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The Future Design of Intellectual Property Provisions in Preferential Trade Agreements

Three Propositions

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5.1 SETTING THE SCENE

The world is facing increasingly pressing challenges. Pandemics, the consequences of climate change, as well as the evolution of digital technologies, which the World Intellectual Property Organization (WIPO) has identified as twenty-first century challenges (WIPO, 2022), require a rapid and coordinated global response. Yet, the interfacing of these issues with intellectual property rights (IPR) protection revives age-old debates about the adequate level of IPR protection vis-à-vis other societal goals.

As the appetite to negotiate IPR rules at the multilateral level has slowed down, preferential trade agreements (PTAs) – long-standing instruments of trade policy – may constitute an opportunity to address these twenty-first century challenges, spearheading solutions that could be multilateralised in the future. In this chapter, we discuss the need to introduce a 'balanced' approach in future IPR PTA policy-making – one that reconciles far-reaching PTA's IPR provisions (TRIPS-plus) with corresponding flexibilities. We do so by structuring this chapter into two parts. Part 1 sets the scene, first providing a brief overview of the history and economics of international IPR. It then addresses the evolution of IPR within PTAs. Finally, it introduces the need to combine higher IPR standards with increased flexibility (what we call a 'balanced approach'). Part 2 delves deeper into the three twenty-first century case study challenges selected for this analysis.

5.1.1 *Overview of the History and Economics of International IPR*

The historical link between the protection of IPR and trade is well documented (Drahos, 1998; Ricketson, 2018; Abbott et al., 2019). It traces its origins back to the nineteenth century and the need to establish minimum standards of IPR protection across borders so that inventors' and authors' intellectual property (IP) could be

protected in overseas markets. The 'first globalisation wave' and the Second Industrial Revolution, in the late nineteenth century/early twentieth century, led to enhanced trade and investment worldwide, showcasing the need to establish rules and standards for the protection of IPR at the international level. Such rules and standards were later embedded in international treaties. The Paris Convention for the Protection of Industrial Property (1883) established industrial protection through patents, trademarks, and industrial designs. The Berne Convention for the Protection of Literary and Artistic Works (1886) established the protection of authors' rights. The Madrid Agreement (1891) established an international registration system for trademarks. These agreements further led to the foundation of the United International Bureaux for the Protection of Intellectual Property in Bern, Switzerland, in 1893, which was subsequently replaced in 1970 by the World Intellectual Property Organisation (WIPO), headquartered in Geneva, Switzerland.

The link between IPR protection and trade is further reinforced by the adoption in 1995 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement,[1] which incorporates by reference several provisions of these earlier IP treaties. The TRIPS Agreement sets out minimum standards of IPR for all members of the World Trade Organization (WTO). Unlike previous IPR conventions, it has the additional peculiarity of providing most-favoured-nation (MFN) treatment – a cornerstone principle of trade law. The MFN principle in Article 4 of the TRIPS Agreement provides that 'any advantage, favour, privilege or immunity granted by a [WTO] Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other [WTO] Members'. Few exceptions are envisaged in this rule, one of them being the case of customs unions (Cottier, 2022). However, with regard to all other advantages, favours, privileges, and immunities, including those found in PTAs, the MFN principle is applicable. This means that third-party WTO Members are entitled to MFN treatment in any PTA involving at least one WTO Member. The MFN provision contributes to the common law of international IP protection (Cottier, 2015).

The historical link between IPR and trade law and policy also has underlying economic considerations. IPR, according to the economic literature, contribute to addressing the market failures associated with the nature of public goods (typically, non-rival and non-excludable) and information asymmetry. Patents, one type of IPR, provide quasi-monopoly rights for inventors, granting them incentives to invest in the research and development (R&D) of public goods (Maskus, 2000, 2022). Moreover, IPR can enhance the dissemination of knowledge through technology transfer. Although a specific invention/technology cannot be used during the

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M.

protected time, Lall (2003) shows that the disclosure of the patents' full description may lead to innovations 'around' the patented technology (i.e. innovators can still use some of the knowledge enclosed in the patent). In other cases, IPR can reduce asymmetries of information for consumers. For example, geographical indications (GIs) and trademarks, two types of IPR, provide guarantees on products' characteristics and origins.

Despite the positive effects of the creation of knowledge and innovation described above, IPR have also been criticised for their adverse effects. First, higher levels of IPR protection could potentially translate into higher prices as innovators and other patent holders benefit from a temporary or lasting monopoly. The higher prices would affect not only consumers but also producers who depend on the invention as input for the production of other goods. In addition, there is a risk that temporary monopolies can slow down economic activity through the lack of competitors and potentially lead to monopoly abuse (Lall, 2003). The regulation of standard essential patents and the obligation to license such patents under fair, reasonable, and non-discriminatory (FRAND) terms is an example of measures taken to offset the risks of the abuse of patent protection. Second, the spillover effects of IPR on the economy have been debated. According to Maskus (2000), '*[t]he evidence suggests that there are large spillover gains from major inventions, while IPR on smaller inventions generally do not create significant monopoly rents*'. In a more recent study, Kelly et al. (2021) traced technological waves based on patent text similarity and showed that patented breakthrough innovations have a long-lasting impact on technological change. There remains, however, limited evidence of the impact of smaller innovations. Third, opponents of IPR also pointed out its opacity. Trade secrets, by nature, prevent the dissemination of information. Information on patents and trademarks is only accessible once published (often eighteen months after the patent filing, which varies across countries).[2]

However, empirical evidence regarding IPR, innovation, and growth is mixed. Neves et al. (2021) conducted a meta-analysis showing that many studies led to different results when looking at the impact of IPR on innovation and growth. Beyond disparities caused by different data and methods used, IPR have an overall positive impact on innovation and growth. Yet this impact may vary depending on a country's level of development and technology (Lall, 2003; Neves et al., 2021). Countries with high levels of economic development are more likely to have strong IPR. As countries develop, there is increased demand from producers for IPR (as more businesses/inventors engage in innovation) and more capacity from governments to establish and enforce those rights (Shadlen et al., 2005). On the contrary, countries with lower innovative capacity have a higher interest in weak IPR in order to facilitate the imitation of foreign technologies. Developing economies typically

