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Designing Pro-Health Competition Policies in Developing Countries

Vitor Henrique Pinto Ido




SOUTH
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IN DEVELOPING COUNTRIES**

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SOUTH CENTRE

DECEMBER 2020

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ABSTRACT

Competition law and policy has become an important tool for countries to promote access to pharmaceuticals. How can countries design and enforce competition policies that are suitable to the particularities of developing countries? What are the main anti-competitive tactics in the pharmaceutical sector, and how should they be dealt with? This paper deals with these issues, taking into account the socio-economic relevance of access to health products. It finds that developing countries should apply their competition laws in the pharmaceutical sector more actively, and that there is ample policy space under international law to do so. It provides an overview of the way in which competition policies have been applied in some industrialized and developing countries and explores how such policies can be designed and implemented in the context of developing countries.

El derecho y la política de la competencia se han convertido en un instrumento importante para que los países promuevan el acceso a los productos farmacéuticos. ¿Cómo pueden los países diseñar y aplicar políticas de competencia adecuadas a las particularidades de los países en desarrollo? ¿Cuáles son las principales tácticas anticompetitivas en el sector farmacéutico y cómo deben abordarse? En el presente documento se abordan esas cuestiones, teniendo en cuenta la importancia socioeconómica del acceso a los productos sanitarios. En él se llega a la conclusión de que los países en desarrollo deberían aplicar más activamente sus leyes de competencia en el sector farmacéutico, y que existe un amplio espacio de políticas en el derecho internacional para hacerlo. Se ofrece un panorama general de la forma en que se han aplicado las políticas de competencia en algunos países industrializados y en desarrollo, y se examina la forma en que esas políticas pueden elaborarse y aplicarse en el contexto de los países en desarrollo.

Le droit et la politique de la concurrence sont devenus un outil important pour les pays dans la promotion de l'accès aux produits pharmaceutiques. Comment les pays peuvent-ils concevoir et appliquer des politiques de concurrence adaptées aux particularités des pays en développement ? Quelles sont les principales tactiques anticoncurrentielles dans le secteur pharmaceutique, et comment les traiter ? Ce document aborde ces questions, en tenant compte de la pertinence socio-économique de l'accès aux produits de santé. Il constate que les pays en développement devraient appliquer plus activement leur législation en matière de concurrence dans le secteur pharmaceutique et que le droit international offre une grande marge de manœuvre pour le faire. Il donne un aperçu de la manière dont les politiques de concurrence ont été appliquées dans certains pays industrialisés et en développement et examine comment ces politiques peuvent être conçues et mises en œuvre dans le contexte des pays en développement.

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1. INTRODUCTION

Competition policy¹ may be an important tool for countries to promote access to pharmaceuticals for all.² Pharmaceutical markets present multiple failures.³ They are often monopolistic or oligopolistic, as major barriers exist for competitors to enter the market, including intellectual property protections and high investment and regulatory costs for new products. Product differentiation (based on the use of trademarks for equivalent products) also limits the room for price competition. In this context, competition law may be utilized to reduce the negative impacts of market failures and prevent anti-competitive practices. This has become even more the case amid the COVID-19 pandemic.⁴

This paper argues that developing countries should apply their competition laws in the pharmaceutical sector more actively and that there is ample policy space under international law to do so. Given the profound socio-economic consequences related to the control over pharmaceuticals, governments should pay particular attention to anti-competitive practices related to intellectual property rights (IPRs).

The paper starts with an overview of the use of competition laws in this area both in industrialized and developing countries. The paper then briefly discusses the ample policy space that countries enjoy in crafting their own competition laws, which is followed by a description of some of the typical anti-competitive conducts relevant in the pharmaceutical market, such as pay-for-delay agreements, strategic patenting, patent thickets, product hopping, excessive pricing, sham litigation, anti-competitive licenses in R&D, mergers and acquisitions that lead to excessive concentration, cartels, and bid riggings.

The paper then provides an overview of some of the recent international and regional developments in the field, including reports by and debates at the European Commission, UNCTAD, UNDP, the WTO TRIPS Council, and the UN Secretary-General High-Level Panel on Access to Medicines—as well as the trilateral cooperation between the WTO, WIPO, and WHO—where the possibility of using competition laws and policies to enhance access to medicines has been addressed. Subsequently, it notes how access to medicines concerns can be addressed by competition policies, and provides an analysis of how to design competition policies that are suitable to developing countries, while integrating them with other policies (such as on intellectual property). The paper also deals with some obstacles and hurdles to the use of competition laws, which include a narrow definition of competition law as a mechanism to exclusively improve market efficiencies, and institutional challenges

¹ The paper adopts the expression “competition policy” as a broad term that comprises the use of “antitrust law” (as in the United States legal tradition), “anti-monopoly law” (as known, e.g., in China), and “competition laws.” For the purposes of this paper, these three expressions may be used interchangeably.

² See, in particular, the United Nations Sustainable Development Goal (SDG) 3: Ensure healthy lives and promote well-being for all at all ages, agreed upon all Member States of the United Nations.

³ Frederick Abbott argues that global pharmaceutical markets have multiple failures—political, economic, regulatory, and scientific—requiring competition law to have a multi-dimensional approach to the issue of prices in the pharmaceutical industries. See Frederick Abbott, “Using competition law to address high medicines prices: excessive pricing doctrine”, presentation at the Graduate Institute, Geneva, 15 January 2019. Available from: https://graduateinstitute.ch/sites/default/files/2019-02/ghc_webinar%2015.01.19_Abbott%20presentation.pdf.

⁴ Several competition authorities have initiated procedures targeting potential anti-competitive conducts arising from the COVID-19 response and health, including in relation to health products. In the Netherlands, for example, the pharmaceutical company Hoffman La-Roche (Roche) decided to release the recipe of its COVID-19 test after the European Commission explored action for possible abuse of its dominant position. See: <https://www.ftm.nl/artikelen/roche-releases-recipe-after-public-pressure-while-european-commission-considers-intervention-due-to-coronavirus-test> The Brazilian Administrative Council for Economic Defense (CADE) launched a comprehensive investigation mechanism for all possible pricing violations related to COVID-19, including for hand sanitizers, ventilators, etc. See <http://www.cade.gov.br/coronavirus>.

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such as budgetary constraints and lack of expertise. It makes some recommendations to introduce the issue of access to medicines in competition policies.

Finally, the paper concludes by urging developing countries to enact or revise competition laws and policies to effectively address issues relating to access to pharmaceuticals, having in view their local conditions and specificities including local production capacity, level of competition, average prices, and size of population.

2. COMPETITION LAW AND ACCESS TO MEDICINES: AN EMERGING GLOBAL TREND

Competition has never been more prominent in the public agenda: from a reduced number of countries with active competition policies a few decades ago, there are now more than 100 jurisdictions with competition authorities in place,⁵ and many developing countries are contemplating their creation or consolidation. While this trend first emerged as a consequence of market deregulation in developing countries (from regulated sectors to competition-led sectors), competition legislation encompasses a wide diversity of objectives. These may be directed toward improvements of market efficiencies (competition laws also have the authority to define what “efficiency” means)⁶ and protection of consumers⁷, or include explicit development-oriented purposes.⁸

Over the past few decades, various cases dealing with distortions to competition in the pharmaceutical market have been brought forward to competition and judicial authorities in both developed and developing countries. Examples are found in jurisdictions such as South Africa, the European Union (both by the European Commission and by national competition authorities), Brazil, the United States (by both federal courts and the Federal Trade Commission), the United Kingdom, China, and Italy, among others.⁹ This shows that the

⁵ For a broader overview, see Dina I. Waked, “Adoption of Antitrust Laws in Developing Countries: Reasons and Challenges”, *Journal of Law, Economics and Policy*, vol. 12, No. 2 (1 February 2016).

⁶ Eleanor Fox highlights the choice that developing countries have in crafting an antitrust model more suitable to them, an alternative path that “fits the facts of their markets and responds to their condition and needs. They [developing countries] deserve a law so designed and so characterized that their peoples will embrace it as sympathetic and legitimate rather than reject it as foreign.” See Eleanor Fox, “Economic development, poverty, and antitrust: the other path”, *Southwestern Journal of Law and Trade in the Americas*, vol. 13 (2007), p. 211.

⁷ This is best represented by the notion of “consumer welfare”, which became in a sense a standard concept – albeit used differently – under both the USA and EU laws. The Treaty on the Functioning of the European Union (TFEU) posits on Article 102 that “Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in: [...] (b) limiting production, markets or technical development to the prejudice of consumers;” (TFEU, Article 102). However, the notion of consumer welfare is mainly a doctrinal and case law interpretation of what competition law should aim at. Consumer welfare can be defined as “short-term price effects” (focus on ensuring lower prices in the near-term), thus a limited view that dismisses previous notions of antitrust laws being aimed at ensuring market competitiveness, preventing monopolies (which bring other consequences rather than simply higher prices), among others. In this sense, the consumer welfare standard in both the USA and the EU has been criticized as an excessively limited and short-term price-oriented policy. See, as examples of such critique of the consumer welfare standard and calls for a renewed antitrust policy, Khan, L. “Amazon’s Antitrust Paradox”, *Yale Law Journal*, vol. 126, No. 3 (January 2017); Wu, T. *The Curse of Bigness: Antitrust in the New Gilded Age*, Columbia Global Reports, 2018.

⁸ For example, South Africa’s Competition Act (89/1998) notes that among the purposes of the law is “to promote employment and advance the social and economic welfare of South Africans” and “to promote a greater spread of ownership, in particular to increase the ownership stakes of historically disadvantaged persons”. See below item on “Enabling national legislations and institutional designs”. Also see Flynn, S., “The Interface between intellectual property and competition in low- and middle-income countries”, in *Using Competition Law to Promote Access to Health Technologies – A Guidebook for Low- and Middle-Income Countries*, (UNDP, 2016).

⁹ See subsequent sections for an analysis of some of the relevant cases, For a few examples: European Commission Case AT.39226 – Lundbeck, 2013 (pay-for-delay); European Court of Justice Case C-457/10 *AstraZeneca v. Commission* (abuse of IP and registration of medicine), 2012; US Supreme Court Case *FTC v. Actavis*, 2013 (pay-for-delay); UK CMA Pfizer/Flynn (2016; appeal largely upheld in March 2020); Italian Competition Authority (AGCM) Aspen Case (2014) (excessive pricing) – later submitted for broader investigation under the EC, pending final decision; South Africa Competition Commission Case *Hazel Tau v. GlaxoSmithKline* (GSK) (excessive pricing and abuse of patents), 2002; Brazil CADE Case Eli Lilly (sham litigation), 2015; more recently, China’s State Administration for Market Regulation (SAMR) imposed a record fine for abuse of dominant position (through excessive pricing and imposing unfair trading conditions) of companies Shandong Kanghui Medicine (“Kanghui”), Weifang Puyunhui Pharmaceutical (“Puyunhui”), and Weifang Taiyangshen Pharmaceutical (“Taiyangshen”), April 2020 (see <https://www.concurrences.com/en/bulletin/news-issues/april-2020/the-chinese-state-administration-for-market-regulation-fines-three>).

problem affects both developed and developing countries. Many of such cases have dealt with price cartels and distribution restraints, practices commonly found in other sectors as well. For these, conventional competition law arguments and theories have been applied.

However, a number of other cases have touched upon anti-competitive practices that are specific, or at least more prominent, in the pharmaceutical sector, particularly the abuse of intellectual property rights. This has long been a controversial issue, as intellectual property (IP) has been mainly perceived as a realm for limited applicability of competition law—precisely because IP generally grants a temporary legal monopoly that provides a *prima facie* legitimacy to acts covered by the conferred exclusive rights. But as many multiple anti-competitive practices that rely on IPRs to limit, restrain, or block competition in the pharmaceutical sector have been verified, it has become clear that competition law should intervene to preserve or restore competition.

Examples include pay-for-delay agreements, product hopping/switching, and excessively restrictive licensing conditions, which can delay the market entry of generics to the detriment of the public good. Many of these illegal practices often utilize the judiciary, regulatory agencies, and patent office procedures as means to block or create barriers to competition, e.g., filing secondary patents to prevent generic competition (“evergreening”¹⁰) or knowingly that they will not be used (patent trolls), removing regulatory approval of a certain medicine after the patent expires, or filing several claims in courts without any chance of succeeding (sham litigation).¹¹

In this regard, competition and judicial authorities, and notably those of the European Union and the United States (paradoxically, jurisdictions that have long advocated for stringent and comprehensive IP protection), have addressed anti-competitive practices in pharmaceutical markets in relation to intellectual property.¹² In some cases, such practices refer to excessive pricing.¹³ In some jurisdictions, excessive pricing is a cause of action for competition law,¹⁴ as

¹⁰ Evergreening broadly refers to the practices aiming at expanding the patent monopoly beyond its 20 years, usually through filing of secondary patents in pharmaceuticals with small incremental changes – e.g., a crystalline form – to the detriment of legitimate competition. For an overview of the issue, and the impacts of filings and subsequent approval of patents under a low threshold of patentability criteria, see: See C.M. Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective*, (UNDP, 2016). For a comprehensive analysis of the topic of secondary patents in the medical sector, see Ducimetière, C. *Second Medical Use Patents – Legal Treatment and Public Health Issues*, Research Paper No. 101 (Geneva, South Centre, December 2019). Available from <https://www.southcentre.int/research-paper-101-december-2019/>.

¹¹ See the following sections for a description of each of them and others.

¹² For example, a WHO/HAI report notes that “In the USA, litigation has been brought successfully against originator companies for fraudulent patent applications, frivolous lawsuits to delay generic entry, reverse payments to first generic entrant not to compete, among other charges. For example, the Federal Trade Commission (FTC) issued a consent order against Bristol-Myers Squibb (C-4076, 2003) after it found the company had committed these types of offences over a period of 10 years to maintain its monopoly over three branded medicines (BuSpar, Taxol and Platinol).” Hawkins, L. WHO/HAI Project on Medicine Prices and Availability – Review Series on Pharmaceutical Pricing Policies and Interventions. Working Paper 4: Competition Policy, 2011 (<https://haiweb.org/wp-content/uploads/2015/08/Competition-final-May-2011a1.pdf>). A 2018 overview of the US case law on antitrust in the pharmaceutical sectors further notes multiple cases. See Carrier, M. A. “Antitrust in the Pharmaceutical Sector: An overview of US case law”, e-Competitions – Antitrust Case Laws e-Bulletin, (8 October 2018). Concerning the EU, the AstraZeneca (Losec) case at the European Court of Justice, its highest court, clearly delineated the abusive conduct of supplementary protection certificates (SPCs) – a *sui generis* exclusivity right present in the EU – and linkages with the registration of medicines.

