

## Chapter 12

### TRIPS Implementation in Developing Countries: Likely scenarios to 2025

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#### Abstract

This chapter sketches future scenarios of TRIPS implementation in developing countries by looking at past experience, current trends and by comparing historical and cross-country patterns. The chapter focuses on the three largest emerging economies – Brazil, India and China (BICs), since they are those with the highest potential to shape the intellectual property regime. Through international contestation, domestic implementation and even novel rule-making, they have been able to ensure that some flexibilities in the implementation of TRIPS remain. Their domestic policies and coalition-building efforts have been followed by many other developing countries. Shifts in the political economies of Brazil and India towards 2025 due to increased patenting and rise in innovation could mean that they will calibrate or even drop their opposition to TRIPS. China will likely be an innovation giant by then and eager to join the club of proponents of strong and enforceable intellectual property (IP) rights. In the area of access and benefit sharing of genetic resources and related traditional knowledge (ABS), the BICs are likely to remain opposed to stringent IP, and could even become active rule-makers. A degree of homologation between the TRIPS and the Nagoya Protocol, which has codified ABS, appears likely. In general, access to health, as one of the typically contentious domains of IP law and policy, is likely to remain a hotly debated issue. Challenges to pharmaceutical patents by developing countries that use TRIPS flexibilities will continue, as will the efforts by industrialized countries to constrain the available flexibilities through bilateral and regional trade agreements. Overall, the domain of IP law and policy is likely to remain complex and dynamic, with different interests colliding. This may reduce the chances of new multilateral law-making – for instance in the area of substantive patent law, while increasing the chances of new rule-making through domestic practice by BICs in the shadow of the TRIPS.

## 12.1 Introduction

This chapter sketches future scenarios of TRIPS implementation in developing countries by looking at past experience, current trends and by comparing historical and cross-country patterns. The chapter focuses on the three largest emerging economies – Brazil, India and China (BICs), since they bear the highest potential to shape the intellectual property regime. Through international contestation, domestic implementation and even novel rule-making, these countries have been able to ensure that some flexibilities in the implementation of the Agreement on Trade Related Intellectual Property Rights (TRIPS) remain. Their domestic policies and coalition-building efforts have been followed by many other developing countries. The BICs have taken different paths in the implementation of TRIPS. Brazil and India have contested a strict application of the agreement and sought ways of using its flexibilities – what is known in the literature as a ‘minimalist’ approach. In contrast, China has, despite having faced continuous accusations of IP violation, followed a more rigorous domestic interpretation of the TRIPS that is in line with the agenda pursued by industrialized countries and often referred to as a ‘maximalist’ approach.<sup>1</sup> In addition to these differences at the meta-level, there are others that reflect the economic, social and cultural specificities of each BIC country and their political economies, which shape their domestic and international positions on IP. There are also a number of commonalities that have to do with the rising economic and political importance of the BICs and specifically for the area of IP policy, with their transition into innovation engines and actual beneficiaries of a strong IP regime, which may also prompt shift in the at least so far minimalist approach. Against this backdrop and taking into account the performance of the BICs on the international plane, it is a valid and interesting question to ask, whether at this stage we can predict the trajectories of their future TRIPS implementation. If we can answer this question in the positive, we can pose a further one with regard to the likely scenarios that we can sketch up to 2025.

This chapter seeks to answer this combined question by evaluating the approaches in the IP domain followed by the BICs so far. It will be shown that the approaches of the three countries towards TRIPS are not devoid of contradictions and they have supported the agreement in some areas, while challenging it in others. There is one aspect of crucial importance to the BICs and other developing countries and that is the area of the intersection between IP and public health that has had repercussions for the treatment of pharmaceutical patents. This area is particularly interesting also because India and Brazil have been proactive there and have engaged as alternative rule-makers (Serrano and Burri 2017). Another important area in which the BICs have been active and have brought about new rules is the domain of access and benefit sharing of genetic resources and related traditional knowledge (ABS).

The shift from rule-taking to rule-making that the BICs have undergone with regard to TRIPS has taken place through multilateral negotiations at the TRIPS Council and domestic practice. Both of these mechanisms are explored in detail in this chapter.

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<sup>1</sup> Maximalist and minimalist policies have to do with the trade-offs involved in IP policies, in particular the conflicting objectives of creating and using/disseminating knowledge (Shadlen 2005). A crucial aspect which affects choices has to do with the extent to which policy-makers believe that restricting access to knowledge is a precondition to innovation and improving economic welfare (what is known as a maximalist approach to IP) or on the contrary (a minimalist understanding) if they believe that the exclusion from knowledge is an obstacle to innovation, cultural flourishing, and economic development (Haunss and Shadlen 2009).

