

Regional Issues Brief:

INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES

For the Asia-Pacific Regional Dialogue
of the Global Commission on HIV and the Law

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Download the Report of the Regional Dialogue and four accompanying Issues Briefs at:
<http://asia-pacific.undp.org/practices/hivaids/Publications.html>

Video of the Regional Dialogue is available at:
<http://vimeo.com/channels/aprdglobalcommission>

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1. Introduction

This Regional Issues Brief has been written to provide an overview of an area of enquiry that the Global Commission on HIV and the Law is examining – issues of laws pertaining to intellectual property rights and access to medicines. It has been undertaken through a literature review of laws and documentation of their enforcement in the context of Asia and the Pacific. It serves as an information resource and complements the report of the Regional Dialogue for Asia and the Pacific that was held under the auspices of the Global Commission on HIV and the Law in Bangkok on 16 and 17 February 2011.

Significant advances in treatment access in the Asia Pacific region have resulted from the work of activists who have campaigned to ensure that intellectual property laws do not impose unreasonable constraints on access to HIV medicines. Activists have achieved a number of successes through campaigning and litigation in Thailand and India. The focus of campaigning has been on challenging overbroad patents and trade agreements that block production and importation of affordable generic versions of HIV medicines. The legal response to access to medicines in the region continues to be influenced by heated policy debates between consumer activists and the mainstream pharmaceutical industry.

Special attention is given in this paper to the legal position in India because India is a major source of generic medicines for most low and middle-income countries globally.¹ Thailand also produces significant quantities of generic HIV medicines. China does not yet occupy a comparable position to that of India as a source of end-product generic ARVs. The legal position in China also requires attention because it is a major producer of active pharmaceutical ingredients (API) of antiretroviral (ARV) drugs. APIs represent the largest component of the manufacturing costs of ARVs.² It is likely that China will continue to expand its role as supplier of APIs and technology to developing countries globally, which will strengthen generic ARV production capacities. However, patent protections on APIs of newer ARVs are constraining this expansion. If patent obstacles can be overcome, China could also become a major source of generic ARVs. It has been argued:

“China could become the ARV factory for the developing world because of its cheap APIs and industrial scale-up, coupled with steady penetration of under-served markets.”³

1 Waning B., Diedrichsen E., and Moon S. (2010) A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. *Journal of the International AIDS Society* 13:35.

2 The company Shanghai Desano produces 29 percent of the APIs of ARVs for low and middle-income countries : Shanghai Desano Pty Ltd (2010) *Industry Perspective on Practical Approaches and Experiences in Development Pharmaceuticals*, available at: http://apps.who.int/prequal/trainingresources/pq_pres/workshop_China2010/english/23/003-IndustryPracticalApproaches-Desano.pdf

3 Dionisio D., Khanna A., Nicolaou S., et al For-profit policies and equitable access to antiretroviral drugs in resource-limited countries. *Future HIV Ther.* (2008) 2(1), 25–36, p.27.

2. Patent laws and requirements of the TRIPS agreement

Patent laws can restrict access to medicines because when a new drug is patented the company that owns the patent enjoys a monopoly and can set a high price for the drug. Patent laws prevent competitors from manufacturing and selling low cost generic versions of the same drugs. Patent owners can prevent others from making, selling or importing the medicine that is under patent for a prescribed period, usually 20 years.

Generic versions of medicines are usually much cheaper than the patented equivalent. Fluconazole, a medicine used to prevent and treat HIV-related fungal infections, was marketed under patent in Thailand by Pfizer until 1997. After the patent expired, prices fell to 3% of its original level due to competition from generic equivalents.⁴

Whether a generic version of a patented medicine can be locally manufactured or imported legally depends on the intellectual property law in the country concerned. The patent laws that a country introduces are influenced by the country's trade agreements with other countries and whether the country is a member of the World Trade Organization (WTO). WTO members of Asia and the Pacific are Australia, Bangladesh, Brunei, Cambodia, China, Fiji, India, Indonesia, Japan, Republic of Korea, Malaysia, Maldives, Myanmar, New Zealand, Nepal, Pakistan, Papua New Guinea, Philippines, Singapore, Solomon Islands and Vietnam.

Countries that are members of the WTO are required to comply with the TRIPS Agreement.⁵ The TRIPS Agreement stipulates the minimum standards of patent protection that member states are required to have in place including a minimum 20-year patent period. Before the TRIPS Agreement was introduced, WTO member states were allowed to exempt medicines from patent laws, so that no medicines could be patented. The TRIPS Agreement requires WTO member states to provide a legal framework for granting patents on medicines. The requirement is being phased in globally over a twenty-year period. Since 2005, developing countries that are members of the WTO have been required by TRIPS to issue patents on medicines. WTO members that are categorized as Least Developed Countries do not have to grant or enforce patents until 1 January 2016, with a possibility of further extension. In Asia and the Pacific, Least Developed Countries are Bangladesh, Cambodia, Myanmar, Nepal and Solomon Islands.

The TRIPS Agreement allows countries to design their patent laws to address public health concerns. The TRIPS Agreement needs to be interpreted in the context of the *Doha Declaration* (2001).⁶ The Doha Declaration acknowledges the right of WTO members to take necessary measures to protect public health. The flexibilities allowed by the TRIPS Agreement include, in particular:

- (i) compulsory licenses; and
- (ii) exceptions to exclusive rights of a patent holder which can operate without the need of a specific authorization by a court or administrator, e.g.
 - a) parallel importing; and
 - b) early working.

These flexibilities are discussed in separate sections below.

Patent activity is currently low in the Pacific island states, but high in most of Asia. Patent applications for medicines are expected to increase in the region overall as more countries join the World Trade Organization (WTO) and enter free trade agreements requiring them to have patent protections in place for pharmaceutical products.

Pacific island countries

Most Pacific island countries gain access to affordable HIV medicines through pooled procurement arrangements managed by the Secretariat of the Pacific Community (SPC), as part of the Global Fund multi-country Western Pacific grant. SPC's drug procurements are required to take into account national patent laws, which vary between Pacific Island countries. As more Pacific island countries introduce patent legislation to comply with TRIPS, pooled procurement approaches will become more complex to implement and may rely on exercise of TRIPS flexibilities by national governments. Papua New Guinea sits outside of the pooled arrangements.

4 Mayne R. (2005) *Regionalism, Bilateralism, and 'TRIPS Plus' Agreements: The Threat to Developing Countries*, Occasional Paper for Human Development Report 2005, UNDP.

5 WTO (1995) *Agreement on Trade-Related Aspects of Intellectual Property Rights*.

6 WTO (2001) *Declaration on the TRIPS Agreement and Public Health*. (WT/MIN(01)/DEC/2 20 November 2001)

Currently, of the Pacific island countries, only Fiji, Tonga, Papua New Guinea and Solomon Islands are members of WTO and therefore subject to TRIPS requirements. Samoa and Vanuatu have engaged in consultations on membership, while most other Pacific countries are currently not seeking membership.

Pacific island countries can be classified in three categories:⁷

- (i) Registration countries: countries that re-register United Kingdom, EU or other overseas patents and do not have the capacity to examine and register in their own country e.g. Kiribati, Nauru, Solomon Islands, Tuvalu and Vanuatu. In Kiribati the *Registration of UK Patents Act Cap 87* refers to the *Patents Act 1977* (UK). In Solomon Islands, the *Patents Act 1949* (UK) applies. The *Patent Act 1953* (New Zealand) applies in Niue, Tokelau and Cook Islands. Vanuatu has legislated to re-register EU patents: *Registration of United Kingdom Patents (Amendment) Act 2008*. In Marshall Islands and Federated States of Micronesia, it is assumed that the patent law of USA applies as there is no domestic patent legislation.
- (ii) WTO-based reform countries: these countries have joined WTO, or are in the process of doing so, and have revised their patent laws to comply with TRIPS e.g. Papua New Guinea, Tonga, Fiji. Fiji and Papua New Guinea were required to provide patent protection for pharmaceutical products from 2005. Solomon Islands does not have to comply until 2016. Under its WTO accession package, Tonga had until 1 June 2008 to implement TRIPS obligations. Some legislation goes beyond the minimum standard required by the TRIPS Agreement. The World Intellectual Property Organization is providing technical assistance to countries to draft laws. As a result, the patent legislation of these countries is similar.
- (iii) Transitional countries: these countries are in the process of reviewing and amending their patent laws to ensure TRIPS compliance (e.g. Fiji, Samoa, Vanuatu). These reviews are undertaken in the context of either the country being a WTO member or seeking to accede to the WTO. Vanuatu's *Patents Act 2003*, which was introduced to comply with TRIPS, has not yet commenced operation as law.

