

## **D4 | THE TRIPS AGREEMENT: TWO DECADES OF FAILED PROMISES**

In 1994 the agreement on Trade Related Intellectual Property Rights (TRIPS) was signed as part of the World Trade Organization (WTO) agreement. Low- and middle-income countries (LMICs) were aware of the grave risks posed by the TRIPS agreement to sustainable access to medicines. The TRIPS agreement harmonized laws that protect intellectual property (IP) in all countries and thus forced LMICs to allow patents on medicines, irrespective of the domestic situation. However, at the insistence of many LMICs, the TRIPS agreement incorporated a number of ‘flexibilities’ (also called ‘health safeguards’) that were designed to mitigate the adverse impact of a strong patent regime in LMICs. Almost two decades have gone by since the signing of the TRIPS agreement and there is substantial experience regarding the actual use of TRIPS flexibilities. In this chapter we take stock of the experience of using TRIPS flexibilities. We also examine a number of emerging trends in the global trade environment that act as barriers to medicines access in different parts of the world.

### **TRIPS flexibilities: do they work?**

The global consensus regarding the use of TRIPS flexibilities to ensure access to medicines was articulated in the ‘Doha Declaration on Public Health and the TRIPS Agreement’ (announced at the ministerial meeting of the WTO in Doha, in 2001), which stated ‘... we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose’ (WTO 2001). This consensus, subsequently, found mention in resolutions and outcome documents of various international conferences and summits – for example, the MDG declaration, declarations on HIV/AIDS and non-communicable diseases (NCDs), and the Rio +20 declaration. However, the experience of the past two decades shows us that LMICs have found it extremely difficult to make effective use of the TRIPS ‘flexibilities’. We discuss below the constraints faced by LMICs in this regard.

*Low technological capacity in LMICs* A majority of LMICs, including almost all least developed countries (LDCs), lack manufacturing capacity in the



**Image D4.1** Opposition to Novartis in India after it challenged India's patent law (Rajeev Chaudhury)

pharmaceutical sector. Most LMICs import pharmaceutical products, especially Active Pharmaceutical Ingredients (APIs). In the absence of local manufacturing capacity, most LMICs cannot make effective use of TRIPS flexibilities as they are dependent on imports from, and therefore on IP laws that exist in, the exporting countries. The TRIPS agreement was amended to allow imports to countries without manufacturing capacity, unencumbered by obligations imposed by the TRIPS agreement (MSF 2010). However, the mechanism proposed by the amendment required extremely cumbersome procedures. This made it almost impossible for countries to use the new mechanism to procure affordable generic medicines through imports. As a result, there have been only two instances of this mechanism being used.

*Bilateral pressures by HICs* Often high-income countries (HICs), especially the USA and those in the European Union (EU), try to prevent the use of TRIPS 'flexibilities' in LMICs through various means. In 2007, when Thailand issued a compulsory licence (CL), the EU Commissioner wrote a letter stating 'neither the TRIPS Agreement nor the Doha Declaration appear to justify a systematic use of compulsory license wherever medicine exceeds certain prices'.<sup>1</sup> Similarly, in August 2013, the US International Trade Commission asked that an investigation be launched against India. This investigation, entitled 'Trade, Investment and Industrial Policies in India: Effects on the US Economy', interrogates India's domestic policies related to the local content

requirements in green technologies and information technology, and IP protection and enforcement in the area of patent and copyrights (Gopakumar 2014). Further, the USA, under its ‘Special 301 process’, regularly identifies countries that do not provide ‘adequate and effective’ protection for intellectual property rights. US law also empowers the United States Trade Representative (USTR) to impose unilateral retaliatory measures (Flynn 2010).

*Pharmaceutical companies block entry of generic medicines* Pharmaceutical companies use multiple strategies to block or delay the entry of affordable generic medicines. These include the filing of numerous patent applications for the same medicine (termed ‘patent clusters’ or ‘patent thickets’) to delay or block the market entry of generic medicines (ibid.). Another common ploy used is to extend the life of a patent by a method known as ‘evergreening’, where small changes are made to the original patented molecule, in order to perpetuate the patent monopoly of the originator company. Under the TRIPS agreement, countries have the flexibility to determine what is patentable under national law. This means that country laws can have provisions that prevent ‘evergreening’ – a clear example is Section 3(d) of India’s Patent Act. In a landmark judgment in 2013, the Supreme Court of India upheld the validity of this section of the Indian law (which had been challenged by the Swiss MNC, Novartis). Now, Argentina and the Philippines also incorporate such provisions in their national laws and attempts are under way in Brazil and South Africa to do likewise.