The most notable example of multilateral negotiations are efforts by the BICs on ABS policies through a homologation of TRIPS and the Nagoya Protocol. As to domestic practice, in effect, as argued by Okediji (2004), the contested TRIPS negotiations left gaps that are subject to interpretation. The interpretation of IP norms through domestic practice, especially but not only in cases when such practice leads to disputes at the WTO and to favorable appellate body decisions, may thicken the agreement by filling such gaps and making the requirements more or less stringent, depending on the public interest at stake. A good example of this contestation is the complaint filed by the United States in 2000, which challenged the legality of local working requirements by Brazil under the TRIPS – something that we discuss in more detail below. New global rules may also evolve through domestic interpretation of TRIPS, if they diffuse to other developing countries. The most notable example of this is Section 3(d) of the 2005 Indian Patent Act, which sets stricter limits to secondary patents and has been widely copied by other emerging and developing countries with serious repercussions for pharmaceutical companies and public health policies, as we show below.

The chapter is structured as follows. A first section provides a brief overview of the main features of the IP regime and how the BICs and other developing countries have attempted to adapt the TRIPS. This is followed by a detailed evaluation of the approaches taken towards TRIPS in each one of the BICs, and their impact in other developing economies. The third section draws some lessons from these previous experiences to suggest what the likely positions of the BICs will be on TRIPS implementation up to 2025. Some concluding thoughts are offered in the last section.

## **12.2 Features of the IP regime and adaptation by emerging economies to TRIPS.**

IP rights have become a disputed issue between industrialized and developing countries ever since US leadership and concerted efforts with the European Union, Japan, Canada brought about the conclusion of the TRIPS in 1995 under the umbrella of the World Trade Organization (WTO). The agreement codified a set of binding international rules, including on patents, trademarks and copyrights (Correa 2000; Sell 1995). Strong resistance from developing countries led by Brazil and India during the negotiations left room for interpretation, what is known as TRIPS flexibilities. These offer some opportunities for developing countries to resist the maximalist IP agenda furthered by industrialized countries, which sets high standards of protection in all areas of IP protection, limits users' rights, seeks effective enforceability in both civil and criminal and the installment of domestic institutions to ensure this (Krizic and Serrano 2017). Many developing countries have considered that in some cases such an enhanced IP protection can be detrimental to development and have attempted to secure exceptions on the basis of distinct public interest concerns, such as public health and access to knowledge – subscribing to the so-called minimalist approach. After all, it should be kept in mind that developing countries only acquiesced to the TRIPS because of the pressures of the WTO as a single undertaking and bargains linking IP protection to improved market access for textiles and agriculture (Deere Birkbeck 2008). Post-TRIPS, India and Brazil have continued to lead coalitions of developing countries with the aim of limiting and calibrating the impact of the changes brought about by the TRIPS (Serrano and Burri 2017).

Global public health is amongst the few areas where emerging countries have taken a major role in interpreting the TRIPS and shaping IP rules by promoting limits to pharmaceutical patents. These efforts have been followed and supported by other developing countries. While this issue may appear narrow in scope, in fact pharmaceutical patents have great economic significance for industrialized countries and have mobilized lobbyists, both domestically and internationally, in driving the expansion of the IP regime. Pharmaceuticals has been indeed, together with audiovisuals and IT, one of the main sectors which pushed for the establishment of the TRIPS during the Uruguay Round. Pharmaceutical patents can thus be seen as a focal point of wider debates about the underlying question of whether patents, as the 'hardest' IP form created to protect inventions and promote innovation, are potentially detrimental for development or not.

TRIPS offered transition periods for emerging countries, often up to 10 years as in the case of India, so that the full effects of the agreement were not immediately perceived, nor felt on the ground. However, once the transition was over bureaucratic actors in India and Brazil realized the enormous costs that came with the agreement. This was particularly the case with regard to pharmaceutical drugs. The threat posed by a full TRIPS implementation to the survival of Brazil's HIV/AIDS program and India's vast generics industry mobilized domestic and international stakeholders in seeking a more flexible interpretation of IP norms. Brazil and India have been also especially successful in these endeavours. They have amongst other things made use of compulsory licensing, enacted domestic legislation limiting patents, such as domestic working requirement and setting limits to secondary patents, and launched agendas on development issues, such as access to medicines, promoting the linkage between human rights and health, protection of traditional knowledge and access to biological resources (Kapczynski 2008). These initiatives have been furthered in venues including the WTO, but also through other channels offered by the World Intellectual Property Organization (WIPO), the World Health Organization (WHO) and the Convention on Biological Diversity (CBD) among others. The 2001 Doha Declaration on TRIPS and Public Health<sup>2</sup> and the 2005 launch of the Development Agenda at WIPO stand out as significant achievements.

