

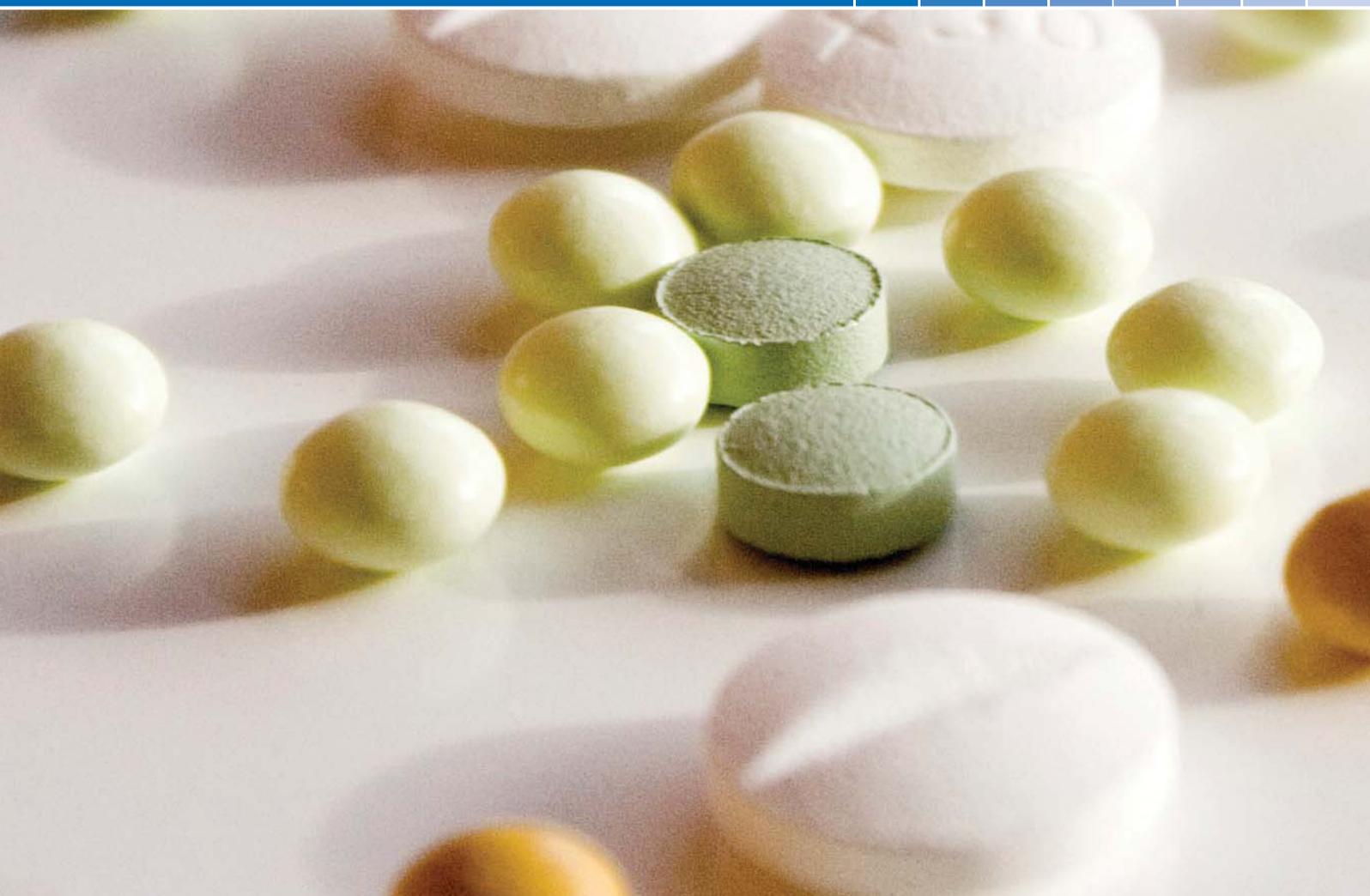


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USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES

A guidebook for low- and middle-income countries

United Nations Development Programme





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Resilient nations.*

Using Competition Law to Promote Access to Health Technologies:

A guidebook for low- and middle-income countries

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ABOUT THE GUIDEBOOK

This guidebook originated from a small meeting of experts convened by UNDP in March 2011 to explore how competition law and policy in low- and middle-income countries might be better harnessed to increase access to essential health technologies. Following that meeting, UNDP partnered with a subset of experts from the meeting to develop this guidebook, which was finalized in May 2014. UNDP and the authors are particularly grateful to Frederick Abbott for his stewardship in coordinating the review and amalgamating the papers as a single resource, and to Brook Baker, Kazuyuki Uji, Boyan Konstantinov, Lisa Hamelmann, Katie Kirk and Tenu Avafia for their helpful suggestions and editorial reviews. This project was overseen by Katie Kirk, Consultant, and Tenu Avafia, Policy Advisor within the HIV, Health and Development Group of UNDP's Bureau of Development Policy.

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There is a strong and reciprocal relationship between health and human development—just as health shapes development, development shapes health. The right of every human being to access the highest attainable standards of health is recognised by numerous international human rights treaties and national constitutions. With access to essential medicines, diagnostics and vaccines now regarded as a critical component of the right to health, countries are increasingly focusing on enabling laws and policies to achieve that right.

With 9.7 million people on antiretroviral treatment at the end of 2012, the AIDS response has provided a powerful example on realising the right to health, especially in terms of expanding access to life-saving essential medicines. Fourteen years ago, the cost of HIV treatment was US\$ 10,000 per patient per year. Today, internationally approved first-line treatment regimens are a little more than US\$ 100 per patient per year. As a result, many low- and middle-income countries (LMICs) have made dramatic gains in scaling up life-saving HIV treatment. Generic competition for antiretroviral medicines has been an indispensable part of this success, and is well accepted as one of the key drivers for expanding access to HIV treatment.

Competition law is one of the least discussed flexibilities within the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. There remains great untapped opportunity for countries to achieve price reductions for health technologies by instituting competition law and policy frameworks and complementing them with strong enforcement mechanisms. The need for greater use of competition law was highlighted by the Global Commission on HIV and the Law, an independent body of eminent persons tasked with interrogating the relationship between human rights, law and public health in the context of HIV. The Commission recommended that *"countries must proactively use other areas of law and policy, such as competition law, price control policy and procurement law which can help increase access to pharmaceutical products."*

This resource provides practical guidance on using competition law and policy in LMIC settings to increase access to affordable health technologies. The guidebook provides a number of model interpretations of key aspects of competition law, and uses country case studies to examine the successes and challenges experienced in using competition law and policy.

This guidebook is intended for use by government authorities in LMICs who may have an interest in promoting access to health technologies through the effective use of competition law—including competition authorities, procurement and health authorities, judges and members of legislatures. It is also intended as a resource for civil society to inform their advocacy, policy and programmes work on treatment access and consumer/patient rights, including addressing anti-competitive activities that may affect consumer/patient welfare.



By elucidating the relationships between intellectual property rights, competition law and access to treatment, and through the study of examples where competition law and policy have been successfully used to address anti-competitive practices, we hope this Guidebook will serve as a valuable starting point for expanded cooperation within and among countries on this important area of law and policy. Ultimately, we hope it will contribute to the capacity of countries to enhance value for money, allowing for greater purchasing power in essential health technologies and leading to the improved health outcomes which are critical to accelerating progress on the Millennium Development Goals and the post 2015 development agenda.

This Guidebook has been developed by UNDP's HIV, Health and Development Group, Bureau for Development Policy with the support of numerous experts and field partners. We are grateful for their valuable contributions and welcome your comments and feedback.



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1. Global Commission on HIV and the Law, 'Risks, Rights & Health', Global Commission on HIV and the Law, New York, 2012.



ABBREVIATIONS AND ACRONYMS

| | |
|------------|--|
| API | Active pharmaceutical ingredient |
| ARV | Antiretroviral |
| ATC system | Anatomical Therapeutic Chemical Classification System |
| ECJ | European Court of Justice |
| EU | European Union |
| FTA | Free trade agreement |
| FTC | Federal Trade Commission |
| GATS | General Agreement on Trade in Services |
| GATT | General Agreement on Tariffs and Trade |
| GDP | Gross Domestic Product |
| IP | Intellectual property |
| LMIC | Low- or middle-income country |
| NNRTI | Non-nucleoside reverse transcriptase inhibitor |
| NRTI | Nucleoside reverse transcriptase inhibitor |
| NtRTI | Nucleotide reverse transcriptase inhibitor |
| OECD | Organisation for Economic Co-operation and Development |
| OTC | Over the counter |
| R&D | Research and development |
| TFEU | Treaty on the Functioning of the European Union |
| TRIPS | Trade Related Aspects of Intellectual Property Rights |
| UNCTAD | United Nations Conference on Trade and Development |
| UNDP | United Nations Development Programme |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |



Using Competition Law to Promote Access to Health Technologies: A Tool for Human Development

There are some important reasons why low- and middle-income countries (LMICs) may choose to make greater use of competition law and policy to reduce the cost of treatment. First, multilateral trade rules allow substantial flexibility in the development and application of competition law and policy, taking into account different perspectives and approaches in this field that can and do shift over time. There is considerable room to manoeuvre. Second, as a consequence of accommodating the variety of potential competition approaches, remedies available to address anti-competitive behaviour may permit a broader range of remedial action than some other public health-related flexibilities associated solely with patents. Third, competition law typically empowers a broad range of affected parties to request or initiate enforcement action. Intellectual property (IP) law, by way of comparison, may limit remedial or enforcement action to narrowly defined parties and interests. These limitations may exclude various parties that might otherwise seek to vindicate the public interest.

Measures against anti-competitive behaviour are not suggested to be the preferable launching pad in every case from which to pursue better access to health technologies, compared to other areas of law. But as a relatively underdeveloped yet promising mechanism for doing so, competition policy should be given greater prominence for its potential to complement efforts in other areas. The increased use of competition law and policy is not without its challenges. These include the relative novelty of these measures in many developing countries; the lack of a substantial body of precedent; underdeveloped competition law frameworks; and capacity constraints concerning enforcement structures in developing countries.

This guidebook includes five chapters, each of which addresses a different aspect of the competition law environment and framework. This executive summary presents a brief overview of the content of each chapter. The guidebook also includes several 'model policies' addressing different areas of competition law enforcement that may be adaptable and useful in the LMIC context, and two annexes containing case studies in the development of competition law frameworks in different countries and examples highlighting the results of competition law put into practise.

The objectives of competition law vary: promoting consumer welfare, increasing access to important commodities or as an industrial policy objective to increase local participation in a sector. These objectives will often overlap. A core objective around the protection of consumer welfare operates by restricting or regulating unfair business practices and anti-competitive concentrations



of economic power. The objective of protecting consumer welfare is closely tied to the promotion and protection of human rights—in this particular context to the protection of the rights to life and health. For many LMICs, providing access to safe, effective and affordable health technologies is a major challenge that places a substantial burden on government and individual/family budgets.