¹³ See, for instance, the already mentioned UK CMA Pfizer/Flynn case, and the Italian AGCM Aspen Case (2014).

¹⁴ A landmark case in that sense is the Hazel Tau v. GlaxoSmithKline (GSK) case considered by the South African Competition Commission (2002). It had been argued that the prices of antiretroviral drugs were three to ten times more expensive than the generic versions of the same medicines. GSK, the company holding the patents, had furthermore refused to license them to generic companies. The Competition Commission formally signalled that this was a case of abuse of a dominant position and that GSK would be ordered to license such patented medicines and receive reasonable royalties in exchange. Before the decision was adjudicated, GSK settled an agreement and voluntarily licensed the patented medicines in question, thus reducing prices substantially. This is often considered to be a global first for excessive pricing related to abuse of a dominant position generated by patent monopolies. For a summary of the case, see Matthews, D. and Gurgula, O., “Patent

it may be considered in itself an illegal practice.¹⁵ Some jurisdictions recognize the very possibility of abuse in the exercise of patents.¹⁶ This means the recognition of abusive conduct, even if the right itself is not anti-competitive. In others, abusive prices of off-patent drugs were the basis for the competition authority's intervention, as it was assumed that those medicines should be subject to more competition and therefore reduced prices.¹⁷

Finally, some cases reflect the possibility of excessive concentration of intellectual property rights in one single undertaking, which leads to unjustified market power that has potentially harmful competitive consequences.¹⁸ In many mergers-and-acquisitions cases, trademarks, patent portfolios, and even know-how (protected by trade secrets) have been demanded to be transferred to competitors and/or not be used as conditions for the approval of the operations.¹⁹ In other situations, multiple patenting filings, often with overlapping claims, made by one single company, leads to "patent thickets. The web of patents so created in practice impedes competitors from entering certain markets, even if only for the risk of a potential infringement claim). These cases reveal the possibility of anti-competitive practices deriving from to the mere presence of intellectual property rights, even without its immediate exercise.

These trends suggest two main conclusions. The first is that the use of competition laws and policies in the field of pharmaceuticals has increased and clearly addresses the possible anti-competitive consequences of intellectual property rights. The second is that the impacts of

strategies and competition law in the pharmaceutical sector: implications for access to medicines", Legal Studies Research Paper, No. 233/2016 (Queen Mary School of Law, 12 May 2016). Available from SSRN: <https://ssrn.com/abstract=2779014>.

¹⁵ One exception is the current understanding in the United States of America (see sections below for a better understanding). However, even in this country, a recent decision in the Qualcomm v. Federal Trade Commission (FTC) case on 21 May 2019 could lead to a change in that regard. The decision by Judge Lucy Koh from the US District Court in San Jose, California recognized abusive unilateral licensing fees by Qualcomm that harmed consumers. The decision was overruled on 11 August 2020 by the Ninth Circuit Court of Appeals, but it still highlights that excessive pricing may be an issue even for theoretically resisting courts such as those in the United States. The decisions are available at the following links: https://www.ftc.gov/system/files/documents/cases/qualcomm_judgment.pdf and <https://cdn.ca9.uscourts.gov/datastore/opinions/2020/08/11/19-16122.pdf>.

¹⁶ For instance, Brazilian Competition Law N° 12.529/2011 explicitly characterizes "[...] to abusively exercise or exploit intellectual or industrial property rights, technology or trademark" (Article 35, XIX, Competition Law Act) as a specific violation of the economic order. This broader notion recalls, in fact, much older antitrust understandings. As reported by Flynn, S., "Beginning in a series of landmark cases in the 1910s–1930s, the USA began applying the Sherman Act or Patent Act 'misuse' standards to prohibit a series of restrictive licensing and sales terms by patent holders" (Flynn, S. "The Interface between intellectual property and competition in low- and middle-income countries", in Abbott, F., Flynn, S., Correa, C., et al., *Using Competition Law to Enhance Access to Medical Products*, [UNDP, 2014], p. 25).

¹⁷ Many took place in the European Union, where excessiveness and unfairness are the two criteria to be assessed in order to prove the occurrence of excessive pricing. It follows the jurisprudence of the United Brands Company case (European Court of Justice, Case 27/76). Examples of excessive pricing in the pharmaceutical market include the Aspen Case (2016) of the Italian Competition Authority (AGCM), in which the generic company Aspen was fined for charging excessive prices for off-patent drugs, and the Pfizer-Flynn case of the UK Competition and Markets Authority (CMA) involving price hikes of Epanutin, an epilepsy drug, when the companies were fined in 2016 for the same reasons. The Competition Appeal Tribunal (CAT) overruled the fines in 2018 but attempts to reinstate it are under discussion. The CMA is further expected to reassess the case by utilizing a different methodology.

¹⁸ For a discussion on the subject, see Lemley, M.; McKenna, M. "Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP", in *The Cambridge Handbook of Antitrust, Intellectual Property, and High Tech.*, Blair, R. and Sokol, D., (Cambridge University Press, 2017).

¹⁹ Among the various cases, see the requirements of the European Commission to conclude the merger of generic firms Teva and Allergan (Case M.7746/2016) and that of Pfizer and Hospira (Case M.7559/2015) for biosimilar products, both due to concerns with high prices. Also, in a developing country context, see the Brazilian Colgate-Kolynos merger case (1996), which ordered one of the trademarks not to be used for a period of four years, thus avoiding excessive market concentration without acknowledgement to consumers, and the Bayer-Monsanto antitrust decision (Concentration Act 08700.001097/2017-49, 2018), also in Brazil, which resulted in a number of different measures, including divestment "of all [...] Bayer's assets that are related to the soybean seeds and cotton businesses" as the companies retained too much market power.

anti-competitive practices in this sector are not a concern exclusive to developing countries, as many of the cases originated and have been decided in developed countries.²⁰

²⁰ This is not to suggest that developing countries' institutions are unable or less apt to perform such kinds of competition enforcement, but rather to highlight that even jurisdictions that have been strong defenders of liberal market rules and strong intellectual property rights in the pharmaceutical sector (especially at the international level) need to directly face the effects of anti-competitive practices and structures in their own markets. There are multiple reasons why the majority of cases are in the USA and Europe, jurisdictions with long standing operational and well-funded competition authorities. Increasing attention to the matter in developing countries may create a more varied scenario in upcoming years if such countries keep moving in that direction. An analysis of some of the hurdles that developing countries may have is found in the subsequent sections of this paper.

3. AMPLE POLICY SPACE UNDER INTERNATIONAL LAW FOR COMPETITION POLICY

Countries have ample policy space to decide upon their competition laws and policies. Unlike other areas of international law and policy, there are not major binding international norms regulating the use of competition law, especially as it is not directly regulated by WTO agreements.

At the World Trade Organization, the General Council decided in 2004 that the consideration of the interaction between trade and competition in the Work Programme set out in the Doha Ministerial Declaration (WT/L/579) was discontinued.²¹ Proposals for a multilateral framework on the subject were unsuccessful beyond a study prepared for the WTO Working Group on the Interaction between Trade and Competition Policy (WT/WGTCP/M/228). Therefore, there is no particular agreement on competition-related aspects at the WTO. Some treaties, such as the WTO Trade Facilitation Agreement (TFA, 2017), do contain measures that aim at facilitating trade that could have competition repercussions, but they provide nonetheless no restrictions on the deployment of competition policies.

In particular, the TRIPS Agreement provides a broad framework under articles 7, and article 8(2), and some disciplines in article 40 in relation to competition law to intellectual property rights. It highlights that the protection and enforcement of IPRs should “contribute to the promotion of technological innovation and to the transfer and dissemination of technology” (Article 7),²² and that countries may take appropriate measures to “prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology” (Article 8[2]).^{23 24} Further, article 40 stipulates some disciplines on restrictive practices in licensing agreements on IPRs,²⁵ notably that nothing prevents Member States “from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market” (Article 40[2]).²⁶

²¹ “Relationship between Trade and Investment, Interaction between Trade and Competition Policy and Transparency in Government Procurement: the Council agrees that these issues, mentioned in the Doha Ministerial Declaration in paragraphs 20-22, 23-25 and 26 respectively, will not form part of the Work Programme set out in that Declaration and therefore no work towards negotiations on any of these issues will take place within the WTO during the Doha Round” (World Trade Organization, WT/L/579).

²² “Article 7. Objectives. 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”.

²³ “Article 8. Principles. [...] 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

²⁴ For an overview, see Nguyen, T., *Competition Law, Technology Transfer and the TRIPS Agreement: Implications for Developing Countries*, (Edward Elgar 2010).

²⁵ “Section 8: Control of anti-competitive practices in contractual licences. Article 40. 1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.”

²⁶ “Article 40.2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member [...]” 2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this

Moreover, Article 6, which covers exhaustion of rights,²⁷ incorporates a pro-competitive policy by allowing for parallel imports. Article 31(k)²⁸ alludes to anti-competitive practices as grounds for the granting of a compulsory license (CL). In this specific case, a CL may be granted without or under reduced payment of royalties—an exception to the general rule.²⁹

The aforementioned articles provide the leeway for WTO members to adopt policies to address the potential anti-competitive conduct arising from the use (or lack thereof) of intellectual property rights. Thus, under the TRIPS Agreement countries can use competition for developmental purposes, including access to medicines. It does not deal exactly with the contours of how a competition policy (except, albeit in a limited manner in respect of licensing agreements) **ought** to look, leaving countries to decide.

It should be noted that concerns of anti-competitive consequences of the intellectual property system were raised during the negotiations of the TRIPS Agreement, and the above-mentioned provisions do reflect those. This provides an important in-built balance within the global IPRs international regime (i.e., “built-in TRIPS flexibilities”).³⁰

Many current bilateral and regional free trade agreements do include competition provisions.³¹ While the majority of these treaties currently do not contain specific obstacles to applying competition law to address practices that may negatively affect access to medicines, developing countries should make the effort to ascertain whether this will continue to be the case in the future.

Finally, the policy space available in this area may be somehow diminished in an indirect way, if competition policy is only targeted towards ensuring market efficiency and “consumer

Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member [...]”.

²⁷ “Article 6. Exhaustion. For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

²⁸ “Article 31 Other Use Without Authorization of the Right Holder Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: [...] (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur”.

²⁹ Carlos Correa notes that “Article 31(k) of the TRIPS Agreement confirmed the right to use such licenses as anti-competitive remedies. Largely inspired by the US experience, this provision allows for the granting of a compulsory license with that purpose without prior negotiation with the patent owner, as otherwise required by Article 31(b) of the Agreement. Two important additional elements of flexibility are introduced by Article 31(k): (i) A compulsory licensee is exempted from the limitation imposed by Article 31(f) regarding the destination of the products sold under the license: a major part or the totality of such products may be exported. (ii) The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration to be established in accordance with Article 31(h). This means that payment may be lower than the “economic value of the authorization”, as otherwise required by Article 31(h). As the US practice (prior to TRIPS) shows, payment might be excluded altogether. Remedying an anti-competitive situation may require that the compulsory licensee or licensees be exempted from such payment, to allow them to enter the market or compete effectively with the right-holder.” Correa, C. “Intellectual Property and Competition – Room to legislate under international law”, in Flynn, S., Abbott, F., Correa, C., et al. *Using Competition Law to Promote Access to health Technologies*, UNDP, 2016.

³⁰ For a comprehensive overview of the policy space under the TRIPS agreement, including the use of parallel importation as a pro-competitive policy and compulsory licensing as remedy for anti-competitive practices, see Correa, C., “Intellectual property and competition – room to legislate under international law”, in Abbott, F., Flynn, S., Correa, C., et al., *Using Competition Law to Enhance Access to Medical Products* (UNDP, 2014).

³¹ For a development-oriented perspective on competition provisions in trade agreements, see the chapters in the collection by Brusick, P., Alvarez, A.M., and Cernat, L., *Competition Provisions in Regional Trade Agreements: How to Assure Development Gains* (UNCTAD, 2005).

welfare”, which, as noted before, is only one amongst multiple possible goals of such policy, which can include industrial development, poverty reduction, curbing racial and income inequalities, ensuring media diversity, and ensuring access to health products. In most developing countries, the current competition laws and authorities were set up in the 1990s onwards; they were generally part of economic liberalization initiatives. In this sense, their adoption was associated in some cases to international pressure and conditionalities.³² A narrow view on the goals of competition policy, which leads to insufficient attention to non-efficiency related goals, is often advanced by the technical assistance provided by international institutions such as the OECD and the International Competition Network (ICN). In this context, it is important to stress the existing policy space that allow countries to tailor their competition law and policy in accordance to their specific needs and overall national objectives.

³² See Waked, D., “Adoption of Antitrust Laws in Developing Countries: Reasons and Challenges”, *Journal of Law, Economics and Policy*, vol. 12, No. 2 (2016).

4. OVERVIEW OF ANTI-COMPETITIVE PRACTICES IN THE PHARMACEUTICAL SECTOR

This section presents a brief description of some of the main recognized anti-competitive practices in the pharmaceutical sector. A particular focus is given to intellectual property-related practices, as they are likely to be the most controversial ones in the light of the often-articulated argument that IP should be treated as an immune/restricted zone for the application of competition law.³³

The following is not an exhaustive enumeration of such practices. The nomenclature given has a more conceptualizing than normative purpose, as it is important to identify the occurrence of anti-competitive practices in the pharmaceutical sector rather than define them. Furthermore, a number of attempts to systematically review these practices have been published and serve as useful resources.³⁴

It should be noted that there are multiple remedies to address anti-competitive practices in the pharmaceutical sector. While the most typical ones are imposition of fines (sometimes with punitive damages in order to discourage further misconduct) and sometimes prohibiting certain practices, competition authorities may oblige patent holders to license their technologies or grant compulsory licenses, as specifically allowed under Article 31(k) of the TRIPS Agreement, which provides a specific hypothesis of compulsory licenses to remedy anti-competitive practices.³⁵ These remedies may also include the selling or transfer of know-how, trademarks, and/or patents to other companies in order to avoid excessive concentration. Overall, enforcement of competition laws is relatively broad and flexible, and may provide for a wide array of remedies to address anti-competitive practices.