China has taken a different path. The country "has been reluctant to press for a structural reform of IP regulation in the WTO, despite lending its support to developing countries when the negotiations over the Decision on Implementation of Paragraph 6 of the Doha Declaration were under way" (Chan 2010, 115). The reason for this has to do with China's long quest to join the WTO which gave the US and the EU significant leverage. It took China fifteen years to attain WTO membership and the country was not granted the developing countries' grace period for implementing the TRIPS. Besides making use of WTO-entry negotiations, the US and EU have sought to modify China's approach towards IP through bilateral cooperation in the area of IP legislation and enforcement – such as the EU-China IP dialogue launched in 2004 and the US-China IP Cooperation Dialogue set up in 2013. Due to these pressures and the fact that

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<sup>2</sup> The 2001 Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) affirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all" (para. 4). The Doha Declaration went on to reaffirm the key flexibilities available under the TRIPS Agreement, such as the power of WTO Members "to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted", as well as "the right to determine what constitutes a national emergency or other circumstances of extreme urgency" (para. 3, lit. b and c). The Doha Declaration also addressed the constraints on exports set out in Article 31(f) TRIPS and instructed the Council for TRIPS "to find an expeditious solution to this problem" (para. 6).

the country remains the prime target of IP violations complaints, China has taken a subdued position in meetings of the TRIPS Council. However, it has supported public health concerns of other developing and emerging countries. More recently, China has taken a more activist approach with regards to ABS. It has also launched a deep reform of the China Drug Administration (CDA), which has allowed it to negotiate with patent holders to reduce the price of pharmaceutical drugs in the country. Interestingly, rather than making use of TRIPS flexibilities to reduce the rising costs of its healthcare system, as other developing and emerging economies have done, China has taken advantage of its market power to do so; it is now the world's second largest consumer of medicines.<sup>3</sup>

In sum, the establishment of TRIPS was largely resisted by developing countries, which under the leadership of Brazil and India have sought to weaken it, or at least to keep its flexible implementation. When leading coalitions of developing countries, Brazil and India have taken advantage of the fragmentation present in the IP regime. The proliferation of fora and the multiplication of transnational networks have helped them preserve flexibilities (Morin et al. 2018). Thus, minimalist approaches have been sought not just at the TRIPS/WTO but at the WIPO. The latter, as part of the Development Agenda, has established committees and divisions that, alongside the traditional structure, explore emerging and unconventional issues (Netanel 2009). Other international fora where IP and in particular patent-related issues have been discussed include public health, human rights, biological diversity, food and agriculture, climate change, and indigenous knowledge. These efforts have been supported by different types of transnational networks, including NGOs and other types of activists, generic producers, academics and civil servants (Sell and Prakash 2004; Matthews 2011; Morin et al. 2018).

The next section looks in detail at the discrete policies followed by Brazil, India and China when implementing the TRIPS. They provide valuable lessons about the opportunities and challenges faced by emerging and developing countries when implementing the TRIPS and clues for likely scenarios towards 2025.

### **12.3 TRIPS implementation in Brazil, India and China (BICs)**

Emerging and developing countries face dilemmas when tailoring their approaches to TRIPS implementation. On the one hand are the costs of having a stronger IP regime – some relate to administrative costs stemming from building patent offices, providing for specialized personnel and proper patent application procedures; others relate to the effects of stronger IP rights, such as the already mentioned costs of pharmaceutical patents for public health programs. On the other hand, developing and emerging countries feel substantial domestic and international pressure to adopt measures and institutions of strong IP protection. International pressure by industrialized countries often occurs through bilateral dialogues, capacity building programs, bilateral and macro-regional trade agreements that seek to limit flexible TRIPS interpretations and increase existing standards of protection in time, scope and in enforceability. Domestic pressure stems from those economic sectors that are highly innovative and seek to capture the rents that arise from the temporary monopolies granted by patents. Other sources of

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<sup>3</sup> The Economist (2018) "Swallowing bitter pills: China is sprucing up its pharma sector", 30 August 2018.

domestic pressure can come from multinational corporations, mostly from developed countries, seeking to protect the economic gains derived from their technological lead.