1. The interface between intellectual property and competition in low- and middle-income countries

Chapter 1 begins with a discussion of the economics of patents and innovation in the pharmaceutical sector as relates to LMICs. For high-income countries, the high profits secured by patent holders by charging extremely high prices for newer health technologies are used for, among other purposes, funding research and development (R&D) of additional new treatments. For these countries, the incremental spending on R&D is presumed to be justified by improvements in health care outcomes. Even if the originator/innovator pharmaceutical companies make profits greater than those for other industries, many consider there to be a net benefit to society. For most LMICs, on the other hand, the profits do not result in new treatments specifically useful to the local patient population, and few of these profits accrued by foreign originator companies are earned by locally owned and/or operated businesses (that are less likely to invest in new drug R&D). Local patients/consumers are likely to secure immediate benefits from paying lower prices for health technologies. Paying higher prices and contributing to R&D taking place mainly abroad (and addressing diseases prevalent in developed countries) has a more marginal benefit. What this means from a competition law standpoint is that a national pharmaceutical market dominated by patent-owning originator companies may be reducing the welfare of the local population by blocking the entry of generic (i.e. those that are produced outside patent protection) and/or competitive patented products, with few offsetting benefits. An LMIC may be justified in adopting a more vigorous approach toward addressing anti-competitive conditions in its pharmaceutical market.

1.a. Comparative perspectives through country case studies

This chapter also provides a brief historical background on the development of early competition law, and presents a comparative perspective of competition frameworks: how greatly they vary, as well as within individual countries over time and at different stages of development. This comparative perspective is illustrated through cases studies of a number of countries or economic trading blocs: the United States, the EU, Canada, South Africa and India.

The sub-chapter—chapter 1.a.—demonstrates that competition law and policy has a long history, dating back at least to the British Statute of Monopolies in 1623. Application of competition (or anti-trust law, as it is called in some countries) to control harmful business practices really emerged in the late 1800s in the United States, as government authorities and courts sought to curtail the power of large ‘trusts’ that dominated substantial segments of the US economy, at that time controlling the railroads and oil sectors. Competition law principles were considered important to the rebuilding



and restructuring of European economies after the Second World War, since prior to that period of restructuring, European economies had been dominated by large industrial alliances, and often to the detriment of individual citizens. The European Commission Treaty established competition law and its enforcement as a foundational element of EU law and policy.

Largely due to the long history of development and application of competition law in the United States and EU, and to the resources available to government authorities in these countries, the dominance of 'precedent' in terms of the enforcement of competition law emanates from these countries. However, in recent years, strong interest has emerged in LMICs towards implementing and strengthening competition law enforcement, particularly as many such countries have taken steps to 'privatize' their economies, opening up greater possibilities that private operators may undertake anti-competitive acts that affect social welfare.

National attitudes towards competition policy tend to vary over time, as do other industrial policies. For example, in the 1960s and 1970s, antitrust law in the United States was applied aggressively, and there were a substantial number of restrictive business practices presumed to violate the law. By the late 1980s, a shift in sentiment towards accepting greater risks from unregulated markets led to a relaxation of antitrust enforcement, and a reduced focus on practices presumed to be anti-competitive. As of 2013, we see US antitrust (or competition) authorities are once again more vigorously pursuing challenges to restrictive business practices involving the pharmaceutical industry, such as attempts to delay the entry of generic products onto the market (and active in areas such as controlling mergers and acquisitions in the telecommunications sector). It is important to draw attention to the ebb and flow of attitudes about the appropriate application of competition law, because countries at different stages of economic and social welfare development are likely to have good reasons for choosing competition policies best suited to their local interests. As with many other areas of the law, including intellectual property, there is no 'one size fits all' best approach to competition law.

Chapter 1.a. illustrates different approaches that national authorities have taken to developing and implementing competition law, particularly with respect to the pharmaceutical sector. Canada, for example, has paid particular attention to the price of patented health technologies and the enhanced efficacy or benefit that such products are offering over existing products, including generic ones. Canada operates a Price Review Board that continuously monitors the pharmaceutical market, and may order remedial action in terms of price reduction when it considers that step warranted. South Africa has perhaps been the most active LMIC in terms of using competition law to reduce prices for health technologies important to treating its local patient community.

2. Competition law flexibility in the international legal framework

Chapter 2 notes that there is considerable flexibility in international law regarding the adoption and implementation of competition law within national legal systems. There are a few international legal constraints likely to be found in treaties to which individual countries are bound. Pursuant to



the 'national treatment' principle which underpins several World Trade Organization (WTO) agreements as well as bilateral and regional treaties, national authorities, generally speaking, are obliged to treat foreign-owned businesses in the same manner as they treat domestically owned businesses from the standpoint of business regulation, including in applying competition law. The WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement refers to competition law in a general way but, as discussed in the chapter, permits national authorities to address anti-competitive conduct involving IP in the manner best suited to the national situation. Also, customary rules of international law may place some constraints on extending jurisdiction to acts taking place in foreign countries when there is not a sufficient effect on the local economy.

Article 8.2 of the TRIPS Agreement provides flexibility for governments to adopt: "Appropriate measures, provided that they are consistent with the provisions of this Agreement, [that] 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." The TRIPS Agreement requires that governments make available certain forms of IP rights protection, and sets out some general conditions for that availability, but the TRIPS Agreement does not significantly restrain national authorities from choosing the appropriate way to address abuses of IP rights through competition law. Article 40 of the TRIPS Agreement expressly addresses restrictive licensing practices that may, *inter alia*, inhibit transfer of technology, and it provides illustrations of the types of practices that may do so. Article 40 authorizes national authorities to take action to control such practices. Article 6 of the TRIPS Agreement, as confirmed by the Doha Declaration, authorizes WTO Members to allow parallel importation of health technologies, a major pro-competitive form of activity that can be used to secure the lowest priced products available on international markets.

Chapter 2 highlights one risk to the degree of flexibility national authorities currently enjoy to adopt and implement competition law: this risk arises from bilateral and regional trade and/or investment agreements. One of the particular challenges concerns the inclusion of IP among the types of 'property' that may be subject to third-party arbitration initiated by private enterprises based on alleged unlawful 'takings'. An IP right holder subject to an order from a competition authority may spuriously challenge that order in an arbitration proceeding, tying up limited government legal and financial resources for a period of years. The mere threat of such an eventuality may discourage actions to address anti-competitive behaviour of IP right holders. National governments clearly have the power to regulate IP rights under competition law. However, a recent trend towards initiation of private arbitration claims involving IP rights, based on alleged unlawful 'takings', should serve as a warning against including IP rights within the scope of investment dispute chapters.

3. Competition law doctrine and typology of anti-competitive practices

In **Chapter 3**, core doctrines of competition law generally applied by national authorities are reviewed. Most competition laws examine anti-competitive behaviour in relation to agreements between enterprises, on the one hand, and monopolization or abuse of dominant position, on the other. Anti-competitive activity is further viewed as either 'horizontal' or 'vertical'. Horizontal



anti-competitive activity refers to conduct among independent enterprises that are suppliers of competitive (or potentially competitive) goods or services. Vertical anti-competitive activity refers to the supply chain controlled by a producer, beginning with inputs to production, into production, intermediate distribution and, ultimately, the retail sale of goods or services.

Some types of agreement between enterprises are so inherently anti-competitive that proof of the existence of the agreement is sufficient to establish a violation. Such agreements are referred to either as *per se* anti-competitive or *hard-core* competition law violations. Other types of conduct that may seem anti-competitive on their face may also have a pro-competitive justification, such that competition authorities assess the balance. This balancing is often referred to as assessment under the 'rule of reason'. For a competition law violation to be found, the anti-competitive aspect of the arrangement should outweigh potential pro-competitive benefits.

Examples of horizontal anti-competitive behaviour that are *per se* illegal in most jurisdictions include price-fixing among competitors, output restraints and allocation of geographic territories. Examples of vertical restraints that are *per se* illegal in many, but not all, jurisdictions are resale price maintenance (or fixing the minimum price at which retailers may sell) and 'exclusive grantback' requirements in patent licences.

There are some significant risks of anti-competitive conduct in pharmaceuticals markets that are fairly widespread and deserve close attention from competition authorities. These include bid manipulation in procurement of health technologies, whereby a group of potential competitors may agree not to submit bids below a set price and to allocate the 'lowest set price' bid to a particular firm. Such activity may also involve inappropriate payments to government officials who might otherwise report the anti-competitive practice. Anti-competitive conduct by patent-owning enterprises may include requiring a distributor or retailer of health technologies to purchase a complete line of products as a condition of purchasing a particular product or products (i.e. a tying arrangement). Perhaps the most widely discussed form of anti-competitive conduct involving patent owners involves 'buying out' generic challenges to patents that might otherwise result in generic products entering the market at an early date. Such buyouts upset the balance legislators strive to achieve between granting patents and authorizing their challenge to foster competition.

Mergers and acquisitions may adversely affect product markets by, for example, allowing combined companies to raise prices for therapies previously in competition with each other.

Anti-competitive conduct affects markets for innovation, such as when a patent is illegitimately used to prevent the development of new products not within the scope of the patent, or when patent-owning companies combine to control markets. Mergers and acquisitions can affect markets for innovation by reducing potential R&D targets and opportunities.

As noted earlier, competition law addresses dominant enterprises and monopolies as well as agreements between enterprises. A single enterprise (or a small group of enterprises) may alone exercise such significant power in a relevant market as to be able to raise prices above competitive market



prices without concern that others will enter the market and undercut it. When an enterprise dominates a market, it does not need consensual agreements with potential competitors to control them; it may unilaterally dictate terms. One objective surrounding the control of mergers and acquisitions is to prevent an enterprise from combining with others precisely to take a dominant position in the market.

Chapter 3 concludes with a discussion of the types of remedies that are available to national authorities and private parties as redress for anti-competitive conduct. It is not uncommon for the government to enter into some form of settlement agreement with an accused enterprise pursuant to which that enterprise agrees to cease its anti-competitive activities and may also make a payment either as damages or as a penalty. Such settlements may be approved and/or supervised by courts. In some jurisdictions, particularly the United States, a good deal of competition enforcement is undertaken by private actors suing for damages. Anti-competitive conduct may also be subject to criminal penalties including substantial fines, and imprisonment for individuals. Specific types of remedies may be used to address anti-competitive conduct that is undertaken to block the introduction of generic products. This may include requiring pharmaceutical patent owners to compensate public procurement authorities, generic producers and others for damages occasioned by the unwarranted invocation of patents. Strong consideration should be given to prohibiting patent owners from 'buying out' generic producers' challenges to patent validity or assertions of non-infringement. Other types of specific remedies may be considered (see Model 6).

4. Market dominance and market definition

Chapter 4 addresses one important aspect of competition law as it applies to access to health technologies: how to define the parameters of the market to which a claim in competition law might be made. To assess whether an enterprise or firm holds a dominant or monopoly position, it is first necessary to define the relevant market. If a market comprises a substantial number of products and/or competing companies, it is less likely that a single firm can achieve a dominant position. If a market is relatively narrow—for example, comprising a single product and/or firm—it is substantially more likely that a single firm can control it.

The pharmaceuticals market is relatively unique. While there are a substantial number of competing originator firms, some of the products developed and sold by these firms are unique, or comparatively unique. If, for example, an originator firm develops a new pharmaceutical therapy that successfully treats a disease that was not previously treatable, it may control or dominate the market for that treatment by virtue of its uniqueness. And, typically, that new treatment will be patented, thereby preventing other companies from producing and marketing a substantially identical product.