⁷ Farran, S., Paterson D. (2004) *South Pacific Property Law* Cavendish, London; S Meads (2008) *Trade, Medicines & Human Rights: Protecting Access to Medicines in Fiji & the Pacific* (Thesis) Victoria University of Wellington. Reid Smith, S *Access to Medicines and Intellectual Property, Presentation to Regional High Level Consultation on HIV and the Law*, Auckland 11 April 2007.

3. Compulsory licensing

3.1 Overview

If a country has introduced patent laws and an ARV is still under patent protection, a generic version can only be lawfully manufactured or imported if: (i) done so under a compulsory; license; (ii) the patent holder enters into a voluntary licensing agreement; or (iii) the patent holder agrees not to enforce the patent.

Under voluntary licensing, a government, individual or organization negotiates a license from a pharmaceutical company that owns the patent to allow generic drugs to be supplied, either through imports or by local production in exchange for an agreed fee.

Where a country has patent laws that provide for compulsory licensing, it is possible for patent authorities to grant licenses for importing or manufacturing generic medicines. Compulsory licensing enables a government to license a company or government agency to use a patent without the patent holder's consent. The person granted the license must generally compensate the title-holder, by payment of royalties. The government can prescribe a fee that is appropriate given the need for the drug to be affordable.

The TRIPS Agreement does not restrict the freedom of states to stipulate grounds for issuing compulsory licenses, such as those related to public health or public interest. The Doha Declaration states that each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.⁸ The TRIPS Agreement requires conditions to be met should a compulsory license be granted. These conditions include the requirement, in certain cases, that a license be voluntarily requested before being granted on compulsory terms, non-exclusivity, and adequate remuneration to the patent holder. Patent laws often provide for compulsory licenses to be made in the following circumstances:

- emergencies;
- anti-competitive practices;
- public interest;
- government or non-commercial use (e.g. public programmes to provide ARVs to people on low incomes).

Government use

Compulsory licenses for government use are often framed in broad terms and may be subject to less procedural requirements than are compulsory licenses,⁹ e.g. the waiver of the requirement for the government or an authorized party to first seek a voluntary license.¹⁰ This waiver provides flexibility and allows for the license approval to be 'fast-tracked'. Compulsory licenses for HIV medicines that have been issued in Asia have been for government use. According to one commentator:

"This form of licensing has certain advantages because it is widely practiced in rich countries, including the U.S.A, because it obviates the need for prior negotiations with the drug company, and because it reserves the private sector to the patent holder's monopoly control, undermining claims that all profits are foregone and that research and development will be undermined."¹¹

Ensuring simple procedures for applying for a compulsory license is important. Procedures that are burdensome may discourage use of the system. A significant barrier to the use of compulsory licensing is the absence of straightforward legislative and administrative procedures. The setting of compensation to the patent owner (as required by Article 31(h) of TRIPS) needs to be predictable and easy to administer (e.g. adoption of royalty guidelines).

8 Clause 5(b) *Doha Declaration*.

9 Musungu S., Oh C. (2006) *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?* Geneva: South Centre and WHO.

10 Article 31(b) TRIPS Agreement.

11 Baker B. 2007 *Victories: Fewer Deaths and More Compulsory Licenses* <http://www.healthgap.org/camp/ftaa.html>

Examples of government use licenses in Asia¹²

Date	Jurisdiction	Product	Duration	Royalty
2003	Malaysia	HIV: didanosine, zidovudine - idanosine + zidovudine	2 years	not indicated
2004	Indonesia	HIV: Lamivudine - nevirapine	7-8 years (patent term)	0.5%
2006	Thailand	HIV: Efavirenz	until 31 December 2011	0.5%
2007	Thailand	HIV: lopinavir/ritonavir	until 31 January 2012	0.5%
2007	Thailand	Heart disease: Clopidogrel	patent expiry or no longer needed	0.5%
2007	Indonesia	HIV: Efavirenz	until 07 August 2013	0.5%
2008	Thailand	Cancer drugs	patent expiry or no longer needed	3-5%

Potential negative impacts of compulsory licensing include the possibility of discouraging foreign investment from the pharmaceutical industry and disruption to trade relationships with high-income countries that often strongly favor patent enforcement, particularly the USA and countries of the EU. As a result, even when the law allows compulsory licensing, governments may be reluctant to use the law.

Prescribed export/import system for WTO member states

The TRIPS Agreement states that if a country issues a compulsory license, it has to be predominantly for the supply of the domestic market.¹³ This rule is harmful to generic exporters, especially Indian producers. The rule also creates a problem for developing countries that want to issue a compulsory license, but do not have generic manufacturers capable of manufacturing under the license. Countries facing this situation have to import, but any potential exporting country like India faces the restriction on exporting.

To address this issue, the WTO agreed a waiver system in 2003 for export of medicines under patent to countries that have no capacity to manufacture drugs. This was subsequently enshrined through an amendment to the TRIPS Agreement.¹⁴ The system requires the issue of a compulsory license in the exporting country. It imposes notification requirements on the importing country, and the issue of a compulsory license in the importing country (assuming that country already has a patent law and the product's patent is recognized in that country). To take advantage of the system there needs to be provision in the importing country's patent legislation for compulsory licenses to be issued for the purpose of importing medicines to address public health needs.

Asian jurisdictions that have formally notified WTO of changes to their domestic laws to enable the system to operate are India (to export), Hong Kong (to export, and to import in extreme urgency), the Philippines (to import and export) and Singapore (to import in extreme urgency).¹⁵ China's *Revised Patent Law* also integrates the system into its domestic law.¹⁶ The WTO-approved exporting system has only been used once, to export ARVs from Canada to Rwanda.¹⁷ Use of the system may become more important as countries seek to access affordable second-line ARVs.

3.2 India

India's patent laws have become much more complex since being amended to comply with the TRIPS agreement in 2005. This is affecting its position as a supplier of generic ARVs, especially drugs brought to market after 2005. Indian generic manufacturers have technical capacity to produce ARVs, including second-line drugs. However generic companies face legal obstacles and commercial risks due to the complexity of patent laws introduced in 2005.

12 Adopted from: World Health Organization (2008) *Briefing Note: Access to Medicines*, WHO WPRO Manila.

13 Article 31.

14 WTO (2005) (WT/LJ/641) *Amendment of the TRIPS Agreement: Decision of 6 December 2005*.

15 WTO (2010) *Little-used 'Par.6' system will have its day, WHO tells intellectual property and health review*. http://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm

16 Third World Network (2010) *TRIPS Council holds in-depth review of "Para 6" system*. <http://www.twinside.org.sg/title2/wto.info/2010/twninfo101102.htm>

17 Ibid.

The *Patents Act* (India) allows for compulsory licences to be issued, including for export.¹⁸ India's new patent legislation does not affect medicines that were invented before 1995. For patent applications filed between 1995 and 2005 a patent may be granted, but an automatic licensing system allows for the continued production of the generic version of drugs in relation to which patent applications were filed between 1995 and 2005 if a reasonable royalty is paid. For patents on drugs granted for applications submitted after 2005, only patent holders have the right to produce the drug unless a compulsory license has been issued or the patent holder licenses the patent of the drug voluntarily.¹⁹

An Indian company sought compulsory licenses to export medicines to Nepal in 2007. The request was dropped after the Indian company claimed that the importing country had found the conditions for using the system too onerous to proceed.²⁰ There are concerns about the costs associated with compliance with the requirements for seeking a compulsory license for export, which will particularly affect new, second line ARVs that are under patent.