Overall, it may be hard for most developing countries to resist maximalist IP policies. Large emerging economies like the BICs have nevertheless, for a number of reasons, have been in a better position to do so. These reasons include possessing larger market power and resources for capacity-building. Large diasporas from which to draw knowledge and expertise also often translate into better staffed and trained bureaucracies and wide spanning transnational networks. Well staffed and trained bureaucracies, as well as stronger courts, can better face legal challenges raised by patent holders. Additionally, in order to take advantage of TRIPS flexibilities such as compulsory licensing,<sup>4</sup> developing countries need to be able to produce domestically the pharmaceutical drug in question. Few developing countries have these capacities, which explains why most of them have followed and supported the flexibilities practiced by large emerging economies with regard to the TRIPS agreement. This again justifies our selection of countries and the focus of this contribution on the BICs.

### *Brazil*

Brazil's implementation of the TRIPS has been mainly shaped by the costs borne by the agreement to its highly successful and politically sensitive public health system. Deriving from activist networks from as early as the 1960s, known as the Sanitary Movement (Movimento Sanitário), the right to health was enshrined in the 1988 Constitution that ended military rule in the country (Souza 2007). Since the movement was a crucial part of the coalition leading to democratization, the establishment and maintenance of a public and universal health system (Sistema Único de Saúde) has been a non-negotiable issue for any Brazilian government since then. A strict implementation of TRIPS and a large HIV-AIDS epidemic threatened to bankrupt this program given the high costs of patented anti-retroviral drugs. This explains why Brazil took a leading role in pushing for a flexible implementation of TRIPS. Together with India, albeit driven by different motives, it became the leading voice of the developing world to ensure a minimalist approach to IP endured, despite the coordinated efforts by industrialized countries for a strict application of TRIPS.

International and domestic pressures have challenged this approach leading to interbureaucratic strife and blockages of flexibilities-seeking legislation at the Brazilian Congress. This pressure has however done little to influence Brazil's positions in multilateral fora, which have remained remarkably consistent. Besides the relevant domestic incentives mentioned earlier, this approach on the international scene derives in part from having one of the best-staffed and most professional Foreign Ministries (known as *Itamaraty*) amongst developing and emerging economies. While the Health Ministry has been a crucial actor ensuring for flexible interpretations of TRIPS and enacting domestic policies, the Brazilian patent

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<sup>4</sup> The 2001 Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) affirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all" (para. 4). The Doha Declaration went on to reaffirm the key flexibilities available under the TRIPS Agreement, such as the power of WTO Members "to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted", as well as "the right to determine what constitutes a national emergency or other circumstances of extreme urgency" (para. 3, lit. b and c). The Doha Declaration also addressed the constraints on exports set out in Article 31(f) TRIPS and instructed the Council for TRIPS "to find an expeditious solution to this problem" (para. 6).

office (INPI) has followed the opposite approach and subscribed to strong IP protection. This has translated into bureaucratic infights, which reached a highmark when INPI sued the health surveillance agency of the Health Ministry (ANVISA) at the Constitutional Court. INPI's modernization in the 1990s, in terms of resources and expertise led to strong bilateral exchanges with leading patent offices from industrialized countries – US, EU and Japan, known as the Trilateral offices – and this explains a culture of expanding patents.

The most important domestic efforts, which reflect Brazil's aim to keep a flexible implementation of TRIPS have been the prior consent norm and local working requirements. ANVISA, through prior consent has been given a veto right over pharmaceutical patents given by INPI (thus explaining the constitutional fight between the two). Brazil has also made use of so-called 'local working requirements', which allows the issuance of compulsory licenses for patented goods that are not produced locally after a certain time (usually 3 years) after the granting of the patent. Brazil made apt use of this provision as a means to force US pharmaceutical companies to reduce the price of certain medicines. For this reason in 2000, the United States filed a complaint at the WTO challenging the legality of local working requirements under the TRIPS. The case was settled but revealed the possibilities of using the grey legal zone of the local working requirement as a balancing mechanism within TRIPS (Mercurio and Tyagi 2010).