By no means are all new health technologies, including patented ones, unique therapies. Such new products may be entering a market crowded with potential alternative treatments. In such case, even if the new pharmaceutical demonstrates some improved characteristic as compared with earlier treatments, purchasers (including public health plans) are likely to take cost considerations into account when deciding whether to buy the new treatment or use an existing one. And it is often



rather difficult to objectively characterize rather similar treatments as decidedly better than one another. In such cases, a firm may have a dominant position in a very narrow sense (that is, for the slightly different product), but it may not dominate the therapeutic class used for treatment. In such cases a firm should not be able to raise prices above competitive market prices and keep them there.

Chapter 4 explains how competition authorities can and should determine the relevant market for a patented pharmaceutical product when considering a potential claim relating to market dominance. It suggests that competition authorities begin by assuming that the patented medicine is unique, focusing on the narrowest therapeutic class (which at the international level is described as Anatomical Therapeutic Chemical (ATC) level 5), and inherently dominant in its relevant market. The burden then shifts to the originator firm to prove that there are acceptable substitutes for the product (at a broader ATC level) and that there is competition in the relevant market such that consumers are not unduly burdened with high prices as a result of the originator's dominant position.

Dominant position and assessment of the relevant market is also important in the context of evaluating mergers and acquisitions. When two or more pharmaceutical companies combine, they are combining their portfolio of health technologies. Prior to the merger or acquisition, there may be competition between drugs in the respective portfolios, and this would place downward pressure on prices. Once the merger or acquisition takes place, the incentive for price competition is removed. A sale will benefit the combined company regardless of which product is purchased.

In the merger and acquisition context, not all drug portfolios are in competition with each other prior to a combination. It is in the interests of the combining companies to argue that drugs in the portfolios were not in competition with each other so that the merger will not eliminate competition. In this regard, Chapter 4 recommends that competition authorities approach combining health technologies firms by assuming that their portfolios are in competition, and in this context identifying drugs in a broad therapeutic class, either ATC level 2 or 3. The burden then shifts to the combining companies to prove that drugs in the portfolio are not in competition—for example, by demonstrating their uniqueness from a market standpoint.

5. Increasing the use of competition law in low- and middle-income countries

The great majority of LMICs have come to the adoption and implementation of competition law fairly recently. **Chapter 5** explores some of the particular challenges they face in making greater use of competition law in the health technologies sector.

There are first challenges in deciding on the legislative approach. The most common approach involves relying heavily on existing models—largely from the United States and the EU—a legal transposition. A second and more contextual approach adapts these pre-existing models to local



conditions. A third approach creates a new set of rules based on local needs. Chapter 5 assesses the various approaches, and suggests that a combination of the contextual and new rule approaches may be the most effective.

Chapter 5 highlights a number of issues in terms of implementation. There are different approaches to competition law adopted in different countries and regions, often reflecting different national and regional economic and social circumstances. As discussed in the guidebook, there are good reasons why LMICs may pursue competition policy in the health technologies sector somewhat differently from high income countries. This chapter is focused on the interests of LMICs in providing more equitable access to health technologies.

Competition authorities in LMICs are almost certain to face budgetary constraints that directly affect their ability to hire and retain qualified personnel and to pursue anticompetitive conduct in the health technologies sector. Because most LMICs are at early stages of implementing competition laws and regulations, and because many continue to have relatively concentrated industries, resistance to implementation from business stakeholder groups may be substantial. This may manifest itself in political obstacles.

While large stakeholders from the business community may be in a position to provide material support for competition enforcement activities, governments should be cautious of any potential conflicts of interest. Large commercial stakeholders may not be the best candidates for supporting vigorous competition law enforcement. Large commercial stakeholders may not be the best candidates for supporting vigorous competition law enforcement, since large companies themselves may be the targets of government enforcement action. Support for enforcement should come from the governments, as well as from the public and small to medium-sized businesses that may be shut out of markets dominated by the interests of large businesses. In the health technologies sector, producers and importers of generic products may have a strong interest in challenging the market position of patent holders and may be supporters of competition law enforcement.

There is no simple or common solution to making budgetary resources more readily available. Government agencies are in competition for resources. But the competition authority may stress that creating a vibrant, competitive economy will cut costs of procurement in some sectors and increase business activity and, therefore, tax revenues. Competition authorities may to a certain extent finance their own activities through fees on activities such as providing opinion letters, and they may benefit from penalties that are assessed when competition violations are found.

It is important to establish a 'competition culture' in which private citizens have a broad appreciation for its benefits—that competition places downward pressure on prices and encourages the introduction of new and better products. From the perspective of this guidebook, governments, competition authorities and non-governmental organizations seeking to enhance public support for the adoption and implementation of competition law may point to the substantial potential benefits from lowering the price of health technologies.



6. Models

Following the first seven chapters, this guidebook presents five model sets of policies with respect to specific elements of competition law that may be well suited for LMICs, in particular, to address issues affecting access to health technologies. The models concern:

1. Restrictive practices in licensing agreements
2. Defining the relevant market in access to health technologies cases
3. Refusals to license IP
4. Excessive pricing
5. Extraterritorial application of competition law
6. Remedies to address generic pathway-related abuses
7. Model provisions of competition-related TRIPS flexibilities

Background for these models can be found in the various chapters.

7. Additional resources

This guidebook has been developed with the specific purpose of assisting relevant stakeholders in promoting equitable access to health technologies through the integrated use of competition law. There are a variety of components involved in the general development of effective competition law frameworks, including the introduction of legislation which is suitable to local conditions; the establishment and operation of competition law authorities; capacity for the investigation and prosecution of cases; mechanisms for the effective engagement of the private sector; and the involvement of civil society in these activities. For a responsive overall competition framework to emerge, the policymaking process must be an inclusive one, ensuring that user-needs, priorities and expertise of all stakeholders (government and non-government) are brought together to ensure that the competition framework works effectively across all these components.

There are a range of resources available through various organizations with an interest in competition law to assist in these activities. Many are made available on the Internet. In addition, there is education and training assistance offered by national competition authorities and other interested groups. While these resources seem relatively numerous, it is not always easy to discern which of them are offered from neutral perspectives of best overall national interests, and which may be driven by more vested interests. As a starting point to help distil the resources available, the bibliography accompanying this guidebook lists what the authors view as a number of the more significant publications and organizations in this area. It also provides a list of websites where additional information and resources may be found.



8. Annex

Annex: Examples of price reductions achieved through use of competition law flexibilities available in the TRIPS Agreement

The Annex contains a series of examples from the guidebook – in summarised form – where countries have successfully used competition law and policies to reduce costs of health technologies, either by reducing royalties required from third-party manufacturers, through fines for anti-competitive behaviour or through the establishment of funds for purchasers of health technologies to recoup excessive payments due to anti-competitive practices. For comparison's sake, a similar table of cost-reducing results achieved through compulsory licensing is also provided. The tables, considered together, illustrate that although less well recognized as a tool to address high prices, competition law is also effective in enhancing the environment for access-promoting prices for health technologies. The annex concludes with some discussion about the advantages and disadvantages of using competition law, as compared with compulsory licensing alone, and when these two areas of law might be used to complement each other.



Introduction—the interface between intellectual property and competition in low- and middle-income countries

Sean Flynn

KEY MESSAGES

- ▶ Determining the appropriate relationship between competition law enforcement and intellectual property protection involves a policy choice.
- ▶ For LMICs, an emphasis on promoting competition and reducing prices in the health technologies sector may be preferable to strong IP protection and enforcement.

“IP laws and competition laws are two complementary instruments of government policy that promote an efficient economy. IP laws provide incentives for innovation and technological diffusion by establishing enforceable property rights for the creators of new and useful products, technologies and original works of expression. Competition laws may be invoked to protect these same incentives from anti-competitive conduct that creates, enhances or maintains market power or otherwise harms vigorous rivalry among firms. [C]ompetition law may result in limitations on the terms and conditions under which the owners of IP rights may transfer or license the use of such rights to others, and on the identity of those to whom the IP is transferred or licensed[.]”

—Canada Competition Bureau, ‘Intellectual Property Enforcement Guidelines’



“ Intellectual property law bestows on the owners of intellectual property certain rights to exclude others. These rights help the owners to profit from the use of their property. An intellectual property owner’s rights to exclude are similar to the rights enjoyed by owners of other forms of private property. As with other forms of private property, certain types of conduct with respect to intellectual property may have anti-competitive effects against which the antitrust laws can and do protect. Intellectual property is thus neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them. ”

—US Department of Justice and Federal Trade Commission, ‘ Antitrust Guidelines For The Licensing Of Intellectual Property’ (1995)

When can and should a certain practice of an IP owner, when undertaken to decrease competition and obtain high profits, be held to violate competition laws?

Countries have the authority under international law to fashion their own doctrines and approaches to the interface between IP and competition laws.¹ The question is one of policy—when **should** an LMIC seek to use competition law to restrict a given exclusionary or exploitative practice by an IP holder?

IP and competition laws are most commonly, but not exclusively (see Box 1.1), justified in economic terms. In principle, both IP policies and competition laws can promote consumer welfare by enhancing economic efficiency. The two fields focus on different means to this end. Competition laws have as a primary concern, the creation of optimal competition between producers of products to promote short-term ‘static efficiency’ in the form of the lowest possible prices for products. The idea pursued by competition law is that in a fully competitive environment new producers will continue to enter a market in competition with existing producers until a given product is sold at the marginal cost of its production—benefiting consumers with the lowest possible prices for the good. This in turn raises consumption—all consumers who value a good at a high enough level to pay for its costs of production will be able to enjoy it. Competition can also promote longer term ‘dynamic efficiency’ in the form of innovation of new products not already offered in the market. Firms in a competitive market will seek to benefit from ‘first mover’ and other advantages of offering new products to attract more consumers.²

1. See Chapter 2.

2. See Jonathan B. Baker, Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation, *Antitrust Law Journal*, Vol. 74, 2007.



BOX 1.1: Social and economic purposes of competition law

Competition laws in LMICs often seek to promote a range of social and developmental purposes, and these purposes are legitimately considered in the interpretation of any competition law.³ The South African Competition Act, for example, is intended to “advance the social and economic welfare of South Africans,” “correct structural imbalances and past economic injustices” and “reduce the uneven development, inequality and absolute poverty which is so prevalent in South Africa.”⁴

Interpretation and enforcement of competition law may also be a key ‘available resource’ that can and should be used to promote the fulfilment of international and national rights to the highest attainable standard of health and the right to benefit from the products of science.⁵

IP laws, and especially patents, are often explained as serving dynamic efficiency concerns at the expense of static aims. Such laws allow a certain degree of exclusion from competition, which allows the firm to raise prices higher than would occur in a competitive market. Patent laws permit these reductions in static efficiency to encourage investment in research and development (R&D) of new products and processes. The new products benefit consumer welfare by delivering new items of consumption that would not have existed otherwise.

In an ideal policy environment, the tools of IP protection and promotion of competition would be perfectly balanced. A society would provide only that monopoly protection for a new innovation that was absolutely necessary to provide the incentive for its creation. In this environment, consumer welfare would be maximized—there would be no more harm to static efficiency from higher prices than was needed to incentivize the creation of new products. Where competitive forces were better at promoting innovation, competition would be preferred, and the length of monopoly rights for such innovations would be set to zero.⁶

One set of means to tailor IP protection to best promote aggregate consumer welfare is through policy tools internal to IP law. Prior to the establishment of the World Trade Organization (WTO) and its enabling agreements, including its Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), countries were free under international law to exclude some industries from IP protection either completely or on a limited basis. In the field of pharmaceuticals for example, many

3. See E.M. Fox, ‘Equality, Discrimination, and Competition Law: Lessons from and for South Africa and Indonesia’, *Harvard International Law Journal*, 2000, 41: 579.