"To the extent that patent rules make producing and exporting generics more labourious (i.e. raise the legal and transaction costs), they may encourage Indian pharmaceutical firms to abandon this line of business."²¹

There are also concerns that government of India may be reluctant to issue licenses:

"(Compulsory licenses) will hardly be issued by the Indian government because of threats to keeping partnerships with research-based enterprises and risks of retaliation by wealthy country governments."²²

According to another expert on patent law:

"In the longer term, it may be hard for India to remain a source of high-quality, low-cost ARVs... Inevitably patent litigation will increase. This suits pharmaceutical multinationals more than it does Indian generic companies."²³

That being said, India's patent legislation applies very stringent criteria to patent applications, and generic companies and consumer groups have had a series of recent successes in challenging patent applications (see section on 'Evergreening' below). It has been argued that the criteria established by legislation may work in favor of access to medicines:

"By establishing stricter criteria for obtaining a patent, fewer patent monopolies are created, thus creating more space for generic competition to enter the market with lower-cost alternatives. And where there are no patents on an essential drug, there is no need to issue a compulsory license."²⁴

3.3 Thailand

The Thai *Patents Act* authorizes the government use of patents to "carry out any service for public consumption" or to meet a list of specific public needs, including "to prevent or relieve a severe shortage of . . . drugs or other consumption items."²⁵

Thailand was the first middle-income country to issue compulsory licenses on second-line ARVs. A history of community mobilization to challenge patents and advocacy by people living with HIV for expanded access to generic ARVs have been key factors that contributed to Thailand's preparedness to issue compulsory licenses.²⁶

The successful use of compulsory licenses has occurred in Thailand after a history of successful consumer challenges against ARV patents. In 2002, Thailand's Central Intellectual Property and International Trade Court ruled in favor of the AIDS Access Foundation, the Thai Network for People Living with HIV/AIDS and two people living with HIV and ordered Bristol Myers Squibb (BMS) to amend its Thai patent on the ARV didanosine. The court ruled that the company had the exclusive right to produce didanosine only in low doses, while other drug companies could produce the drug in higher doses. The Thai court ruled that because pharmaceutical patents can lead to high

18 Section 92A *Patents Act* (India) provides for compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. This enables export of pharmaceutical products to any country having insufficient or no drug manufacturing capacity in certain circumstances, to address public health problems. The importing country must either grant a compulsory license for importation or issue a notification for importation into that country.

19 WHO *Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS*. <http://apps.who.int/medicinedocs/en/d/Js8112e/11.1.html>.

20 Third World Network (2010) *op cit*.

21 Destin K. (2005) *Patents, India and HIV/AIDS treatment*. London: LSE.

22 Dionisio D., Khanna A., Nicolaou S., et al For-profit policies and equitable access to antiretroviral drugs in resource-limited countries. *Future HIV Ther.* (2008) 2(1), 25–36, p.27

23 Drahos P. in *HIV Matters* Vol.2, No.1, February 2007. <http://www.anu.edu.au/fellows/pdrahos/articles/pdfs/2007universalaccesstreatmentHIVAIDS.pdf>

24 Park C., Menghaney L. TRIPS Flexibilities: The Scope of Patentability and Oppositions to Patents in India. in Krikorian G and Kapczynski, A. eds (2010) *Access to Knowledge in the Age of Intellectual Property* New York: Zone Books. p.416.

25 Section 51 *Patents Act* (Thailand).

26 Krikorian G., Kapczynski A. eds (2010) *op cit*. pp.440-441.

prices and limit access to medicines, patients are injured by them and can challenge their legality.²⁷

In 2004, BMS reached an agreement to return its patent for didanosine to Thailand. In exchange, the Foundation for Consumers and three HIV-positive people agreed to settle the legal suit filed against the drug maker in 2002. Thailand's Government Pharmaceutical Organization had alleged that the BMS patent on Videx was invalid because the drug is "merely a combination of an antacid and the active ingredient didanosine," for which BMS did not hold a patent. BMS developed Videx after licensing didanosine from the US National Institutes of Health. BMS had argued that Videx was patentable because the antacid improves the drug's effectiveness.

These consumer victories allowed the Thai government's treatment programme to scale-up using generic medicines. Thailand's subsidized ARV programme was extended nationwide through production of generic ARVs by the Government Pharmaceutical Organization for the public sector. The legal and political advocacy of the Thai Network for People Living with HIV/AIDS played a critical role in these developments. Involvement in litigation was also beneficial to the growth of organized treatment activism among people living with HIV in Thailand:

"people infected with HIV braved stigmatization to stage public demonstrations and proved to be a watershed event in terms of awareness and self confidence for people with HIV/AIDS."²⁸

Thailand has issued a number of compulsory licenses for ARVs since 2006. In response, Thailand was placed on a US Trade Representative 'priority watch list', which places countries at risk of retaliatory trade sanctions from the USA.

The Thai government was willing to utilize compulsory licenses despite pressure from USA. In August 2010, the Thai government extended compulsory licensing for Efavirenz and Kaletra until their patents expire (2012 for Efavirenz and 2016 for Kaletra).

According to Thailand's National Health Security Office, compulsory licensing had saved the national ARV scheme 1.18 billion baht in procurement costs by mid-2010 and will save an additional 3.2 billion baht by extending the compulsory licenses until the end of their patents. Thailand's compulsory licensing has also forced down the prices of Efavirenz and Kaletra (Lopinavir-Ritonavir combination) by 3.4 and 6.4 times respectively. Before the compulsory licensing of the two drugs, about 4,539 people living with HIV obtained access to Efavirenz and only 39 to the Lopinavir-Ritonavir combination. After the compulsory licensing of the drugs, the number of patients receiving Efavirenz increased to 29,360 and the number of people receiving the Lopinavir/Ritonavir combination increased to 6,246.²⁹

The example of Thailand shows that issuing a compulsory license carries political risks. Abbott Laboratories, the owner of the patents on Kaletra, retaliated against Thailand by withdrawing all of its pending drug-approval applications, with the implication that it would refuse to register its new drugs in any country that issues a compulsory license on its patents.³⁰

Lessons learned from Thailand's experience in compulsory licensing include: middle-income countries are unable to pay the high prices of multinational pharmaceutical companies; compulsory licensing has brought treatment with newer ARVs within reach in Thailand, but has resulted in pressure from industry and the US government; and an informed and engaged civil society is essential to support governments in putting health before trade relations.³¹

3.4 Malaysia

The Malaysian *Patents Act* allows the Minister to authorize a government agency or third person to exploit a patented invention in the case of a national emergency or where the public interest requires.³² In 2003, the Malaysian government issued compulsory licenses to import generic ARVs from India for use in public clinics from 2003-2005.³³ The effect was to reduce the monthly cost of treating a patient by between 68 to 83 percent, depending on the combination of drugs. As a result, the patent holders lowered their prices by 50-80 percent,

27 Ford, N., Wilson, D., Bunjumong, O., Angerer, T. (2004). The role of civil society in protecting public health over commercial interests; lessons from Thailand. *Lancet*, 363, 560-563, p.560.

28 Ibid; and see. Lyttleton, C., Beesey, A., & Sitthikriengkrai M. Expanding community through ARV provision in Thailand, *AIDS Care*, 2007; 19(Supplement 1): S44-S53, p.S45.

29 NHSO extends drug licensing, Move ensures Aids medications available *Bangkok Post* 15/06/2010. <http://www.bangkokpost.com/news/local/38771/nhso-extends-drug-licensing>

30 Park C., Menghaney L. *op cit.* p.417.

31 Ford N., Wilson D., Costa Chaves G., Lotrowska M., Kijtiwatchakul K. (2007) Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand. *AIDS* (July 2007);21 Suppl 4:S21-9.

32 Section 84.

33 Didanosine (ddl), zidovudine (AZT) and lamivudine+zidovudine (Combivir).

benefiting patients who receive private treatment.³⁴ The authorization contained specific conditions with regard to price, differentiation in shape and colour from the patented product, and labelling of the medicines with the words “Ministry of Health Malaysia”. The number of patients treated with generic ARVs in the public sector more than doubled.

Malaysia has now ceased using compulsory licensing and is negotiating a free trade agreement with the USA that limits its future ability to use compulsory licensing for government use.³⁵

3.5 Indonesia

In 2004, Indonesia issued a compulsory license to allow state-owned drug company PT Kimia Farma to manufacture generic versions of two ARVs (lamivudine and nevirapine) for government use until the end of the patent terms in 2011 and 2012 respectively. A compulsory license to manufacture Efavirenz for government use was issued in 2007 to replace nevirapine as the first-line drug. Indonesia uses lamivudine, efavirenz and zidovudine as the three first-line ARVs for its national programme. A compulsory license for zidovudine is not required as its patent has expired. These three drugs are now produced locally.