(a) Pay-for-delay agreements (“reverse settlements”)

Pay-for-delay agreements, also known as ‘reverse settlements’, are contractual arrangements between a company that holds a patent (‘originator’ company) and generic companies whereby the originator pays the latter certain amounts of money (or other remuneration in the form of licenses, etc.). In return, generic companies agree not to enter the markets after the patent expires. In the United States, where generic competition after a patent expires tends to be high, many of these agreements consisted of a settlement pursuant to a patent dispute for patent infringement.³⁶ The agreement reached between the companies avoids further litigation, but also means that generic companies will agree to

³³ This is often argued, for instance, in relation to excessive pricing cases where there are patents in force, thereby dismissing that an abuse of a dominant position may take place, even if the exploitation of a patent is considered to be lawful (see below). Also, for a broader overview and a proposal of integration of IP and competition law principles, see Calixto Salomão Filho, “Industrial Law, Competition Law and Public Interest”, in *Critical-Structuralist Theory in Commercial Law (Teoria Crítico-Estruturalista em Direito Comercial)*, (São Paulo, Marcial Pons, 2015).

³⁴ For a few attempts to systematically review anti-competitive practices in this field, see Matthews, D. and Gurgula, O., “Patent strategies and competition law in the pharmaceutical sector: implications for access to medicines”, Legal Studies Research Paper, No. 233/2016. (Queen Mary School of Law, 12 May 2016). Available from <https://ssrn.com/abstract=2779014>; Danzon, P.M., Competition and Antitrust Issues in the Pharmaceutical Industry – Final Report (The Wharton School University of Pennsylvania, 2014); European Commission, Pharmaceutical Sector Inquiry – Final Report (2009); see also Rodríguez Gómez, M. J. *Intersección entre Competencia y Patentes: Hacia un Ejercicio Pro-Competitivo de los Derechos de Patente en el Sector Farmacéutico*, Research Paper No. 105 (Geneva, South Centre, March 2020). Available from <https://www.southcentre.int/documento-de-investigacion-105-marzo-2020/>.

³⁵ Also see section on *Ample Policy Space under International Law for Competition*.

³⁶ Matthews and Gurgula, “Patent strategies and competition law in the pharmaceutical sector”, p. 7.

abstain from entering the market for a certain period. This means that competition will be hampered. Patent holders have argued that such agreements should be deemed to be legal, as trading patents is part of the bundle of exclusivity rights conferred by a patent, at least while the patent is valid.³⁷ However, those agreements may impede judicial outcomes that could possibly even invalidate a patent (since an agreement is reached between the parties, the judicial authority does not have the opportunity to decide upon the validity of the patent, and in many cases also apply after a patent expires. Multiple decisions by the United States Federal Trade Commission and the US Supreme Court, such as *FTC v. Actavis Inc.* (2013) (where case law was until this leading case very divergent, with both decisions that recognized pay-for-delay agreements to be legal and illegal),³⁸ and the European Union, such as the *Lundbeck* case (2013),³⁹ have addressed this issue. Other jurisdictions have also started to pay attention to the issue, including China and India.⁴⁰

(b) Strategic patenting, defensive patents, and patent thickets (or clusters)

Applying for a patent bears in itself no competition consequences, being a perfectly legitimate act. However, some patterns in patenting may result in anti-competitive outcomes. In such cases, they are to be sanctioned under competition laws. The practice, known as “strategic patenting,” denotes the intentional patenting of certain inventions to extend the monopoly’s scope or time conferred by the law as much as possible.

When companies apply for patents on certain technologies that they know will never be used, mainly to protect them against potential competition, this is known as “defensive patenting.”⁴¹ This strategy may have anti-competitive effects, as the patents obtained with that purpose may block the production and commercialization of the protected products thereby eliminating competition with the patent holder in the same or secondary markets.⁴² Hence, these defensive patenting practices may also restrict the possibility of competitors to generate follow-on innovation. They have been clearly outlined by the European Commission in its 2009 Pharmaceutical Sector Inquiry.⁴³

³⁷ Matthews and Gurgula, “Patent strategies and competition law in the pharmaceutical sector” p. 7.

³⁸ The divergent opinions on pay-for-delay agreements in the United States, according to Matthews and Gurgula, “employed different tests of assessment (i.e. per se illegality, scope of patent test, rule of reason and quick look test) and focusing on different facts (presumption of patent validity, transfer of funds etc.)” (Matthews & Gurgula, 2016, p. 8). In the *FTC v. Actavis* case, however, the US Supreme Court decided that “these type of agreements are not immune from antitrust scrutiny and firmly rejected the settled ‘scope of patent’ test largely used by the courts, as well as the FTC’s “quick look” test, suggesting that reverse payment agreements must be analyzed under the antitrust ‘rule of reason’ test”.

³⁹ *Lundbeck v. Commission*. Case 39226/2013.

⁴⁰ Matthews and Gurgula, “Patent strategies and competition law in the pharmaceutical sector” p. 9.

⁴¹ European Commission, “Pharmaceutical Sector Inquiry”.

⁴² In this regard, a reference to the importance of the definition of secondary markets in competition law could be drawn. For example, see European Commission Notice on the definition of relevant market for the purposes of Community competition law (97/C 372/03), par. 56, notes that “*There are certain areas where the application of the principles above has to be undertaken with care. This is the case when considering primary and secondary markets, in particular, when the behaviour of undertakings at a point in time has to be analysed pursuant to Article 86. The method of defining markets in these cases is the same, i.e. assessing the responses of customers based on their purchasing decisions to relative price changes, but taking into account as well, constraints on substitution imposed by conditions in the connected markets. A narrow definition of market for secondary products, for instance, spare parts, may result when compatibility with the primary product is important. **Problems of finding compatible secondary products together with the existence of high prices and a long lifetime of the primary products may render relative price increases of secondary products profitable. A different market definition may result if significant substitution between secondary products is possible or if the characteristics of the primary products make quick and direct consumer responses to relative price increases of the secondary products feasible***”.

⁴³ European Commission, “Pharmaceutical Sector Inquiry”.

Under this spectrum, numerous sub-practices may be highlighted – as already mentioned briefly in the first section above–, including divisional patent applications (filing an application that contains matter from a previously filed application) and “evergreening” (filing patent applications relating to minor improvements on, derivatives or uses of existing products, such as formulations, salts, ethers, and second medical uses of a known substance).⁴⁴

“Patent thickets” (or “patent clusters”) describe the situation in which multiple layers of patenting result in a legal situation where a certain invention or technology is legally bound and protected by various different patents, each with varying scope and coverage. Carl Shapiro defines them as “a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.”⁴⁵

For example, many medicines are protected by multiple patents – some for the compound itself (whether individually or as one element of a generic chemical formula as in the case of ‘the so-called Markush claims’⁴⁶), some for combinations, others for the formulation, polymorphs, enantiomers, etc. some for a broad formula that comprises the compound individually, and many others. More than 800 patents were identified for ritonavir, a treatment for HIV/AIDS by the World Property Organization. Kaletra, an important combination drug also for HIV/AIDS treatment, is said to be protected by 108 patents since its launch.⁴⁷

Not all patents are necessarily held by the same legal entity. In fact, in many cases they are not, which sometimes obliges the dominant market player to negotiate licenses with other patent holders, leading to heightened transaction costs. In this sense, these practices also negatively affect competitors, a situation known as “tragedy of the anti-commons,” i.e., an excessive number of rights holders that obstructs the utilization of a particular technology.⁴⁸

Patent thickets generate a situation of legal uncertainty and restrain legitimate competition as generic producers face the risk of costly legal challenges if they aim at marketing the covered product. Competitors are often unclear about the boundaries of protection, both in scope and duration. It takes time, financial resources, and technical expertise to perform an assessment of the ‘freedom to operate’. Moreover, even if such assessment is completed, they may not avoid infringement claims by patent holders. The uncertainty and excessively broad scope of patent protection leads to increased litigation costs, as even unjustified claims are likely to lead to the grant of preliminary injunctions and therefore restrain legitimate activities. Small and medium-sized companies, in particular, will not have the same financial capacity to bear litigation costs and may opt to stay out of the market.

Even though the roots of patent thickets can be found in patenting practices themselves, the issue is likely more prominent in jurisdictions whose patent policy adopts lax patentability requirements and/or has a lack of substantive analysis, in which cases multiple patents with reduced to no real innovation are granted.⁴⁹ The outcomes of permissive patent policies have

⁴⁴ Again, for a comprehensive overview, see Ducimetière, C., 2020.

⁴⁵ Shapiro, Carl., “Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting” (March 2001). Available from: <https://ssrn.com/abstract=273550> or <http://dx.doi.org/10.2139/ssrn.273550>

⁴⁶ “Markush claims consist of a generic chemical structure with multiple alternatives that allow for the protection, under a single patent, of several variants of a claimed invention. The admission of pharmaceutical patents for such claims raises complex issues because a single patent may potentially block research and development and the commercialization of up to several million molecules. Recent studies show a growing use of Markush claims in several developing countries, where such claims accounted for more than 50 percent of all patent applications relating to pharmaceuticals.” Correa, C. *Guidelines for the Examination of Patent Applications Relating to Pharmaceuticals*, (UNDP, 2016), p. 16.

⁴⁷ Matthews and Gurgula, “Patent strategies and competition law in the pharmaceutical sector” p. 10.

⁴⁸ Heller, M. *The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives* (Basic Books, 2008). ISBN 978-0-465-02916-7.

⁴⁹ For Correa, C.: “In the case of the pharmaceutical sector, in particular, low patentability standards can have detrimental impacts. A low inventive step is prone to abuses, leading to extension of patent monopolies through products embodying every minor change. [...] A lax inventive step allows the grant of patents that extend existing

been extensively addressed and criticized for the granting of patents without the benefits to be accrued by a new technology, and for reducing the realm of the public domain.⁵⁰ This has led to arguments of a system in “crisis”⁵¹ that hinders innovation rather than promotes it.⁵² Some arguments question the role of patents in promoting innovation at all, which questions the very basis on which they are granted.⁵³ Unwarranted pharmaceutical patents, in particular, may bear profound social consequences as they allow undue legal monopolies that increase prices and reduce access to treatments.⁵⁴ A solution to this problem is the implementation of rigorous patentability criteria to avoid the grant of patent applications with little to no innovation.

In accordance to one minority view, the concept of ‘patent thicket’ is a rhetorical proposal that intends to undermine the validity of patents overall and is not empirically verifiable.⁵⁵ However, a UK Intellectual Property Office report confirmed in 2013 the anti-competitive impact of the accumulation of patents around a certain technology: “Econometric analysis of the probability of entry into patenting by technology area shows that the density of a patent thicket in a particular technology area is associated with reduced entry into patenting in that area by UK firms. Given the importance of holding patents in such areas, we interpret this result as indicating reluctance to enter technological areas with patent thickets.”⁵⁶

monopolies and guarantee markets for international firms to overcome constraints.” See Correa, C. *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (Geneva, South Centre, 2011), p. 21. For other commentators, the increased number of patent filings is one of the factors that lead to the reduction in patent quality, as well as to increased technological complexity and interdependence of technological components. See Hall, B., Helmers, C., and Graevenitz, G., *Technology Entry in the Presence of Patent Thickets*, IFS Working Paper W16-02. Available from <https://www.ifs.org.uk/uploads/publications/wps/wp201602.pdf>.

⁵⁰ For implications in developing countries and a critique of the disregard of the crucial role of examination in patents, see Correa, C. *Patent Examination and Legal Fictions: How Rights are Created on Feet of Clay*, Research Paper No. 58 (Geneva, South Centre, December 2014). Available from <https://www.southcentre.int/research-paper-58-december-2014/>.

For a general critique, see Kang, Hyo Yoon “Patents as Assets: Intellectual Property Rights as Market Subjects and Objects”, in *Assetization: Turning Things into Assets in Technoscientific Capitalism*, Kean Birch and Fabian Muniesa, (eds.), (Cambridge, MIT Press, 2020).

⁵¹ Burk, D., Lemley, M., *The Patent Crisis and how the Courts can solve it*. (Chicago, University of Chicago Press, 2009).

⁵² A well-known argument was proposed by M. Heller and R. Eisenberg based on the notion of “The Tragedy of the Anticommons”, later applied to biomedical research in a critical way. See Heller, M., Eisenberg, R., “Can Patents Deter Innovation? The Anticommons in Biomedical Research”, *Science*, vol. 280, (1998), p. 698.

⁵³ Boldrin, M., Levine, D., “The Case against patents”, *Journal of Economic Perspectives*, vol. 27, No. 1, (Winter 2013), pp. 3-22 for one of the most radical argument against patents: “there is no empirical evidence that they [patents] serve to increase innovation and productivity, unless productivity is identified with the number of patents awarded—which, as evidence shows, has no correlation with measured productivity.”

⁵⁴ See Report of the United Nations Secretary-General High Level Panel on Access to Medicines, 2016, available from <http://www.unsgaccessmeds.org/final-report>; also the comments by Carlos Correa on the matter: “The increase in the number of patents reflects, to a large extent, the low requirements of patentability applied by patent offices and courts. Patents granted despite the absence of a genuine invention detract knowledge from the public domain and can unduly restrain legitimate competition. [...] The proliferation of patents is particularly high and problematic in the pharmaceutical sector, where large companies actively seek to acquire broad portfolios of patents in order to extend patent protection beyond the expiry of the original patents on new compounds. These evergreening strategies allow them to keep generic producers out of the market and charge prices higher than those that would otherwise exist in a competitive scenario.” (Correa, C., *Tackling The Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain* Research Paper No. 52 (Geneva, South Centre, August 2014). Available from <https://www.southcentre.int/research-paper-52-august-2014/>.