4. Department of Trade and Industry, ‘Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development’, Department of Trade and Industry 2.4.11, Pretoria, 27 November 1997.

5. See Committee on Economic, Social and Cultural Rights, ‘General Comment No. 14: The right to the highest attainable standard of health’, E/C.12/2000/4, Committee on Economic, Social and Cultural Rights, Geneva, 2000, <http://www.unhchr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En>; United Nations General Assembly, ‘International Covenant on Economic, Social and Cultural Rights’, United Nations, New York, 1966, <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>.

6. See Jonathan B. Baker, *Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation*, *Antitrust Law Journal*, Vol. 74, 2007.



countries around the world exempted pharmaceutical technologies from patent protection; others had special compulsory licensing programmes to lessen their monopoly effect. Today the TRIPS Agreement bans ‘discrimination’ by field of technology and requires that all patent terms, including for pharmaceutical technologies, be the same (20 years). The TRIPS Agreement allows, however, and most domestic laws have, compulsory licence regimes that permit governments to promote competition to serve the public interest.

Another policy tool available to governments to balance intellectual property monopolies with the public interest lies in the interaction between IP and competition law. The TRIPS Agreement allows, however, and most domestic laws have, compulsory licence regimes and other limitations and exceptions to patent rights that permit governments to promote competition to serve the public interest.

The different potential applications of the IP–competition interface can be charted along a spectrum. At one end, competition norms can be established as dominant over IP rights—with IP rights subject to the same or heightened standards for refusing to deal, excessive pricing, contractual restrictions on competition (tying, resale restrictions etc.) as are applied to other forms of property. At the other end of the spectrum, IP rights may be established as dominant—granting complete immunity from competition law claims that may ordinarily arise from similar uses of other property. Here, IP owners would be free, for example, to enforce tying, resale requirements and other contracts that would be per se illegal if practised by a non-IP-holding dominant firm.

Where a particular country’s law falls along the spectrum is a matter of policy choice. Such policy should be made in reference to the underlying policy aims of each doctrine. Countries should select policies towards the competition law-dominant side of the spectrum where the exercise of monopoly harms consumer welfare—in terms of both higher prices and reduced innovation—more than it benefits consumer welfare through increased incentives to innovate.⁷

In the specific case of monopoly rights on essential health technologies in LMICs, the balance between short- and long-term efficiency concerns will often favour the competition law-dominant side of the spectrum. On the one side of the balance, it is well accepted among economists that most LMIC markets play little role in providing sufficient rewards to incentivize pharmaceutical research and innovation for consumers in those countries. While patents in wealthy countries may provide incentives for innovation for consumers in those markets, consumers in LMICs normally receive the benefits of innovation only where their interests are aligned with those of the wealthy consumers in countries. The difficulty in striking the balance is that such innovation markets are global, and the economies of most LMICs represent relatively small portion of global income. The

7. Louis Kaplow framed the question in terms of a “ratio between the reward the [IP holder] receives when permitted to use a particular restrictive practice and the monopoly loss that results from such exploitation” (L. Kaplow, ‘The Patent-Antitrust Intersection: A Reappraisal’, *Harvard Law Review*, 1984, 97: 1813, 1816). See also H. Hovenkamp, M.D. Janis and M.A. Lemley, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Aspen Publishers, New York: 1–10 (2nd ed. 2010 and Supp. 2012) (calling for “balancing the social benefit of providing economic incentives for creation and the costs of limiting diffusion of knowledge”).



36 countries classified by the World Bank as low-income countries, which are home to 2.4 billion people, account for just 3.3 percent of global Gross Domestic Product (GDP).⁸ While there is substantial wealth in middle-income countries (about 20.7 percent of global GDP), there are high levels of income inequality with the bulk of wealth located in the hands of a few. One effect of this inequity in the global distribution of income is that there is negligible investment in R&D for health technologies particularly for the health needs of LMICs.⁹ For instance, a *Lancet* article revealed that in a 30-year period between 1975 and 2004, only 21 drugs targeting neglected diseases were introduced into the market out a total of 1556 new drugs, or only 1.3 percent.¹⁰ In contrast, these neglected diseases, which include malaria and TB, account for 11.4 percent of the world's disease burden.¹¹ From a purely economic point of view, it has been posited that aggregate global welfare is increased when poor countries are allowed to free ride on the investments in R&D of wealthier countries.¹² This is because, in large part, patented products would normally have been created without the added prices paid by people in poorer countries (i.e. there is relatively low impact on R&D incentives) and because the marginal utility of income saved in poorer countries is higher than in wealthy countries.

On the other side of the policy balance, the cost of market exclusivity for pharmaceuticals in poor countries can be extreme. In many LMICs, there is often a small wealthy segment of the population with high willingness and ability to pay, and a great majority who are so poor that even a small price increase will force them to give up the purchase. In such markets, the most profit can often be captured by a monopolist by serving only the wealthy sliver of the population, leaving the great majority unserved.¹³

Given these characteristics of global markets, the profit-maximizing behaviour of a firm with no duties to license other firms, and no duty to avoid excessive pricing, would be likely to pursue relatively uniform high global pricing. In high-income countries the firm might set prices to serve most of the market, but in a middle- or low-income country with high income inequality only the very wealthy would be able to afford the product. In simple terms, the cost of the monopoly in such countries will be to price the great majority of the population out of access to the medicine.

8. A. Shah, 'Poverty Facts and Stats', *Global Issues*, 7 January 2013, <http://www.globalissues.org/article/26/poverty-facts-and-stats>.

9. See UK Commission on Intellectual Property Rights, 'Integrating Intellectual Property Rights and Development Policy', Commission on Intellectual Property Rights, London, 2002: 32–33, http://www.iprcommission.org/papers/pdfs/final_report/cipr-fullfinal.pdf.

10. P. Chirac and E. Torreele, 'Global framework on essential health R&D', *Lancet*, 2006, 367(9522): 1560–1561.

11. J.-R. Ioset and S. Chang, 'Drugs for neglected disease initiative model of drug development for neglected diseases: current status and future challenges', *Future Medical Chemistry*, September 2011, (3–11): 1361–1371.

12. See F.M. Scherer, 'Global Welfare in Pharmaceutical Patent Policy', *Federal Reserve Bank of Philadelphia Working Paper*, No. 03-11, Federal Reserve Bank of Philadelphia, Philadelphia, 2003, <http://www.phil.frb.org/research-and-data/publications/working-papers/2003/wp03-11.pdf>.

13. Flynn, Hollis and Palmedo describe this problem as one characterized by overly 'convex' demand curves. The authors explain: "Convexity indicates that some segment of the market (the flatter part of the demand curve) will be highly elastic—giving up the purchase with a slight price increase. Another segment of the market is likely to be more inelastic—willing to pay much higher prices for access. ...Attempting to capture a significant portion of the flat/elastic part of the demand curve is unprofitable. There, small price increases knock large numbers of consumers out of the market. The monopolist will target its price toward the steep end of the curve where large price increases will cause minimal decreases in additional sales" (S. Flynn, A. Hollis and M. Palmedo, 'An economic justification for open access to essential medicine patents in developing countries', *Journal of Law, Medicine & Ethics*, 2009, Summer; 37(2): 184–208).



The pricing of HIV medicines has been a case in point. In the late 1990s, originator pharmaceutical companies priced their products at over \$10,000 per patient per year in nearly every country. After a global campaign challenged the fact that patents were causing high prices and blocking access to the vast majority of people living with HIV in LMICs, suppliers began implementing price discrimination between countries. But the prices remained exceedingly high in many LMICs. In South Africa's Hazel Tau case (see Annex and Chapter 4), well after suppliers implemented preferred pricing programmes, the branded prices for a patented treatment were the equivalent of a quarter of the annual income of a household in the top 20 percent income bracket, and completely unaffordable for the remaining 80 percent (at least) of the country. With no public treatment programme in place, these prices effectively wrote off at least 80 percent of the entire country as deadweight loss.¹⁴

The implications of the above scenario, which lead to the death of millions of people who could not afford antiretroviral treatment, reaffirms the general finding of this guidebook, namely, that LMICs should adopt standards particular to their context. Directly copying the same standards and interpretations adopted by high-income or industrialised countries—where the exclusionary practices of pharmaceutical firms may not have the same anti-competitive impacts—neither enables LMICs to effectively respond to public health threats—or leads to better innovation outcomes for LMICs. The potential for great social and economic harm from anti-competitive practices by dominant firms in pharmaceutical markets, paired with the minimal incentives that such markets provide for global innovation, lead to the conclusion that LMICs should consider adopting policies and enforcement priorities that are on the competition law-dominant side of the enforcement spectrum. In this context, it will be generally preferable for LMIC officials to implement IP and competition laws to favour duties to license and constraints on pricing and other exploitative behaviour. The standards presented in subsequent chapters of this guidebook generally follow from this policy perspective.

14. The pricing in India's Natco compulsory licensing case (see Annex) is even more extreme, with the annual price of over US \$62,000 per year, amounting to 41 times the average per capita income in the country.



Comparative perspectives through country case studies

1. Early history

For centuries, authorities have sought to balance the rights of inventors with those of the consumer. The word ‘patent’ emerged from King Edward’s *quo warranto* campaign to regulate, rather than enable, excessive pricing by the holders of royal franchises. The name ‘*quo warranto*’ derives from the Latin: ‘by what authority?’. The campaign was so named because it required franchise holders to receive a ‘letter patent’ (Anglo-Norman *lettre patente*: ‘open letter’) designating any franchise to be free from competition in a certain activity. The purpose of the decree was to allow an enforcement of laws against excessive pricing—the letter was to be revoked from those that charge “outrageous Toll, contrary to the common Custom of the Realm.”

Mandates to balance between exclusionary rights and reasonable pricing were common through the development of patent law over the following several centuries. The 17th century British Statute of Monopolies, for example, included the requirement that the use of a ‘letter patent’ for new and useful inventions “be not contrary to the Laws nor mischievous to the State, by raising prices of Commodities at home.” Laws setting out the conditions for using a patent in compliance with local commercial laws became known as ‘working’ requirements. The Paris Convention for the Protection of Industrial Property of 1883 explicitly referenced such requirements, instructing that “the patentee shall remain bound to work his patent in conformity with the laws of the country into which he introduces the patented objects.” Patents granted by US states in colonial times, before the Constitution federalized the power, often contained within them duties to refrain from excessive pricing.

2. USA

The interpretation of the US competition law in IP cases has varied substantially over time. The IP laws pre-dated the Sherman Antitrust Act by over 100 years. The Sherman Act of 1890 was passed “to protect the consumers by preventing arrangements designed, or which tend, to advance the cost of goods”. Section 1 prohibits “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce”. Section 2 makes it a crime to “monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce”. Some of the earliest decisions under the Act made clear that every contract restrains trade in some way, and, therefore, it would only be contracts that “unreasonably” restrain trade that would be prohibited under the Act. Much of the ensuing case law under the Sherman Act has been concerned with identifying such cases of unreasonable restraint.