In 2009 it was reported that Indonesia was considering issuing compulsory licenses for three second-line ARVs (tenofovir, didanosine and lopinavir). Indonesia procures second-line ARVs through participation in the Global Fund to Fight AIDS, Tuberculosis and Malaria Voluntary Pooled Procurement scheme. However, there are concerns that alternative arrangements are required should access via Global Fund arrangements terminate.³⁶

3.6 Philippines

In 2008, the *Universally Accessible Cheaper and Quality Medicines Act of 2008* amended provisions of the *Intellectual Property Code* relating to compulsory licenses as well as patentability and exhaustion criteria. The amendments provided for parallel importation and government-use licenses.³⁷ The Philippines has not issued compulsory licenses for HIV medicines. ARVs are procured through the Global Fund’s Voluntary Pooled Procurement (VPP) arrangements.

3.7 Cambodia

In Cambodia patent legislation specifies that there will be no patents for pharmaceuticals until 2016 (which is permitted for Least Developed Countries by TRIPS).³⁸

3.8 China

China’s *Patent Law 2008* allows for compulsory licensing in a national emergency or if an extraordinary state of affairs occurs, or where the public interest so requires, but there is no specific provision for licensing for public non-commercial use. If enforcement of a patent is deemed to amount to monopolistic conduct a compulsory license can be granted to increase competition in China’s domestic market. Chinese commentators have observed:

“It is more possible that the government will use the new stipulation to negotiate with international pharmaceutical companies on their drug price, rather than directly licensing their drugs... given huge foreign investment in China and the country’s keen desire to absorb more, the government would be highly cautious in using the licensing clause.”³⁹

The NGO Asia Catalyst has raised concerns about failure of Government of China to issue compulsory licenses for second line ARVs.

“the director of a national network of people living with HIV/AIDS, says that this urgent need has created a black market for the medications smuggled in from countries where drugs are produced at low cost due to compulsory licensing there. ...As the situation becomes desperate, Chinese AIDS activists are raising increasingly urgent concerns about the lack of second-line ARVs. In March 2009, a group of leading AIDS advocates in China issued a public resolution calling on the government to issue compulsory licenses for second-line treatment.”⁴⁰

34 Ling Y (2007) Use of TRIPS flexibilities: some experiences and observations. University of Toronto. And see: Third World Network (2010) *Malaysia: Some progress, multiple challenges*. Kuala Lumpur: TWN.

35 Oxfam (2006) *Patents versus Patients: Five years after the Doha Declaration*. p.3. http://www.maketrade-fair.com/en/assets/english/doha5_101106.pdf

36 Tunsarawuth S. (2007) Indonesia mulls compulsory licenses on three more HIV/AIDS drugs. *Intellectual Property Watch*. <http://www.ip-watch.org/weblog/2007/11/26/indonesia-mulls-compulsory-licenses-on-three-more-hivaids-drugs>

37 Universally Accessible Cheaper and Quality Medicines Act of 2008. Bringing Cheaper Medicines to Filipinos. *DevPulse* Vol. XII, no. 12, 2008.

38 *Law on Patent, Utility Model Certificates, and Industrial Designs* (Cambodia)

39 Revised Chinese patent law aims at quality, compulsory licensing *Intellectual property watch* 15 January 2009. <http://www.ip-watch.org/weblog/index.php?p=1394>

40 http://www.aidslex.org/site_documents/CY-0078E.pdf

3.9 Papua New Guinea and other Pacific island countries

Papua New Guinea has provision in its *Patent Act* for compulsory licenses for government use.⁴¹ In Pacific island countries that have patent legislation but do not have capacity to manufacture drugs, compulsory licenses to import generic ARVs or parallel imports (below) may be important to facilitate legal importation. Importation is the only alternative where the size of the local market does not justify local manufacturing.

41 UNDP (2009) *Enabling effective responses to HIV in the Pacific island countries: options for human rights-based legislative reform*. Suva: UNDP Pacific Centre.



4. Parallel imports

Laws that enable parallel importing can allow countries to import medicines that have legitimately been put on the market in other countries at a cheaper price than is available locally. The pharmaceutical industry generally sets prices differently throughout the world for the same medicines. Importation of a patented medicine from a country where it is sold at a lower price will enable more consumers in the importing country to gain access to the product. Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented medicine that has already been put on the market of the exporting country by the patent holder or in another legitimate manner (e.g. under a compulsory license).

The rationale for allowing parallel imports is that, since the inventor has been rewarded through the first sale and distribution of the product in the exporting country, the inventor thereafter has no right to control the use or resale of goods. In other words, the inventor's rights have been exhausted. Whether parallel importing is legal depends on how the question of patent "exhaustion" is dealt with under the importing country's legal system. "Exhaustion" refers to the loss of the right to enforce a patent on the resale of the protected product after the first sale.

Parallel importing is one of the measures that member countries may take to protect public health under the TRIPS Agreement.⁴² The TRIPS Agreement establishes that each Member country has the freedom to incorporate the principle of international exhaustion of rights, the underlying justification for parallel imports, in its national legislation.⁴³ The Doha Declaration clarified that WTO Members are free to adopt laws regarding patent exhaustion that best fits their needs. This means that countries do not breach TRIPS requirements by allowing parallel importing.

Legislation in the Philippines allows parallel imports under the *Universally Accessible Cheaper and Quality Medicines Act of 2008*.

It has been argued that, to support access to medicines, restrictions on parallel imports should be avoided, such as requirements for the express consent of the patent holder before a patented product is imported. If the consent of the patent holder is required for the import of a patented product, the ability to parallel import will be restricted to those cases where the patent holder has given consent, which may be rare.⁴⁴

The US-Singapore Free Trade Agreement restricts parallel importation by requiring patent holders to block importation of patented drugs from outside the country, when it is done without the authorization of the patent holder or in violation of a distribution agreement abroad.⁴⁵

A Thai commentator has argued that parallel imports may not run the same risk of retaliation that compulsory licensing attract:

"In the case of parallel imports, developing countries may possibly expect the less intimidating action under trade sanction from the U.S. for the following reasons. First, developing countries that are TRIPS members are free to allow parallel imports by applying an international exhaustion doctrine. Second, compared to compulsory licensing, there is less government involvement in parallel imports because there is no need of government approval of the importation. Third, unlike compulsory licensing, under parallel importation the owners of IPRs receive a benefit from the first sale of their products at prices they set."⁴⁶

As is the case for compulsory licensing, parallel importing requires a legislative framework (assuming patent laws are already in place). A review of Indonesian patent law and ARVs observed:

"Parallel import of the lowest-priced patented medicines is not possible because there is no specific provision for this in Indonesian law. Only the patent holder or its authorised agent could import a patented drug, which

42 Article 8.1.

43 Article 6.

44 Musungu S., Oh C. (2006) op cit.

45 Humaira Zia Mufti (2010) *TRIPS Plus provisions pertaining to Patents in the Bilateral FTAs*

Government of Pakistan. WIPO/ESCAP High-level Forum on Intellectual Property Rights and Trade. 224th July, 2007 http://www.unescap.org/tid/projects/iptrade_s5mufti.pdf

46 Boonfueng K. (2004) Parallel imports in pharmaceuticals increase access to HIV drugs. *Thailand Law Forum Journal*. <http://www.thailawforum.com/articles/hivdrugs2.html>

meant that they were free to determine prices, thus making the medicines expensive."⁴⁷

Pooled procurement has been used in the Pacific for ARVs and is likely to be the preferred approach of most Pacific island countries to ensuring a reliable supply of quality HIV medicines. However, if this is not available for particular products or a country is not participating in a regional pooled procurement initiative, another option may be to source cheaper products through parallel importing.⁴⁸

47 Hanim L., Jhamtani H. *Indonesia: Manufacturing generic AIDS medicines under the 'government use' approach* www.twinside.org.sg/title2/resurgence/196/cover9.doc

48 UNDP (2009) *Enabling effective responses to HIV in the Pacific island countries : options for human rights-based legislative reform*. Suva: UNDP Pacific Centre.



