a Commission should deliberate about what legal changes could ensure that the world's trade regime does not burden or restrict access to medicines in any way. Proposals for reform might, for example, exempt medicines from TRIPS, and make it a trade violation to enter into agreements or use threats of trade sanctions to encourage developing countries to increase IP protection in the area of pharmaceuticals. (These efforts should be paralleled by efforts to create global cost-sharing mechanisms for R&D that delink the cost of medicines from R&D incentives, and commit revenues particularly to diseases of the poor.) The Commission could also be asked to examine the question of the consistency of continued unilateral measures, such as the Special 301 process, with WTO law and human rights norms.

2. **Developed countries should:**

   a. **Commit to an indefinite moratorium on increased international IP standards, at least as regards medicines.**

      The negative consequences for human health of increased international IP standards are now clear. As a result, developing countries should stop seeking to impose higher IP obligations on developing countries, where those obligations could affect medicines.[125] Such obligations are sometimes imposed in free trade agreements, and at other times via plurilateral initiatives (such as ACTA) that may influence the availability of medicines in developing countries either indirectly (for example via interruption of shipping routes), or directly (if developing countries are involved, or eventually pressured to join).

   b. **Credibly commit to not using unilateral threats (including "watch-lists") to pressure or encourage developing countries to apply more restrictive IP rights in the context of medicines.**

      Unilateral pressure discourages legitimate use of TRIPS flexibilities, and in some guises is inconsistent with WTO law. Little systematic progress can be made in the implementation and use of TRIPS flexibilities in developing countries, and particularly the more vulnerable ones, if such practices continue.

   c. **Support revisions to the August 30th agreement, with a view to making it more user-friendly and easily accessible to developing countries.**

      The existing measure addressing the problem posed by Article 31(f) for countries with limited manufacturing capacity does not solve the problem. These countries should be able to make use of compulsory licences in a manner that is no more onerous than the ordinary Article 31 of TRIPS process as available to countries with manufacturing capacity. Developed countries should also adapt their local law to ensure that generic medicines can be produced within their own borders for export to countries with limited manufacturing capacity.

   d. **Exempt all least-developed countries from TRIPS-compliance with respect to pharmaceutical products.**

      The existing transition period offered to these countries should be made permanent. Countries should incur no TRIPS obligations with respect to medicines until they move out of least-developed country status.

3. **Developing countries should**

   a. **Adopt robust TRIPS flexibilities into national law as a matter of urgency.**

      Developing countries should incorporate and preserve under national law to the widest possible extent the existing flexibilities available under TRIPS. They should also ensure that these laws are supported by adequate and user-friendly regulations enabling those who wish to utilise such flexibilities at the national level easily. The creative implementation of IP policy should form a vital component of such a process. Spreading awareness nationally about these flexibilities and their use is of equal importance. Finally, countries should coordinate regionally, and in South-South fashion, to ensure that they take advantage of emerging ideas about how to creatively implement TRIPS, and to benefit from the power of counter-harmonisation.[126] When countries adopt

125 IP agreements affect other fundamental rights, such as rights regarding access to information, participation in cultural life, and education, but these are beyond the scope of this paper.

126 Kapczynski, A (2009), *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 Cal. L. Rev. 1571, 1597. at 1639 (describing the benefits of counter-harmonisation, in which developing countries coordinate their legal frameworks to create an alternative to the form of harmonised law promoted by Northern countries).

and utilise similar flexibilities, they can pool expertise and administrative resources, and develop authoritative interpretations of their rights under international agreements.

More specifically, developing countries should:

- Incorporate into their domestic law and utilise provisions on compulsory licensing and government use where cost, supply or other barriers to access to medicines exist. These provisions should take full advantage of the flexibilities afforded by TRIPS.
- Make use of parallel importation, by adopting national exhaustion regimes.
- Adopt explicit limits on scope of patentable subject matter and create legal frameworks that facilitate patent opposition by any interested parties (discussed further below).
- Retain remedial flexibility and encourage that judicial discretion regarding patent remedies be applied in the public interest. The judiciary should be attuned more generally to the important implications of decisions in the area of IP for health and human rights.
- Incorporate under national law additional exceptions to patent law, including but not limited to the "Bolar" exemption and strong research and experimental use exceptions.
- Promulgate and use unfair competition laws that effectively curb anti-competitive IP practices, particularly in the area of access to medicines and public health.
- Least developed countries should take full advantage of the transitional periods that allow them to defer patents on medicines until 2016, and mobilise efforts to make this transitional period permanent.

b. Reject TRIPS-Plus obligations

Concurrently, developing countries should reject legal commitments that reduce TRIPS flexibilities that may arise as a result of bilateral and plurilateral arrangements. Notably, since TRIPS-plus demands are ever-evolving, and vary from one agreement to another, developing countries must remain vigilant and guard against any new demands made during negotiations which may impact public health. A thorough analysis of all IP provisions should be undertaken before their acceptance, and countries should make efforts to include health experts in negotiations about IP. The lack of transparency in FTA and other IP negotiations (such as ACTA) is a significant threat to democratic accountability in these domains. Countries should reject demands for secrecy from trading partners, and ensure that the public, as well as health experts, have meaningful opportunities to participate in the process. Finally, when joining the WTO no new member should be required to adopt TRIPS-plus measures.