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. A large number of restrictive licensing practices (See Chapter 3 for examples) were deemed to be prohibited as per se (outright) violations of competition law. Many of the cases used an analysis identifying whether the given practice was an exercise or extension of market power “beyond the scope of the patent”. The reach of antitrust law in this area is commonly said to have peaked in the 1970s with US enforcement agencies’ use of ‘Nine No-No’s’: a list of IP licensing practices deemed to be per se illegal.¹

Despite its history in seeking to limit the privileges of patent holders, US law today is commonly described as being in an era of IP maximalism. Relative to the 1970s, there has been a dramatic increase in the length, scope and enforceability of statutory IP rights. This has been accompanied by a shift of most licensing and other potentially anti-competitive practices involving IP being reviewed under the ‘rule of reason’ rather than per se standards.²

The current enforcement policies with respect to IP licensing practices are expressed in two guidance documents from the Federal Trade Commission and Department of Justice. Despite the general shift of law and policy toward the IP-dominant side of the spectrum, the federal agencies still do not endorse any wholesale exemption of IP matters from the competition laws. They rather treat the use of IP in a similar way to how they would treat the use of “any other form of property”.

BOX 1.a.1: US Department of Justice antitrust guidelines

The US Department of Justice and Federal Trade Commission, ‘Antitrust Guidelines for the Licensing of Intellectual Property’ (6 April 1995) describe three basic principles for interpreting competition law requirements applicable to uses and licensing of IP:

- a) for the purpose of antitrust analysis, the agencies regard IP as being essentially comparable to any other form of property;
- b) the agencies do not presume that IP creates market power in the antitrust context; and
- c) the agencies recognize that IP licensing allows firms to combine complementary factors of production and is generally pro-competitive.

US competition law differs from the European model and that of many LMICs in that it does not regulate the exploitation of monopoly power unless there is conduct that maintains or extends such power through exclusionary conduct. Thus, for example, the US law does not regulate excessive pricing as such. One contentious and largely unresolved issue in current US law is the extent to which competition law duties banning ‘refusals to deal’ with competitors apply to refusals to license IP.

1. See Charles M. Haar and Daniel Wm. Fessler, *The Wrong Side of the Tracks: A Revolutionary Rediscovery of the Common Law Tradition of Fairness in the Struggle Against Inequality*, 55–78 (1986).
2. See Oren Bracha, *Symposium: Intellectual Property at a Crossroads: The Use of the Past in Intellectual Property Jurisprudence: The Commodification of Patents 1600-1836: How Patents Became Rights and Why We Should Care*, 38 *Loy. L. A. L. Rev.* 177, 188-89 (2004).



The US Patent Act affirmatively states that a patent holder has not misused its rights merely because it “refused to license or use any rights to the patent”. How this standard applies to dominant firms that would otherwise be under a duty to deal with competitors is left unresolved in the legislation, however. One appellate court held that a refusal to license a patent may be a violation of competition law if the patent-holding firm is dominant in a market (e.g. the market for machines) and uses the refusal to extend dominance into a downstream market (e.g. the repairs market) without a legitimate business justification. Another court on similar facts refused to recognize a duty to license.³

The enforcement agencies’ ‘Antitrust Guidelines’ explain that their “general approach in analyzing a licensing restraint under the rule of reason is to inquire whether the restraint is likely to have anti-competitive effects and, if so, whether the restraint is reasonably necessary to achieve procompetitive benefits that outweigh those anti-competitive effects”. The agencies have instructed that, as they interpret Section 271(d)(4) of the Patent Act quoted above (stating that it is not abuse to refuse to license or use any rights to the patent), it “does not create antitrust immunity for unilateral refusals to license patents”. The agencies generally opine, however, that “[a]ntitrust liability for mere unilateral, unconditional refusals to license patents will not play a meaningful part in the interface between patent rights and antitrust protections.” Conditional refusals to license, on the other hand, such as where the licence is conditioned on the acquisition of a licence to another patent or purchase of a separate product, can more frequently be found to cause competitive harm and “are subject to antitrust liability”. The agencies have also indicated that they will scrutinize licensing arrangements where they extend market power from one market to the next, explaining:

“[L]icense restrictions with respect to one market may harm such competition in another market by anti-competitively foreclosing access to, or significantly raising the price of, an important input, or by facilitating coordination to increase price or reduce output.

...A licensing arrangement may have competitive effects on innovation that cannot be adequately addressed through the analysis of goods or technology markets. For example, the arrangement may affect the development of goods that do not yet exist. Alternatively, the arrangement may affect the development of new or improved goods or processes in geographic markets where there is no actual or likely potential competition in the relevant goods.”⁴

3. European Union

Unlike in the United States, EU competition law bans “exploitative” conduct by firms that lawfully acquired market power (see Chapter 3 for examples).⁵ As a prime example, EU law prohibits firms with market power from directly or indirectly imposing “unfair purchase or selling prices or other

3. Compare *Image Technical Services, Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1209 (9th Cir. 1997) with *In re: Independent Service Organizations Antitrust Litigation* (CSU et al. v. Xerox Corporation), 203 F.3d 1322 (2000).

4. See Bellamy and Child, *European Community Law of Competition*, 9-072 (PM Roth ed. 2001).

5. See Parke, *Davis v Probel*, [1968] CMLR 60 para 5; Anderman, *EC Competition Law and Intellectual Property Rights, The Regulation of Innovation*, at 230 (Clarendon Press Oxford 1998) (discussing cases).



unfair trading conditions". In cases not involving IP, EU courts have held that the provision bans a dominant firm from charging a price "appreciably higher" than would be possible in a competitive situation. To determine when prices are excessively high, courts have compared prices charged by the respondent to estimates of production costs and to prices in other markets or for similar products.

Courts have opined that the EU excessive pricing prohibition can be applied to IP owners, but also that IP right holders may charge prices that are higher than the competitive price would be absent their exclusive rights. Enforcement officials have further advised that the assessment of costs for an IP-protected good must include an adequate return on investments in R&D, as well as an allowance for recouping the costs associated with failed investments in R&D. In practice, the task is likely to be exceedingly difficult, and a successful case is "not likely to affect IPR owners unless their conduct is egregiously and demonstrably excessive in the light of their own previous conduct".

Excessive pricing of intermediary products can be exclusionary. Such cases have been suggested, for example, where a dominant firm excessively prices spare parts with the effect of blocking the development of secondary repair markets.

EU cases have developed a fuller set of standards than exist under US law to be used in determining when a unilateral refusal to license IP may be illegal under competition law. These standards have been developed in interpretation of Article 82(b) of the European Commission Treaty which states that an illegal abuse of a dominant position "may, in particular, consist in... (b) limiting production, markets or technical development to the prejudice of consumers". Under this norm, the European Court of Justice (ECJ) has recognized that a refusal to license in and of itself does not violate competition law.⁶ But in a series of cases, summarized in the box below, EU courts have held that IP owners have a duty to license technology or sell protected products at least when a refusal would either harm competition in a secondary market not itself protected by the IP right or prevent the appearance of a new innovative product not supplied by the IP owner and for which there is potential consumer demand.

BOX 1.a.2: Judgments by the European Court of Justice against monopolies

AB Volvo v Erik Veng (UK) Ltd., Case 238/87

The ECJ affirmed that the car maker could lawfully use its design and other rights over various car parts to monopolize the primary market for those protected goods. But it further opined that there could be liability if it engaged in "arbitrary refusal to supply parts to independent repairers" or "the fixing of prices for spare parts at an unfair level" so as to damage the development of secondary car repair markets dependent on such supplies. The concept of abuse at issue here is that the firm that is dominant in the primary market is prohibited from 'leveraging' its market power to the secondary market through actions that would unduly harm existing competitors or exclude new entrants.

6. Volvo v Erik Veng [1988] E.C.R. 6211.



BOX 1.a.2 (continued)

RTE v Commission ('Magill'), 1995 ECR I-743

Magill sought to publish a combination television guide featuring the copyrighted listings of various broadcasters which each supplied their own individual guides. The ECJ ultimately held that the refusal to license violated Article 82(b) because of the “exceptional circumstances” that there was potential consumer demand for the new product, the company had a *de facto* monopoly over the listings, the licence was an indispensable input for the new product, and the copyright holders did not themselves offer the new product to consumers. The opinion is often cited as establishing the viability of an ‘essential facility’ doctrine in EU law—accessing the copyright licences under question being essential to the production of the combination guide sought to be produced.

BOX 1.a.3: IMS Health v. NDC Health, Case C-418/01 (2004)

IMS, a firm providing marketing data on pharmaceutical sales around the world, developed a map of Germany segmented into geographic reporting known as the ‘1860 Brick Structure’. It copyrighted that structure and refused to licence it to other potentially competing firms. National Data Corporation (NDC) attempted to develop its own brick structure but discovered that customers and suppliers of data insisted on using the 1860 Brick Structure. IDC complained to the Commission. The case ultimately reached the ECJ on referral from a German court asked by IMS to enforce its copyright against NDC. The ECJ articulated standards for assessing whether IMS’s refusal to grant a licence to NDC contravened Article 82. The ECJ explained that the “exceptional circumstances” present in the Magill case, where a new product in a secondary market is blocked by a refusal to license, are not exhaustive of the situations in which IP may be required to be licensed under Article 82. The Court explained that the refusal by a dominant firm to license an IP right may constitute an abuse where: (1) the potential licensee seeks to offer new products or services not offered by the copyright owner and for which there is a potential consumer demand; (2) the refusal is not justified by objective considerations; and (3) the refusal is such as to reserve to the copyright owner the market, eliminating all competition on that market. Importantly, the court stated that the IMS refusal to license may contravene Article 82 even though NDC sought to create a directly competing product in the same market as IMS. The ECJ ultimately explained that it was for the national court to decide the indispensability of the licence in this case.

Although the standards above have been applied to other cases of blocking copyrights—including to require Microsoft to license interoperability with its systems to another software provider—there has not yet been a case in the EU applying similar reasoning to the case of patents or the particular case of patents on medicines.



4. Canada

Canada has long imposed obligations to license patents through both its patent and competition laws. These obligations have historically been far more assertive than the standards in the United States or the EU.

Canada's 1969 amendment to the Patent Act created a presumption in favour of granting compulsory licences for health technologies, after a series of competition inquiries. The presumption for compulsory licensing was taken out of the Patent Act in 1992 at the time of the country's entry into the North American Free Trade Agreement (NAFTA). Canada's current Competition Law, however, continues to contain a process for authorizing compulsory licensing for patents for a broad range of competitive infractions.

BOX 1.a.4: Canada's Competition Act on abuse of patent privileges

Competition Act

32. (1) In any case where use has been made of the exclusive rights and privileges conferred by one or more patents for invention, by one or more trade-marks, by a copyright or by a registered integrated circuit topography, so as to:

- (a) limit unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any article or commodity that may be a subject of trade or commerce,
- (b) restrain or injure, unduly, trade or commerce in relation to any such article or commodity,
- (c) prevent, limit or lessen, unduly, the manufacture or production of any such article or commodity or unreasonably enhance the price thereof, or
- (d) prevent or lessen, unduly, competition in the production, manufacture, purchase, barter, sale, transportation or supply of any such article or commodity,

the Federal Court may make one or more of the orders referred to in subsection (2) in the circumstances described in that subsection.