5. Evergreening

'Evergreening' refers to the practice of making minor modifications to an existing patented drug to make it appear to be a new one. A company that owns a patent on a drug may attempt to artificially extend the patent by 20 years by making minor modifications and seeking patent protection for the modified drug. This practice can be challenged on the basis that there is no 'inventive step' involved, and hence there is no invention that can be patented. The practice can also be challenged under specific legislation introduced to prevent evergreening. For example, the *Patents Act* (India) states,

"The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant (Section 3(d))."

After this section proved effective in challenges to evergreening practices in India, the *Intellectual Property Code of the Philippines* was amended in 2008 in identical terms.⁴⁹ In India, the pharmaceutical company Novartis unsuccessfully challenged section 3(d) of the *Patents Act* in 2007.⁵⁰ In a comment to the press, the Secretary-General of the Indian Pharmaceutical Alliance noted that Malaysia, Bangladesh and Indonesia were waiting for this ruling upholding section 3(d) to amend their patent law to address evergreening practices.⁵¹

Rather than risk a negative precedent, after the Novartis court decision GlaxoSmithKline chose to withdraw two ARV patent applications in India (Abacavir and Trizivir).⁵²

In 2008, the Indian Patent Office rejected a patent application for a pediatric formulation of the ARV drug nevirapine as a "new form" of a "known substance" and thus not patentable under section 3(d). The Patent Office recognized the need to give a strict interpretation of patentability criteria, given the need for people living with HIV to access essential medicines.

In 2009, India's Patent Office rejected patent applications on two ARVs (tenofovir and darunavir).⁵³ The pharmaceutical companies argued that the drugs demonstrated enhanced efficacy. A Brazilian advocacy group and the Indian NGO SAHARA (Centre for Residential Care and Rehabilitation) successfully opposed the grant of a patent in India on the ground that the drug consists of a previously known compound.

In India (as in Thailand), successful challenges to patent applications have been made possible by the availability of pre-grant opposition procedures, which allow consumer groups and generic companies to intervene and challenge weak patent applications.

In *Boehringer Ingelheim v. Indian Network for People Living with HIV/AIDS (INP+) and Positive Womens Network (PWN)*, the Delhi Patent Office rejected the patent application on Nevirpaine Hemihydrate which is used in the treatment of pediatric HIV.⁵⁴

A challenge of Roche's patent for its drug Valcyte considered issue the validity of the patent for a new form of a known drug and the right of patient groups to question the grant of patents.⁵⁵ Valcyte is a variant of an existing drug, ganciclovir, which is used for treatment for cytomegalovirus, which is a common opportunistic infection associated with HIV. In 2007, Roche was granted the patent on Valcyte by the India Patent Office, without hearing the arguments of public interest groups, the Indian Network for People Living with HIV/AIDS and the Tamil Nadu Networking People with HIV/AIDS. Four generic drug companies and three consumer groups challenged the patent. In 2010, the Indian Patent Office set aside the patent on the grounds that the drug lacked an inventive step that qualifies a product for patent protection and that the drug did not satisfy the requirement of showing

49 Amended by section 5 of the *Universally Accessible Cheaper and Quality Medicines Act of 2008*.

50 *Novartis AG represented by it's Power of Attorney Ranjina Mehta Dutt vs. Union of India (UOI) through the Secretary, Department of Industry, Ministry of Industry and Commerce and Ors.* (MANU/TN/2007/1407)

51 *Novartis Loses Patent Law Challenge* International Centre for Trade and Sustainable Development. News and Analysis 11(5) August 2007.

52 GSK drops claims on two AIDS medicines, *The Economic Times*, 7 Dec 2007.

53 Tenofovir is used in first and second-line drug regimen. Darunavir is an important second-line treatment.

54 *In the matter of an application for patent having no. 2485/DEL1998*, Delhi Patent Office, 11 June 2008.

55 *Victory for access to medicine as Valganciclovir patent rejected in India* 06/05/2010; *Why Roche lost a patent battle in India* <http://business.rediff.com/column/2010/may/13/guest-why-roche-lost-a-patent-battle-in-india.html> May 13, 2010.

increased therapeutic efficacy as required under section 3(d) of the patent law.⁵⁶

In 2010, the India Patent Office also rejected an application filed by Abbott Laboratories for Aluvia, a combination of lopinavir and ritonavir. The patent claim of Abbott was opposed by three Indian generic companies. The patent office concluded that the drug was not a new invention, so was not eligible for a patent. There was no need to rely on section 3(d). The patent application was for a heat-resistant version of the drugs.⁵⁷

56 Patent office strips Roche of rights over Valcyte, *The Economic Times*, Delhi 6 May 2010, p.5; Krikorian G and Kapczynski, A. eds (2010) *op cit.* p.431.

57 Intellectual Property Watch. *Patent on AIDS Medicine Denied in India.* 4 January 2011.



6. Early working

National legislation generally requires medicines to be registered by a country's national drug regulatory authority prior to being placed on the market. This process is important to ensure safety and efficacy of drugs that are marketed, but can result in delays in generic medicines becoming available unless appropriate provisions are included in legislation.

It often takes at least a year between the time a patent expires and the time a generic alternative is available on the market. During this period, the previous patent holder still enjoys an effective monopoly. Delay is largely due to the drug registration process. Delay can be minimized by completing the drug registration process during the life of the patent, so that generic alternatives are already registered and can therefore be sold immediately when the patent expires. However, beginning the registration process during the life of the patent may be a violation of the patent, because the law normally prevents anyone from using a patented product without the express authorization of the patent holder.

This problem can be overcome by including an early working exception in patent legislation (also known as a 'Bolar' provision). An early working provision allows generic manufacturers to register a generic version of a medicine during the life of the patent of the original version.

Early working provisions under India's *Patents Act* have recently become a major focus of litigation between generic producers and patent holders in India. In 2010, the drug company Bayer Corporation sought to prevent a generic manufacturer Cipla from seeking marketing approvals for a generic cancer medicine that is still under patent. Bayer Corporation had sought an order to refuse marketing approval to the generic version. The Delhi High Court found in favor of Cipla. The Supreme Court refused Bayer's petition for leave to appeal.⁵⁸

A review of options for Pacific island countries considered the importance of Bolar provisions in national legislation, and concluded:

"Even where they are not likely to be producers of medicines, developing countries should incorporate a Bolar provision within their domestic law, to enable generic medicines to gain regulatory approval to be imported and marketed soon after the expiry of the patent. This permits the foreign manufacturers of generic medicines to use the technology of a patented pharmaceutical to perform work that would assist in the marketing or regulatory approval of the generic version of the product, while the patent is in force."⁵⁹

58 *Bayer v the Union of India and Cipla* (High Court: MANU/DE/1756/2009); Supreme Court: DC 6540/2010); And see: <http://genericpharmaceuticals.blogspot.com/2010/12/india-supreme-court-dismisses-bayer.html>; <http://patentsnmore.wordpress.com/2010/01/18/india-patent-linkage-with-regulatory-approval/>.

59 UNDP Pacific Centre (2009) *op.cit.*

7. Trade agreements, investment agreements and 'TRIPS-plus' requirements

7.1 Overview

The supply of generic medicines can be restricted when countries enter trade agreements containing requirements additional to those contained in the TRIPS Agreement.⁶⁰ In addition to the minimum standards for patent laws that TRIPS prescribes, trade agreements may require additional patent safeguards, referred to as 'TRIPS-plus' requirements. Numerous bilateral agreements that may affect access to HIV medicines are in negotiation, including between EU-India, EU-Thailand and US-Thailand. Thailand and Vietnam are currently in the process of informal talks with the EU on draft agreements.⁶¹ Upcoming multilateral trade agreements include an EU-ASEAN agreement, EU-Pacific agreement, the Trans Pacific Partnership (which may eventually evolve into an Asia Pacific regional free trade agreement) and the potentially global Anti-Counterfeiting Trade Agreement (ACTA)(see 9 below).

