TRIPS Flexibilities and the Use of Competition Laws

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Competition Law[1]

The use of competition law and policy to address anti-competitive conducts and structures, and to promote access to health technologies, is an increasingly utilized TRIPS flexibility in both developed and developing countries.

Such use entails the antitrust/anti-monopoly/competition law and agencies, but may also include regulatory agencies, administrative provisions, and other forms of regulation of anti-competitive conducts and monopolistic or oligopolistic structures. Institutionally, there is a lot of variation. But the use of competition in relation to access to health technologies also includes pro-competitive norms and policies in the IP system, such as rigorous patentability criteria that impede frivolous patent applications (which would undermine competition).

There is no comprehensive international agreement disciplining competition. As such, international law provides ample leeway for countries to conduct their national competition policies in accordance with their own objectives, goals, and institutional settings. Some countries may prioritize an intersection with industrial and innovation policies, while others may focus on ensuring access to products and combatting economic power.

TRIPS refers to competition in articles 7 (objectives), 8 (principles), 31(k) (compulsory licensing for anti-competitive practices) and 40 (control of anti-competitive licensing). This sets minimal requirements for countries to take into account in their respective domestic systems: jurisdictions *shall* contain mechanisms to address anti-competitive practices and the promotion of competition is overall an objective of the TRIPS Agreement. However, this does not pre-empt jurisdictions from taking *additional* measures, and does not mandate a specific institutional arrangement (e.g. a single authority or various regulatory bodies), nor does it dictate the goals and premises that should orient a competition system with respect to IP.

[1] This document is largely based on IDO, Vitor Henrique Pinto. **Designing Pro-Health Competition Policies in Developing Countries.** South Centre Research Paper 125. Available from: https://www.southcentre.int/research-paper-125-december-2020/

Articles 7, 8, 31(k) and 40 of TRIPS

*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.

*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.

*Article 31 - **Other Use Without Authorization of the Right Holder***
Where the law of a Member allows for other use (7) 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;

*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.
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 grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.
3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually

satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.
4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

Competition Law and Intellectual Property

While competition law aims at combatting monopolies and anti-competitive conducts, intellectual property rights create temporary legal exclusivities which may in principle lead to anti-competitive situations. At first sight, this seems an unsurmountable paradox. Doctrinal sources clarify, however, that intellectual property is not an 'immunity' against competition law scrutiny or intervention. In fact, the interface between IP and competition law is usually referred to as a relation of **complementarity**, while some commentators even propose that they should be **integrated**, i.e., the public principles that underpin the protection of competition and innovation should lead to a coherent, integrative interpretation of competition and IP.

By definition, IPRs restrain competition (since they provide legal exclusivities). The interpretative task is therefore to define in which uses and under which circumstances the exercise or the ownership of IP can be deemed anti-competitive. One issue to be considered is whether the necessary evidence for such assessment needs to be thoroughly collected *ex post*, based on proof of effects, or whether this can be done in an *ex ante* manner with pre-set standards. This is part of competition authorities' ordinary activity, which adopt guidelines with econometric standards such as the Herfindahl-Hirschman Index (HHI) for the definition of market concentration, or the so-called 'rule of reason'. Jurisdictions may also craft specific understandings with respect to the limits and scope of illegalities involving the use or excessive concentration in the ownership of IP.

In this sense, the list of recognized conducts at the interface between IP and competition law is ample and continues to expand (see also section below). They include pay-for-delay agreements, sham litigation (vexatious litigation), refusal to license, evergreening of patent applications, bad-faith trademarking practices, product hopping, among others. In addition, in some cases, the ownership of an IP portfolio in a single market entity may bring such concentrating economic power that, even without their utilization, IP rights may be anti-competitive and therefore alienation of IP assets is required.

Competition law and policy contains multiple remedies to cease and compensate anti-competitiveness that include the following: monetary fines, obligations to license an IP or an essential technology to competitors, issuing a compulsory licensing, and imposing the obligation to alienate an IP portfolio (e.g., sell a brand during a merger or acquisition of two companies). This is a non-exhaustive list and countries also have freedom to define which remedies are most suitable to their own realities and priorities. Some of them may also be integrated in IP offices practices, such as nullification of patents and trademarks registrations. In many jurisdictions, judicial authorities may also determine such sanctions – including, for example, issuing a compulsory licensing or nullifying a patent which has been granted – and/or conduct judicial review of administrative decisions.