Amongst Brazil's most relevant international initiatives to preserve TRIPS flexibilities was the launching in 2004 together with Argentina of a Development Agenda at the World Intellectual Property Organization. The WIPO Development Agenda went beyond curbing the effects of strong IP and aimed at ensuring that development considerations form an integral part of WIPO's work, therewith challenging the pro-IP dynamics of WIPO and the strong impact of industrialized countries (May 2006). Brazil pursued in parallel similar initiatives in other fora such as the World Health Organization, United Nations High Commissioner for Refugees, United Nations Development Program, and the United Nations Environment Program. Brazil made in particular good use of the existing normative debates (Sell and Prakash 2004) on the harmful effects of TRIPS on development and public health (Wade 2003). It also used its central position within Mercosur to torpedo the US-led Free Trade Area of the Americas initiative, and block the TRIPS-plus provisions that had been included in the draft agreement (Carranza 2004). Brazil also took a leading position in the joint effort to codify ABS legislation both at the Convention of Biological Diversity (CBD) which culminated with the Nagoya Protocol, and at WIPO through the Working Group on ABS. Yet, as previously mentioned Brazil has also adopted a strong patent legislation that goes well beyond TRIPS' minimal requirements, which reflects its domestic cleavages. Brazilian policymakers have been divided between those in favor of developmentalist policies and those favoring more liberal positions (Montero 2014). The economic importance of FDI in Brazil and the dominance of transnational corporations in the Brazilian pharmaceutical industry, lent the latter significant influence in the Brazilian Congress. For this reason, maximalist IP legislation gets passed in Congress in spite of Brazil's strong minimalist positions at multilateral fora.

These domestic contradictions are also observable on ABS policies. Itamaraty and the Environmental Ministry have been robust supporters of the codification of ABS and its inclusion in the IP system, in part since these efforts have largely taken place within the CDB, which was adopted during the Rio Earth Summit in 1992 (Muzaka and Serrano 2019). Opposition to these policies has come from unexpected quarters. Some activists in Brazil have claimed that the commodification of genetic resources

as envisaged by the CBD goes against the traditions of many indigenous groups and thus have blocked efforts to codify ABS. The agro-business lobby, a very influential actor in the Brazilian Congress, has also opposed ABS codification. For these reasons, Brazil has at times expressed concerns about the negative effects that may occur from benefit sharing policies and has so far failed to ratify the Nagoya Protocol, despite having played an important role in the efforts to codify ABS at the CBD and WIPO.

### *India*

The implementation of TRIPS in India was contested, in particular with regards to patents and to a large extent due to the powerful Indian generic drugs industry. India had been one of the most vocal challengers to the TRIPS during the Uruguay round negotiations and managed to secure a 10-year transition to implement the agreement, as well as guarantees on compulsory licensing. Nonetheless, India was the first country taken to 'court' under the TRIPS, as it had failed to fulfill its obligations during the transition period and secure proper patent applications and the United States could successfully prove that (Ganesan 2015)<sup>5</sup>. TRIPS posed a challenge to the survival of the Indian thriving generic industry and triggered mobilization and opposition to stronger patenting requirements from domestic and international actors. NGOs such as Doctors Without Borders and the Third World Network supported the Indian state in various ways. The process of applying the agreement itself was complex, involving multiple state and non-state actors and various amendments to the Indian patent law (in 1995, 1999 and 2002) culminating with the 2005 Indian Patent Act (Shaffer et al. 2015). These changes were significant since India had tailored its colonial-era IP laws to further its development needs through its 1970 Patents Act (Drahos 2010). India proved adept at making use of TRIPS flexibilities to protect its developmentalist policies, in particular its generic drug industry and the protection of traditional knowledge (Oke 2015; Unni 2012).

At the international level, India has supported minimalist positions at WIPO regarding the reform of the Patent Cooperation Treaty and in negotiations on the Substantive Patent Law Treaty. At the TRIPS Council, India has been together with Brazil a leading voice endorsing the use of flexibilities available under the agreement. India was one of the most active WTO members advocating for additional exceptions and limitations to patent protection, especially in the process that led to the 2001 Doha Declaration on the TRIPS Agreement and Public Health, the 2003 WTO decision on public health and the 2005 amendments to the TRIPS.<sup>6</sup>

Beyond this international activism, through its domestic practices India has also become a major player in IP disputes. Other emerging and developing countries have copied India's adaptation of TRIPS, which has tested the limits of the flexibilities included in the agreement. Notable examples of these domestic legal innovations are: Section 3(d) of the 2005 Patent Act which limits secondary patents, the Right to Information Act passed in October 2005, and the use of Public Interest Litigation, by which NGOs, individuals and other institutions have gained the right to file public concern lawsuits. Section 3(d) of the Indian Patents Act of 2005 in particular has become known for its potential to dramatically alter the TRIPS agreement given that it redefines what an invention is as it bans patents on both new uses of known substances and on new forms of known substances that do not enhance 'efficacy'. Although limits to the

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<sup>5</sup> WTO Appellate Body Report, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, 19 December 1997.