[2] WIPO, 'Frequently Asked Questions: Patents', www.wipo.int/patents/en/faq_patents.html, accessed on 6 June 2023.

have fewer resources to innovate and less government capacity and therefore derive fewer benefits from IPR (Lall, 2003; Shadlen et al., 2005). As countries' level of development increases, they have more interests in raising IPR standards to promote domestic innovations (Chen and Puttitanun, 2005; Chu et al., 2014). Empirically, the positive impact of strengthening IPR on growth and welfare increases as a country's innovative capacity comes closer to the world technology frontier and participation in world trade. IPR will also generate more innovation spillovers across businesses/sectors the higher the current levels of in-country innovation (Lall, 2003). This leads to great variations in countries' levels of domestic IPR and can further generate trade conflicts (Maskus, 2000, 2022).

One might argue that IPR, which establish temporary quasi-monopoly rights, go against the idea of trade liberalism and the progressive decrease in barriers to trade. However, Snorrason (2012) contends there are instances in which trade barriers might be preferable, including when they compensate for market failure. The multilateral and bilateral coordination for setting common IPR standards, be it at the WTO- or PTAs-level, addresses those market failures internationally. Yet, those who benefit are the ones better equipped to take advantage of it. Maskus and Ridley (2021), for instance, find a significant impact of IPR provisions in PTAs involving the United States (US), the European Union (EU), or parties to the European Free Trade Association (EFTA) on exports. Export-competing industries of these countries benefit from protection to produce abroad.

5.1.2 *International IPR Protection within PTAs*

PTAs, as laboratories of higher standards of IPR protection, often go beyond the minimum standards established by the TRIPS Agreement, in part to compensate for tremendous changes in technology and business practices in the past decades (Ezell and Cory, 2019) and in part because these changes, and their implications for IPR protection, have not been reflected in multilateral treaties. The trend to include higher standards of protection for IPR through PTAs, which accelerated during the 1990s–2000s, was mostly led by the US and the EU, followed by other technology-based economies, such as Japan and Switzerland (Cottier 2017b; Cottier et al., 2017). These standards set in these PTAs are known as TRIPS-plus provisions. In the long run, these enhanced standards are likely to facilitate and influence future multilateral developments, in particular in revising the TRIPS Agreement due to the dialectical relationship between bilateral agreements, plurilateral agreements, and multilateral agreements and the pervasive effect of MFN in the areas of IP (Cottier et al., 2015).

Developed and developing countries undertake TRIPS-plus commitments in a different way. The US is one of the most vocal advocates of TRIPS-plus provisions in PTAs. The North American Free Trade Agreement (NAFTA) was the first PTA to include an IPR chapter in 1994, a year before the TRIPS Agreement entered into

force. In 2020, NAFTA was replaced by the Agreement between the United States of America, the United Mexican States, and Canada (USMCA), incorporating even more comprehensive TRIPS-plus provisions. The origins of these provisions can be traced back to the Trans-Pacific Partnership Agreement (TPP). Other US PTAs also showcase heightened TRIPS-plus standards of protection in areas such as pharmaceutical patents, amplify governance on digital goods copyrights, and augment penalties for IPR breach (Maskus and Ridley, 2021).

The EU has also acted as a rule-maker by advocating TRIPS-plus provisions. However, unlike the US, the EU has only slowly pushed for TRIPS-plus provisions in its PTAs since 2008 (Erixon et al., 2022). This is partly due to the wider enhancement of the EU's trade policy, which envisages a more active use of PTAs as an economic policy tool. The EU approach favours far-reaching provisions on enforcement and GIs. For example, the 2008 Economic Partnership Agreement (EPA) signed between the EU and the Caribbean Forum (CARIFORUM) includes provisions specifically concentrating on enforcement, which is unprecedented (Spence, 2009). The language adopted here is substantially identical to the EU's original proposal, which was transferred essentially from EU domestic comprehensive instruments on enforcement. The breadth and scope of these obligations raises major concerns over the administrative and judicial systems in CARIFORUM countries (Center for International Environmental, 2008). In the 2012 EU–Colombia/Peru Trade Agreement (which Ecuador joined in 2017), the three Andean parties must amend current or enact new GI legislation to comply with their obligations (Viju et al., 2013).

Since the first comprehensive PTAs (e.g. NAFTA) were concluded, TRIPS-plus provisions permeated into the negotiation of subsequent PTAs. This is an aspect that has been studied by a wealth of literature; nonetheless, there are interesting developments worth highlighting. For example, Australia and Canada's PTA practice, which traditionally followed the US lead on TRIPS-plus provisions, reveals that these countries might be reconsidering their approach to IP provisions negotiated in their PTAs. Australia has shown less ambition to conclude a stringent IP chapter with TRIPS-plus provisions in multiple fields (Townsend et al., 2016). Moreover, Australia previously resisted some of the IPR provisions included in the TPP, which were removed from the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) (Australian Government Department of Foreign Affairs and Trade, 2019). It has also recently started implementing the Regional Comprehensive Economic Partnership (RCEP), which contains less stringent TRIPS-plus provisions, which were mostly proposed and pushed by Japan and Korea. The RCEP incorporates a few critical TRIPS-plus articles regarding public health and none concerning IP enforcement.