One area of increase development at this interface refers to the so-called standard essential patents (SEPs) and the associated obligation to ensure FRAND (fair, reasonable, and non-discriminatory) licenses to competitors. Patents that refer to standard-setting technologies, such as those in the field of telecommunications, are a precondition for competitors to enter a certain market – in this sense, there is a public interest and a necessity in ensuring that the technology is accessible to competitors, and that the conditions for such access in the form of a licensing instrument are not excessively restrictive. This is the context where courts in multiple countries have crafted the notion of FRAND, as well as disputes pertaining to anti-suit injunctions (and even anti-anti-suit injunctions). While this has not yet been applied to the IP in the pharmaceutical sector, numerous 'base technology' patents (e.g., patents on mRNA technologies for Covid-19 vaccines) may be considered to be essential to competitors, and demand accordingly competition scrutiny.

Major Considerations regarding the interface between competition and IP

- IP is not an immunity against competition law.
- Various anti-competitive conducts based on the use of IP have been recognized by antitrust authorities and courts around the world, including in the US and the EU.
- Under certain circumstances, the very existence of IP may be deemed anti-competitive.
- There are multiple remedies available for competition authorities, including fair, reasonable and non-discriminatory (FRAND) licensing for standard essential facilities (SEPs); compulsory licensing of IP; monetary fines; obligation to sell an IP portfolio (e.g., a trademark) to approve a merger or acquisition; among others.

For more information, see:
South Centre and IDEC Conference on *Fair and Equitable Pricing in Health: Competition Law and Access to Medicines* (December 2020). Recordings available here: https://www.youtube.com/playlist?list=PLZdHFQBFVjThTBeKtmswACPeSAoaqzMbq

Role and Objectives of Competition Law

Competition law and policy may entail numerous objectives, including poverty reduction, diminishing inequalities, improving access to essential products, promoting racial and gender equality, facilitating industrial policies, among others. For example, the South African and Brazilian legislations contain explicitly different objectives for their antitrust authorities. As noted by Eleanor Fox, developing countries may experiment more and benefit from the lack of uniformity, and modulate their mandate and activities.

For decades, antitrust agencies in the US and the EU have been deeply influenced by the principles of the Chicago School and notions of 'law and economics'. This produced an interpretation whereby antitrust/anti-monopoly/competition law should have a rather limited role, largely accepting monopolies and anti-competitive conducts as a result of efficiency by large companies, which would justify its acceptance. The paradigm of 'consumer welfare' was used to interpret competition law under a very narrow objective of 'maximizing efficiencies', in which all other objectives are considered to be excessively interventionist and inadequate. This broad view has permeated most competition law discussions over the last four decades. In this context, the scrutiny over the pharmaceutical sector, and the role of IP in particular, has been mostly marginal.

This was not always the case. At its origins, antitrust had a clear intent to control economic power and combat the pervasive effects of monopolies. The US Sherman Act of 1890, for example, was designed to break up big monopolies and avoid excessive concentration of economic power. This anti-monopoly tradition has been clearly revamped in the most recent antitrust reforms in the US, targeting the economic power of big tech platforms, the high cost of medicines (with a particular focus on pay-for-delay agreements), and ensuring a more comprehensive view of the role of antitrust authorities (the Department of Justice and the Federal Trade Commission, in the case of the US).

Since the 1990s, competition authorities with independency and autonomy were created in multiple developing countries around the world. They were

institutionalized under a paradigm of trade liberalization and market reforms that would leave a residual policy space for competition law to address exceptional situations. On the other hand, many also attempted to consider the particular needs of developing countries' markets and envision alternatives to the paradigm of other countries. **Hazel Tau**, the first major case involving IP and competition in the pharmaceutical sector, with a focus on access to medicines, took place in South Africa in early 2000s. The case ultimately ended with a settlement with the pharmaceutical company which detained the patent rights, drastically reducing prices in the country.

The issue of the role and objectives of competition law should therefore not be treated merely as an interventionist v. free market deregulation trade-off, nor as an ideological clash. For example, it is noteworthy that many neoliberal economists, such as Friedrich Hayek and Milton Friedman, expressed skepticism towards the protection of IP by considering them to be anti-competitive and against free markets. And yet, these were precisely the arguments that were behind the justification of lax competition policies that included a low level of analysis of IP for competition.

The main issue in this discussion refers to how developing countries should craft their policies and institutions in a manner that is pro-development and consistent with their broader societal goals, rather than exclusively promoting the maximization of utilities. This is where the issue of access to health technologies should be integrated, although the specific elements and institutional design may largely vary.

Major considerations in interpreting the role and objectives of competition law

- There are multiple goals for competition law and policy. Although the idea of 'maximizing efficiencies' and 'consumer welfare' are widely shared, they are only two out of various interpretative options.
- Coherence with other policies, inter-agencies dialogue, and consistency with national objectives are important for concrete interpretations of competition law.
- Understanding that competition law should not only have a subsidiary and limited scope of applicability does not equate direct intervention in the economy, but rather a careful balance between development objectives, countering economic power, and promoting better competitive markets.
- Guidelines for specific sectors, such as for digital platforms or for the pharmaceutical sector, may be useful tools to clarify a policy approach in a country.