Examples of public health implications arising from trade agreements include:⁶²

- (i) requirements on countries to join the Patent Cooperation Treaty, which usually leads to an increase in patent applications for medicines;
- (ii) limitations on the circumstances under which compulsory licenses may be issued;
- (iii) extending the minimum period of patent protection beyond the 20 years required by TRIPS;
- (iv) requiring drug regulatory authorities to consider the patent status of drugs before granting marketing authorization to generic manufacturers (known as 'linkage' requirements, which delay the process of granting marketing approval, thereby delaying the entry of generic medicines into the market);
- (v) data exclusivity requirements, which restrict the use of data submitted to regulatory authorities (see below); and
- (vi) requirements restricting parallel imports e.g. restricting imports to certain geographic areas, which may prevent developing countries from sourcing generics from the cheapest global supplier.

In addition to trade agreements, TRIPS-plus requirements may be introduced through bilateral investment agreements and investment chapters of free trade agreements. There is an increased use of investment agreements by developed countries to undermine the provisions of the TRIPS that provide exceptions and flexibilities for developing countries. The South Centre recommends that investment agreements should clearly stipulate that the protection and enforcement of intellectual property will not exceed TRIPS Agreement requirements, except where there is clear evidence that the overall economic and social benefit to the developing country of any new rules would exceed the costs.⁶³

Data exclusivity refers to the granting of exclusive rights over the test data required for registration of medicines (clinical and preclinical trial data). Generic manufacturers rely on access to this data to submit to regulatory authorities to establish the efficacy and safety of generic products. Data exclusivity delays generic drugs from being marketed until the end of the exclusivity period. Granting exclusive rights to data to the patent holders can also prevent compulsory licensing from operating. Although a compulsory license may enable the legal manufacture of the generic version of a patented medicine, the generic manufacturer may still not be able to register the generic medicine if the generic manufacturer is not able to rely on the test data submitted for marketing approval of the patented product.

The TRIPS Agreement requires WTO Members to provide protection for undisclosed test or other data submitted for the purposes of obtaining marketing approval against "unfair commercial use".⁶⁴ In response to this requirement, some countries have legislated to guarantee data exclusivity periods e.g. of five or ten years. Drug regulatory authorities are then not permitted to rely on an originator's test data to approve other registration applications

60 See: Correa C. (2006) Implications of bilateral free trade agreements on access to medicines. *Bulletin World Health Organization* 2006, 84(5):399-404.

61 Chea C., (2010) *Engaging in the Free Trade Agreement Debate*, University of Victoria Center for Asia Pacific studies, 7 December 2010, <https://capi.uvic.ca/blogs/chany-chea/regional-shame-campaign-no-free-trade-agreements>.

62 UNDP Pacific Centre (2009) *op cit*.

63 *Intellectual property in investment agreements: The TRIPS-plus implications for developing countries. Analytical note*. South Centre, Geneva, May 2005.

64 Article 39.3.

during this period of exclusivity. However, the TRIPS Agreement does not require data exclusivity; the obligation is to protect against unfair commercial use.

Some trade agreements require patent holders to be granted data exclusivity. WTO accession may also require commitments to grant data exclusivity periods. If a country, as a result of entering a trade agreement, does grant data exclusivity, it is important to limit its potential negative implications on access to medicines. This can be done by limiting its duration and/or scope and by providing that reliance on the originator's safety and efficacy data is allowed in case of compulsory licensing.

7.2 European Union-India trade agreement

The EU-India draft Free Trade Agreement (FTA) recognizes the importance of the Doha Declaration. The EU-India draft FTA provides that '[I]n interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with this Declaration'. This clause is an important provision should a dispute arise.⁶⁵ The draft stipulates that the Parties 'shall contribute to the implementation and respect' of the WTO Decision of August 30, 2003 – which allows for the export of pharmaceutical products under compulsory licenses to countries without manufacturing capacity in pharmaceuticals – and agree to take the necessary steps to accept the Protocol amending the TRIPS Agreement, agreed in 2005. It further provides that '[N]othing in this Agreement shall be construed as to impair the capacity of the Parties to promote access to medicines'.

Despite these provisions, the EU proposal includes provisions which, if adopted, would likely limit access to medicines.⁶⁶ Proposals include:

- (i) Patent term extensions beyond the 20 years required by TRIPS. The FTA would compel India to extend the monopoly accorded by a patent for up to five additional years in order to compensate for the time required for the marketing approval of a medicinal product. This may in practice delay the entry of generic competition. The EU argues that patent term extension is a mechanism to address the issue of delays in the processing of marketing approval applications and compensates drug innovators for long delays, during patent life, in the obtaining of marketing approval.⁶⁷ As a result of these delays, the medicine is often available in the market only several years after the patent application has been filed. Such measures give the right holder effective patent protection up to 15 years from the time the drug first receives marketing authorization. Treatment activists argue that patent extension will restrict access to medicines.⁶⁸
- (ii) Data exclusivity, which would delay the registration of generic medicines. Article 10 would impose on India the obligation to create protections for test data submitted for the approval of pharmaceutical products, a form of protection not required by the TRIPS Agreement. This would create market exclusivity after the approval of a product by the regulatory authority. Generic competitors would be prohibited from producing and marketing the drug during the test data exclusivity period (even if no patent has been granted on the drug). Currently, when a generic manufacturer applies to register a version of an already-registered medicine, the drug regulatory authority relies on the efficacy and safety data provided by the original manufacturer. If data exclusivity protections are in place, the only option for the generic manufacturer would be to repeat the clinical trials. For example, MSF point out that a patent on nevirapine syrup to treat children was rejected by the Indian patent office, allowing generic producers to begin manufacturing right away. If data exclusivity had been in place, they would have had to wait up to 10 years to be able to start producing this drug, even though it had not been granted patent protection.⁶⁹
- (iii) Border enforcement measures that could block international trade in generic medicines when they are suspected of infringing patents in the countries through which they transit.⁷⁰ These types of border measures enabled European customs authorities to seize Indian-produced generic ARVs, which prevented the drugs from being transported to Africa in 2008–2009.

The EU is pushing for greater enforcement of intellectual property rights through various channels. The EU FTA text seeks to have India incorporate different types of enforcement measures, including use of court injunctions. This

65 Correa C. (2009). *Negotiation of a free trade Agreement European Union-India: Will India accept TRIPS-plus protection?* Oxfam Germany and the Church Development Service.

66 Correa (2009) Ibid.

67 EU-India FTA negotiations and access to medicines Questions and answers, http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf

68 Naz Foundation Letter to Ms. Bruni-Sarkozy http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2010-December/000543.html

69 MSF (2010) *The Truth Behind the Spin: How the Europe-India Free Trade Agreement Will Harm Access to Medicines* http://www.doctorswithoutbordersusa.org/publications/article_print.cfm?id=4839#_edn1

70 Waning B, Diedrichsen E., Moon S., (2010) Lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries *Journal of the International AIDS Society* 13:35.

would mean that when a dispute occurs, the generic manufacturer would have to halt production until the court determines the matter.

The European Parliament has passed a resolution asking for no TRIPS-plus provisions affecting public health in the EU's FTA negotiations. It restricts the European Commission's mandate "so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licenses, within the framework of the EPA negotiations."⁷¹ There are strong differences of views as to whether current proposals will restrict access to affordable medicines.

In response to concerns raised by the Thai Network of People Living with HIV/AIDS (who are concerned about Thailand being unable to access imported generic medicines from India), the EU published a statement in 2010 stating:⁷²

"The EU fully recognizes India's right to issue compulsory licensing for medicines and has no intention of weakening India's capacity to manufacture and export medicines to other developing countries, including Thailand, facing public health problems... On the contrary, the EU has proposed a clause in the negotiations to ensure that nothing in the proposed agreement would limit India's freedom to produce and export medicines in accordance with the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, notably through compulsory licensing. Furthermore, this Agreement will not interfere with the trade of generic medicines in transit."

7.3 Trans-Pacific Partnership

The Trans-Pacific Partnership (TPP) is a multilateral trade agreement that aims to integrate the economies of the Asia-Pacific region. The original agreement between the countries of Brunei, New Zealand, Singapore and Chile entered into force in 2006. USA, Australia, Malaysia, Vietnam and Peru are currently negotiating to join the group. US supported TRIPS-plus proposals are being opposed in the negotiations by New Zealand.⁷³ The existing bilateral trade agreements between the USA and Singapore and between the USA and Australia contain TRIPS-plus intellectual property provisions. It is considered likely therefore that the multilateral TPP will contain similar provisions.