On the other hand, Canada has kept pace with negotiating stringent TRIPS-plus provisions, following the path established by the US and EU. The Canada–EU Comprehensive Economic and Trade Agreement (CETA), for instance, contains

strong TRIPS-plus provisions for GIs, mostly proposed by the EU (European Union, 2019). In this agreement, Canada has accepted the obligation to protect all types of food products in the EU's proposal at a comparable level to that offered under EU law, thereby raising the standards of protection for GIs in Canada. On Canada's side, even though the CETA essentially changes the current domestic IP protection framework vis-à-vis EU products, domestic companies from different IP-related industries generally support the significant enhancement of IPR. Representatives from Canadian pharmaceutical research companies claim that the CETA would strengthen the IP system and robust industrial innovation, which would help the healthcare sector and the Canadian economy (House of Commons Canada, 2012).

In contrast, developing countries usually tend to accept TRIPS-plus provisions in PTAs because of political or economic concerns (Maskus and Ridley, 2017). China had an early start to concluding IP-only bilateral agreements with the US to counteract the lack of IP protection in China. Over the years, China has joined multilateral agreements on IPR and increased its internal IP legal and administrative capacities, while gradually pursuing stronger IP protection in its PTAs (Yu, 2019; Shaffer and Gao, 2021). Notwithstanding its economic power, China, like other developing countries, has accepted TRIPS-plus provisions as trade-offs. As part of the Economic and Trade Agreement between the Government of the United States of America and the Government of the People's Republic of China, 2020 (US–China Phase One Trade Agreement), China agreed to reform the economic and trade regime in IPR in exchange for the US' modification of its Section 301 tariffs actions (Upreti and Vasquez Callo-Müller, 2020). In comparison, the RCEP, an agreement led by China, adopts a moderate approach to IPR.

India, on the other hand, has only recently taken up substantive IPR obligations in its PTAs. India eventually dropped out of the RCEP negotiations in 2019 for domestic political reasons (Mohamad and Cheng, 2020). The final agreement contains an extensive (but modest in terms of TRIPS-plus standards) IP chapter. Since 2002, India has concluded PTAs with IP chapters with selected trading partners. Of its thirteen fully fledged FTAs[3] only those with the United Arab Emirates (UAE), Japan, and South Korea include these obligations. The UAE Agreement is the most extensive, containing TRIPS-plus provisions, largely modelled after RCEP's IP chapter. The rest of its PTAs, however, which are mainly with other developing countries, do not have IPR chapters. Interestingly, the 2022 agreement with Australia (a developed country), also does not have IPR provisions (Government of India (Ministry of Commerce and Industry), 2023).

The divergent approaches to IPR protection in PTAs showcase that the negotiation of TRIPS-plus protection is not a given and that the shaping of international IP

[3] India signed other trade agreements, more limited in scope, with Afghanistan, Chile, and Mercosur and is also part of the Asia-Pacific Trade Agreement, the Global System of Trade Preferences, and the South Asian Free Trade Area.

norms has evolved, in certain ways, away from traditional US or EU approaches. In the following section, we discuss the need to combine the ever-proliferating TRIPS-plus provisions with flexibility in PTAs to create a more balanced approach to the global IP regulatory framework.

5.1.3 *Combining Higher Standards and Flexibility: Towards a More Balanced Approach*

In raising the standards of IPR protection and by including new obligations, TRIPS-plus agreements have been subject to persistent critique: they are considered to erode policy space to regulate issues such as access to medicines and climate change. Such critiques have been accentuated by the understanding of IP (and TRIPS-plus standards) as protected investments under international investment agreements (IIAs). This opens the possibility of bringing claims against a state under investor–state dispute settlement mechanisms,[4] exposing the complex interaction between the IP and IIA regimes. The '*investmentisation* of intellectual property' carries the risk that the IP sets aside its societal objectives 'so that the sole incentive rationale protection of IP protection becomes investment protection' (Upreti, 2022). In addition, by moving beyond the standards of protection found in multilateral IP treaties, TRIPS-plus agreements are deemed to affect the balance between IP protection and other societal interests (Dinwoodie and Dreyfuss, 2012). This balance is embedded in Article 7 of the TRIPS Agreement, which provides as follows:

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

This perspective finds support in how TRIPS-plus agreements are negotiated, that is, in secrecy and without public scrutiny.

Notwithstanding these critiques, the flexibilities included in recent TRIPS-plus agreements – in the form of limitations and exceptions to certain IP rights – are less explored in the legal academic literature. For example, certain agreements include provisions on 'balance in copyright and related rights systems', which aim to provide

[4] High profile cases include: *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, Award (8 July 2016); *Eli Lilly and Company v. The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Award (16 March 2017); *Bridgestone Licensing Services, Inc. and Bridgestone Americas, Inc. v. Republic of Panama*, ICSID Case No. ARB/16/34, Award (14 August 2020); *Theodore David Einarsson, Harold Paul Einarsson and Russell John Einarsson v. Canada*, UNCITRAL, Notice of Arbitration (18 April 2019).

more leeway for a country to design its copyright policy in a way that may be more conducive, for example, to innovation in the digital realm (Vásquez Callo-Müller 2023). This is the case of Article 18.66 of the CPTPP, which provides that:

> Each Party shall endeavour to achieve an appropriate balance in its copyright and related rights system, among other things by means of limitations or exceptions that are consistent with Article 18(65), including those for the digital environment, giving due consideration to legitimate purposes such as, but not limited to: criticism; comment; news reporting; teaching, scholarship, research, and other similar purposes; and facilitating access to published works for persons who are blind, visually impaired or otherwise print disabled.

But also, more recent PTAs, such as RCEP, contain innovative provisions not observed before in TRIPS-plus agreements. Namely, Article 11(18) (4) provides that a party may adopt or maintain limitations or exceptions to copyright for fair use, a notion present in domestic US copyright law,[5] but largely absent in other jurisdictions. Fair use is deemed to provide enough flexibility for digital industries to innovate (Sag, 2019), and to some, it has been considered to be one of the factors allowing the development of technology hubs such as Silicon Valley (Chander, 2015).