<sup>6</sup> See footnote 4.



subject matter of patents exist in many countries, the scope of section 3(d) and its expansive exclusion of patents on new forms of known substances is new to patent law (Mueller 2007, 550; Kapczynski 2009, 1590).

Another issue besides pharmaceutical patents where India has taken a strong stance has to do with the misappropriation of traditional knowledge, genetic resources, and traditional plant varieties. India has challenged foreign companies' patents on the grounds that they may be based on pre-existing traditional knowledge and biological material. For this reason, the Indian government has created a digital library of traditional knowledge, which aims to provide information to international patent offices, so as to pre-empt foreign patenting on the grounds of lack of novelty and ensured that the TRIPS provisions on the protection of plant varieties do not affect farmers' rights to keep and trade seeds (so-called "farmers' rights" as opposed to "breeders' rights"). This debate has become particularly salient since the Indian parliament passed the Plant Variety Protection and Farmers' Rights Act in August 2001.

As in Brazil, there has been some domestic opposition to this minimalist stance by actors seeking a stronger IP regime (Kher 2013; Kapoor and Sharma 2015). In particular the Council of Scientific and Industrial Research (CSIR), which has filed most of India's existing patents, stand out. Since the early 1980s, India has sought to develop a biotechnology industry and has made substantial R&D investments. The CSIR has been a main beneficiary of these efforts and became domestically one of the strongest voices calling for a stronger patent regime with the alleged aim of promoting innovation. Yet, India's particular domestic constellation makes it hard for this voice to overcome the powerful opposition of the domestic generics industry, the alliances that exist with international NGOs which depend on the generic industry for providing low-cost drugs to developing countries, and the proactive Indian courts, together with strong pressure from civil society. For example, when the issue of access to patented medicines was debated at the WTO, the Indian generic producer Cipla strategically campaigned alongside MSF, KEI, Oxfam, and other NGOs, and their partnership enhanced the credibility of rule-changers, both domestically and internationally (Sell and Prakash 2004; Watal and Taubman 2015). Thus, despite some domestic opposition India remains a bulwark against a strict interpretation of the TRIPS.

### *China*

The case of China is puzzling for two reasons. On the one hand, China has shown a much more moderate approach towards pursuing TRIPS flexibilities. As a latecomer to the WTO, it was not able to obtain transition periods as other developing and emerging countries and has largely implemented maximalist IP policies at the domestic level, including an impressive revamp of its patent office (SIPO), which is now one of the leading patent offices in the world (Serrano 2016). SIPO could even soon become the largest patent office globally with the greatest number of patents issued (Reynolds and Sell 2012). On the other hand, China remains the main target of IP violation complaints, being accused of infringing IP in all its forms (patents, copyrights and trademarks) and massive counterfeit production. The United States International Trade Commission (USITC) has targeted China on 187 occasions for violations in a large number of sectors (e.g. automotive, electronics, semiconductors, chemicals and machinery).<sup>7</sup> The

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<sup>7</sup> USITC, IP Infringement Notices for 337 Investigations, available at: [http://www.usitc.gov/secretary/fed\\_reg\\_notices/337/](http://www.usitc.gov/secretary/fed_reg_notices/337/)

European Commission for its part claims that European firms have lost one out of every fifth dollar of profits made in China to IP theft (Devonshire et al. 2011). Unlike complaints related to Brazil and India, which have to do with their IP systems, in the case of China complaints are not due to Chinese legislation but rather due to its enforcement. This is exacerbated by the fact that China has only recently created a modern legal system. Criminal and procedural laws, domestic contract and law regulations, trademark and patent laws, and laws allowing for private investment had all to be passed after Deng Xiaoping's reforms in 1978 (Cheung 2009, 66-67).

Concerns by industrialized countries also relate to China's aims of becoming an innovation-based economy and the domestic policies enacted to support this aim. These policies go well beyond IP, and include broader industrial tools such as subsidies, forced technology transfer through joint ventures, and even accusations of cyber-spying. These industrial policies have been part of large campaigns such as: autonomous innovation, strategic pillar sectors, strategic emerging industries initiatives and more recently the ambitious 'Made in China 2025' strategy, which seeks to upgrade China's industrial production and drastically reduce the proportion of imported components in it.

At the international level China has nominally supported agendas seeking flexibilities under the TRIPS by other emerging and developing countries but it has not taken an active role as Brazil and India have done. The only forum where China has assumed a leading role has been with regard to the access to medicines campaign at the World Health Organization. This paradox may be explained by the fact that the organization was headed by a Chinese national (Margaret Chan) from 2012 to 2017.