(2) The Federal Court, on an information exhibited by the Attorney General of Canada, may, for the purpose of preventing any use in the manner defined in subsection (1) of the exclusive rights and privileges conferred by any patents for invention, trade-marks, copyrights or registered integrated circuit topographies relating to or affecting the manufacture, use or sale of any article or commodity that may be a subject of trade or commerce, make one or more of the following orders:

- (a) declaring void, in whole or in part, any agreement, arrangement or licence relating to that use;
- (b) restraining any person from carrying out or exercising any or all of the terms or provisions of the agreement, arrangement or licence;



BOX 1.a.4 *(continued)*

- (c) directing the grant of licences under any such patent, copyright or registered integrated circuit topography to such persons and on such terms and conditions as the court may deem proper or, if the grant and other remedies under this section would appear insufficient to prevent that use, revoking the patent;
- (d) directing that the registration of a trade-mark in the register of trade-marks or the registration of an integrated circuit topography in the register of topographies be expunged or amended; and
- (e) directing that such other acts be done or omitted as the Court may deem necessary to prevent any such use.

The Canadian Competition Bureau's 'Intellectual Property Enforcement Guidelines' explain that "[t]he circumstances in which the Bureau may apply the Competition Act to conduct involving IP or IP rights fall into two broad categories: those involving something more than the mere exercise of the IP right, and those involving the mere exercise of the IP right and nothing else."

With respect to the grounds on which a compulsory licence may be granted for anti-competitive conduct, the Guidelines explain that "in very rare circumstances... the mere exercise of an intellectual property right may raise competition concerns". In reference to such "rare circumstances" the Guidelines elaborate that Canadian law "requires that... the competitive harm should follow directly from the refusal to license", and that "the Federal Court is to balance the interest of the system of protection of intellectual property and the incentives created by it against the public interest in the market under consideration and competition in general." The Guidelines therefore advise:

"The Bureau will first have to determine that the holder of the intellectual property is dominant in the relevant market and that the intellectual property is an essential input, and that the refusal to license prevents competition in the relevant market; and secondly, that the refusal to license is stifling further innovation and that by invoking a special remedy against the intellectual property right holder will not adversely affect the incentive to invest in innovation markets."

5. South Africa

South Africa's Competition Commission has investigated several cases involving the interface of IP and competition concerns, particularly in cases where complaints of excessive pricing and refusals to license competitors have been alleged. The landmark case in South Africa arose out of a September 2002 complaint by Hazel Tau and the South Africa Treatment Action Campaign (TAC) and others against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI), suppliers of the first-line antiretroviral medicines zidovudine and lamivudine.



In the Hazel Tau case, the prices for antiretroviral medicines from the patent holders were, at the time, from three to ten times higher than the least expensive generic version of the same medicines. There had been requests for licences by generic pharmaceutical producer Cipla and from the medical services humanitarian organisation, Médecins Sans Frontières (MSF, or Doctors without Borders). Respondents admitted in documents filed with the South African Competition Commission that it had a general policy to refuse licences for the generic supply of its products. It also admitted that its prices were unaffordable by at least 80 percent of all South Africans.

The case resulted in an order of the Commission finding that high prices and a refusal to license Indian generic manufacturers constituted three abuses of dominance under Section 8 of the Competition Act: (a) excessive pricing; (b) refusing to give a competitor access to an essential facility, when it is economically feasible to do so; and (c) engaging in exclusionary conduct if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gains. In reference to remedy, it stated that it would “request the Tribunal to make an order authorising any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty”.

The South African Competition Commission has not issued specific guidelines on application of the Competition Act to IP. However it has explained its general approach in its publication *The Competition Act: An Introduction*.⁷ That publication explains that “firms are not automatically exempted from the rules of the Competition Act as a result of the rights granted in terms of laws like the intellectual property laws”; “firms cannot be automatically allowed to continue with a particular prohibited practice as outlined in the Competition Act because that practice is allowed by another Act.” The publication further states that the general approach of the Canadian Competition Bureau’s guidelines for refusal to license cases would be “applicable to the South African legislative and economic circumstances”. It described this analysis as including the following steps:

1. Identify the transaction or conduct.
2. Define the relevant market.
3. Establish whether the firm involved has market power.
4. Determine if the transaction would lessen competition in the relevant market.
5. Consider efficiency rationales.

In balancing the costs and benefits to competition of a given practice enabled by intellectual property in steps 4 and 5 of the analysis, the Competition Commission describes four relevant factors to take into account, listed below. The most important of the factors is likely to be the last – i.e. that conflicts between intellectual property rights and competition mandates should be resolved according to the extent to which the “long-term pro-competitive benefits” of a practice outweigh its “short-term ‘anti-competitive’ effects.”

7. Available at <http://www.compcom.co.za/assets/Uploads/AttachedFiles/MyDocuments/Nov-01-The-Competition-Act-An-Introduction-Book1.pdf>.



BOX 1.a.5: The Competition Commission of South Africa, the Competition Act: an introduction

The Competition Commission would consider the following principles when analysing a situation with an interface between intellectual property rights and competition law:

1. Competition law should recognise the basic rights granted under intellectual property law. The creation and maintenance of innovation markets are necessary for economic progress and development.
2. Intellectual property does not necessarily create market power.
3. A practice involving intellectual property should not be prohibited if the practice leads to a less anti-competitive situation than without the said practice.
4. The long-term pro-competitive benefits should outweigh the short-term 'anti-competitive' effects of intellectual property rights.

6. India

India's Patent Law was amended in 2005 to comply with the WTO TRIPS Agreement, which provides the minimum standards of protection required by WTO Members. In doing so, Indian authorities adopted several standards that authorize compulsory licences for the specific purpose of responding to high prices or health needs with respect to needed health technologies.

BOX 1.a.6: Indian Patent Act (2005)

83. General principles applicable to working of patented inventions—Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely: —

- (a) That patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
- (b) That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- (c) That the protection and enforcement of patent rights 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;
- (d) That patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
- (e) That patents granted do not in any way prohibit Central Government in taking measures to protect public health;



BOX 1.a.6 (continued)

- (f) That the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
- (g) That patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

...

84(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—

- (a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,—
 - (i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading manufacturing in India is prejudiced; or
 - (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or
 - (iii) a market for export of the patented article manufactured in India is not being supplied or developed; or
 - (iv) the establishment or development of commercial activities in India is prejudiced; or
- (b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or
- (c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing, or
- (d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or
- (e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by —
 - (i) the patentee or persons claiming under him; or
 - (ii) persons directly or indirectly purchasing from him; or
 - (iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.



An Indian compulsory licensing example: sorafenib

Bayer received a patent on a cancer pain medication, Nexavar (sorafenib), in India in 2008. Thereafter, it set the price in India at over INR280,000 a month (approx. US \$5200) at the time, and over the next few years shipped a negligible amount of the drug to India for commercial sales (serving less than 2 percent of the total demand). The majority of sales of the drug in India was supplied by the Indian firm Cipla, whom Bayer was suing for patent infringement. In June 2010, another generic firm, Natco, requested a voluntary licence from Bayer to market a generic version of the drug for INR10,000 a month (approx \$180). The voluntary licence was rejected, and Natco successfully petitioned the Controller General of Patents for a compulsory licence at a 6 percent royalty rate on net sales. On appeal, the decision of the Controller was upheld by the Intellectual Property Appellate Board (IPAB).

The IPAB affirmed the compulsory licence on the central issues. In doing so, it found the “reasonable requirements of the public” standard in Section 84 must be read against the requirement to supply at a “reasonably affordable” price in section 83: “The failure to meet the demand on reasonable terms must logically mean both quantity and price” (Para. 38).

The IPAB rejected Bayer’s argument that the price should be considered reasonable viewed against a claim in an unsupported affidavit that “R&D investments of more than €2 billion are required to bring a new molecular entity (NME) on to the market” (Para. 36). The IPAB found that these figures are “neither particular to the drug nor to India” (Para. 41), and in any case disregarded their relevance under the statute, explaining:

“The reasonably affordable price necessarily has to be fixed from the view point of the public and the word, ‘afford’ itself indicates whether the public can afford to buy the drug and therefore, we must consider this question from the view point of whether Rs.280,000/- per month is a reasonably affordable price to the public. All the evidence filed by the appellant; the affidavits, the reports, etc. relating to the cost are not relevant to decide what the public can reasonably afford.”

The IPAB found that the high price of the drug (over \$5000 a month in a country where GDP per capita is about \$1500 a year) is a significant factor in the miniscule sales in the country, making the drug eligible for a compulsory licence based on a failure to meet the reasonable requirements of the public.



Intellectual property and competition—room to legislate under international law

Carlos M. Correa

KEY MESSAGES

- ▶ Competition law may serve a variety of policy objectives, including protection of consumers and promoting industrial development.
- ▶ The WTO Agreements, including the TRIPS Agreement, provide LMICs with wide flexibility to develop and implement competition laws that address intellectual property-related restraints, including abuse of patents, restrictive licensing conditions and restraints on transfers of technology.
- ▶ Authorization of parallel importation of intellectual property-protected health technologies is a pro-competitive policy.
- ▶ Compulsory patent licensing is an acknowledged remedy for anti-competitive practices under the TRIPS Agreement, which provides specific supplementary flexibilities for such licences.
- ▶ Bilateral and regional free trade agreements so far do not significantly restrain competition policy options for LMICs, but caution should be exercised in negotiating new provisions.

Introduction

IP legislation may contain some elements (sometimes called ‘safeguards’) to mitigate the legal power conferred by the exclusive rights that title holders normally enjoy. Those elements include exceptions to the exclusive rights, compulsory licences and the principle of exhaustion of rights. These safeguards are often put in place and used to balance and protect the right of inventors with the rights of society to benefit from the fruits of invention—often in general respect of protecting the ‘public good’ and often specifically for protecting public health. They may not be sufficient, how-



ever, to prevent an adverse impact of such rights on consumers and, particularly, patients, when there is an abusive exercise of IP rights. Competition law can be applied to address these situations.

While the TRIPS Agreement has set out minimum standards of IP rights protection that significantly limit the freedom of the WTO Members to legislate on a large number of IP rights issues, competition law is in a significantly different situation. There is an important body of national administrative and judicial precedents, doctrinal work and guidelines, particularly in developed countries, which delineate principles and conditions for the application of competition law in relation to IP.

However, despite some attempts examined below, there are no binding international rules limiting the policy space to design national disciplines on competition law. So far, only non-binding principles have been internationally agreed. Hence, countries are free to design the competition laws in accordance with their domestic interests and needs, taking their level of development into account, subject only to the limitations arising from the territorial applicability of such laws.

Despite the considerable degree of flexibility all countries enjoy against their international obligations, in respect of competition law and policy, many LMICs have not implemented competition regimes. Furthermore, where these regimes are in place, enforcement issues remain—for a variety of reasons, but often tied to financial and capacity resource constraints. Therefore, most LMICs lack the capacity to use competition law to achieve public health objectives, and examples of LMICs using the flexibilities concerning competition law under the TRIPS Agreement to address IP rights-related anti-competitive practices are extremely limited.

This chapter¹ briefly examines, first, the significant diversity that currently exists with regard to the objectives, scope and remedies in different national competition laws. Second, it reviews international developments in the field of competition law in the context of the United Nations and in the General Agreement on Tariffs and Trade (GATT)/WTO framework. Third, the content and scope of competition-related provisions incorporated into the TRIPS Agreement are analysed. Finally, the chapter reviews the competition law components in free trade agreements (FTAs).