These examples showcase, as Baccini et al. (2015) have previously argued, that there is a link between the depth of PTAs and the flexibilities included in these same agreements – 'deeper PTAs are more flexible' (Baccini et al., 2015). While we acknowledge that TRIPS-plus agreements include higher standards of protection for IPR, we consider that it is similarly important to observe to what extent new limitations and exceptions to IPR are included in these treaties.

First, PTAs precisely enable leveraging flexibility in IPR provisions (Trimble, 2022), which will be key in tackling these challenges to strike a better balance between reaping a return on investment and societal benefits. Reducing IPR standards as such is unlikely to facilitate better access to medicines or enhance the development of new climate change-mitigating technology across the world. There is a need to promote domestic governments' and businesses' innovative capacity. We suggest technology transfer could be carried out by establishing public–private partnerships (PPPs) to ensure access to medicines in countries with lower levels of technological innovation. This would enable policymakers to strike a balance between ensuring access to medicines in countries with lower levels of technological innovation while incentivising pharmaceutical companies to pursue R&D. Technology transfer could also be enhanced through granting tax rebates to businesses investing in green technologies in low-income countries and redistributive funds to further promote technology dissemination. Additional flexibility in PTAs can also mitigate adverse effects of the increased use of trade secrets. Unlike other

[5] US Copyright Act, Section 107.

types of IPR (e.g. patents, trademarks, GIs), trade secrets hinder information dissemination and technology transfer opportunities. In the context of the digital revolution, the increasing use of trade secrets can lead to fewer innovation spillovers in other sectors, security threats, and information asymmetries with users. We suggest that PTAs could help to harmonise rules on setting limitations and exceptions to trade secrets.

Second, PTAs constitute a better tool than the multilateral fora to negotiate such provisions. Multilateral fora have encountered many barriers to negotiating IPR (although not limited to this area). Since the TRIPS Agreement, no major IPR agreements have been signed or updated as part of the WTO framework. The IPR question was dropped from the WTO's Doha Round agenda. The Anti-Counterfeiting Trade Agreement (ACTA) was signed in 2011 by ten countries outside the WTO (and WIPO) and has still not been ratified by all (Morin and Surbeck, 2019). Since the mid-1990s, the WIPO has been a more active and successful multilateral negotiation forum leading to the signature of six treaties. Most of these treaties expanded the scope of existing international IPR agreements to include digital creations and promote harmonisation across domestic IPR procedures.[6] Nevertheless, countries have increasingly turned to the use of PTAs, allowing them to simultaneously negotiate a wide range of market access issues at a faster pace. Indeed, multilateral negotiations gather countries with many different interests increasing transaction costs and time required to negotiate. The COVID-19 pandemic has shed light on the difficulties for WTO Members to reach an agreement given the time limitations and high divergence in countries' interests. PTAs, in turn, involve low[er] transaction costs with often a limited number of members. Further, Trimble (2022) argues bilateral and plurilateral negotiations of IPR provisions can leave more room for countries to experiment with different types of standards and set the ground for further multilateral agreements. Lastly, as previously mentioned, Article 4 of the TRIPS Agreement includes MFN treatment for all IPR provisions in PTAs, giving the latter a multilateral nature almost by default.

In the following subsections, we analyse how this proposed balanced approach in PTAs could contribute to meeting the needs of 'twenty-first century challenges', namely, global health pandemics, climate change, and digital technologies.

[6] The WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) were both signed in 1996 and established IPR of authors, performers, and producers of phonograms in the context of the digital environment. The Patent Law Treaty (2000) harmonised patenting procedures across national and regional systems. The Singapore Treaty (2006) harmonised procedures for registering trademarks. The Beijing Treaty (2012) established IPR of audiovisual performers. The Marrakesh Treaty (2013) authorised exceptions to copyright rules to facilitate published content access to people with visual disability. The Geneva Act (2015) extended the scope of the Lisbon Agreement to geographical indications.

5.2 THREE MAIN AREAS OFFERING A MORE BALANCED APPROACH

5.2.1 *Access to Essential Medical Products and PPPs*

The COVID-19 pandemic exposed, in a dramatic fashion, the tension between IPR and access to medical products. The world experienced, in real time, confined in our homes, the clear delineation between the haves and have-nots when prioritising access to COVID-19 vaccines and related medical products. The geopolitics of COVID-19 vaccine access spun off a slew of new terms such as 'vaccine inequity' (Tatar et al., 2021), 'vaccine nationalism' (Bollyky and Bown, 2020; Liz, 2022), 'vaccine diplomacy' (Suzuki and Yang, 2022), and 'vaccine apartheid' (Joseph and Dore, 2022), to mention a few.

The challenges in accessing COVID-19 vaccines and medical products occurred notwithstanding the flexibilities granted to WTO Members under the TRIPS Agreement. Articles 31 and 31*bis* of the TRIPS Agreement permit countries to issue compulsory licenses on patented products in times of national health emergencies, both for domestic production and, under specific conditions, also for exports. The issued compulsory licences also cover the importation of these potentially life-saving medical products if the issuing country does not have the domestic capacity to produce them. However, there are practical and legal challenges to using this system to access essential medical products. Among others, the compulsory licence regime only applies to patents and the procedures to access these products, established in the annex of the TRIPS Agreement, are complex (Sucker and Kugler, 2022).

COVID-19 medical products (including vaccines) are not only protected by patents but also by, potentially, copyrights, industrial designs, and trade secrets. Unlike patents (and some copyrights), there is no mechanism for issuing compulsory licences for these IPR under the TRIPS Agreement (Sucker and Kugler, 2022). Therefore, while suspending patent protection goes far, it does not guarantee access to a specific medical product if it is covered by other IPR that are *not* subject to the TRIPS flexibilities.