Some important changes have occurred over the past few years, which may suggest the new path that China may be taking towards IP policies. With regard to pharmaceutical patents, while generally being cooperative with industrialized countries (Bird and Cahoy 2007), China has recognized, as other developing countries have, that it has a stake in ensuring the affordability of pharmaceuticals. However, despite having domestic legislation allowing the use of TRIPS flexibilities, such as compulsory licensing, China has not used any of these tools, which have been considered too aggressive.<sup>8</sup> Instead, it has relied on negotiations with patent holders and anti-corruption policies to reduce pharmaceutical prices and clean up its costly and bloated healthcare system. These measures have been possible due to China's growing healthcare market, at present the world's most attractive for foreign investors.<sup>9</sup>

China has also recently created specialized IP courts to address some systematic shortcomings in IP implementation. Three such courts were established in the major urban centres of Beijing, Shanghai, and Guangzhou in 2014. More recently, four IP tribunals with similar functions to the IP courts have been established in Nanjing, Suzhou, Chengdu and Wuhan. There are strong domestic incentives to do so, as China has become a rising innovator and lobbying for a stronger enforcement of IP has increased. For example, Chinese patent filings have grown unprecedentedly in the last decade, becoming higher than those of the US, EU and Japan. This has particularly improved IP laws implementation on patents where clearly defined rules, enforcement, transparency and consistency can be now found (Dimitrov 2009). Zhang (2011) shows that even at the problematic local level, where authorities have often turned a blind eye on

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<sup>8</sup> Author's interview with a public official from the State Intellectual Property Organization (SIPO), 13 August 2013, Beijing.

<sup>9</sup> China Briefing 2018: China's healthcare reforms underscore market growth.

infringement, local Chinese firms increasingly ally with western multinationals, and successfully lobby for stronger IP protection (also Kennedy 2005).

Overall, we see China following a similar approach to other rapidly industrializing East Asian nations, in particular Japan and South Korea, that shifted from challenging the IP system to becoming its strong supporters. The ongoing trade war between the United States and China, where IP plays a central role, together with grievances from EU Member States, China's two most important export markets, related to its industrial policy "Made in China 2025", could speed up this process. There remains one area of joint efforts with Brazil and India and that is the protection of genetic resources, traditional knowledge and folklore. Chinese support includes a proposal to include these matters in the negotiated Substantive Patent Law Treaty at WIPO (WIPO 2005) and taking a leading position at the TRIPS council for the homologation of TRIPS and the Nagoya Protocol (Muzaka and Serrano 2019).

#### **12.4 Likely scenarios to 2025**

The overview provided above on the ways the BICs have implemented TRIPS gives us clues as to their likely evolution towards 2025 and the possibilities other developing countries have to implement the TRIPS in flexible ways. However, it remains to be seen whether other emerging and developing countries without the clout of the three BICs can take advantage of these flexibilities. In particular, since some or all of the BICs are likely to shift towards stricter IP policies. Put otherwise, the question is whether and in how far it is conceivable that in the absence of BICs' support, developing countries can resist industrialized countries' pressure to enact maximalist IP policies. Out of the three BICs, China is the most likely to follow a path similar to that of industrialized countries, with some slight exceptions, such as in the area of ABS. Indeed, to a large extent and despite disputes related to its "Made in China 2025" policy, China is already doing so as the rising number of cases and substantial fines applied by its IP courts prove. Brazil could well follow, as the government of Michel Temer has been succeeded by what appears to be another market-friendly administration. President-elect Jair Bolsonaro's Chicago University educated chief economic advisor Paulo Guedes, is expected to head a super-ministry merging the current planning, finance and industry ministries and enact just such type of reforms. Brazil also recently submitted an application to join the OECD. As a member of this mainly industrialized-country club, it is prone to follow other emerging OECD countries such as Chile, Mexico and Turkey in supporting maximalist IP policies. This means that India may remain the only large emerging economy that continues to push for keeping flexibilities allowed under TRIPS and setting some limitations to its stringent implementation and enforcement. The failure to complete negotiations on a trade agreement with the European Union launched in 2007, despite 16 rounds in large part due to India's reluctance to make concessions on IP, reflects the strength of this position and suggests India may continue to lead the Global South on IP issues for some time.