TRIPS-plus commitments of the following sort are particularly problematic, and should be rejected:[127]

- Provisions requiring the implementation or extension of data exclusivity protection under national law.
- Restrictions on the right to use compulsory licensing and government use.
- Restrictions on the right to use parallel importation.
- Restrictions on the right to limit the scope of patentability and to implement patent opposition and revocation proceedings.
- Extensions of the term of patent protection beyond what is stipulated under TRIPS.
- Demands which would impose burdensome TRIPS-plus enforcement measures, including *ex-officio* measures at the border; the application of border measures to exports or in transit goods; the application of border measures to patents; and enhanced civil or criminal penalties.
- Provisions stemming from regional patent organisations (such as ARIPO /OAPI) that encourage or require the granting of TRIPS-plus protections to patents.

c. Explore the possibility of concluding South-South trade agreements that codify maximum IP standards and TRIPS flexibilities.

There is increasing interest in using international IP agreements to codify *maximum* rather than minimum

127 This is a non-exhaustive list.

IP standards. Agreements of this sort may be difficult to achieve in multilateral settings, but a coalition of developing countries could lead the way by negotiating a framework agreement together. Such an agreement could act as a mode of counter-harmonisation, setting forth best practices for IP in the area of medicines, and committing signatories to not trade away exceptions and limitations in negotiations with other countries.

d. Act cooperatively to limit the scope of patentability and to ensure patent quality.

Countries must find ways to shape and administer their patent laws in order to increase patent quality, and ensure that patents are limited to inventions of a high degree of innovativeness. More specifically:

- Countries should adopt expansive limits on the scope of patentability, that include limits on patents for new uses of known substances, as well as new forms of known substances. Section 3(d) of India's *Patent Act* offers a potential model. Strict inventive step standards are also important.
- Countries should implement pre-grant and post-grant oppositions and revocation proceedings, with broad standing and no assumption of patent validity, to harness the information and expertise of third parties in the process of patent evaluation.
- Countries should coordinate to make the terms and results of patent examinations, and particularly oppositions, available to other developing country patent offices. A South-South network that shares opposition and examination files would help resource-poor patent offices accurately examine patents, particularly if countries coordinate exceptions and limits to their patent laws, such as limits on the scope of patentability.
- To enable the participation of public health groups and generic companies in patent evaluation, countries must make patents and patent applications more readily accessible, for example through digital databases. Countries should also consider requiring patentees to disclose what patents they hold on a particular drug, upon request by an interested party. Patent status should not be held as a trade secret, and indeed should be conceived of as necessarily public information that the patent-holder is in the best position to provide.

e. Developing countries should build local capacity and technical expertise in patent law, focusing on implications for health.

Developing countries should heavily invest in national capacity building and technical expertise through training programmes and policy briefs for their officials, judges, and stakeholders. Such national programmes should focus on applying IP with a pro-development approach, and encouraging the use of flexibilities with the view of preserving public health and enhancing access to medicines. Countries should also strengthen the technical and personnel capacity of negotiation teams who are involved in IP discussions in various bilateral, regional and multilateral fora.[128] Developing countries should carefully consider the contours of technical assistance offered to them, and reject any such assistance that is not specifically tailored to their local law, and designed to meet national policy objectives. Such assistance may be free in the short term, but costly in the long term.

Regional and South-South cooperation in this area is vital. Countries should explore the various options beyond the IP regime in order to reduce the prices of drugs hence increase access to medicines. Options such as the consideration of joint procurement arrangements should be encouraged, because they permit countries to pool resources when determining where action is needed, weathering political pressure, and in obtaining volume discounts for drugs purchased.

Within this context, South-South technical assistance also is essential. In particular, developing countries including India, Brazil and Thailand that have managed to successfully utilise TRIPS flexibilities should provide guidance and policy advice to other developing countries. Countries should also consider developing exchange programmes among national patent offices and trade officials, to establish strong local expertise in the implications of IP and patents for health, and to reduce reliance on training programmes in the global North.

128 On the need for capacity building in the case of Malawi see the individual submission made by Chikosa Moses Ulendo Banda, of Malawi for the Africa Regional Dialogue of the Global Commission on HIV and the Law.