7.4 EU-Pacific trade agreements

An Economic Partnership Agreement (EPA) is being negotiated between Pacific Island countries and the European Union. The EU is seeking EPAs with Timor Leste and 11 Pacific island countries (Cook Islands, Kiribati, Marshall Islands, Federated States of Micronesia, Nauru, Palau, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu). Fiji and Papua New Guinea signed EPAs in 2009. Depending on the terms negotiated, additional patent protection requirements could apply to all the countries that agree to the EPA, regardless of their WTO member status.

The TRIPS Agreement does not require countries to join the Patent Cooperation Treaty (PCT). However, the EPA being negotiated in the Pacific requires countries to join the PCT.⁷⁴ The PCT enables companies to apply for a patent in multiple countries through simplified procedures.⁷⁵ It does this by standardizing the application procedures. A medicine may not be patented in a small developing country that is not a PCT country (such as Pacific island states) because the market is too small for a company to warrant the resources required to apply for a patent in that country. If there is no patent, then the country can import generic medicines without restriction.

China's patent applications increased five-fold and Vietnam's increased 15-fold after joining the PCT.⁷⁶ Patent applications in Papua New Guinea have also increased rapidly since joining PCT in 2003. If other Pacific island countries join the Treaty, the current low rate of patent registration in the Pacific region is expected to escalate dramatically.⁷⁷ It has been estimated that 15 times more patents on medicines are likely to be granted in countries after joining the PCT.⁷⁸

71 *European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines* <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN&language=EN>.

72 *Message by Mr. David Lipman, Ambassador of the EU Delegation to Thailand, to the Thai Network of People Living with HIV/AIDS*, 21 October 2010, http://ec.europa.eu/delegations/thailand/documents/news/message_thai_network_hiv_en.pdf

73 *Leaked New Zealand paper challenges major pharma companies in Trans Pacific trade negotiations*, *The Pharma Letter* 7 December 2010; <http://www.thepharmalletter.com/file/100446/leaked-new-zealand-paper-challenges-major-pharma-companies-in-trans-pacific-trade-negotiations.html>

74 Meads S. (2008) op cit. p.51.

75 *Intellectual Property Quarterly Update*, South Centre, CIEL, Fourth Quarter 2006.

76 Lim Kit Siang. (2006) *Malaysia should not accede to the four WIPO Treaties until we have a National IP Policy and fullest consultation with civil society and stakeholders: Speech on the Patents Amendment Bill 2006*.

77 Meads op cit p.51

78 *EU EPAs: Economic and Social Development Implications: the case of the CARIFORUM-EC Economic Partnership Agreement*, Third World Network February 2009

7.5 China-India trade agreement

Even where there are no formal bilateral trade agreements affecting patent laws, the context of a country's broader trade relationships can influence domestic legislation. Countries not wishing to jeopardize their relationships with high-income trading partners may be pressured to avoid use of TRIPS flexibilities or to introduce TRIPS-plus measures. Since joining the WTO, China has resisted use of TRIPS flexibilities to enable it to scale up domestic production of first and second-line ARVs or to import Indian generic ARVs.⁷⁹ China is under pressure from the USA and EU to strengthen intellectual property laws and enforcement. As a result, China has been reluctant to use imported generic medicines in its HIV programme. Chinese State Food and Drug Administration decided to import the ARV lopinavir produced by Abbott rather than procuring Indian generic copies.⁸⁰ According to a review conducted for the UK Department for International Development:

“China is a classic example of a country that has bent to bilateral pressures and has implemented few TRIPS flexibilities in its domestic legislation. The sub-optimal domestic access to ARVs is partly a result of that... IP enforcement in China means Chinese generic firms are unable to circumvent the IP restrictions on the finished product formulations of 3TC, efavirenz and tenofovir.”

This situation may improve as a result of the China-India trade agreements signed in December 2010, which may act as a catalyst for bilateral transactions for the manufacturing and marketing of ARVs. Under the trade agreement, measures will be taken to promote greater Indian exports to China with a view to reducing India's trade deficit.⁸¹

7.6 US-Thailand trade agreement

A US-Thailand trade agreement has been proposed but negotiations have been protracted. TRIPS-plus requirements that have been discussed in negotiations include the period of patent extension to compensate for delays in patent registration or drug registration, data exclusivity that would result in a delay in generic drug entry, and linkage between patenting and the enforcing role of the Thai Food and Drug Administration.

A study assessed the potential impact of drug prices based on proposals from the text of the Thai-US negotiations in 2006. The impact was estimated using a macroeconomic model to compare the impact of the current patent situation and the proposed changes to intellectual property rights.⁸² The study concluded that the impact on the cost of medicines calculated to 2027, would be: (i) a 32% increase in the medicine price index, (ii) spending on medicines would increase to approximately USD 11,191 million, and (iii) the domestic industry could lose USD 3.3 million. The results suggest there would be a severe restriction on the access to medicines under the TRIPS-plus proposal.

Another study of the impact of the proposed Thai-US agreement found that that total expenditure on ARVs under a TRIPS-plus scenario would be three to seven times higher than in the current situation.⁸³

79 Daniele D., Daniela M. Impending Flop for Brand Antiretrovirals in the Emerging Markets? *Open AIDS J.* 2008; 2: 68–71.

80 Dionisio D, Fabbri C, Messeri, D. HIV drug policies and South markets: settling controversies *Therapy* (2008) 5(5), 707–717.

81 India, China Sign Trade Agreement, 17 December 2010 *The Journal of Commerce Online - News Story*

82 Kessomboon N.; Limpananont J., Kulsomboon V., et al. (2010) Impact on access to medicines from TRIPS-Plus: a case study of Thai-US FTA. *Southeast Asian J. Trop. Med. Public Health* Vol. 41, p.667.

83 Assessing the impact of TRIPS-plus on access to ARVs in Thailand . Dr Jongkol Lertiendumrong http://203.90.70.117/PDS_DOCS/B2072.pdf



8. Patent pools

A patent pool is a voluntary licensing arrangement where drug companies agree to pool their patents and license them to generic companies to allow the import and local generic manufacture of patented drugs at mutually-agreed license fees. Patent pooling has been recommended as an approach that would support pooled procurement in regions such as the Pacific.⁸⁴ In 2010, UNITAID (an international drug purchase facility) established a voluntary Medicines Patent Pool as a legal entity. The initial focus of the Medicines Patent Pool is to increase access to newer ARVs. The Pool aims to promote reductions in the price of existing ARVs and stimulate the production of newer first and second-line ARVs by increasing the number of generic producers. The pool may also expand access to fixed-dose combinations of newer ARVs and pediatric formulations.⁸⁵

In 2009, concerns were raised by Médecins Sans Frontières (MSF) and Indian public health organisations, that middle-income countries would be barred from accessing the MPP, including China, India, Philippines and Thailand - both from getting the generic medicines and from producing them. Several drug companies opposed the inclusion of middle-income countries. Thai civil society groups sent a letter to the UNITAID executive board protesting the position of the drug companies and asking that this position not be accepted by UNITAID or the patent pool.⁸⁶ Letters by Indian groups and the Peoples Health Movement were also written to UNITAID raising concerns that the patent pool could undermine the use of TRIPS flexibilities by developing countries. The pool that UNITAID subsequently established is open to middle-income countries, but it is as yet unclear whether drug companies will consent to inclusion of middle-income countries for specific products. It has been argued that India is ideally suited for a patent pool strategy for ARVs given the existing capacity of Indian generic companies to manufacture ARVs.⁸⁷ The Medicines Patent Pool has invited patent-holders to negotiate licenses to enable the development and production of low-cost generic HIV medicines for use in developing countries. License conditions sought by the Medicines Patent Pool are:⁸⁸

- (i) licenses will be for products needed for the treatment and prevention of HIV.
- (ii) licenses will be available on a non-exclusive and non-discriminatory to enable the production and development of HIV medicines, including adapted formulations and fixed dose combinations, for use in developing countries.
- (iii) licensors will be compensated through royalties. Reasonable rates of remuneration that take into account different countries' ability to pay, disease burden, and other relevant factors, will be considered in an effort to expand the benefits of the licenses to as many low- and middle-income countries as possible.