Compulsory licences are often issued by countries for domestic public health emergencies. These licenses are regularly issued by countries to authorise the production of medical products that are owned by mainly Western pharmaceutical companies. These transactions rarely involve the home state of the pharmaceutical company (Feldman, 2009; Epstein and Kieff, 2011; Moser and Voena, 2012; Urias and Ramani, 2020). In contrast, the WTO's compulsory licensing regime has, thus far, only been used once. This regime was established under Paragraph 6 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health and was subsequently incorporated into the TRIPS Annex under its paragraphs 2(a) and 2(c).

The single time the 'Paragraph 6' procedures were used was when a Canadian firm, Apotex, wished to export an anti-retroviral (Apo-TriAvir) to Rwanda (Epstein and Kieff, 2011; Correa, 2019). This initiative was initiated by Doctors Without

Borders to test the Paragraph 6 mechanism and the suitability of the Canadian legislation, the Canadian Access to Medicines Regime, which was adopted in 2004 to implement Paragraph 6. One of the challenges was that the active ingredients of Apo-TriAvir were protected under a patent held by Canadian companies Boehringer Ingelheim (Canada) Ltd and GlaxoSmithKline Inc., Canada. Thus, Apotex had to first request a voluntary licence from these companies. It is reported that the company lost USD 3–4 million by offering a lower price to win Rwanda's tender to compete with lower-cost products from other countries, including India. Apotex initiated the process in December 2005. However, the first batch of Apo-TriAvir was shipped to Rwanda in September 2008, almost three years after the process began (Correa, 2019). To underscore the scepticism with which WTO Members (especially developing countries) regard the TRIPS Annex paragraphs 2 (a) and 2(c) procedures, even with the massive health crisis that the entire world faced during the COVID-19 pandemic, only Bolivia submitted a notification to use the system in May 2021 (WTO, 2021).

Another issue plaguing the compulsory licensing procedures under the TRIPS Agreement is the fact that, currently, only twenty-five WTO Members have notified their national implementing legislation to facilitate these procedures (WTO, 2022a). Noticeably absent from this list is the US, which has a large pharmaceutical industry and even South Africa, which, with India, was the original co-sponsor of the WTO's COVID-19 TRIPS Waiver (WTO, 2022b). The waiver, which was adopted at the WTO's 12th Ministerial Conference in June 2022, establishes a special temporary regime for WTO Members to produce COVID-19 vaccines without the permission of the patent holder. A major advantage of the waiver is that countries that have not adopted the requisite national implementing legislation can access the TRIPS Agreement flexibilities that allow them to participate as exporting or importing countries, respectively.

The counterarguments provided against the use of the WTO's compulsory licensing mechanism have largely been centred around the possible negative effects of using compulsory licences in general. Commentators argue that these instruments discourage innovation in the pharmaceutical sector. They further posit that the frequent use of compulsory licenses will lead to more global health suffering because pharmaceutical companies will be disincentivised from innovating, as they will not be able to recover returns on their investments. Moreover, they argue that pharmaceutical companies will invest less in developing countries because they know that developing country firms will just obtain the right to produce generics of their medical products through compulsory licences. It is moreover argued that economic growth will decline in traditional knowledge economies that rely on strong IPR protection (like the US) (Feldman, 2009). Another argument is that other mechanisms, like price negotiations and voluntary licences, are more effective in facilitating access to medication than compulsory licenses (Beall et al., 2015; Raju, 2017; Ramani and Urias, 2018).

Some have also argued that the current IP regime has sufficient flexibility to allow countries in need to access medical products. Hence, the problem is not high IPR protection but rather the supply of the products (including key ingredients) (Ozili and Arun, 2020; WTO, 2022a) and logistics, infrastructure, and manufacturing capacity, the latter three being attributed to developing countries themselves (Organisation for Economic Co-operation and Development (OECD), 2021, Sucker and Kugler, 2022). Indeed, the lead-up to the adoption of the WTO's COVID-19 TRIPS Waiver garnered international attention and captured the global imagination because it was framed in the popular media as a David versus Goliath issue (Cviticanin, 2021; Das, 2021): the 'suffering' developing countries that do not have pharmaceutical IPR versus the 'evil' developed countries that have those rights and are denying the poorer countries access to, inter alia, critical COVID-19 vaccines. Essentially, the debate was focused on the barriers that IPR created for equitable access to medicines and medical products. However, a less sensationalised issue was the fact that most developing countries do not have the capacity to manufacture medical products and face severe infrastructural and technical skills shortages – even if the IPR were waived (Sucker and Kugler, 2022).

The above sketches a polemic global debate on the balance of IPR and access to essential medicines in pandemics and other public health crises. This conversation has become even more relevant because global pandemics have been projected to increase in number and frequency in the future (Marani et al., 2021). Due to the current impasse at the WTO, it is unlikely that the multilateral legal framework will change – this presents an opportunity for PTAs to cover the regulatory shortfall.

Currently, most concluded PTAs, including those that were concluded recently, only reinforce the WTO legal framework on TRIPS and public health (EU–UK TCA, Article 250; EU–New Zealand FTA, Article 18.71; RCEP, Article 11.8; and India–UAE CEPA, Article 11.6). Some recognise that the parties are not prevented from taking measures to protect public health (CPTPP, Article 18.6; India–UAE CEPA, Article 11.6; RCEP, Article 11.8). The China–New Zealand FTA Upgrade Agreement (2021) contains few substantive commitments. However, a provision has been included on cooperation and capacity building, where the parties undertake to encourage and facilitate 'cooperation between their respective government agencies, educational institutions and other organizations with an interest in the field of intellectual property rights' (Article 164(2)). It is anticipated that countries might use provisions like this to address access to medical products in public health crises.