⁵⁵ For example, an industry representative said in a speech at the Biotechnology Innovation Organization (BIO), in Washington, DC, that “a close look reveals that most patents [in biological pharmaceutical products] are tangential and ought to have little effect on how soon a product comes to market...”; see: <https://www.centerforbiosimilars.com/news/patent-thickets-are-not-the-obstacle-they-appear-to-be-bio-patent-counsel-claims>.

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/311234/ipresearch-thickets.pdf.

(c) Product hopping (or product switching)

Product hopping refers to the launch of a new version of a patented drug right before the expiration of the patent of the main product in order to block generic competition. According to Matthews and Gurgula, “In order to induce such product switch originator companies may employ different tactics, such as withdrawing the old drug from the market, raising the relative price of the old drug, or promoting the new drug differentially.”⁵⁷ Therefore, there are many strategies to create strong incentives and/or impediments to access the off-patent drug.

These cases have also been recognized by courts in the USA, e.g., in the *State of New York v. Activis Case* (Case No. 14-4624 [2d Cir. 2015]), in which an older medicine was withdrawn from the market and this conduct was deemed to be an antitrust violation.⁵⁸

In the European Union, the most important precedent in this regard is the AstraZeneca case,⁵⁹ which reached and was judged by the European Union’s top jurisdictional body, the European Court of Justice (ECJ). The case dealt with a situation involving both patent and market approval regulations. AstraZeneca withdrew its own market authorization for Losec capsules – a commercially successful drug for treatment of ulcers - when it introduced new Losec tablets.⁶⁰ By doing so, generic companies were unable to rely on the pre-existing market authorization’s clinical trials, effectively forcing them to redo the trials or stay out of the market. In this case, the de-registrations of the previous product was found to be an abuse of a dominant position.⁶¹ AstraZeneca had also misinformed national patent offices about the dates of market authorization. The case was particularly important as it was the first time a pharmaceutical company was fined for an abuse of market dominance.⁶²

Another and much more recent example related to Delzicol, a medicine for active ulcerative colitis symptoms developed by Allergan. In 2020, a full report on the practices of the company in the United States showed that it had substituted the original capsule of Delzicol with a new version that was essentially based on a larger capsule.⁶³ According to the analysis, this capsule in reality merely included an extra outside layer of the very same previous capsule. This small change enabled a new patent that extended the patent monopoly.

(d) Excessive pricing as an abuse of dominant position

A large number of cases have dealt with excessive pricing of medicines. Many have taken place in the European Union. The Napp case in 2002 in the UK is considered to be the very first on the continent.⁶⁴ At the EU level, following the landmark United Brands Company case (European Court of Justice, Case 27/76), excessiveness and unfairness are the two criteria

⁵⁷ Matthews and Gurgula, “Patent strategies and competition law in the pharmaceutical sector” p.10.

⁵⁸ *State of New York v. Activis* (Case No. 14-4624 [2d Cir. 2015]),

⁵⁹ *AstraZeneca v. Commission*, Case C-457/10 P.

⁶⁰ For a short summary, also see Bushell, G. Case C-457/10 P, Astra Zeneca v. Commission, Judgment of 6 December 2012. http://competitionlawblog.kluwercompetitionlaw.com/2012/12/07/case-c-45710-p-astrazeneca-v-commission-judgment-of-6-december-2012/?doing_wp_cron=1595974207.9077529907226562500000.

⁶¹ Former Article 82 EC, current Article 102 of the Treaty on the Functioning of the European Union (TFEU).

⁶² Drexl, J., “AstraZeneca and the EU sector inquiry: when do patent filings violate competition law?”, in *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Drexl, J. and Lee, N., (Edward Elgar, 2013).

⁶³ Rizvi, Zain, “By any means necessary. How Allergan gamed the system to raise drug prices and flood the country with pills” (Public Citizen, 6 January 2020). Available from <https://www.citizen.org/article/by-any-means-necessary/>.

⁶⁴ Napp Pharmaceutical Holdings Ltd: alleged abuse of a dominant position – CA98/2D/2001 (Office of Fair Trading – predecessor of Competition and Markets Authority, CMA).

utilized to assess whether an excessive price is charged.⁶⁵ Other examples include the Pfizer-Flynn case of the UK Competition and Markets Authority (CMA), which in 2016 fined the companies for the spike in the prices of Epanutin, an epilepsy drug.⁶⁶

Another interesting case is Aspen (2016) decided by the Italian Competition Authority (AGCM).⁶⁷ The generic company Aspen imposed very hard negotiation conditions and sharply raised prices, which were finally found to be excessive for off-patent drugs that had not been developed by it.⁶⁸

It is generally understood that the US law and jurisprudence do not consider excessive pricing to be a cause of action under antitrust law, either by the FTC or the federal courts.⁶⁹ However, a relative exception was found in the first decision of the *Qualcomm v. FTC Case*: in 2019, a Californian federal court deemed licensing practices anticompetitive based on pricing issues. The decision has since been overruled by the Ninth Circuit Court of Appeals in August 2020, but may signal a shift towards the adoption of a different approach on the matter in the future.⁷⁰

Possibly the most groundbreaking case in developing countries is the *Hazel Tau v. GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI)* case before the Competition Commission of South Africa (2002),⁷¹ despite the fact that it was not finally adjudicated as the companies reached an agreement to drastically reduce prices (about three to ten times more expensive than generics), through voluntary licenses and reduced royalties schemes.⁷² The Competition Commission considered the companies' refusal to license under reasonable conditions in the light of the 'essential facilities' doctrine.⁷³ This case is particularly relevant as it dealt with *patented* medicines and not off-patent ones.

(e) Sham litigation or vexatious litigation

The practice known as "sham litigation" (or "vexatious litigation" in the European Union) refers to an abuse of the right to petition, i.e., inappropriate and excessive use of the courts (both judicial and quasi-judicial) in order to delay or impede competitors from entering the

⁶⁵ European Court of Justice, Case 27/76.

⁶⁶ In 2018, the Competition Appeal Tribunal (CAT) overruled the £90 million fines imposed by the CMA. In March 2020, the Court of Appeal upheld the decision of the Competition Appeal Tribunal (CAT) but sent the case back to the CMA to reassess the occurrence of excessive pricing. The case is still pending as of the conclusion of this paper.

⁶⁷ AGCM, A480B - Incremento prezzi farmaci Aspen – Inottemperanza.

⁶⁸ For an overview of the decision, see description in the submission by Italy to the OECD: "Excessive Pricing in Pharmaceutical Markets – Note by Italy", (28 November 2018). Available from [https://one.oecd.org/document/DAF/COMP/WD\(2018\)106/en/pdf](https://one.oecd.org/document/DAF/COMP/WD(2018)106/en/pdf).

⁶⁹ For a critical assessment of the US approach, see Frederick M. Abbott, "Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health", 6 U.C. Irvine L. Rev. 281 (2016).

⁷⁰ *Qualcomm v. Federal Trade Commission (FTC)* case on 21 May 2019 (also already mentioned in the Introduction of this article). For the full decision, still on appeal, see: https://www.ftc.gov/system/files/documents/cases/qualcomm_judgment.pdf.

⁷¹ See STATEMENT OF COMPLAINT IN TERMS OF SECTION 49B(2)(b) OF THE COMPETITION ACT 89 OF 1998. <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf>.

⁷² Excessive Pricing in Pharmaceutical Markets – Note by South Africa to the OECD. DAF/COMP/WD(2018)117 "In its investigation, the CCSA found that GSK and BI had abused their dominant positions in the market for their respective ARVs by charging excessive prices for ARV drugs under patent and for excluding generic manufacturers from the market by not issuing licenses to these generic manufacturers to supply ARV drugs to the market. Before the case could be referred to the Competition Tribunal for adjudication, GSK and BI opted to resolve the matter by negotiating settlement agreements with the CCSA. The eventual settlement agreements required that BI and GSK allow generic manufacturers to use their patents to produce ARV treatment." [https://one.oecd.org/document/DAF/COMP/WD\(2018\)117/en/pdf](https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf).

⁷³ Submission by South Africa to the Roundtable on "Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers", Seventh UN conference to review the UN Set on Competition Policy, 6-10 July 2015.

market. Akin to the anti-competitive effects arising from strategic patenting practices, sham litigation attempts to use legal instruments knowingly that there is little chance, if any, to succeed with the exclusive purpose of blocking or restraining competition.

Sham litigation practices may entail high costs for competitors, who will be forced to spend time and money in legal proceedings despite the lack of grounds of the claims. Competitors may therefore refrain from entering certain markets. Much debate revolves around the possible ways to characterize sham litigation and how to differentiate it from lawful litigation practices. An excessively broad interpretation of that concept may have the unwanted effect of creating disincentives for legitimate litigators. In this sense, the Brazilian CADE authority, for instance, pointed out to the following conditions with regard to identification of sham litigation in the Eli Lilly Case (2016): “(1) implausibility of the claims, (2) provision of erroneous information and (3) unreasonableness of the means used.”⁷⁴

(f) Refusal to Deal

The most common form of anti-competitive practice related to licensing is the simple **refusal to deal**.⁷⁵ Many of the cases that deal with other anti-competitive practices also include a refusal by the originator pharmaceutical company (or the one holding the exclusivity rights) to license to competitors. While deciding upon the transfer of rights of a patent is part of the bundle of rights, as acknowledged in the sub-section on pay-for-delay agreements, unjustified restriction of access can be anti-competitive. This is particularly applicable in pharmaceuticals, which are socially crucial goods.

In the United States, this is a consequence of the “essential facilities” doctrine, applied originally to critical infrastructures without which an economic activity cannot be operated. The doctrine was later expanded from physical infrastructure to various other essential goods, leading to its recognition in the patent sector through the idea of “standard essential patents” (SEP). Other jurisdictions, such as the European Union, Australia, and India, have achieved the same recognition through the notion of “refusal to deal” incorporated into their legislations and case law. Therefore, failure to license crucial technologies (essential facilities and/or SEPs) may be deemed anti-competitive.

(g) Restrictive Practices in Licensing Agreements

In addition, restrictive practices in licensing agreements are another form of anti-competitive practice. In fact, a common remedy by antitrust authorities is to impose the obligation to license under free, reasonable, and non-discriminatory terms (FRAND licenses).⁷⁶ As a consequence, under certain conditions, the imposition of **abusive licensing conditions** can also be found to be anti-competitive, either for excessive pricing or other ancillary conditions.

One yet unexplored area that competition to which authorities should direct attention refers to licensing agreements between large transnational pharmaceutical companies with national generic companies and national laboratories, in particular **voluntary licenses** for certain essential medicines. This has become an ever-increasing model to ensure production of and

⁷⁴ For a full analysis of the decision, see CADE Councillor Paula Azevêdo’s document prepared for WIPO ACE Committee https://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_13/wipo_ace_13_5.pdf.

⁷⁵ For an overview on the issue, see also World Trade Organization, World Health Organization and World Intellectual Property Organization, *Trilateral Study – Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade*, 2nd Edition, (2020).

⁷⁶ It should be further noted that certain business sectors have voluntarily adopted FRAND standards in order to enhance competition. Conditions for injunctions under FRAND licenses have also been interpreted by the European Court of Justice (*Huawei v. ZTE Case*, C-170/13, ECJ), albeit not in the pharmaceutical sector specifically.

access to medicines in many LMICs, and it is usually perceived to be a more effective measure leading to simultaneous transfer of technology and reduction of prices. In Brazil, for instance, Productive Development Partnerships (PDPs) was a policy launched in 2009 that allowed domestic production of medicines.⁷⁷ Globally, Gilead, a transnational pharmaceutical company, licensed multiple generic companies for the production of Sofosbuvir, a crucial drug for hepatitis C treatment,⁷⁸ which is exported to multiple countries. However, the policy has also been criticized for excluding countries such as Malaysia that, though they are considered middle-income/developing, have very high disease burdens.

While these licenses may indeed become effective models to ensure more access to medicines, they should not *a priori* be excluded from competition authorities' scrutiny. Some countries do impose restrictions on the antitrust control of public companies'/entities' conduct (including contracts), but many others do not. In particular, the effects of confidentiality agreements and restrictions on exports to certain countries (which in competition law jargon means dividing markets) should be assessed. If competition policies intervene in such cases, they might identify anti-competitive practices according to their national laws.⁷⁹

(h) Restrictions on R&D, particularly through licensing

Furthermore, restraining conditions of innovation and R&D, particularly through (but not limited to) unfair licensing practices, are also an anti-competitive practice. They negatively affect the incentives for innovation, which is precisely the main justification for IPRs to be granted in the first place. This is also a new realm for the application of anti-licensing doctrines.

The already-mentioned 2019 European Commission report (drawing on the work of the 2009 Pharmaceutical Sector Inquiry) addresses the fact that market players engage in conduct that affects incentives to innovate (such a patents, interventions before authorities, and acquisitions of competing technologies) and thus may breach competition law. The report describes cases that have received the intervention of the European Commission in order to keep the existing incentives and R&D in the pharmaceutical sector.⁸⁰

⁷⁷ Moehlecke, R., "Parcerias produtivas estimulam produção nacional de vacinas e medicamentos." Available from: <https://portal.fiocruz.br/noticia/parcerias-produtivas-estimulam-producao-nacional-de-vacinas-e-medicamentos>

⁷⁸ See Gilead's global website: <https://www.gilead.com/purpose/medication-access/global-access/access-partnerships>.

⁷⁹ Two possible issues that such authorities might need to address are the definition of "relevant market" and the possibility of extra-territoriality of domestic competition law. Both of these topics have received a lot of attention from academia and the antitrust community in recent years, particularly due to prospective digital economy cases (and the attempt to control conduct by large technology platforms—an explicit discussion at the European Commission and part of the programme of work of the ICN until 2022, for instance) and increased cases that recognize extra-territoriality (so far, an instrument deployed mostly—or even exclusively—by high-income countries' competition authorities). For instance, the Japanese Supreme Court upheld the decision of the Japan Fair Trade Commission which sanctioned foreign companies in a cartel of cathode ray tubes (CRTs) for televisions, only indirectly affecting national Japanese companies that operated in the countries through subsidiaries (*Sup. Ct., Dec. 12, 2017, 2016 (Gyo-hi) No. 233*). See Nikkei Asian Review, "Japan can go after foreign cartels, Supreme Court rules. The law applies whenever domestic competition is hindered, the top court says" (13 December 2017). Available from: <https://asia.nikkei.com/Politics-Economy/International-Relations/Japan-can-go-after-foreign-cartels-Supreme-Court-rules>.