It has also been argued that:

"For the large under-served market in China, a patent pool could become a win-win strategy for the government and brand companies."⁸⁹

In September 2010, the Medicines Patent Pool received its first license from the USA Government's National Institutes of Health (NIH) on a patent for darunavir. However, this license does not allow manufacture of darunavir as the patents in relation to manufacture are held by a multinational company. No other patent holders have joined the Medicines Patent Pool as yet.

84 WHO (2007) *Multi-country Regional Pooled Procurement of Medicines: Identifying key principles for enabling regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean and Pacific Island Countries*. Geneva, WHO.

85 Patent pool decision heralds era of cheap HIV drugs *SciDevNet* 16 March 2010.

86 Golikeri P (2009) HIV patent pool hobbles as drug firms want India, China excluded, Agency: DNA. http://www.dnaindia.com/money/report_hiv-patent-pool-hobbles-as-drug-firms-want-india-china-excluded_1321644.

87 Satyanarayana K., Srivastava S. Patent Pooling for Promoting Access to Antiretroviral Drugs (ARVs) - A Strategic Option for India. *Open AIDS J.* (2010)4:41-53.

88 See: http://www.unitaid.eu/images/news/REVISED_letter_to_CEOS_patent_pool_15_12_10.pdf http://www.medicinespatentpool.org/pdf/Letter_Abbott.pdf

89 Liu L., Hongzhou L., (2010) Technology Development Through Pooling ARV Drug Patents: A Vision from China, *Open AIDS J.* (4): 54-59.

9. Intellectual property enforcement

Fake HIV medicines and the activities of ‘quacks’ can be extremely harmful to people living with HIV. National legislation is required against fake or spurious medicines and the fraudulent promotion of unproven remedies, and cooperative arrangements are required between countries to combat the trafficking of counterfeit medicines and unproven cures.⁹⁰ However, it is argued that recent initiatives introduced in the name of dealing with fake or spurious medicines have instead blurred the lines between issues related to improving drug regulation with those relating to the enforcement of intellectual property. The use of the term “counterfeit” to describe these measures furthers the confusion as the term in common parlance may refer to fake products but under the TRIPS Agreement is defined to mean the infringement of trademark rights. It is also argued that over-broad laws claiming to address the problem fake or spurious medicines but labeled as “anti-counterfeiting” laws can seriously restrict the availability of generic HIV medicines.⁹¹

Since 2005, there has been an increased focus on strengthening mechanisms for enforcement of intellectual property rights through so called “anti-counterfeiting” initiatives.⁹² This includes proposals for increased penalties for people alleged to have infringed patents. Extension of intellectual property rights protection to label generic medicines as ‘counterfeit’ can restrict access to medicines. For example, in 2008, Dutch authorities seized a shipment in transit of the second-line drug abacavir produced in India, purchased by UNITAID and on its way to Africa on grounds that the generic version of the medicine violated patent rights in Europe.

Rather than focusing on enforcement, it is argued that a public health approach requires a focus on efforts to strengthen drug regulatory authorities, promote rational use, and require transparency and accountability in the pharmaceutical sector.⁹³

The enforcement agenda is being promoted in free trade agreement negotiations with the European Union and in relation to the draft Anti-Counterfeiting Trade Agreement (ACTA). In July 2010, international civil society groups formulated the *Berkeley Declaration on Intellectual Property Enforcement and Access to Medicines*. The Declaration calls on governments not to proceed with the ACTA. Civil society organizations from Thailand and India endorsed the Declaration, which states that the draft ACTA “has a chilling effect on the manufacturing of and trade in legitimate generic medicines...(and) has serious implications for substantive areas of intellectual property law.”⁹⁴ Indonesia has argued against ACTA as follows:⁹⁵

“in our opinion, the ACTA initiative has failed to keep in line the TRIPS standards and thus undermined the safeguards provided by the TRIPS Agreement. For Indonesia, the most problematic part of the ACTA arises in the Chapter concerning the *Legal Framework for Enforcement of Intellectual Property Rights*. The points relating to civil enforcement, border measures, criminal enforcement and internet provisions all appear to have intrinsic problems, which we think merit further clarification.”

Representatives of eleven South Asian and South East Asian governments considered counterfeiting issues at a WHO meeting in 2010. At the meeting, WHO Southeast Asia regional director stated that WHO is in the process of working with the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to ensure equitable access to generic drugs is not undermined by vague definitions of counterfeit drugs or infringement of intellectual property rights.⁹⁶ Civil society organizations, including Centre for Trade and Development (CENTAD, India), the Delhi Network of Positive People (DNP+, India), Research Foundation for Science Technology and Ecology (India), and Third World Network have raised concerns that IMPACT legitimizes the TRIPS-plus enforcement agenda and undermines public health.⁹⁷

90 Amon J. (2008) Dangerous medicines: Unproven AIDS cures and counterfeit antiretroviral drugs. *Globalization and Health*.

91 Oxfam (2011) Briefing Paper. *Eye on the Ball Medicine regulation – not IP enforcement – can best deliver quality medicines*.

92 Abbott F. (2009) Seizure of generic pharmaceuticals in transit based on allegations of patent infringement: a threat to international trade, development and public welfare. *World Intellectual Property Organization Journal*, 1:43.

93 Oxfam (2011) *Briefing Paper: Eye on the Ball Medicine regulation – not IP enforcement – can best deliver quality medicines*.

94 *Berkeley Declaration*, signed by inter alia William Aldis, Assistant Professor (Global Health), Faculty of Public Health, Thammasat University, Bangkok, and Kajal Bhardwaj, India

95 *Statement by the Delegation of Republic of Indonesia at the WTO Trips Council*, 26 October 2010.

96 WHO pushes for regional medicinal production, *Bangkok Post* 8 September 2010. <http://www.bangkokpost.com/news/local/195131/who-pushes-for-regional-med>

97 *NGOs concerned over WHO's role in "counterfeit" drugs, IMPACT*. 17 May 2010, <http://www.twinside.org.sg/title2/wto.info/2010/twninfo100507.htm>



10. Conclusions

Increasing implementation of the TRIPS Agreement in Asia and the Pacific and pressure for adoption of TRIPS-plus measures means that patents on medicines are becoming more widespread. Generic competition for newer ARVs is being restricted. Some companies have offered voluntary licenses for new ARVs, but such licenses often come with restrictive conditions.⁹⁸ For ARVs that are widely patented, additional interventions beyond voluntary licensing will be needed to address intellectual property barriers in both importing and exporting countries.

The 2009 report of the UN Special Rapporteur on the Right to Health on access to medicines concluded:⁹⁹

“The framework of the right to health makes it clear that medicines must be available, accessible, acceptable, and of good quality to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS and (free trade agreements) have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfill the right to health.”

Consistent with states obligations under international law regarding the right to the highest attainable standard of health, TRIPS flexibilities will be required in national legislation to reduce prices and facilitate the use of new fixed-dose combination ARVs. TRIPS flexibilities are being employed with some success in India, Thailand and Indonesia, but remain under-utilized in the Asia Pacific region as a whole. Application of high standards of patentability in national laws and legislation that enables flexibilities such as compulsory licensing, non-observation of pharmaceutical patents (which is permitted for least-developed country WTO members until at least 2016) and patent pools can be considered as options.

98 Waning B, Kyle M, Diedrichsen E, et al (2010) Intervening in global markets to improve access to HIV/AIDS treatment: an analysis of international policies and the dynamics of global antiretroviral medicines markets. *Glob & Health* 6(9).

99 Human Rights Council (2009) Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover to the Human Rights Council, 11th session, A/HRC/11/12 31 March 2009; See also: Human Rights Council Resolution 12/27 of 22 October 2009:

Para 10: TRIPS “does not and should not prevent members from taking measures now and in the future to protect public health and [...] that the Agreement can and should be interpreted and implemented in a manner supportive of the right to protect public health and, in particular, to promote access to medicines for all including the production of generic antiretroviral drugs and other essential drugs for AIDS-related infections.”

Para 12: “Encourages all States to apply measures and procedures to enforce intellectual property rights in a manner that avoids the creation of barriers to legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures.”



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