*Weak laws and regulatory systems in LMICs* In order to use the TRIPS ‘flexibilities’, these have to be incorporated in country laws on IP. Many LMICs have not done so, or have done so very inadequately (MDG Gap Taskforce 2012). Further, optimum use of the flexibilities requires, as a first step, a national system to examine patents that are filed (so that national priorities are reflected in decisions regarding which patents should be allowed). Many LMICs do not have such a system in place (South Africa, for example). Moreover, under the guise of providing ‘technical assistance’, international organizations such as the WTO and the World Intellectual Property Organization (WIPO) misguide LMICs and encourage patent examination systems that mimic those in HICs. When LMICs incorporate such ‘advice’ in their national systems, they give up the advantages that are allowed in the TRIPS ‘flexibilities’ (Birkbeck and Roca 2010). A similar role (of providing biased assistance) is also regularly played by the European Patent Office (EPO), the US Patent and Trademark Office (USPTO) and the Japanese Patent Office (JPO) (Drahos 2007).

HICs are also engaged in undermining TRIPs flexibilities by working for a harmonization of the process of examining patent applications (thus imposing their standards of patent examination on the entire world). They have made a



**Image D4.2** Communities oppose free trade agreements in Colombia (Third World Health Aid)

proposal to reform the Patent Cooperation Treaty (PCT), which would treat a patent application as granted in PCT member states if the patent is granted in three member states of PCT (Syam and Li 2009).

*Lobbying and biased ‘technical assistance’* LMICs that have country laws which incorporate TRIPS ‘flexibilities’ face further challenges in ensuring that the flexibilities are actually used. Many do not have the financial and human resources that are necessary for effective implementation of national laws. In situations where regulatory capacity is weak, HICs intervene to derail the working of patent offices in LMICs. The EPO, USPTO and JPO regularly train personnel in patent offices of LMICs, thereby introducing a bias in how the latter work.

HICs also attempt to influence judges, so that they interpret IP laws in a manner that is beneficial to the interests of HICs. For instance, since 2003, the George Washington University (GWU) Law School coordinates an IP lobby programme known as the ‘India Project’. GWU coordinates an annual visit to India by a delegation consisting of pro-IP academics, corporate executives and judges of Federal Circuit Courts.<sup>2</sup> This delegation meets Indian judges of High Courts and the Supreme Court to advocate the need for strong IP protection.

*Barriers to the issue of compulsory licences (CLs)* The compulsory licensing system lies at the heart of TRIPS ‘flexibilities’. Countries have the right to

grant licences to domestic generic companies, so that they can manufacture and market patented drugs. When used, CLs curb the monopoly of MNCs and have been effective in reducing medicine prices by 95 per cent or more. However, too few CLs are actually being issued – just twenty-four have been issued in seventeen countries since the signing of the TRIPS agreement. Most CLs issued to date are for HIV/AIDS treatment, and a few for the treatment of NCDs (including a CL issued in India in 2013 for an anti-cancer drug, sorafenib).

There are several reasons why more CLs have not been issued. As we have noted earlier, the lack of local manufacturing capability acts as a major barrier against the optimal use of CLs. HICs regularly pressurize LMICs, asking them not to issue CLs (as we noted earlier, in the case of Thailand). LMICs are also reluctant to issue CLs, fearing reprisals from MNCs that control their pharmaceutical market. Further, most LMICs have inadequate or ineffective institutional mechanisms to monitor the impact of patented drugs on access to medicines. As a result they are unable to use the CL provisions, even when they are incorporated in their domestic laws (to issue a CL, evidence needs to be generated to show that a patent monopoly is a threat to public health).