⁸⁰ "In merger control, the Commission has prevented transactions that could compromise R&D efforts to launch new medicines or to extend the therapeutic use of existing medicines. The Commission intervened to protect innovation competition in a number of cases which, for example, threatened to thwart advanced R&D projects for life-saving cancer drugs (Novartis/GlaxoSmithKline Oncology) or for pipeline insomnia medicines at an early stage of development (Johnson & Johnson/Actelion). In the Pfizer/Hospira case, the Commission was concerned that the merger would do away with one of the two parallel projects to develop competing biosimilars. The Commission cleared all these transactions but only after the companies offered remedies to ensure that pipeline projects were not dropped and found a new operator to drive them forward." See European Commission,

It also recognizes a positive spill-over effect: “In addition to safeguarding innovation, antitrust enforcement also fosters patients’ choice by intervening against various exclusionary practices such as a rebate scheme designed to exclude competitors from hospital tenders or the spreading of misleading information about the safety of a medicine when used to treat conditions not mentioned in the marketing authorization (off-label use).”⁸¹

Intertwined with such debate are the continued efforts to ensure broader transparency in the pharmaceutical industry in its multiple dimensions (such as R&D costs, marketing costs, net pricing mechanisms around the world, distributional costs, etc.), which led to the approval of the landmark Transparency Resolution at the 2019 World Health Assembly.⁸² Apart from increasing transparency overall, these transparency measures may also serve as the basis for competition authorities to launch investigations and discover yet publicly unknown illegal market conduct.

(i) Mergers and acquisitions that lead to excessive concentration of IP

Since a large number of mergers and acquisitions in the field of pharmaceuticals involve the accumulation of R&D data and patent portfolios, a careful assessment of their implications on competition by competition authorities is required.⁸³ Possible efficiency gains of the merger may be counterbalanced by the negative impacts of the concentration of IPRs in the hands of a single company. In this context, selling or giving away brands, patents, and other IPRs to competitors may be a needed condition for the approval of a merger or acquisition. These options limits the market power conferred by IPRs.⁸⁴

(j) Cartels and bid riggings

Cartels are agreements between competitors to harmonize conduct, especially prices, between the participants. By agreeing on prices, cartelists benefit from higher prices as they avoid the burden of competition; the result is to generate higher prices for consumers. Sometimes, cartels may also be deployed to exclude new entrants from the market.

Cartels are one of the most well-known anti-competitive conducts. They gave rise to the creation of competition law and are still considered to be one of the main and most direct means of extracting welfare from consumers and the public at large to the benefit of themselves.

Bid riggings are agreements between competitors in public bids. Similar to cartels, they benefit the participants by enabling them to win a bid without the price that otherwise would have been offered, which is typically much higher.

Competition Enforcement in the Pharmaceutical Sector (2009–2017) – European competition authorities working together for affordable and innovative medicines (European Union, 2019), pp. 2-3.

⁸¹ European Commission, *Competition Enforcement in the Pharmaceutical Sector (2009–2017) – European competition authorities working together for affordable and innovative medicines* (European Union, 2019), p. 3.

⁸² WHA 72.8. Improving the transparency of markets for medicines, vaccines, and other health products.

⁸³ See Gilbert, R. Tom, W. *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*. For an overview of some approaches taken by US’ DOJ and FTC in pharmaceutical mergers, including reflections on the relevant market and the innovation in case of a joint patent portfolio.

⁸⁴ See, for instance, Brazilian CADE Kolynos-Colgate merger (1996), where a key trademark needed to be removed from the IP portfolio of the new company to avoid excessive market concentration. For an analysis, see Salgado, L. *O Caso Kolynos-Colgate e a Introdução da Economia Antitruste na Experiência Brasileira*; Mattos (org.), *A Revolução do Antitruste no Brasil: A Teoria Econômica Aplicada a Casos Concretos*, (Editora Singular, São Paulo, 2003).

There have been multiple cases of cartels and bid riggings in the field of pharmaceuticals.⁸⁵ As stated before in this article, the majority of competition authorities' interventions originally started due to such kinds of practices – for example, an agreement between pharmacies to charge similar prices in a certain city. Also, as argued before, increased coordination between competition agencies may lead to the identification of transnational cartels in the field of pharmaceuticals, including questionable practices related to price discrimination between countries. Whether this will be turned into an effective case is yet to be seen.

Although these practices are not necessarily related to IP or their exercise, for many developing countries, especially smaller ones, these may be practices that significantly affect access to medicines.

⁸⁵ For example, see Igami, M and Sugaya, T., "Measuring the Incentive to Collude: The Vitamin Cartels, 1990-1999", 21 May 2019. Available from https://som.yale.edu/sites/default/files/IgamiSugaya_190521pm_VitaminCartels.pdf.

5. DEVELOPMENTS AT THE REGIONAL AND INTERNATIONAL LEVEL

The increasing attention of international organizations, particularly UN agencies, with strong participation and leadership of developing countries, as well as the recent developments at the European Commission, highlight that competition law and access to health products has become a central policy discussion.

Multiple regional and international organizations have examined the competition dimension of the pharmaceutical sector, with particular attention given to the role of intellectual property. This section briefly refers to some of the reports and studies produced by selected regional and international organizations, as well as discussions brought by Member States and other stakeholders, on the role of competition law and its enforcement in curbing IP-related anti-competitive practices that may limit access to medical products. This section also describes some international debates held on the matter.

(a) European Commission

An important landmark for the consideration of the interface between competition and IP in the pharmaceutical sector was the European Commission's *Pharmaceutical Sector Inquiry - Final Report* (2009). This is a comprehensive report on the competition-related aspects of the pharmaceutical market, including declining innovation levels and the negative impact of various anti-competitive practices that have taken place at the European Union level. It points out regulatory factors that may affect generic competition and describes practices such as patent filing strategies and agreements that delay generic competition. It states that "originator companies apply patent strategies, which may interfere with the development of a competing medicine. When such strategies mainly focus on excluding competitors without pursuing innovative efforts, they are called by some originator companies 'defensive patent strategies'"⁸⁶ The consequence is that generics do not enter into markets as early as they potentially could.⁸⁷ As a conclusion, the report calls for intensified scrutiny by competition law in the pharmaceutical sector, as well as streamlining of the marketing authorization process, among other measures.

In 2019, the European Commission launched a review of the competition enforcement in the EU pursuant to the 2009 inquiry report. The report to the Council and the European Parliament was called *Competition enforcement in the pharmaceutical sector (2009-2017) – European competition authorities working together for affordable and innovative medicines*.⁸⁸ It notes 29 antitrust decisions against pharmaceutical companies in the period of 2009–2017. Some of them refer to newly identified practices. It also anticipates other decisions as more than 20 cases were being investigated during the time of conclusion of the report.

(b) WTO-WHO-WIPO trilateral study

In 2012, a trilateral study entitled *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, conducted jointly by the World Trade Organization (WTO), the World Health Organization, and the World Intellectual Property Organization (WIPO) argued:

⁸⁶ European Commission, "Pharmaceutical Sector Inquiry", pp. 520-521.

⁸⁷ European Commission, "Pharmaceutical Sector Inquiry", p. 521.

⁸⁸ European Commission, "Competition Enforcement in the Pharmaceutical Sector" (2019). Available from https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf.

“Competition policy promotes effective innovation and helps shape the conditions for access. Competition policy is relevant to all stages in the process of supplying medical technology to patients, from their development to their sale and delivery. The creation of sound competitive market structures through competition law and enforcement has thus an important role to play in enhancing both access to medical technology and fostering innovation in the pharmaceutical sector. It can serve as a corrective tool if IP rights hinder competition and thus constitute a potential barrier to innovation and access. Competition authorities in several jurisdictions have taken action to address anti-competitive practices in the pharmaceutical sector, including some patent settlements, certain licensing practices and pricing policies. Competition policy also has an important role to play in preventing collusion among suppliers of medical technology participating in procurement processes.”⁸⁹

Typically, the WTO and WIPO adopt a stance with regards to the role of IP as a tool that promotes innovation in all sectors and contexts,⁹⁰ independently of the level of development of the countries concerned (an assumption that is not theoretically or empirically proven).⁹¹ In this sense, their acknowledgement in the trilateral study (including WHO) of IP as a potential barrier to competition, innovation and access, is to be noted.⁹² In July 2020, a second edition of the study was released, with the view that IPRs tend or can be positive to innovation and competition, and that their exercise is not *per se* illegal.⁹³ Yet, the trilateral study continues to acknowledge the important need to utilize competition law and policies to combat anti-competitive conducts.⁹⁴

⁸⁹ World Health Organization, World Intellectual Property Organization, and World Trade Organization, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (2012). Available from: https://www.wto.org/english/res_e/booksp_e/pantiwhowipowtoweb13_e.pdf.

⁹⁰ For an analysis of the understanding of “development” at WIPO and the use of IP as an “end in itself”, see Syam, N., *Mainstreaming or Dilution: Intellectual Property and Development at WIPO*, Research Paper No. 95, (Geneva, South Centre, July 2019). Available from <https://www.southcentre.int/research-paper-95-july-2019/>. The topic of IP and innovation has been a matter of contested debates and to a certain extent both the WTO and WIPO do acknowledge that IP is not necessarily conducive to innovation in all cases. For example, the WTO website on the matter states that “the role of intellectual property (IP) rights in enabling and promoting innovation, and in facilitating the dissemination of the outcomes of innovative activities, is widely debated internationally and domestically, and is the subject of active policy consideration in many countries”. (https://www.wto.org/english/tratop_e/trips_e/innovationpolicytrips_e.htm).

⁹¹ For a well-known critique of IP, and patents in particular, as instruments of innovation, see : “The case against patents can be summarized briefly: there is no empirical evidence that they serve to increase innovation and productivity, unless productivity is identified with the number of patents awarded – which, as evidence shows, has no correlation with measured productivity”. Boldrin, Michele & Levine, David K. *The Case Against Patents*, *Journal of Economic Perspectives*—Volume 27, Number 1—Winter 2013—Pages 3–22. Also see “Intellectual Property rights are becoming increasingly badly configured in the developed world, leading to a stifling of innovation, distortions in the direction of innovation, and a reduction in the benefits which accrue from any innovation that occurs. Many of these failures arise because there is, especially under currently prevalent IPR regimes, no clear relationship between the social returns to innovation and the private returns. The proliferation of me-too drugs, the increase in patent hold-ups and similar excesses buttress the argument that the IPR system in the developed world is poorly configured.” Baker, Dean, Jayadev, Arjun; Stiglitz, Innovation, *Intellectual Property and Development: A Better Set of Approaches for the 21st Century*, July 2017, available from <http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf>). For general considerations, see Mario Cimoli, Giovanni Dosi, Keith E. Maskus, Ruth L. Okediji, Jerome H. Reichman, and Joseph E. Stiglitz (eds.), *Intellectual Property Rights: Legal and Economic Challenges for Development*, Oxford, UK and New York: Oxford University Press, 2014.

⁹² “Competition law enforcement provides a useful tool for correcting abuses of IPRs on a case-by-case basis”. WHO, WIPO, WTO. *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade – 2nd Edition* (2020), p. 97.

⁹³ “IP protection [is not] presumed to confer market power or to indicate anti-competitive behavior. Indeed, IPRs are considered useful in creating functioning markets and fostering innovation. Competition law does not, as a general rule, prevent IPR holders from exercising their exclusive rights. This general respect for IPRs under competition law is based on the assumption that IPRs were acquired legitimately through a system that does not confer overly broad IPR”, in WHO, WIPO, WTO. *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade – 2nd Edition* (2020), p. 97.

⁹⁴ “Competition policy has informed the legal framework for IP protection in that international agreements as well as national IP laws recognize the role competition policy has to play in providing “checks and balances” to IPRs. Legal provisions on competition can be considered an integral part of rules on IP protection.” WHO, WIPO, WTO.

(c) The Report of the UN Secretary-General High-Level Panel on Access to Medicines

Competition policy has been explicitly discussed in the United Nations Secretary General's High-Level Panel on Access to Medicines (2016), a highly influential report on the matter. The Panel Report considers a number of measures that countries can implement to enhance the overall status of access to medicines in the world. The role of competition policy is specifically noted in the report:

“Competition policy has been used to remedy anti-competitive conduct in the biomedical industry and to promote treatment access in many countries. Various organizations have published guidance on competition law and offer support to WTO Members who may wish to regulate anti-competitive conduct in the health sector. Competition policies are important levers that governments can employ to ensure that health technology markets operate competitively and that the public benefits from low prices and innovation. Should governments pay closer attention to competition law, it could serve as an important policy tool for increasing access to health technologies.⁹⁵”

(d) United Nations Development Programme (UNDP)

The United Nations Development Programme (UNDP) 2014 publication *Using Competition Law to Enhance Access to Medical Products: A guidebook for low- and middle-income countries*⁹⁶ provides a very comprehensive framework to address the possible uses of competition law and its broad policy space under international law. This document is a useful tool for developing countries to think about the main issues to take note of when developing and updating competition policies. Apart from case studies and a description of some anti-competitive behaviors and available remedies, it also contains an analysis of the policy space under international law, ways to define “market” (a crucial feature for antitrust intervention), and some suggestions for frameworks in LMICs. It also contains some model interpretations, provisions, and remedies (Models 1 to 7, p. 141-153).⁹⁷

Furthermore, UNDP also provides technical assistance on matters related to competition law, supporting developing countries and least developed countries in the endeavors of crafting national policies and ensuring cohesion with access to medicines. The UNDP has published in 2014 an important contribution to this field: *Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries* (by Frederick Abbott, Sean Flynn, Carlos Correa, Jonathan Berger and Natasha Nyak).⁹⁸

(e) United Nations Conference on Trade and Development (UNCTAD)

UNCTAD is the focal point in the United Nations for competition policy issues. It has conducted activities in the field for over three decades in the Set of Multilaterally Agreed

Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade – 2nd Edition (2020), pp. 96-97.