We consider that future PTAs might include undertakings, in the form of non-binding provisions or, more likely, side letters or memoranda of understanding on facilitating PPPs. Through this, cooperation between the government, research-based industries, and civil society organisations (CSOs) steps in where market forces are insufficient to bring about adequate supplies and care to those in need (de Vries and Yehoue 2013). These undertakings seek to strengthen medicine and medical product-related manufacturing capacity in less resourced countries so that they can

be less reliant on imports from better-resourced countries in global medical emergencies, while protecting IPR held by mainly developed country firms.

Indeed, there are already global PPP initiatives like the COVID-19 Vaccines Global Access (COVAX) Facility, Gavi (the Vaccine Alliance), and the World Health Organization's mRNA technology transfer hub and its COVID-19 Technology Access Pool (C-TAP). Resources are pooled to support the research, development, and distribution of COVID-19 vaccines, and their prices are negotiated (Berkley, 2020). Moreover, trusted platforms are provided for the developers of COVID-19 medical products to share their IP, knowledge, and data with high-quality manufacturers in countries that require affordable access to medical products through transparent, voluntary, and non-exclusive licences. These platforms also facilitate technology transfer agreements. Ultimately, through voluntary licensing and patent pooling, IP holders can reach new markets and increase production by using the untapped capacity of manufacturers around the world, while securing appropriate royalties. Simultaneously, the World Health Organization (WHO) and its partners provide capacity-building and technical assistance to more manufacturers to produce high-quality essential COVID-19 medical products, while increasing access and affordability of those products (Bosch, n.d.; WHO/Bosch, n.d.).

We thus submit that in the context of bilateral or even plurilateral PTAs, provisions could be included that obligate countries that are strong in pharmaceutical R&D and wish to protect their IPR to enter into PPPs with their pharmaceutical industries, government, and respective NGOs. These partnerships, under the auspices of the PTA, will allow the development of cooperation between research-based industries, local institutions, government agencies, and CSOs. It will enable bringing about knowledge and technology transfer by means of publicly funded voluntary licensing to local producers and securing adequate distribution and administration of medicines in the health system. This model directly addresses the weakness of domestic productive capacity in some developing countries and efforts to improve it, while maintaining IPR protection for the pharmaceutical industry.

More concretely, this type of provision could be included in already existing sections on the TRIPS Agreement and Public Health that are included in the IP chapters of most PTAs. Alternatively, a section on Cooperation During Public Health Crises can be added to the IP chapter. We propose to include the following provisions:

- The supporting state party would undertake to conclude PPPs with its pharmaceutical companies and CSOs to provide jointly funded technical assistance to pharmaceutical manufacturers in countries needing support to produce and disseminate medical products.
- The supporting country and industry will collaborate with the beneficiary government to identify the industry beneficiaries, health institutions, and

CSOs that will participate in the technical assistance and capacity-building and dissemination efforts.
- The supporting industry will permit the manufacture of the medical products under jointly funded voluntary licenses and share the requisite data, information, and know-how required to manufacture these products.
- The beneficiary government will protect the IPR of the supporting government and industry, and the beneficiary industry will not act in any manner to contravene IP laws or any confidentiality agreement they conclude.
- A Medical Product Knowledge Transfer Working Group will be established, which will comprise all the partners (and interested parties, including civil society and academia). They will meet periodically and review the efficacy of the cooperation.

5.2.2 *Diffusion of Sustainable Technologies and Knowledge*

As the discussion of PPPs in the health sector indicates, fundamental questions relating to access to technology have not been properly addressed in WTO law and have not been adequately addressed in PTAs (Brewer and Falke, 2012; Brewer, 2016). They are of particular importance in the context of trade and climate change (Delimatsis, 2016). While the framework for technology diffusion by means of voluntary licensing is workable for commercial transactions and is successful among industrialised and emerging economies, it fails to address the needs of lower-income countries short of finance and funding and a private sector able to engage forcefully by means of commercial acquisition of technology (Lybecker and Lohnse, 2015; Barton 2017; Zhuang, 2017). Low-income countries depend on concessionary aid and development cooperation which in turn depends on budgetary allocations of scarce funds in industrialised countries. At least in policy areas recognised as a common concern of humankind, such as climate change, loss of biodiversity, or health (Cottier 2021a, 2021b), this should change. Proper tools are needed to compensate for market failures as all share a common interest in effectively addressing these common concerns around the globe. It is no longer a matter of concessionary aid. It is a matter of effectively implementing and realising shared policy goals of equal interest to developed and developing countries alike.

Achieving these policy goals increasingly depends on the adoption of modern and sustainable modes and processes of production. These methods, in return, depend on access to advanced technologies. Access to such technologies thus moves centre stage in the process of shifting product standards to standards of process and production methods (PPMs) (Conrad, 2011; Holzer, 2014). Developing countries are more likely to accept PPMs, perceived as non-tariff barriers to their exports, if state-of-the-art technology for producing these exports in a sustainable manner is

made available. In this process, IPR are important (Ockwell et al., 2010; Ockwell and Mallet, 2012).

Two types of measures should be contemplated in a new generation of PTAs with developing countries, next to concessionary aid support programmes and PPPs. Based on WTO law, they contribute to the common law of international trade (Cottier, 2015) as all WTO Members arguably will be entitled to benefit, as discussed above, from the benefits of such IPR-related measures due to the application of MFN (Cottier, 2022). PTAs could serve to develop and spearhead a set of ideas as discussed next.

5.2.2.1 Tax Rebates for Technology Dissemination

Commitments and pledges on the transfer of knowledge and technology in international agreements ignore that governments rarely have access to the technology that the private sector has. Article 66:2 of the TRIPS Agreement obliges developed members 'to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed countries in order to enable them to create a sound and viable technological base'. This provision has largely remained a dead letter, and special and differential treatment (SDT) here has remained an empty promise. This is because most governments making such promises do not legally have the technology (Cottier, 2017a). It is in the hands of companies and the private sector. Governments, however, should explore the possibility of financial incentives to foster technology transfer to developing countries.