### **Free trade agreements: going beyond TRIPS**

Free trade agreements (FTAs) are now the preferred route adopted by HICs to impose even higher standards of IP protection than what the TRIPS agreement demands (hence IP provisions in FTAs are called ‘TRIPS plus’ measures). An examination of 165 FTAs (in force or under negotiation) found that one quarter of them had provisions that undermine the ability of LMICs to incorporate flexibilities regarding the criteria for patentability. Further, a majority of FTAs involving the USA incorporate pharma-related provisions (Valdés and Tavengwa 2012).

Many FTAs involving the USA contain provisions that can result in patent terms that go beyond the twenty years mandated by the TRIPS agreement. The ongoing negotiations on the Trans Pacific Partnership Agreement (TPP) may lead to a treaty with very serious consequences for medicines access, and public health in general (see Box D4.1).

#### **Box D4.1 The Trans Pacific Partnership (TPP)**

The proposed Trans Pacific Partnership Agreement started out (in 2005) as a trade agreement between Brunei, Chile, New Zealand and Singapore. It was then known as the Trans-Pacific Strategic Economic Partnership Agreement.

In 2008 the USA proposed expanding the agreement to include a diverse range of countries bordering the Pacific, hence the Trans Pacific Partnership Agreement. The negotiating countries comprise Peru, Chile, the USA, Mexico, Canada, Japan, Vietnam, Malaysia, Singapore, Brunei, Australia and New Zealand. Reports from the negotiations all describe the USA as the main proponent, preparing draft materials for meetings of negotiators, and promoting the most extreme provisions.

The proposed TPP agreement includes twenty-nine chapters, most of which go far beyond traditional trade issues such as tariffs and quotas. The bulk of the chapters deal with the regulatory environment within which corporations operate. It appears that the USA is pursuing two objectives: first, regulatory harmonization so as to reduce the complexities of working across different jurisdictions; and secondly, creating a more accommodating environment within which US corporations might operate. These 'economic integration' chapters deal variously with trade in services, intellectual property (easier patents, greater privileges, tighter enforcement), investment protection, pharmaceutical pricing, capital controls, operations of state-owned enterprises, non-tariff barriers, government procurement, e-commerce, labour standards, environmental standards, and dispute settlement.

The negotiations are conducted in secret with national negotiating teams committed to tight security regarding the proposals and debates. The exception is the trade policy committees which advise the US Trade Representative (USTR). It appears that around six hundred corporate lobbyists and industry association officials have full access to the negotiating texts. Notwithstanding the tight security there have been some important leaks of chapters (Behsudi 2014) and memoranda (Washington Trade Daily 2014).

The debates around the agreement involve broadly three sets of stakeholders: US corporations, exporters from other negotiating partners seeking access to the US market, and a mixed constituency of opponents, based in the USA and beyond. Driving the USTR is the aggregate clamour from various corporations and industries in the USA seeking new markets (lower tariffs, tighter disciplines on state-owned enterprises, etc.); extended privileges for information-rich industries in the form of extended intellectual property rights and stronger enforcement; new privileges for investors in the form of investor state dispute settlement arrangements and new constraints on national economic autonomy (e.g. forgoing capital controls, new disciplines on monetary policy) (English 2012).

While most of the USA's negotiating partners are apprehensive regarding the implications of such extreme demands, what holds them at the

table is the possibility of access for their exports to the US market. New Zealand wants access for dairy; Vietnam wants access for clothing and footwear; Australia wants access for sugar, and so it goes. Japan may be an exception in that the Japanese corporates share many of the aspirations of their US counterparts but are apprehensive about the costs to specific Japanese industries of reducing protection and about the terms of the agreement privileging the USA vis-à-vis Japanese corporations.

The third group of stakeholders comprises a wide range of civil society interests concerned about the impact of some or all of the US programme on public interest policy space (e.g. regulation for public health), on access to information-rich technologies (e.g. pharmaceutical pricing), on domestic economic autonomy, on labour standards and environmental protection and other public interest areas. This group stands outside the negotiating rooms and with the exception of occasional leaks is not privy to negotiating texts. However, over the course of the negotiations this loose coalition of opposition networks has exercised increasing influence over policy-makers as mainstream commentators have picked up on their warnings.