⁹⁵ United Nations Secretary-General High-Level Panel on Access to Medicines, *Report of the UN SG High-Level Panel on Access to Medicines – Promoting innovation and access to health technologies* (2016).

⁹⁶ Abbott, F., Flynn, S., Correa, C., et al., *Using Competition Law to Enhance Access to Medical Products* (UNDP, 2014).

⁹⁷ Some of these topics will be covered in the upcoming sections of this paper.

⁹⁸ Abbott, F., Flynn, S., Correa, C., Berger, J., and Nyak, N., *Using Competition Law to Promote Access to Health Technologies – A Guidebook for low- and middle-income countries*, (UNDP, 2014).

Principles and Rules for the Control of Restrictive Business Practices.⁹⁹ It also hosts an Intergovernmental Group of Experts that regularly debates the topic. In this regard, the mandate of UNCTAD on this matter encompasses being a forum for intergovernmental deliberation, research, policy analysis and data collection, as well as technical assistance to developing countries.

UNCTAD has held a number of discussions and sessions on the need for competition in the pharmaceutical sector and the need to curb anti-competitive practices.¹⁰⁰ In this multilateral forum, various countries have highlighted their competition authorities' efforts on this topic, including "regulatory instruments and cases related to pharmaceuticals."¹⁰¹ During the Eighteenth session of the Intergovernmental Group of Experts on Competition Law and Policy, a round-table discussion noted that "the use or misuse of intellectual property rights; barriers to entry of cheaper alternatives, for example through collusion between established pharmaceutical firms; and excessive or unfair prices resulting from anti-competitive practices" impose barriers to access to healthcare, particularly in developing countries. Panelists also asked for more "policy coherence and coordination between authorities on competition and intellectual property rights, in ensuring that excessive pricing based on such rights was treated as abuse of dominance in certain cases."¹⁰²

(f) WTO TRIPS Council

In May 2018, the TRIPS Council of the World Trade Organization received a submission entitled *Promoting Public Health through Competition Law and Policy* (IP/C/W/643) by the delegation of South Africa and China (further co-sponsored by India and Brazil) under the agenda item topic "Intellectual Property and the Public Interest." The document requests other delegations to share national experiences and examples of how competition law is used "to achieve public health goals and related national objectives."

In October 2018, South Africa (later joined by India and Brazil) submitted a follow-up (IP/C/W/649) to the previous paper, stating that:

It is also apparent that clearer competition policy treatment of IPRs has evolved over time through either iterative processes or evolving practice of competition authorities. This evolution is informed by jurisdictional cross-fertilization and peer learning as evidenced by greater interest in and concerns with ensuring an appropriate balance between IP and competition law and policy in these jurisdictions. This development underscores the need for further debate and analysis since competition law and policy is no longer the preoccupation of only a few jurisdictions [...]. As a consequence of accommodating the variety of potential competition approaches, remedies available to address anti-competitive behavior may permit a broader range of remedial action than some other public health-related flexibilities associated solely with patents. **Competition policy has an important role to play in ensuring**

⁹⁹ See <https://unctad.org/en/Pages/DITC/CompetitionLaw/Competition-Law-and-Policy.aspx#:~:text=UNCTAD%20is%20focal%20point%20in,the%20intergovernmental%20group%20of%20experts>.

¹⁰⁰ The majority of discussions take place at the Intergovernmental Group of Experts on Competition Law and Policy. See, for instance, "The role of competition in the pharmaceutical sector and its benefits for consumers" (2015). Available from: https://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_en.pdf

¹⁰¹ See, for instance, the report during the eighteenth session of the Intergovernmental Group of Experts on Competition Law and Policy (TD/B/C.I/CLP/55) held in Geneva on 10–12 July 2019: "During the ensuing discussion, several delegates highlighted the importance of access to health care and that large pharmaceutical firms dictated the price of medicine in many jurisdictions. Several delegates shared national experiences in dealing with health sector issues through studies, regulatory instruments and cases related to pharmaceuticals, pay-for-delay, excessive pricing and government-controlled pricing."

¹⁰² TD/B/C.I/CLP/55.

access to medical technology and fostering innovation in the pharmaceutical sector.¹⁰³

During this session, Brazil argued that competition law and intellectual property are complementary¹⁰⁴ rather than incompatible; that abuses of IP such as “reverse payment agreements, and anti-competitive licensing practices, may favor undue extension of the market power granted by a patent”; and that “[i]n the pharmaceutical industry, **competition policy benefits consumers in the form of increased access to affordable medicines by detecting, halting and correcting anti-competitive practices, without harming the dynamic competition effect granted by IP rights.**”¹⁰⁵

In February 2019, the delegation of South Africa sustained the debate with yet another submission to further advance the topic (IP/C/W/651), aiming specifically to discuss “the linkage between intellectual property and competition law [...] with specific reference to exploitative excessive pricing and restrictive practices such as reverse payment agreements, strategic patenting and more lately, the evolution of niche pricing of off-patent pharmaceuticals.” The submission draws on the multiple national cases around the world, some of them already referred to in this paper, to amplify discussions.¹⁰⁶

(g) World Intellectual Property Organization (WIPO)

The WIPO Development Agenda, adopted in 2007, explicitly refers to competition policies and IP, including the following recommendations:

7. Promote measures that will help countries deal with intellectual property-related anti-competitive practices, by providing technical cooperation to developing countries, especially LDCs, at their request, in order to better understand the interface between IPRs and competition policies. [...],

*22. WIPO’s norm-setting activities should be supportive of the development goals agreed within the United Nations system, including those contained in the Millennium Declaration. [...] The WIPO Secretariat, without prejudice to the outcome of Member States considerations, should address in its working documents for norm-setting activities, as appropriate and as directed by Member States, issues such as: (a) safeguarding national implementation of intellectual property rules (b) **links between intellectual property and competition** (c) **intellectual property-related transfer of technology** (d) potential flexibilities, exceptions and limitations for Member States and (e) the possibility of additional special provisions for developing countries and LDCs. [...]*

¹⁰³ IP/C/W/649.

¹⁰⁴ Some have argued for an even broader convergence that can be deemed an “integration of principles” between both fields, which have notably developed from original legal norms to protect private parties in areas where the public interest at large is aimed at being protected and fostered. See Salomão Filho, C., *Teoria Crítico-Estruturalista do Direito Comercial* (São Paulo, Marcial Pons, 2015).

¹⁰⁵ A summary of the discussions during this session of the WTO TRIPS Council can be found in Catherine Saez, “WTO TRIPS Council Debates Competition Law, Plain Packaging’s Spread to Other Products”, (IP Watch, 12 November 2018). Available from <https://www.ip-watch.org/2018/11/12/wto-trips-council-debates-competition-law-plain-packagings-spread-products/>.

¹⁰⁶ It should be noted that during these occasions the submissions of South Africa were reported to be countered by the delegations of the United States of America and the European Union. They have not, however, argued that there is no link between competition and IPRs, or that there should be no intervention of competition law in the field of IP. Instead, they have argued for other arenas to better deal with the issue, with competition *itself* as a more adequate framework (United States) and for competition law and IP to be complementary and therefore an interaction that should be done with caution (European Union). For an analysis and report of the provisions, see KEI, “TRIPS Council: Statement of the European Union on intellectual property and the public interest: promoting public health through competition law and policy”, (14 February 2019). Available from <https://www.keionline.org/29707>.

32. *To have within WIPO opportunity for exchange of national and regional experiences and information on the links between IPRs and competition policies.”*

In this context, the WIPO Secretariat has produced a number of studies on the intersection between competition policy and intellectual property, including “Survey on the Antitrust Dimension of Intellectual Property Licensing Agreements in Support of Technology Transfer” (May 2015)¹⁰⁷ and “Survey on Intellectual Property, Joint Research and Development Activities and Competition” (June 2015),¹⁰⁸ which touch upon practices related to the pharmaceutical sector, even if not directly.

In 2018, during the 13th Session of the Advisory Committee on Enforcement (ACE), Member States discussed “The Interface of IP Enforcement and Competition Law” (WIPO/ACE/13/5), with presentations by the competition authorities of Brazil and Peru. In particular, Brazilian CADE Councilor Paula Azevêdo presented the landmark case of Eli Lilly (2016), in which the Canadian pharmaceutical company was fined for sham litigation and presented a list of other interventions in the pharma sector in other cases.

(h) Organization for Economic Co-operation and Development (OECD)

The OECD, which has a large department focused on competition policies, has monitored the development of cases and experiences around the world in the sector. In a background note for a discussion on excessive pricing in the pharmaceutical sector, which contained a number of submissions from different countries (including non-members to the OECD), the Secretariat stated:

There are strong arguments for not intervening against exploitative excessive pricing conducts, which have led to the development of stringent enforcement screens for the bringing of such cases. However, **recent years have seen significant calls for intervention against high prices for pharmaceutical products, and there have been a number of competition enforcement cases regarding exploitative excessive pricing in this sector.** These cases meet the criteria set out in the enforcement screens regarding excessive pricing. At the same time, the conditions that justify bringing such cases in the first place seem to be relatively common in the pharmaceutical sector. This raises questions regarding what the best response to high prices in this sector would be, and particularly whether there are alternatives to bringing exploitative excessive pricing cases. The application of competition law against high prices in the pharmaceutical sector requires a deep understanding of market dynamics and sectoral regulation, and of the various regulatory responses that may be deployed to address high prices. As such, it may be appropriate to explore various avenues for intervention, if possible, in cooperation with the applicable sector regulator.

Therefore, the OECD does recognize that policy solutions other than competition laws should be envisioned but nonetheless still considers this to be an appropriate measure in some cases. It particularly calls for cooperation with other sectors, especially regulatory agencies.

¹⁰⁷ See the survey at: https://www.wipo.int/export/sites/www/ip-competition/en/studies/technology_transfer_survey.pdf.

¹⁰⁸ See the survey at: https://www.wipo.int/export/sites/www/ip-competition/en/studies/survey_report_joint_rxd_june2015.pdf.

(i) International Competition Network (ICN)

The International Competition Network (ICN) is a non-governmental group composed of members from the majority of competition authorities around the world, as well as other stakeholders. As stated by the ICN itself, its “mission is to advocate the adoption of superior standards and procedures in competition policy around the world, formulate proposals for procedural and substantive convergence, and seek to facilitate effective international cooperation to the benefit of member agencies, consumers and economies worldwide.”

It is understood to be one of the main arenas for discussion of antitrust in the world, despite the fact it has neither normative mandate nor legal personality under international public law. Still, it has indeed been influential in diffusing certain assumptions and arguments with regards to competition law, which may have the effect of harmonizing practices between different agencies (“convergence”).

The topic of anti-competitive practices in the pharmaceutical sector is rarely addressed by the ICN. It is not a clearly delineated topic of the organization’s current work program, and there are not specific materials such as guidelines/workbooks. In part, this is due to the diversity of practices and relative to the low number of cases compared to other markets. However, the ICN has discussed this on at least two public occasions, during two teleseminars of the ICN Unilateral Conduct Working Group. The first one on “Excessive Pricing,” which took place on 18 November 2009,¹⁰⁹ touched upon the topic even though it covered excessive pricing more generally. The second teleseminar was on “Unilateral Conducts in the Pharmaceutical Sector” on 2 November 2010,¹¹⁰ when authorities shared experiences of relevant cases, such as those of Hazel Tau and AstraZeneca (both discussed in subsequent part of this paper).

These discussions took place without prejudice to other informal and internal discussions related to the governance system, which also allows different authorities to be in touch with one another in a rather direct way. In fact, the aforementioned discussions, which took place at UN agencies and at the European Commission, did not fully—or at least not directly— influence the work of the ICN. It is unclear, however, whether they had an impact in the overall discussions of the network.

¹⁰⁹ See: <https://www.internationalcompetitionnetwork.org/wp-content/uploads/2019/04/UCTSExcessivePricing2009.pdf>.

¹¹⁰ See: <https://www.internationalcompetitionnetwork.org/wp-content/uploads/2018/04/UCTSPharma2010.pdf>.

6. INTRODUCING ACCESS TO MEDICINES CONCERNS IN COMPETITION POLICIES

With an aim to implement a competition policy in developing countries that promotes access to medicines and other health products, at least three recommendations may be submitted: (i) explicit incorporation of health concerns into the objectives of the competition policy; (ii) enactment of competition guidelines with a pro-health perspective, and (iii) cooperation between competition authorities, especially under South-South cooperation principles. There are certainly other needed policies to promote access to medicines and other health products, including adequate technical capacity and resources, the diffusion of a “culture of competition” and specifically IP-related policies, such as guidelines for the examination of pharmaceutical patents, which will not be dealt with in this document.¹¹¹

(a) Incorporation of health concerns into goals of competition policies

The incorporation of public health concerns into competition policies may counter prevalent assumptions on what competition law should address. It has often been argued that competition law aims at maximizing efficiency gains. This is a direct consequence of the deep influence of the Chicago School of Economics since the 1970s in antitrust law around the world.¹¹² In its earliest views, which profoundly impacted North American case law for decades, antitrust intervention tended to protect inefficient competitors, and thus a “laissez-faire” approach would be the most efficient antitrust policy – in short, limiting any interventions to their minimum and leaving markets to determine competition themselves.¹¹³

Indeed, after decades of criticism of the Chicago School approach and the emergence of alternative, competition law scholars and authorities have recognized a broader goal for the discipline, including the protection of consumers and not only of the competitors’ interests.¹¹⁴ More recently, some have argued for an update of traditional antitrust principles and doctrines such as in relation to the presumption of predation and the role of public utilities.¹¹⁵

¹¹¹ For a suggestion of pro-public health IP policies and how to incorporate other TRIPS flexibilities, see: <https://ipaccessmeds.southcentre.int/publications/> and <https://medicineslawandpolicy.org/>, among others.