It is submitted that industries engaging in low-income countries by investment or trade in the fields of healthcare, climate change mitigation, and adaption should benefit from domestic tax reductions in the exporting country and home state, in order to offset financial risks and difficulties encountered in the country of destination. This idea, introduced by Hoekman et al. (2005), still awaits implementation. Climate change is an excellent field, as such rebates can account for abatement measures abroad, contributing to globally agreed targets. There is a shared interest in making available the best IP-protected technologies in reducing climate change as a common concern of humankind. The same applies to the supply of medicines and medical services in combating pandemics under the WHO International Health Regulations, as all share a common interest in containing diseases. The approach can also apply to other fields recognised as a common concern of humankind, such as the protection of biodiversity or cultural diversity. A similar scheme could even be extended to developing countries in general.

The problem we face in trade is that financial incentives may be qualified as export subsidies beyond export credits and thus be contrary to the Agreement on Subsidies and Countervailing Measures (SCM Agreement) (Ahmad 2021a, 2021b). Tax reductions in technology-exporting countries would possibly require

appropriate adaptation revisions in the SCM Agreement and a return to the category of non-actionable subsidies (Condon, 2009, 2017). This makes the adoption of unilateral policies more difficult in trade, compared, for example, to investment law, where no comparable problems exist. However, new and specific rules in PTAs could lawfully provide the foundations of such schemes in trade regulation and help to get them off the ground. They would exist independently of current WTO obligations and could spearhead future multilateral disciplines in the field. As they benefit all WTO Members alike due to the MFN clause of the TRIPS Agreement, implementing measures are unlikely to be challenged in WTO dispute settlement by developing countries seeking access to modern technology. Industrialised countries could avoid potential, but unlikely, disputes on the distortion of competition among themselves by moving forward the scheme in parallel, perhaps coordinated by the work in the OECD and subsequently in the WTO. The dialectical relationship between PTAs and multilateral rules (Cottier et al., 2015) may work again in creating shared foundations for tax rebates and adjustments of the SCM Agreement.

5.2.2.2 Tax and Tariff Revenues for Technology Dissemination

A second avenue to foster the transfer of sustainable technologies to developing countries in line with obligations under the 1992 United Nations Framework Convention on Climate Change (UNFCCC) and the 2015 Paris Accord and subsequent Conference of the Parties (COP) decisions is to earmark revenues generated from carbon tariffs and revenues from border tax adjustment measures, such as the 2023 EU Carbon Border Adjustment Mechanism (CBAM) regulation.[7] Tax revenues generated from import carbon tariffs and border tax adjustments should not be allocated to the general household. Instead, they should be used and earmarked to fund technology dissemination to low-and lower-income country producers with the aim of meeting sustainable production standards and thus avoiding further import restrictions. These funds could be accountable to abatement goals agreed upon by countries imposing tariffs and import restrictions in addressing climate change. Developing countries are entitled to such compensation for Carbon Border Tax Adjustment Measures under the UNFCCC and the Paris Agreement. In addition, part of such income could be used to fund international programmes supporting lower-income countries in readjusting to sustainable production standards beyond climate change.

PTAs are well placed to operationalise such cooperation and support in adjusting structures of industries to sustainable modes of production. Disciplines on refunding carbon tariff and border tax adjustment revenues could be mandatorily linked to sustainable and renewable energy and adaption technology dissemination and

[7] Regulation (EU) 2023/956 of the European Parliament and of the Council of 10 May 2023 establishing a carbon border adjustment mechanism.

transfer. They are thus linked to privileged access to IPR, earmarking and making revenues available for the acquisition and licensing of appropriate technologies on the market, independently of the origin of the technology. Such disciplines could amend chapters on IPR or be developed in a new chapter on technology transfer, squaring IP and climate change and possibly further policy areas. Implementing legislation and practices affecting privileged access to IP-protected technology will arguably apply to all eligible WTO Members alike under the MFN clause of the TRIPS Agreement (Cottier, 2022). The proliferation of such schemes could thus again serve as a template for future rules on IP funding and licensing for developing countries in plurilateral agreements and in the WTO as a matter of SDT.

5.2.3 *Trade Secrets and the Digital Economy*

The third twenty-first century challenge that we tackle in this chapter is the digital economy. We do so by examining one IPR in particular: trade secrets. The relationship between trade secrets and the digital economy is of growing importance, in part because trade secrets may be more easily available to protect important aspects of the digital economy, such as artificial intelligence (AI) algorithms, and data, than other IPR (Aplin, 2017). This draws from the relatively lower threshold for trade secret protection. According to Article 39 of the TRIPS Agreement, to be protected as a trade secret, certain information must be secret, have commercial value, and be subject to measures ('reasonable steps under the circumstances') to keep it secret. In contrast to this moderately low threshold for trade secret protection, other IPR require the fulfilment of more conditions. For instance, patent protection, according to Article 27 of the TRIPS Agreement, is conditional on the determination of a novelty (the invention must not already exist), inventive step or non-obviousness, and the capability of industrial application. In addition, recent case law arising in some jurisdictions showcases that patent protection may not be available for AI inventions, on the grounds that AI is not a 'natural person', and hence it cannot be considered an inventor (Kim, 2022). This has been more clearly exemplified by the recent US Federal Circuit decision in *Thaler v. Vidal*,[8] in which the US Federal Circuit confirmed that an AI software system ('DABUS') cannot be listed as the inventor on a patent application under US patent statutes. The importance of trade secret protection in international trade is also relevant to technological sectors beyond AI, all of them of critical importance to the digital economy. Linton (2016) explains that trade secret protection plays a key role in the computer and electronics, as well as information service sectors.

[8] *Thaler v. Vidal*, No. 2021-2347 (Fed. Cir. 2022).