Diversity in competition law

While the expression ‘competition law’ is generally used to describe a set of rules aimed at addressing anti-competitive behaviour associated with the existence of market-dominant positions and restrictive business practices,² the competition regimes significantly vary across countries with

1. Some information and analysis in this chapter is partially based on C. Correa, ‘Competition law and development policies’, in Roger Zäch (ed.), *Towards WTO Competition Rules. Key issues and comments on the WTO Report (1998) on Trade and Competition*, Staempfli Publishers Ltd, Kluwer Law International, The Hague, London, Boston, 1999; and C. Correa, *Trade Related Aspects of Intellectual Property Rights (Volume VI of Commentaries on the GATT/WTO Agreements)*, Oxford University Press, Oxford, 2007.
2. See Chapter 3.



regard to objectives, scope and remedies used to deal with such behaviour. That variation can even be found over time within a country.

Some national competition laws focus on the effects of regulated conducts on **competitors**, while others on **competition** as such. Consumers (and not just competitors) are protected to a different extent under various national regimes. For instance, the approaches of the United States and the EU differ in the treatment of dominant firm conduct; for instance, the US antitrust statutes have no equivalent to the excessive pricing prohibition under EU rules.³ In the EU, economic integration has been a primary objective, while the development of the national economy has been an explicit objective of South Korean competition law.⁴ In fact, it is “not possible to point to a universally acknowledged, single goal for competition law”.⁵

Diversity in national competition laws reflects different economic, social and cultural needs and interests, which influence and separate national systems.⁶ In particular, the role of competition law is likely to differ depending on levels of development, market size and national policies.⁷ For instance, shielding companies from competition to protect infant industries in an early stage of industrialization may limit the intervention of competition authorities, as was the case in South Korea during the 1980s.⁸ In LMICs the protection of consumers (e.g. in relation to excessive pricing of health technologies) could be instituted as a primary objective of competition law.

Disparate treatment of anti-competitive acts stems in many cases from the interpretation given to basic concepts such as ‘relevant market’, ‘dominant position’ and ‘abuse’. The different objectives and approaches applied in various national jurisdictions have practical implications, as has been the case with the treatment of abuses of a dominant position and vertical restraints under the US and EU regimes.⁹

3. See, for example, W. Kovacic, ‘Competition policy in the European Union and the United States: convergence or divergence in the future treatment of dominant firms?’, *Competition Law International*, October 2008; H. Hovenkamp, M.D. Janis and M.A. Lemley, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, Aspen Publishers, New York, 2008.

4. “Article 1. Purpose. The purpose of this Act is to promote fair and free competition, to thereby encourage creative enterprising activities, to protect consumers, and to strive for balanced development of the national economy by preventing the abuse of Market-Dominant Positions by enterprises and the excessive concentration of economic power, and by regulating improper concerted acts and unfair business practices.”

5. J. Schovsbo, ‘Fire and Water Make Steam: Redefining the Role of Competition Law in TRIPS’, University of Copenhagen Centre for Information and Innovation Law, Copenhagen, 2009: 8, <http://ssrn.com/abstract=1339346>.

6. H. Ullrich, ‘International harmonisation of competition law: making diversity a workable concept’, in H. Ullrich (ed.), *Comparative competition law: approaching an international system of antitrust law*, Nomos Verlagsgesellschaft, Baden-Baden, 1998: 12.

7. See, for example, T. Nguyen, ‘Competition Rules in the TRIPS Agreement – The CFI’s Ruling in Microsoft v. Commission and Implications for Developing countries’, *International Review for Intellectual Property and Competition*, 2008, 558: 584–585.

8. M. Mariniello and M. Antonielli, ‘Competition policy trends in South Korea’, Bruegel, Brussels, 20 February 2013, <http://www.bruegel.org/nc/blog/detail/article/1020-competition-policy-trends-in-south-korea/#.USpqXWdKZbw>.

9. The treatment given by the US and European competition authorities to the Microsoft case in the respective jurisdictions is often used to illustrate differences in the regimes and practices and the lack of sufficient coordination at the international level. For an elaboration, see W. Page and J. Lopatka, *The Microsoft case: Antitrust, high technology, and consumer welfare*, University of Chicago Press, Chicago, 2007; and I. van Bael and J.-F. Bellis, *Competition Law of the European Community*, 4th Edition, Kluwer Law International, The Hague, 2005: 179.



On the other hand, the evolution of competition law in the United States provides a telling example of marked differences in the understanding and application of competition law over time within the same country.¹⁰ In its origin and until the 1970s, a 'structuralist approach' predominated; US antitrust law was seen as a government's tool against monopolies and oligopolies, as a means to protect the weak from exclusion by the powerful.¹¹ Later, under the influence of the 'Chicago school', the application of antitrust policy was dominated by a 'process-oriented approach': market dominance, as such, was seen to reflect efficiency and considered non-objectionable *per se*.¹² This change led, in particular, to a more lenient attitude towards mergers and other forms of increased concentration.

The differences in the approaches, goals and implementation tools of competition law and policies suggest that national needs and objectives—rather than international considerations—are decisive in this area. In the absence of binding international standards, all countries are free to exercise their sovereign rights in the regulation of competition within their own jurisdictions.

The international dimension of competition law

Competition issues in UN forums

Despite the importance of national differences, some scholars have advocated the potential benefits of international harmonization and enhanced cooperation in the area of competition law.¹³ There has also been a government-led initiative to establish international rules and principles in this area.

In December 1980 the United Nations General Assembly adopted a 'Set of Multilaterally Equitable Agreed Principles and Rules for the Control of Restrictive Business Practices' ('the UN RBP Principles'), developed under the auspices of the United Nations Conference on Trade and Development (UNCTAD) (Resolution 35/63).¹⁴

The UN RBP Principles apply to all transactions in goods and services and to all enterprises (but not to intergovernmental agreements). They deal with horizontal restraints (such as price-fixing agreements, collusive tendering and market or customer allocation agreements) and with the abuse of

10. An evolution in thinking on competition law also occurred in the European Economic Community, which relaxed its policies in the early 1980s, partially in response to the perceived failure of some member governments' strategies to build up 'national champions'. See, for example, S. Sell, *Power and Ideas. North-South politics of intellectual property and antitrust*, State University of New York Press, New York, 1998: 161.

11. R. Merges, P. Menell, M. Lemley and T. Jorde, *Intellectual Property in the New Technological Age*, Aspen Law & Business, New York, 1997: 1040.

12. P. Scheyrer, 'Competition policy and industrial adjustment', *STI Review*, No. 10, OECD, Paris, 1992: 95–123: 96, 100.

13. See H. Ullrich (ed.), *Comparative competition law: approaching an international system of antitrust law*, Nomos Verlagsgesellschaft, Baden-Baden, 1998. See also the proposal of an 'International Antitrust Code' (generally known as the 'Munich Code') drafted by a group of competition experts (*World Trade Materials*, 1993, Vol. 5, September: 126). Scherer also proposed the creation of an 'International Competition Policy Office' as well as the adoption of international rules that, inter alia, would require the registration and abolition (after a transitional period) of export and import cartels, the harmonization of merger procedures and the granting of compulsory licences in cases of monopolization for long periods. See F. Scherer, 'Competition policies for an integrated world economy', The Brookings Institution, Washington DC, 1994: 89–97.

14. Based on a decision adopted at UNCTAD-IV, Nairobi, 1976.



dominant position or market power through practices such as discriminatory pricing, mergers, joint ventures and other acquisitions of control.

Although developed countries were generally supportive of the idea of a code on restrictive business practices during the negotiation of the UN RBP Principles, they did not wish to subject their own competition laws and policies to international rules. LMICs, on their side, aimed at an instrument that could help to curb practices that affected economic development at large, including transactions between parent and subsidiaries or among subsidiaries of transnational corporations.¹⁵

Developed countries were successful in keeping the UN RBP Principles as a non-binding instrument and within the boundaries of conventional competition law concepts as applied in those countries.¹⁶ As provided for in the UN RBP Principles, conferences to review it have taken place every five years after its adoption. LMICs eventually attempted (notably at the 1985 conference) to upgrade the UN RBP Principles to a **binding** instrument and the Intergovernmental Group of Experts to a 'committee', but developed countries turned back those efforts.

Through technical assistance provided by UNCTAD, the UN RBP Principles have influenced the adoption of competition laws at the national level in several LMICs.¹⁷ Although UNCTAD also developed a Model Law on Competition,¹⁸ it recognizes that "countries need to continue to exercise their sovereignty over their domestic markets, and elaborate their own 'tailor-made' national competition laws and enforce them effectively".¹⁹

It is worth noting that in two other UN organizations, the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO), the relationship between IP and competition has been addressed. The Development Agenda adopted by the General Assembly of WIPO in 2007 recommended the following work:

"[To][P]romote 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 IP and competition policies" (Recommendation 7).

15. The establishment of rules on competition was promoted by LMICs in the framework of discussions on a 'New International Economic Order' under which those countries also—unsuccessfully—attempted to lay out rules for transnational corporations' behaviour and transfer of technology. See S. Sell, *Power and Ideas. North-South politics of intellectual property and antitrust*, State University of New York Press, New York, 1998; and P. Roffe, 'Control of anti-competitive practices in contractual licenses under the TRIPs Agreement', in C. Correa and A. Yusuf (eds), *Intellectual Property and International Trade. The TRIPs Agreement*, Kluwer Law International, London, 2008.

16. S. Sell, *Power and Ideas. North-South politics of intellectual property and antitrust*, State University of New York Press, New York, 1998: 172.

17. *Ibid.*: 210.

18. See <http://unctad.org/en/Pages/DITC/CompetitionLaw/The-Model-Law-on-Competition.aspx>.

19. See the Opening Address by Supachai Panitchpakdi, Secretary-General of UNCTAD, of the 6th UN Review Conference, 2010, available at <http://www.unctad.info/en/6th-UN-Conference-on-Competition-Policy/Conference/Opening-Address-by-Secretary-General-of-UNCTAD/>. See also the UN General Assembly Resolution A/RES/59/221 on International Trade and Development, 11 February 2005, which in para. 30 encouraged "developing countries to consider establishing competition laws and frameworks best suited to their development needs, complemented by technical and financial assistance for capacity-building, taking fully into account national policy objectives and capacity constraints".



“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” (Recommendation 22).

“To have within WIPO opportunity for exchange of national and regional experiences and information on the links between IP and competition policies” (Recommendation 32).

A number of studies have been prepared by the WIPO Secretariat to address these issues.²⁰

In the case of the WHO, Element 6.3(f) of the ‘Global strategy and plan of action on public health, innovation and intellectual property’²¹ (2008) includes among the actions to be taken to promote “competition to improve availability and affordability of health products” to consider “where necessary, and provided that they are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking 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, in the field of health products”. Follow-up to this recommendation, in the context of WHO, is still pending.

Competition issues in GATT/WTO

a) The Havana Charter

An early attempt to establish binding international rules on restrictive business practices was made in negotiation of the Havana Charter, the draft charter proposing the creation of an International Trade Organization (ITO), of which GATT (1947) formed a part. Article 46 of the Charter stipulated that each member “shall take appropriate measures and cooperate to prevent business practices by private or public commercial enterprises affecting international trade which restrain competition, limit access to markets or foster monopolistic control, whenever such practices have harmful effects on the expansion of production or trade and interfere with the achievement of any of the other objectives set forth in Article 1 of the Charter”. The Charter also provided for consultations, investigation and the possible determination of some practices as ‘restrictive business practices’.