¹¹² For the most relevant exponents of the “Chicago School” in American antitrust law (later exported to multiple countries), see Posner, R., “The Chicago School of Antitrust Analysis” *University of Pennsylvania Law Review*, vol. 127 (1979), which differentiates the approach from the “structuralist” Harvard School and sets the basis for a “laissez-faire” approach to antitrust law. See also Bork, R., *The Antitrust Paradox*, (New York, NY, The Free Press, 1978), which defends consumer welfare in antitrust laws via the pursuit of economic efficiency. For the author, intervention through antitrust law paradoxically raises prices as it protects inefficient companies from competition.

¹¹³ It is remarkable how this was a shift from the very purposes of the original antitrust legislations in the United States—the Sherman Act (1890) and the Clayton Act (1914)—which had as a main objective to impede through state regulation excessive market concentration and anti-competitive practices.

¹¹⁴ For instance, a European Parliament report notes that “*The European Commission firmly believes that competitive markets create a downward pressure on prices, encourage quality of goods and services, widen consumer choice and stimulate innovation and entrepreneurship. Economic evidence further suggests that competition increases the productivity and efficiency of enterprises. It also creates favorable conditions for innovation and growth. Many economists indeed argue that promoting competition is the best available tool for enhancing consumer wellbeing. Effective competition also increases market integration and boosts the competitiveness of European companies both in the single market and globally (European Court of Auditors, 2018). EU competition policy was envisaged by the Treaty of Rome in 1957, which established the creation of a system safeguarding free competition in the common market as one of its goals. Article 3(3) of the Treaty on European Union (TEU) states that the EU ‘shall establish an internal market’, based on ‘a highly competitive social market economy’.*” European Parliament, *EU competition policy - Key to a fair single market*, 2019.

¹¹⁵ See William Novak, “The Public Utility Idea and the Origins of Modern Business Regulation”, in *Corporations and American Democracy*, N. R. Lamoreaux & W. J. Novak (eds.), (Harvard University Press, 2017); K. Sabeel Rahman, “Infrastructure Regulation and the New Utilities”, *Yale Journal on Regulation*, vol. 35 (2018), p. 911.

Authors have similarly criticized the limits of the “consumer welfare” model for being restrictive and near-sighted by focusing, in practice, on prices only.¹¹⁶ In particular, countries may incorporate important goals in their competition policies, such as increasing access to essential infrastructures, public services, etc. and lowering inequalities (redistribution). These goals may change or be adapted according to the priorities set by each country at a specific point in time; notably, developing countries do not need to import any competition law model from developed countries, but can put in place their own model based on the country’s conditions and socio-economic objectives.

When applied to access to medicines, the discussion on competition law goals becomes particularly relevant. For those who defend an efficiency-only approach to competition law, access to medicines is not *per se* a legitimate pursuit. This would exclusively be an indirect result of a competitive pharmaceutical market at most. This model also tends to prioritize non-intervention in the realm of intellectual property rights as a policy choice.

On the other hand, via a broader understanding of the role of competition law, promoting more access – including diminishing existing barriers of any kind – is a clear policy choice. In this sense, lowering inequalities by promoting affordable medicines becomes a legitimate (direct) goal. This model respects IPRs fully but pays more attention to its anti-competitive dimensions. Arguments for the need to sustain incentives for innovation through intellectual property¹¹⁷ can be balanced with the need for access to health products.

While the efficiency-only approach may, under certain conditions, tackle the issue of prices (and still, in a limited way, given the US case law reluctance to acknowledging the issue of excessive pricing), it does not cover anti-competitive practices that deal more prominently with access issues—for instance, cases that involve not only lack of access due to high prices, but also the total inexistence of certain products in a country due to lack of adequate and timely technology transfer, insufficient supply, etc. Competition authorities under a broad mandate may deal with these issues as well. Both pricing and access should be in the sight of regulators and competition policies.

(b) Enactment of competition guidelines with a pro-health perspective

A concrete policy measure that competition authorities can take is the enactment of guidelines on competition in the pharmaceutical sector, including intellectual property-related issues, with an explicit pro-health perspective. The use of guidelines is a common practice of competition authorities.¹¹⁸ They can provide more legal certainty for different stakeholders, clearly delineating methods to measure competitive standards and define relevant markets. Market players are thus better informed as to what constitutes permitted or illicit conduct.

¹¹⁶ See Lina Khan, “Amazon’s Antitrust Paradox”, *Yale Law Journal*, vol. 126, No. 3 (January 2017): “In order to capture these anticompetitive concerns, we should replace the consumer welfare framework with an approach oriented around preserving a competitive process and market structure. Applying this idea involves, for example, assessing whether a company’s structure creates anticompetitive conflicts of interest; whether it can cross-leverage market advantages across distinct lines of business; and whether the economics of online platform markets incentivizes predatory conduct and capital markets permit it. More specifically, restoring traditional antitrust principles to create a presumption of predation and to ban vertical integration by dominant platforms could help maintain competition in these markets”. From the same author, see also Lina Khan, “The New Brandeis Movement: America’s Antimonopoly Debate”, *Journal of European Competition Law & Practice*, Volume 9, Issue 3 (March 2018), pp. 131-132.

¹¹⁷ The assumption that patents lead to more innovation has also received much criticism. For instance, see Stiglitz, J., “Prizes, not patents” (Project Syndicate, 2009). Available from <https://www.project-syndicate.org/commentary/prizes--not-patents?barrier=accesspaylog>.

¹¹⁸ Some of the main competition authorities around the world have adopted and applied guidelines, including on issues relating to intellectual property. Examples include Canada’s Competition Bureau, *Intellectual Property Enforcement Guidelines*, and the US Department of Justice and Federal Trade Commission, *Antitrust Guidelines for The Licensing of Intellectual Property* (1995).

Guidelines could, at least in theory, reduce transaction costs, to use the economic jargon, between national authorities and competitors.

Guidelines relating to the pharmaceutical sector may address, for instance, the potential competitive implications of concentrating IPRs in one single company after a merger. They may focus on issues of particular public health interest (e.g., patents related to medicines for high disease burden), providing mathematical formulas for the determination of a dominant position, give details on the definition of a relevant market, etc.¹¹⁹ Guidelines may also be more general by enumerating in a non-exhaustive list some typical anti-competitive conduct. They may be updated from time to time to allow them to keep pace with the most recent technological developments and changes in market structures (e.g. growing importance of biologicals). Guidelines for countries with nascent pharmaceutical industries should be different from those of consolidated ones, and if a country changes its technological focus, this should be reflected in the guidelines as well.

In sum, guidelines may play an important role by introducing public health-related objectives. However, the risk of regulatory capture cannot be underestimated. “Soft law” instruments such as guidelines are more prone to be influenced by lobbying and political-economic vested interests, which is a real concern for all countries.

(c) Cooperation between competition authorities under South-South cooperation principles

In the same way as for guidelines, cooperation between competition authorities of different countries has also been a very well-established practice.¹²⁰ The recommendation here is to develop it in terms of South-South cooperation principles, particularly equality, solidarity, and mutual benefit. This kind of cooperation does not serve the purpose of internationalizing one country’s own approach or regulations, but takes into account the specific needs of the partner. Exchanges of information, mutual training, and informing about recent cases are useful tools. There are already different “antitrust networks” (including the already mentioned ICN) and direct dialogue channels established between different agencies (“pick-up-the-phone” policies to exchange information and perspectives, for instance). They enable transnational investigations by enhancing the investigative capacity of agencies and may reduce costs also.¹²¹

¹¹⁹ The relevant market is determined through assessment of the territorial and substantive scope of certain economic activities delineating the geographical area covered by a distinct market and what exactly it entails. For the pharmaceutical sector, questions such as whether medicines for the treatment of the same diseases are in the same relevant market or not are important. For example, a long-acting medicine that is taken once a month might not be in the same relevant market as a medicine for the same illness that is required to be taken every day, if the population targeted has specificities that set them apart—for instance, availability of medicines, knowledge, and access to medical facilities. This makes things much less obvious than they seem, and guidelines may be very useful instruments.

¹²⁰ See Zanettin, B. *Cooperation Between Antitrust Agencies at the International Level*, (Oxford, England, Hart Publishing, 2002); see also, as an example, the ICN Framework on Competition Agency Procedures (https://www.internationalcompetitionnetwork.org/wp-content/uploads/2019/04/ICN_CAP.pdf) with specific norms, processes and principles. For an example of how agencies work together, see the list of the US Antitrust Cooperation Agreements with other countries, including Brazil, Canada, China, Colombia, the EU, India, Mexico and Peru.

¹²¹ “[T]he relentless process of globalization has increased the number of antitrust cases with international components. This can be observed in light of how transnational cartels and international merger cases have come to form an increasingly significant part of the work of antitrust authorities worldwide. Not infrequently, such cases involve firms and information located in several jurisdictions. [...] Very often, international antitrust issues can only be effectively addressed through enhanced international co-operation between different antitrust authorities. Such co-operation also provides relief for business firms, which may in some cases face excessive costs, in time in money, caused by concurrent antitrust investigations initiated in different jurisdictions.” See Dabbah, M.M., *The Internationalization of Antitrust Policy* (Cambridge, UK, Cambridge University Press, 2003).

A clear example would be a transnational price cartel setting the prices of medicines, which can only be identified via inter-agency cooperation. In an increasingly globalized economy, operations that are launched in different countries at the same time are becoming also more common. In this particular sense, cooperation fosters the efficacy of competition law, which does not have a global centralized authority. For those cases, cooperation should be expanded overall.

However, unless cooperation is undertaken with full recognition of the diversity in situations and approaches of the cooperating parties, it may lead to the transfer of regulatory models (as it was the case with the United States and European Union) from the more consolidated agencies to the “less developed” partners.

South-South cooperation may be a particularly useful instrument to consolidate new competition authorities through technical assistance, exchange of information, investigation practices, among others. This is even more the case for smaller LMICs who may be particularly affected by budget and expertise constraints. Cooperation under South-South cooperation principles should be fostered between countries that might share similar market structures and economic profiles (including inequality levels, dependency of foreign capital, etc.), but also for larger LMICs to support smaller nations under a solidarity and equality framework. Agencies such as Brazil’s CADE and South Africa’s Competition Commission could play an important role in this regard.

Competition authorities could share information and cooperate, in particular, in the assessment of practices of the pharmaceutical industry, so as to achieve the objectives embedded in competition law and protect public health. For instance, the different pricing strategies that certain companies deploy in countries with similar income levels and disease burdens (but paying sometimes dramatically different prices) could potentially be subject to investigation based on the possible anti-competitive character of such transnational practices.

7. DESIGNING COMPETITION POLICIES SUITABLE TO DEVELOPING COUNTRIES

In light of the above considerations, this section provides some inputs on how best to design competition policies that are better suited to address distortions in the pharmaceutical market in developing countries.

(a) Integration with other policies, such as industrial policy, health and innovation

The implementation of an effective competition policy is not an exclusive task of competition law or antitrust authorities.¹²² It should be reflected in other policies as well. In the field of access to medicines, these may include adequate price regulations, sustainable pooled procurement of medicines, streamlined marketing approval regulations. For instance, the requirement of unnecessary tests for the marketing approval of biosimilars may erect a barrier to access to medicines thereby limiting legitimate competition. Some countries have introduced a facilitated shortened registration route that fosters access to medicines while guaranteeing the safety of biological drugs. This is a pro-competitive policy fully compatible with international law and justified on the grounds of both access to medicines and competition.¹²³

The relationship between regulation and competition is one of *complementarity*. A good example can be found in countries where medicine prices are regulated, even if in a limited way. In certain countries, this is done through caps on prices, while others have specifically designated regulatory agencies that promote affordable prices, and still others focus on a more limited attempt to foster public procurement at lower prices. This does not mean that competition law should not be applied. As much as intellectual property does not create immunity to competition, neither do market regulations. There are still potentially anti-competitive practices, including the misuse of the regulatory system itself. Also, the fact that there is a regulation does not mean that excessive pricing, predatory pricing, and other anti-competitive conduct cannot be verified; it only means that the impact of the regulation needs to be taken into account for the concrete analysis (e.g., how much a price is related to a regulatory imposition or not).

(b) Enabling national legislation and institutional designs

The policy space described in the previous sections includes the determination of the objectives of competition laws, the authority to decide upon the exact mandate of the competition agencies, the adequate instruments for investigation and sanctioning, and coordination with other institutions.

For instance, South Africa's Competition Act (89/1998) includes as objectives "to promote employment and advance the social and economic welfare of South Africans" and "to promote a greater spread of ownership, in particular to increase the ownership stakes of

¹²² Carlos Correa proposes a "competition policy approach". He suggests "that creating and preserving the conditions for competition and market contestability in the area of IPRs is not only the task of competition law or antitrust authorities." See Correa, C., "A competition approach to intellectual property protection", Bridges No. 7 (ICTSD, November-December 2007).

¹²³ For an analysis of the Colombian model, see Gaviria, A. et al., "The debate on regulating biotechnology drugs: Colombia in the international context" ("El debate de la regulación de medicamentos biotecnológicos: Colombia en el contexto internacional"), *Revista Panamericana de Salud Pública*, vol. 40, No. 1 (2016), pp. 40 ff. Accessed 4 February 2020.

historically disadvantaged persons.”¹²⁴ The operative provisions of the Competition Act translate those objectives into integral parts of the competition authority’s mandate, allowing for exceptions to the application of the abuse of dominant position norms in cases of: “(i) maintenance or promotion of exports; (ii) promotion of the ability of small businesses, or firms controlled or owned by historically disadvantaged persons, to become competitive; (iii) change in productive capacity necessary to stop decline in an industry; or (iv) the economic stability of any industry designated by the Minister, after consulting the Minister responsible for that industry”.¹²⁵

The Brazilian Competition Law (Federal Law No. 12.529/2011) states in Article 1 that: “This Law structures the Brazilian System for Protection of Competition – SBDC and sets forth preventive measures and sanctions for violations against the economic order, **guided by the constitutional principles of free competition, freedom of initiative, social role of property, consumer protection and prevention of the abuse of economic power.** Sole paragraph. The People are the holders of the legal interests protected by this Law.”¹²⁶

Article 170, Federal Constitution of Brazil sets out the “general principles of economic activity”; it contains a variety of goals, in particular, the “social function of property” doctrine and “consumer protection” are basic premises for the intervention of the competition authority, the Administrative Council for Economic Defense (CADE). This allows CADE to depart from purely efficiency considerations and take into account more prominently the need to protect consumers and make sure that owners of rights (including IPRs) exercise them for the benefit of the public good.¹²⁷

The Brazilian Competition Law includes specific provisions on the abuse of intellectual property rights as violations of the economic order;¹²⁸ it also contains articles for the competition authority to recommend a compulsory license in the case of an abuse¹²⁹ and to eventually issue one in case of mergers.¹³⁰

¹²⁴ “2. Purpose of Act The purpose of this Act is to promote and maintain competition in the Republic in order – (a) to promote the efficiency, adaptability and development of the economy; (b) to provide consumers with competitive prices and product choices; (c) to promote employment and advance the social and economic welfare of South Africans; (d) to expand opportunities for South African participation in world markets and recognise the role of foreign competition in the Republic; (e) to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the economy; and (f) “to promote a greater spread of ownership, in particular to increase the ownership stakes of historically disadvantaged persons.”