Until recently, PTAs did not incorporate fully fledged provisions on trade secret protection,[9] in part because the main *demandeurs* for this right did not have the relevant statutes in their home countries. Only in 2016 did the US and the EU adopt specific and comprehensive trade secret legal frameworks.[10] However, the increased importance of trade secrets in strategic sectors (including high-end technology) and emerging concerns of trade secret theft, have led to the incorporation of TRIPS-plus trade secret provisions in certain PTAs. The Economic and Trade Agreement between the Government of the United States of America and the Government of the People's Republic of China , signed on 15 January 2020, is a case in point (Upreti and Vásquez Callo-Müller, 2020), but also other agreements, such as the CPTPP, contain detailed provisions going beyond multilateral standards.

Regarding the digital economy, and AI in particular, heightened standards for trade secret protection may impact emerging AI regulations promoting trust, fairness, and accountability of AI systems. Such regulations require the disclosure of algorithms or data necessary for the verification of the functionality of AI systems before these are deployed. For instance, the EU AI Act[11] requests that high-risk AI systems should be subject to more rigorous examination, which may include disclosure of algorithms or training data. However, the same Act provides that the disclosure requirements should be without prejudice of confidential business information or trade secrets.[12]

Some PTAs do not prevent these types of regulatory disclosures. At least the USMCA and the Economic and Trade Agreement between the Government of the United States of America and the Government of the People's Republic of China acknowledge that trade secrets may be submitted during regulatory proceedings, but the confidentiality of such information should be protected against unauthorised disclosure.[13]

Notably, certain PTAs extend the protection afforded to trade secrets to any other confidential information. The definition of trade secrets in Article 1 of the US–China Phase One Trade Agreement exemplifies this point. The object of protection is defined as broadly as:

[9] In the case of US PTAs, trade secret protection is only included in the USMCA and the US–China Trade Deal. As for EU PTAs, specific trade secret provisions going beyond TRIPS standards are only included in two PTAs: the EU–Japan PTA and the EU–UK PTA. Finally, in the case of Asia-Pacific PTAs, trade secret protection is included, to different degrees, in the CPTPP and RCEP, the largest two mega-regional PTAs.

[10] See: US Defend Trade Secrets Act (DTSA) of 2016; Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use, and disclosure.

[11] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

[12] Ibid., Article 70.

[13] See: USMCA, Article 20 (77), US–China Phase One Trade Agreement 1(9).

> [c]oncerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, business transactions, or logistics, customer information, inventories, or amount or source of any income, profits, losses, or expenditures of any person, natural or legal, *or other information of commercial value, the disclosure of which is likely to have the effect of causing substantial harm to the competitive position of such person from which the information was obtained*. (emphasis added)

As more AI regulations will be adopted worldwide, and as TRIPS-plus standards of trade secret protection will increasingly be adopted in PTAs, the boundaries regarding what is a legitimate disclosure of a trade secret will become blurred. In this context, it is still unclear whether PTAs can – or should – provide additional safeguards enabling regulatory oversight. After all, the threshold of protection included in the TRIPS Agreement provides sufficient leeway for governments to adopt a different type of exceptions for trade secret protection at the domestic level. As Rowe and Sandeen put it, while '[a]rticle 39 [of the TRIPS Agreement] may seem onerous . . . [i]n reality, it provides WTO member countries significant leeway in defining the parameters of trade secret law' (Rowe and Sandeen, 2015). Yet, PTA practice denotes that countries may also be willing to elucidate the scope of protection for trade secrets by clarifying the exceptions to protection. For instance, the USMCA provides that reverse engineering of a trade secret does not constitute misappropriation.[14]

Nonetheless, in seeking a balanced approach to IPR and obligations, as explained above, it is possible to contend that expansive trade secret protection in PTAs, should, at least, be coupled with sufficient flexibilities. As the digital economy evolves rapidly, governments require the necessary policy space to regulate AI and other cutting-edge technologies. It is thus important to observe and review how limitations and exceptions to trade secrets are being incorporated, especially under new TRIPS-plus agreements, and how such limitations and exceptions can ensure that while innovation in digital technologies is promoted, other societal considerations are also taken into consideration.

5.3 CONCLUSION

The issue of IPR provisions in PTAs remains a highly debated topic, highlighting once again the need to balance investment incentives with the safeguarding of other public interests. We propose incorporating a more balanced approach to IPR in PTAs by adding flexibilities and exceptions to match higher IPR protection standards. This approach can be customised to address specific challenges and types of IPR. In this chapter, we suggest three types of balanced IPR provisions to tackle the

[14] See: USMCA, Article 20(72).

three main challenges of the twenty-first century identified by WIPO: global public health pandemics, climate change, and the evolution of digital technologies.

For global pandemics, we found that medical products are protected by various types of IPR, not all of which are subject to compulsory licensing. As such, compulsory licensing may not be a viable solution to address inequalities in global access to medical products. Instead, we suggest exploring the potential for establishing PPPs as part of PTAs to promote collaboration among international stakeholders such as global businesses, governments, and CSOs.

Moreover, in the context of climate change, technology transfer has for a long time relied on voluntary licensing. This has, however, mainly benefitted industrialised and emerging economies. We have argued that an alternative approach would be to set up schemes in PTAs incentivising lower taxation of low-carbon technology exports to low-income countries. In the context of the increasing interest in mechanisms such as carbon border adjustment or import carbon tariffs, another possibility would be to leverage the gains derived from such mechanisms to fund technology transfer to low- and lower-income producers, thus promoting the adoption of sustainable production standards and avoiding further restrictions.

Lastly, as the digital economy continues to expand, the ever-increasing trade secret protection standards may have adverse effects on other important societal objectives, such as algorithm transparency. In order to address these concerns, it may be beneficial to implement regulatory checks on the functionality of AI systems. To achieve this, we suggest that limitations and exceptions to trade secrets should be included in PTAs alongside TRIPS-plus provisions.

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