That being said India's aggressive use of Section 3(d), not just on secondary patents as intended but also as a means to invalidate primary patents, as recently documented by Shadlen and Sampat (2018), may have consequences. In particular, if industrialized countries decide to challenge this practice at the WTO. So far, developed economies have not attempted to challenge Section 3(d), given the substantial public pressure that exists on this matter. However, the use of Section 3(d) on primary patents may change

their calculations leading to a shift in strategy. According to a knowledgeable interviewee,<sup>10</sup> the chances for a country to successfully challenge India's use of Section 3(d) at the dispute settlement body of the WTO are high. India's political economy is also shifting and some key domestic generic pharmaceutical companies have been acquired by foreign multinationals. The EU could also offer enough market access and investment incentives, so that India decides to drop its opposition to IP concessions and open the door to a free trade agreement. All of which leaves open the possibility for India to change course and abandon its current opposition to maximalist IP policies.

What would a loss of BICs support mean for other emerging and developing countries seeking to preserve TRIPS flexibilities, and inclined to follow minimalist IP policies? Considering the few cases that have made use of compulsory licensing, e.g. Brazil, India and Thailand, or that through the threat of applying them obtained price reduction agreements, e.g. Malaysia, Indonesia, Brazil, Zambia, Zimbabwe and Mozambique (Reichman 2009; Beall and Kuhn 2012), it becomes clear that pharmaceutical companies apply enormous pressure to limit the use of such measures. Market power thus appears to be important for pursuing flexibilities. The case of South Africa however suggest a different conclusion. In that case, in 1988, 39 drug makers sued the country for using TRIPS flexibilities on parallel imports. However, the legal effort was dropped in 2001 due to mounting public pressure. This suggests that also that where activists are able to produce massive and well socially embedded campaigns, low market power may not impede implementing policies that make use of TRIPS flexibilities.

The issue of pharmaceutical patents will in all likelihood remain one of the most contentious aspects of the IP regime. Given that pressure on affordable drugs is rising in industrialized countries too, as their populations age, it is possible to envision that a middle point can be reached, at which some of the flexibilities allowed under TRIPS are further pursued. An important factor likely to influence this outcome is whether macro-regional agreements such as the Transatlantic Trade and Investment Partnership (TTIP) or the Trans-Pacific Partnership (TPP) are revived in a similar form to its original aims . The current comprehensive and progressive agreement for trans-pacific partnership (CPTPP) has no such limitations, but if the US decides to re-join an adapted form of the pact could well push for their inclusion. Both of these proposed macro-regional agreements included substantial limits to the use of flexibilities under TRIPS, such as India's 3 (d).

As to the issue of access and benefit sharing of genetic resources and traditional knowledge, emerging countries have kept a united front and even managed to win over some industrialized countries. This matter is becoming further codified through efforts at the WIPO and thus, despite the opposition from the United States and other industrialized countries, it is likely that it will be incorporated into the IP regime sooner or later. Countries such as Norway or Switzerland, have already recognized that the principles espoused by the Nagoya Protocol on ABS are not contrary to the existing IP regime. Thus, this is an issue where emerging and developing countries could not only play a role by implementing TRIPS, but also by meaningfully contributing to the building of the IP regime. Whether they will be able to include this new subject matter depends on whether and when TRIPS is homologized with the Nagoya Protocol and the codification efforts on ABS currently taking place at WIPO.

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<sup>10</sup> Author's interview with an official of the TRIPS Council, 10 February 2016, Geneva.

## 12.5 Conclusions

This chapter has shown that in pursuing flexibilities in their implementation of the TRIPS, the three largest emerging economies of Brazil, India and China (BICs) have been able to shape the evolution of the IP regime. The chapter also shows the conditions under which these flexibilities have come into being as well as the substantial changes taking place in these emerging economies, may make it harder for other developing countries to follow. With the exception of India, it seems likely that Brazil and China will give up their minimalist IP agendas and as a result the Global South could lose crucial support in pursuing TRIPS flexibilities. However, the past two decades have created a strong awareness and large coalitions of activists seeking to preserve these flexibilities, in particular with regard to pharmaceutical patents. Thus, it is possible that other developing countries, despite lacking the economic clout of the BICs are able to pursue at least some of these flexibilities. Whether this is the case also depends on happenings outside the WTO, in particular macro-regional agreements. While these appear to have lost impetus following the election of Donald Trump in the United States, if they were to be revived, they could bring about substantial limits to implement TRIPS flexibilities. Finally, the BICs supported by a large coalition of developing countries have succeeded in codifying access and benefit sharing policies related to genetic resources and traditional knowledge at the CBD through the Nagoya Protocol and at the WIPO. It is possible that these efforts will become linked to the TRIPS in the future, which would mark a significant milestone in the efforts of countries from the Global South to shift from rule-takers to rule-makers.

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