From a health perspective the main concerns are: the impact of the extreme IP agenda on the prices of and access to medicines (UNITAID 2014); the proposed prohibition on the use of cost-effectiveness criteria in price-setting for reimbursement and procurement programmes; the reduced policy space for public health regulation associated with investor state dispute settlement (Gleeson and Friel 2013; Mitchell et al. 2014; Aldis et al. 2013).

The TPP is not a trade agreement. It is designed to promote economic integration of the participating countries on terms which are designed to serve the interests of US corporations. According to the TPP strategists, once the agreement is signed pressure will be brought to bear on other countries to join on a take-it-or-leave-it basis. In parallel with the TPP are the more recently launched negotiations for a Trans Atlantic Trade and Investment Partnership (TTIP), which would broadly reproduce the provisions and purposes of the TPP (European Commission 2013).

The TPP represents the corporate world's response to the stalemate in the WTO, where the demands by LMICs for the dismantling of agricultural protection in the rich world, and the demands of the rich countries for market access for industrial and information-rich products, have arrested the project of economic integration.

The principal economic significance of the TPP lies in the project of global economic integration, which promises short- and medium-term profit for the large transnationals but which accelerates the imbalances

which threaten further economic crises, the inequalities which lock millions into marginalization and exclusion and the processes of ecological destruction. In geopolitical terms the purpose of the TPP is to ‘contain’ China. It is not clear how seriously China takes this threat.

Within the USA there is rising opposition to the TPP, in particular around the theme of ‘exporting American jobs’. The concerns of the labour, environment and internet freedom movements are expressed in the refusal of the Democrats in the US Congress to give the US Trade Representative (USTR) ‘fast track trade negotiating authority’. Fast-track authority would enable the USTR to finalize the negotiations without congressional deliberation and then present the Congress with a final text for acceptance or rejection (Congressional Research Service 2012).

### **Using the bogey of ‘counterfeit’ to criminalize generic drugs**

Over the past several years, multinational pharmaceutical companies and some developed countries have been pursuing what has come to be known as the ‘Intellectual Property (IP) Enforcement Agenda’. This involves lobbying with governments to introduce strict IP enforcement norms in their laws and to involve public authorities funded by taxpayers’ money to enforce their IP rights. Recently, attempts have been focused on redefining the term *counterfeit*, which generally refers to trademark disputes. This has been done by blurring the lines between issues of real public health concern (i.e. spurious, substandard and adulterated drugs) with counterfeits.

The issue blew up into a major international incident in 2009 when generic drugs from India, being exported to Latin America, were confiscated in transit in several European ports (Khor 2009) on the suspicion that they were ‘counterfeit’. These drugs were manufactured legally in India and were being exported to countries where these drugs were also legal. The incident served to focus attention on the possible ways in which the IP enforcement agenda could be turned into a ploy to criminalize generic drugs.

Since then, the issue of ‘counterfeits’ has been a subject of considerable discussion in the WHO. Also controversial has been the role of a body called IMPACT (International Medical Products Anti-Counterfeiting Taskforce), which is engaged in criminalizing generic medicines by using the bogey of ‘counterfeit’.<sup>3</sup> IMPACT works closely with several organizations such as Interpol, the Organisation for Economic Co-operation and Development (OECD), the World Customs Organization (WCO), the World Intellectual Property Organization (WIPO), the European Commission and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). Led by India and Brazil, several countries of the South were able to force

WHO to stop hosting IMPACT. Since then a new term (SSFFC – Substandard/spurious/falsey labelled/falsified/counterfeit medical products) has been developed by the WHO to identify the different ways in which medicines can be of compromised quality. A ‘member state mechanism’ (MSM) has also been developed within the WHO to discuss ways in which medicines of compromised quality can be eliminated. However, IMPACT continues to promote its agenda and ambiguities continue to be present in the WHO’s definition of ‘counterfeit’ medicines.

### **Voluntary licences and differential pricing**

Voluntary licences (VLs) are licences negotiated by originator companies and domestic generic companies on mutually agreed terms. They differ from CLs, as in the case of CLs the government issues a licence to a generic company irrespective of whether the originator company is willing to part with its monopoly (hence CLs are also called ‘non-voluntary’ licences). MNCs use VLs to co-opt generic companies (with whom they enter into an agreement) and thus effectively stop the possibility of a CL being issued. VLs usually impose restrictive conditions on the licensee. These can include restrictions that prevent local production, geographical restrictions that prevent marketing in some territories, etc. Such restrictive conditions have limited the effectivity of the ‘Medicines Patent Pool’ initiative (MSF 2013).