Using Competition Law to Promote Access to Medicines

With the general framework above, there is recognition that competition law is a legitimate TRIPS flexibility that should be used in order to promote access to medicines (and health technologies more broadly). The main specificity of the topic is the essentiality of goods involved and the direct implications to the realization of the human right to health. As such, considerations based on public health and a rights-based approach may also be integrated into competition assessments.

As exposed above, the goal of promoting broader access to medicines may even be an explicit objective of an antitrust/competition policy, and measures to that aim may be adopted accordingly. In some countries, this can take the form of direct price and distribution mechanisms; in others, this is left to the regulatory tools and is not considered to be under the scope of a competition mandate. Active investigations in the pharmaceutical sector, such as the EU Pharmaceutical Sector Inquiry (2009), may identify the main issues and practices at stake, and prepare for subsequent real-life cases.

Pro-competitive IP policies such as robust patentability criteria, issuing compulsory licenses in the case of anti-competitive conducts, ensuring FRAND licensing conditions for core technologies related to pharmaceuticals, and coordination between different authorities (judicial, administrative, regulatory, competition, IP offices) also contribute to that aim, both directly and indirectly.

Some landmark cases around the world, such as the **EU Astrazeneca Case (C-457/10, European Court of Justice – ECJ)** and the **Hazel Tau v. GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) case before the Competition Commission of South Africa (2002)**, are clear examples of such interlinkage and the possibility to use competition law to promote access to medicines.
A crucial aspect of the debate is the high level of experimentalism and diversity between jurisdictions, instead of a one-size-fits-all model.

For more information and specific suggestions, see:
Abbott, F., Flynn, S., Correa, C., et al., *Using Competition Law to Enhance Access to Medical Products,* UNDP, 2014.

Typical Anti-Competitive Practices Relating to Pharmaceuticals

Refusal to License

The most common form of anti-competitive practice related to licensing is the refusal to deal. 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.

Abusive Patent Filings such as Divisional Patents, Evergreening, 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." 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. 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**.

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). "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." 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'), 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. 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. 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. The outcomes of permissive patent policies have 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. This has led to arguments of a system in "crisis" that hinders innovation rather than promotes it. Some arguments question the role of patents in promoting innovation at all, which questions the very basis on which they are granted. Unwarranted pharmaceutical patents, in particular, may bear profound

social consequences as they allow undue legal monopolies that increase prices and reduce access to treatments. 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. 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.

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. The agreement reached between the companies avoids further litigation, but also means that generic companies will agree to 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. 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), and the European Union, such as the Lundbeck case (2013), have addressed this issue. Other jurisdictions have also started to pay attention to the issue, including China and India.

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 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.

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. 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 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. Another interesting case is Aspen (2016) decided by the Italian Competition Authority (AGCM). 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. 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. 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. 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)**, 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. The Competition Commission considered the companies' refusal to license under reasonable conditions in the light of the 'essential facilities' doctrine. This case is particularly relevant as it dealt with patented medicines and not off-patent ones.

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." 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. In the European Union, the most important precedent in this regard is the **AstraZeneca case**, 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. 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. 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. 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. 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.

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**). 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 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. Globally, Gilead, a transnational pharmaceutical company, licensed multiple generic companies for the production of Sofosbuvir, a crucial drug for hepatitis C treatment, 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.

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

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)." 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.** 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. 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.

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. 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.

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.

There have been multiple cases of cartels and bid riggings in the field of pharmaceuticals. 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.

Exercise and Points for Discussion

- Can patent offices, competition and regulatory agencies work together to address anti-competitive conducts and structures? What should be the role of judicial authorities?
- In your view, what is the best approach for competition authorities to scrutinize IP-related anti-competitive conducts and structures? Should they be more active, or should they be less interventionist than now?
- What kinds of evidence should a competition or judicial authority require to assess anti-competitiveness? On whom should the burden of proof fall, given the existence of competitors and the public interest?
- What would be specific needs for competition policies in developing countries, particularly regarding the technological gap (i.e., difference in level of technology available to firms and institutions in the country vis-à-vis international competition)?
- Should judicial and competition authorities analyze technology transfer and tech licensing agreements? For example, in many jurisdictions such contracts and agreements need to be registered in administrative bodies.
- Should excessive pricing be a cause of action for competition authorities' intervention, such as in the EU, China, and other jurisdictions? If so, what criteria could be utilized to assess excessive or predatory pricing conditions in the pharmaceutical sector?

- What are the implications of the changes in antitrust laws in high-income countries, particularly the recent trends in the US to adopt a much more active competition policy, including reduction of medicine prices and enhanced availability of biosimilar medicines?
- What mechanisms of transnational cooperation can be envisioned?