¹²⁵ South Africa Competition Act 89/1998, Article 10 (3)(b).

¹²⁶ Emphasis added.

¹²⁷ Given the risk that these relatively open and multi-faceted goals will lead to arbitrary or inconsistent decisions, the CADE has enacted a series of guidelines and attempts to work on the basis of its own case law in order to provide more legal certainty. Critics note, however, that oftentimes this has been done to the detriment of the various interests recognized by the law and the Constitution in favour of a more reduced interpretation of the role of the competition authority: to be a promoter of market efficiencies, deploying econometric arguments close to the “Chicago School of Economics” stream. For a critique of this relatively reduced role as compared to what Brazilian law mandates and enables, see Salomão Filho, C., *Direito Concorrencial*, Malheiros, 2013; Braz de Castro, B. *A que(m) serve(m) o anti-truste? Eficiência e rivalidade na política concorrencial de países em desenvolvimento*, Singular, 2019.

¹²⁸ “Art. 36. The acts which under any circumstance have as an objective or may have the following effects shall be considered violations to the economic order, regardless of fault, even if not achieved: I - to limit, restrain or in any way injure free competition or free initiative; II - to control the relevant market of goods or services; III – to arbitrarily increase profits; and IV - to exercise a dominant position abusively. [...] § 3 The following acts, among others, to the extent to which they conform to the principles set forth in the caput of this article and its clauses, shall characterize violations of the economic order: [...] **XIV – to monopolize or prevent the exploitation of industrial or intellectual property rights or technology; [...] XIX – to abusively exercise or exploit intellectual or industrial property rights, technology or trademark.**”

¹²⁹ “PENALTIES Art. 37. A violation of the economic order subjects the ones responsible to the following penalties: IV – recommendation to the respective public agencies so that: a) a compulsory license over the intellectual property rights held by the wrongdoer be granted, when the violation is related to the use of that right;”

¹³⁰ “Art. 61. During the judgment of the petition for the approval of the act of economic concentration, the Tribunal may fully approve it, reject it or partially approve it, in which case it will determine the restrictions to be observed as conditions to validate the act. § 1 The Tribunal shall determine the applicable restrictions in order to mitigate

Other national laws, such as those of the Philippines and Thailand, enable the authorities to conduct an assessment of the anti-competitive effects of licensing agreements for transfer of technology,¹³¹ which generally involve intellectual property rights in force.

(c) Finding the most suitable model for each country

The above are examples of competition laws that enable the competent authorities to go beyond the mere analysis of market efficiencies. They also exemplify how jurisdictions may craft their own laws without transplanting models from the United States or the European Union.¹³² Countries may also benefit from looking at alternative models, such as the one developed in South Africa¹³³ while engaging in South-South cooperation. There is no “one-size-fits-all” rule, but the creation of a whole system “from scratch” is not necessarily the best option, especially for smaller LMICs.

Eleanor Fox even goes as far as arguing that, in fact, developing countries may have a comparative advantage compared to developed ones, as they are not bound by path dependency and can choose a clearer path in designing competition laws.¹³⁴ In this sense, the differences in the market structures, income distribution, technological capacity, etc. should be taken into account in the competition model to be adopted. Of course, this needs to be contrasted with the institutional, budgetary, and expertise constraints that a country may have, setting up robust authorities is costly and takes time; it may face resistance due to existing practices between businesses and between businesses and governmental entities. A possible way of addressing these challenges comes in the form of cooperation between different competition authorities, as discussed below.

(d) Adopting a pragmatic and realistic approach

Overall, this means that a pragmatic view should be present when designing a competition policy. For countries introducing new legislation and setting up a competition authority, a realistic approach may be to follow a gradual process initially focusing on some anti-

occasional negative effects of the act of economic concentration over the affected relevant markets. § 2 The restrictions mentioned in § 1 of this article include: [...] V – compulsory licensing of intellectual property rights;”

¹³¹ WIPO Survey on the Antitrust Dimension of Intellectual Property Licensing Agreements in Support of Technology Transfer (2015). Available from https://www.wipo.int/export/sites/www/ip-competition/en/studies/technology_transfer_survey.pdf.

¹³² Natasha Nyak proposes three categories that mirror longstanding discussions on transposition/transplantation of laws to developing countries: (i) cut-and-paste model, (ii) contextualized model, and (iii) tailor-made model. See Nyak, N., “Advancing competition frameworks in the low- and middle-income country context”, in *Using Competition Law to Enhance Access to Medical Products* Abbott, F., Flynn, S., Correa, C., et al. (UNDP, 2014). Indeed, there are different reasons, pressures, and incentives for countries to opt for one or the other, including difficulty to draft a national law from scratch and pressure to adopt international standards, allegedly to attract foreign investments (an expectation rarely met, as historical evidence shows).

¹³³ Michal Gal and Eleanor Fox argue that apart from the more well-known models of the United States of America and the European Union, the South Africa competition is a third model given its clear specificities. See Gal, Michal and Fox, Eleanor M., “Drafting competition law for developing jurisdictions: learning from experience”, in *Economic Characteristics of Developing Jurisdictions: Their Implications for Competition Law*, Edward Elgar, ed. (forthcoming); NYU Law and Economics Research Paper, No. 14-11. Available from: <https://ssrn.com/abstract=2425329>.

¹³⁴ “Developing countries are not constrained by path dependence in designing and implementing a competition law because their competition systems are sufficiently young and unformed. Without the baggage of laws on the books, these countries have a clear path to choose their overall goals for controlling market power and its abuses and the route to get there, and they may be informed as they wish by existing models. They have the unencumbered opportunity to build a system based on what conduct harms them the most. They can define important but elastic concepts such as “efficiency” in their own terms. In tailoring law to their needs, they have a flexibility unconstrained by path dependence. See Fox, Eleanor M., “Competition policy: the comparative advantage of developing countries” (1 February 2017), *Law and Contemporary Problems*, vol. 79, No. 69 (2016); NYU Law and Economics Research Paper No. 17-04. Available from: <https://ssrn.com/abstract=2916452>.

competitive behavior and establishing a competition authority with restricted mandate, rather than to envision an excessively ambitious institutional design. Training of officials and staff is paramount, but it takes time and should be done in a manner that is consistent with the goals of the legislation.

In practice, the mandate of competition agencies may vary substantially. Enforcement of competition law in order to secure competitive markets is one of the main existing functions, but not the only one. In many countries, competition authorities also conduct reviews/analysis of other policies, such as regulations of medicines' prices. For instance, in many LMICs, competition authorities have focused on directly supporting and amending price regulations in order to foster competition and lower prices.¹³⁵ These may, for instance, support further actions taken by the ministries of health and by IP offices to prevent the grant and enforcement of patents that unduly restrain generic competition. This type of competition policy may be very effective despite budget constraints to conduct full investigations of specific anti-competitive conducts.

(e) Adopting the right competition doctrines

Another way to reduce the burden of law enforcement is to apply doctrines that allow competition authorities to decide more timely and effectively. For instance, applying *per se* rules as opposed to balancing tests (i.e., conduct that will be *presumed* to be anti-competitive, without the need to prove certain market consequences in practice) or presuming that a patent holder has market power are two legal alternatives in that regard.¹³⁶ These are particularly relevant in socially sensitive markets such as pharmaceuticals. Countries that constitutionally recognize the right to health, for instance, need to incorporate these rights into the balancing of competition provisions with socio-economic rights.

(f) Dialogue with other authorities, including the judiciary

Finally, it is important to ensure coherence between institutions (especially IP offices and ministries of health and trade) and to support and communicate with judicial authorities. Drawing from successful experiences—but also from their shortcomings—developing countries may innovate in their own policies extensively.

¹³⁵ See Abbott, F., Flynn, S., Correa, C., et al., *Using Competition Law to Enhance Access to Medical Products* (UNDP, 2014), for an overview of different practices.

¹³⁶ See the suggestions in Abbott, F., Flynn, S., Correa, C., et al., *Using Competition Law to Enhance Access to Medical Products* (UNDP, 2014), p. 139.

8. CONCLUSIONS

The crucial role that medicines play in ensuring the right to health and achieving universal health coverage, according to internationally agreed-upon commitments such as the Sustainable Development Goals (SDGs), demands competition authorities to be thoroughly engaged in monitoring and, as necessary, correcting the practices of the pharmaceutical industry, including when they are exercised under the coverage of patents and other IPRs protection.

As shown above, recent developments confirm that competition law can be an important tool to promote access to medicines. The interventions (including market investigations) relating to anti-competitive practices in the pharmaceutical industry made in multiple jurisdictions exemplify how competition law can be designed and implemented so as to address, among other abusive practices based on intellectual property rights.

Notable examples come from the European Commission, national European competition authorities such as the UK and the Italian Competition Commissions, and the US Federal Trade Commission (FTC). Noteworthy cases in South Africa (2001, 2003) and Brazil (2016) also show that there is a trend towards the utilization of competition tools, both through competition authorities and the judiciary, in response to the growing demand for ensuring competitive markets that can improve access to medicines for all

Reports and discussions held at multiple multilateral and regional organizations have also consistently signaled the use of competition to promote access to medicines (directly and indirectly), including the UNDP, UNCTAD, WTO, WIPO, WHO, the UN Secretary-General High-Level Panel on Access to Medicines, and the European Commission, among others. Efforts by multilateral institutions to reaffirm the legitimacy of competition laws as a tool to achieve broader objectives related to access to medicines are important. In this sense, the debate at the WTO TRIPS Council, led by the delegations of South Africa, is of particular relevance.

Competition authorities are mandated to ensure that anti-competitive practices and structures are curbed and adequately sanctioned. Importantly, there is leeway for countries to adopt competition policies that are tailored to the specific socio-economic contexts they are part of, including market structures, level of competition and situation of the pharmaceutical industry (nascent, emerging, consolidated, etc.). It is also important so as to be realistic about what a competition authority may deliver in light of budget and expertise constraints, and sometimes a gradual approach may be a better policy choice than an attempt to craft an excessively ambitious regime and authority. Skilled staff and independent jurisdictional bodies are important no matter the size of the competition agency.

Competition laws and policies can – as the examples of South Africa, Brazil, and China show- embed specific values and principles, which may be much broader than purely maximizing economic efficiencies. Examples include ensuring access to goods and services, reducing socio-economic inequality and generating stimulus to certain industrial sectors.

The TRIPS Agreement provides ample policy space for countries to enact competition policies to address the issue of the anti-competitive effects of licensing and patents, simultaneously recognizing the need for technology transfer. As such, competition law is considered one of the built-in flexibilities provided for by the TRIPS Agreement itself and not as an exceptional measure.

While intellectual property has in some cases be regarded as an exception to the general rule of competition—as IPRs provide exclusive temporary rights—they are nonetheless not immune to the applicability of competition law. Duties are an integral dimension of the exercise of any right. Since IPRs are justified in terms of the public benefit they ought to generate, this should be put to the test. Given the social importance of pharmaceutical products, this balance leans even more in favor of more competition.

Coordination between different competition authorities, and particularly between national institutions such as ministries of trade, ministries of health, and patent offices, can be crucial. Another important policy instrument is the enactment of guidelines as to ensure a public health approach to competition law in relation to intellectual property. Examples of such kind of instruments do exist, but could be further developed and expanded. This paper did not delve into details of the possible remedies to the various types of anti-competitive practices described above, but nonetheless highlights the flexibility that competition authorities have to craft a mix of different alternatives which include, but are not restricted to, compulsory licenses under Article 31(k) of the TRIPS Agreement and the use of the essential facilities doctrine.¹³⁷

In conclusion, there are many, still underexplored potentials for competition law and policy to promote access to medicines. They would not be a substitute for other health and access policies and should not be treated as either the primary or only available tool to achieve such societal public goals. However, they are instruments of an ever-increasing relevance that should be used fully by developing countries.

¹³⁷ Carlos Correa provides another set of policy recommendations for developing countries to craft pro-competition intellectual property policies (not exclusive to pharmaceuticals). Many of them are relevant to the framework proposed in this article as well: “establish or strengthen competition laws in order to control, inter alia, possible abuses emerging from the acquisition and exercise of IPRs; consider the competition implications of various policies and regimes that determine market entry, such as marketing approval of pharmaceutical and agrochemical products; ensure an adequate co-ordination among the competition law agency and other agencies whose decisions may influence the market structure and operation, with the aim of maintaining a competitive environment; fully use the flexibilities allowed by the TRIPS Agreement to determine the grounds for the grant of compulsory licences to remedy anti-competitive practices relating to IPRs; consider, in particular, the granting of compulsory licences in cases of ‘refusal to deal’; apply the ‘essential facilities’ doctrine to address situations of control of essential technologies, taking into account the relevant market conditions and public needs; develop policies, including guidelines, to prevent and correct abuses in the acquisition and enforcement of IPRs; address situations that may normally lead to the anti-competitive conduct such as ‘package’ and ‘thicket’ patents; adopt guidelines for the use of patent offices to prevent the granting of frivolous or low quality patents, as well as patents with overbroad claims, which may be used to unduly restrain legitimate competition and block innovation; and avoid ‘linkage’ provisions and data exclusivity in order to promote competition in markets of regulated products.” (Correa, C., “A competition approach to intellectual property protection”, Bridges No. 7 [ICTSD, November-December 2007]).

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