MNCs also try to pre-empt the issuing of CLs by entering into differential pricing arrangements (also called ‘tiered’ pricing) in LMICs (Saez 2014). Typically differential pricing leads to a lowering of the price of medicines in a country, but never to a level that could be reached if a CL was issued to encourage competition in the market. The mechanism is used to deflect criticisms regarding the very high prices of patented drugs. At the same time MNCs retain control over the price at which their product will be sold and also the countries that will be covered by a differential pricing mechanism. Typically originator companies keep many medium-income countries (in addition to all HICs) outside the ambit of differential pricing.

### **International investment agreements**

Investments agreements – either as discrete Bilateral Investment Treaties (BITs) or as part of FTAs – are increasingly being used by MNCs to retain their monopoly over pharmaceutical markets. These agreements contain provisions to protect the investment of foreign investors. They allow foreign investors to seek compensation from the state for actions that undermine their investment, through an international arbitration. Since the definition of investment includes intellectual property, the use of TRIPS flexibilities such as CLs, the rejection of patent claims, etc., can be interpreted as grounds for initiating legal action against country governments (Biadgleng 2013). For example, Eli Lilly has recently filed an arbitration notice against Canada, seeking compensation

#### **Box D4.2 A 'broken' system of innovation**

Problems in the IP-based system of innovation have been frequently articulated. These include the problem that such a system incentivizes only those innovations where profits based on a patent monopoly are secured. There are efforts under way to work towards an innovation system that looks beyond the framework of IP. It is widely recognized that current R&D incentives fail to address the majority of global health priorities in LMICs. Therefore, any comprehensive and sustainable solution should include innovative approaches to govern publicly funded R&D that ensures both needs-driven innovation and affordable access. A way to achieve this is to encourage the use of incentive mechanisms that facilitate knowledge sharing and incorporate the principle of delinkage (i.e. delinking the cost of innovation from the cost of a drug by supporting innovation through public investment and other forms of support).

of CAN\$500 million for the rejection of patents on Strattera and Zyprexa under the investment protection provisions of the North American Free Trade Agreement (NAFTA) (Public Citizen 2013).

#### **The way forward**

Our discussions have focused on the legal, institutional and political bottlenecks which prevent the effective use of TRIPS flexibilities. This situation has prompted the 'Global Commission on HIV and Law' to observe that 'TRIPS has failed to encourage and reward the kind of innovation that makes more effective pharmaceutical products available to the poor, including for neglected diseases. Countries must therefore develop, agree and invest in new systems that genuinely serve this purpose, prioritising the most promising approaches including a new pharmaceutical R&D treaty [see Box D4.2] and the promotion of open source discovery' (Global Commission on HIV and Law 2012).

Clearly, there is an urgent need to think beyond a framework that is bound by the TRIPS agreement. The negotiated outcomes of various international conferences and summits, including the post-2015 development agenda, should go beyond the use of TRIPS flexibilities and clearly state that public health, human rights and inclusive development take priority over IP protection. Finally, LMICs should insist on the initiation of the mandated reviews of the TRIPS agreement, including a review of the implementation of TRIPS under Article 71.1 of the agreement.

## Notes

1 The letter can be accessed at [www.wcl.american.edu/pijip/documents/mandelson07102007.pdf](http://www.wcl.american.edu/pijip/documents/mandelson07102007.pdf).

2 For a brief description of the India Project, see [www.law.gwu.edu/Academics/research\\_centers/india/Pages/Overview.aspx](http://www.law.gwu.edu/Academics/research_centers/india/Pages/Overview.aspx), accessed 31 October 2009. See also see the interview with the dean of GWU Law School, available at: [www.law.gwu.edu/Academics/research\\_centers/india/Documents/India\\_article.pdf](http://www.law.gwu.edu/Academics/research_centers/india/Documents/India_article.pdf).

3 For a detailed discussion on the IMPACT story see: 'World Health Organization: captive to conflicting interests', *Global Health Watch* 3, Zed Books, London, 2011, pp. 237–43.

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