Since the Charter was not adopted and the GATT (which assumed a primary role) did not contain specific disciplines on rules on anti-competitive practices, some efforts were made later (notably

20. See the following documents: ‘Interaction of Agencies Dealing with Intellectual Property and Competition Law’, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_1.pdf; ‘Interface Between Exhaustion of Intellectual Property Rights and Competition Law’, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_2.pdf; ‘An Analysis of the Economic/Legal Literature on the Effects of IP Rights as a Barrier to Entry’, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_3.pdf; ‘Survey on Measures to Address the Interface between Antitrust and Franchising Agreements’, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_4.pdf; and ‘Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses of Intellectual Property Rights’, www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_5.pdf.

21. Available at www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.



in 1954) to remedy this perceived gap, but without success. In November 1958 GATT Contracting Parties recognized that international cartels could hamper expansion of world trade and economic development of countries and interfere with the objectives of the GATT. However, the majority of a group of experts convened that year concluded, in 1960:

“it would be unrealistic to recommend at present a multilateral agreement for the control of international restrictive business practices. The necessary consensus among countries upon which such an agreement could be based did not yet exist, and countries did not yet have sufficient experience of action in this field to devise an effective control procedure. Such agreements could not operate effectively, unless a sufficient number of countries had powers to act against international restrictive business practices in accordance with such an agreement or were able and willing to adopt such powers, or unless the agreement incorporated a supra-national body with broad powers of investigation and control. Therefore, it was at this stage impracticable to set up any procedures for investigating or passing judgment on individual cases within the framework of GATT.”²²

WTO Agreements

The focus of the WTO agreements has been and remains practices and measures adopted by governments, not by economic agents. A few provisions in such agreements, however, address issues related to competition law:

- Article XVII of the GATT 1994 requires undertakings (either public or private) acting under special privileges and State enterprises, to grant non-discriminatory treatment in purchases or sales and to afford undertakings of other Members an opportunity to compete for the participation in such purchases or sales.
- Article 11.1(b) of the Safeguards Agreement prevents Members from “seeking, taking or maintaining any voluntary export restraints, orderly marketing arrangements or any other similar measures on the export or import side”, while paragraph 3 of the same article prohibits Members from encouraging or supporting “the adoption or maintenance by public or private enterprises of non-governmental measures equivalent to those referred in paragraph 1”.
- The Trade-Related Investment Measures (TRIMS) Agreement applies to measures (e.g. local content requirements) that may be used to correct or avoid anti-competitive business practices, such as foreign investors’ sourcing of inputs from abroad to the detriment of local supplies (even if available at competitive prices). In principle, such corrective measures may be prohibited under the TRIMS Agreement,²³ though a judicial or administrative ruling establishing a remedy under competition law might overcome that general prohibition.

22. See <http://www.worldtradelaw.net/misc/rbp2.pdf>.

23. See, for example, C. Correa and N. Kumar, *International Rules for Foreign Investment. Trade-Related Investment Measures (TRIMS) and Developing Countries*, ZED Books/Academic Foundation, London and New Delhi, 2003.



- Article IX.1 of the General Agreement on Trade in Services (GATS) contains a specific provision relating to business practices: “Members recognize that certain business practices of service suppliers, other than those falling under Article VIII, may restrain competition and thereby restrict trade in services”, while Article IX.2 provides for a system of consultations “with a view to eliminating” such practices. However, no obligations are imposed on Members regarding the ways to deal with such practices.²⁴ The only obligation is to “accord full and sympathetic consideration” to a request from a WTO Member to cooperate through the supply of publicly available information, but not to act to curb the practice.²⁵

A WTO panel ruling relating to several provisions of GATS, its Annex on Telecommunications and the ‘Reference Paper’ found in 2004 that the complained-against Member had failed to maintain appropriate measures to prevent anti-competitive practices by firms that are major telecoms suppliers (‘Mexico—Measures Affecting Telecommunications Services’).²⁶ The panel considered that, even if mandated by government regulations, certain acts may constitute prohibited anti-competitive behaviour.²⁷

b) Debates on competition issues in the WTO

As observed in the previous subsection, there is not a comprehensive set of rules in the WTO regime to address competition issues. After the conclusion of the Uruguay Round, some WTO Members (notably the EU) argued for the development of multilateral rules on competition policy in the context of the WTO. During the preparatory process of the WTO Ministerial Conference held in Singapore in 1996, the EU submitted a proposal²⁸ to establish a working group to consider trade and competition policy along four tracks:

“(i) commitment by all WTO Members to adopt effective domestic competition laws; enforcement systems; and access for parties affected by anti-competitive practices to administrative and judicial procedures;

(ii) identify core common competition rules or principles (e.g., combating market-sharing and price-fixing cartels, export cartels, bid-rigging, abuses by firms of a dominant position on a certain market, certain vertical restrictions, approval procedures for mergers of large companies) and procedures (e.g. Transparency, national treatment and deadlines) and work towards adopting these at international level;

24. See, for example, M. Burri and S.Z. Bigdeli, ‘Commentary of GATS Article IX: Business Practices’, 26 January 2008, <http://ssrn.com/abstract=1307671> or <http://dx.doi.org/10.2139/ssrn.1307671>.

25. Provisions relating to competition have also been negotiated in the field of basic telecommunications. See Section 5 of the GATS Annex on Telecommunications and the ‘Reference Paper’ to be used as a guideline in taking additional commitments in that area, which deals with such matters as competition safeguards, interconnection guarantees and the independence of regulators. See www.wto.org/english/tratop_e/serv_e/telecom_e/tel23_e.htm.

26. Dispute DS 240. See a summary at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds204_e.htm.

27. See World Trade Organization, ‘Mexico—Measures Affecting Telecommunications Services—Report of the Panel’, WT/DS240/R, World Trade Organization, Geneva, 2004, [https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=\(@Symbol=%20wt/ds204/r/*%20not%20rw*\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUICanged=true#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds204/r/*%20not%20rw*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUICanged=true#).

28. ‘Possible elements of a WTO Work Programme to explore the feasibility of Developing an International Framework of Competition Rules in the WTO’, 8 July 1996.



- (iii) establish an instrument of cooperation between competition authorities (including for information exchange, consultations on cases, coordination of procedures);
- (iv) identify how the procedural and material elements can be made subject to the WTO dispute settlement mechanism.”

The EU proposal was cautiously received by most WTO Members, both developed and developing countries. For instance, the US Trade Representative (USTR) indicated that work on competition should not “threaten our laws which protect the principles of fair pricing and fair competition... The work plan must focus on the problems of cartels and other private anti-competitive behaviour which can impede US exporters’ access to foreign markets”.²⁹ The US position reflected a general unease of government and businesses³⁰ in the United States with the possible development of disciplines that could affect the practices of US corporations on the international market, particularly if they were to reflect a degree of state intervention greater than that exerted under US law.³¹

Proponents of an international harmonization of competition law argued that LMICs could benefit from an enhanced capacity to curb both **government** and **enterprise** practices that may negatively affect their economies, including:

- protection of the WTO concessions to ensure market access to developed-country markets;
- protection against aggressive use of anti-dumping duties by developed countries;
- better enforcement, through international coordination, of competition law against non-competitive practices by large foreign suppliers; and
- increased competition in their domestic markets.³²

Multilateral disciplines on competition policy would restrict sovereign rights to design and implement policies in this area and may, in particular, limit the ability of LMICs to use certain instruments to deal with distortive business practices. However, LMICs can be especially vulnerable to the effects of anti-competitive practices by multinational corporations. Hence, an effective international coordination of competition policies could have represented a significant gain for those countries, since government controls in developed countries are limited to the activities of such firms that have an impact in their own markets.

29. See <http://www.usembassy-israel.org.il/publish/press/ustr/archive/december/ot41216.htm>.

30. See, for example, E. Graham and D. Richardson, ‘Global competition policy’, Institute For International Economics, Washington, DC, 1997: 561.

31. See, for example, E. Fox, ‘Toward World antitrust and market access’, *The American Journal of International Law*, No. 91, January 1997: 1–25.

32. C. Perroni and J. Whalley, ‘Competition policy and the developing countries’, in H. Thomas and J. Whalley (eds), *Uruguay Round Results and the Emerging Trade Agenda. Quantitative-based analyses from the development perspective*, UNCTAD, New York and Geneva, 1998: 493. These authors even attempted to quantify the potential gains of LMICs from the introduction of disciplines on competition: “the potential gains for developing countries could be large, perhaps in the region of 5–6 percent of national income” (Ibid.).



However, the WTO proposal was unlikely to lead to significant progress, given the domestically centred position of developed countries on this matter.³³ There was also the perceived risk that, as a result of a strong linkage between trade and competition policy under the WTO philosophy, possible multilateral disciplines to be developed would focus on **market access**, rather than on curbing the multiplicity of restrictive business practices that raise the main concerns of LMICs.³⁴

The Singapore WTO Conference ultimately set up a Working Group on the Interaction between Trade and Competition Policy. The Singapore Ministerial Declaration, however, clearly stipulated that it was understood that future negotiations, if any, regarding multilateral disciplines would take place only after an explicit consensus decision was taken among WTO Members regarding such negotiations (paragraph 20).³⁵ The Working Group conducted an 'educative' process on the application and effects of competition policy and its relationship with trade, investment and IP policies.³⁶ In view of the opposition by LMICs to enter into negotiations within WTO on this and other 'new' issues proposed at the Singapore Conference (investment, transparency in government procurement and trade facilitation) and of the lack of cohesion among the developed countries themselves, the issue of competition was taken off the negotiating agenda in 2004.³⁷

Competition-related provisions in the TRIPS Agreement

Despite the lack of progress in establishing a multilateral binding agreement on competition law, a number of provisions in the TRIPS Agreement are relevant to competition law. Article 6 of the TRIPS Agreement on exhaustion of rights is one of the important pro-competitive provisions in the Agreement. It is reviewed in this subsection jointly with three provisions that specifically refer to competition law issues: Article 8.1, Article 31(k) and Article 40. These provisions leave WTO Members broad policy space³⁸ to apply competition law in respect of acts related to the acquisition or exercise of IP rights.³⁹

33. Under the US Foreign Trade Antitrust Improvement Act, for instance, foreign firms and consumers cannot invoke US law against US firms for acts that lessen competition only in foreign countries.

34. See M. Khor, 'Competing views on "competition policy" in WTO', Third World Network, 1997, <http://www.twinside.org.sg/title/views-cn.htm>.

35. See http://www.wto.org/english/thewto_e/minist_e/min96_e/wtodec_e.htm.

36. See WT/WGTCP/2, para. 154.

37. See 'Doha Work Programme – Decision Adopted by the General Council on 1 August 2004', WT/L/579, 2 August 2004, http://www.wto.org/english/tratop_e/dda_e/draft_text_gc_dg_31july04_e.htm.

38. See, for example, T. Nguyen, 'Competition Law in Technology Transfer under TRIPS Agreement - Implications for Developing Countries', Lund University, Lund, 2009.

39. Although EU competition law has been deemed applicable to the 'exercise' of IP rights and not to their 'existence', this doctrine is based on a formalistic distinction that needs not to be adopted in other jurisdictions. See, for example, J. Schovsbo, 'Fire and Water Make Steam: Redefining the Role of Competition Law in TRIPS', University of Copenhagen Centre for Information and Innovation Law, Copenhagen, 2009: 12, <http://ssrn.com/abstract=1339346>.



Article 6: exhaustion of rights

Article 6 of the TRIPS Agreement⁴⁰ allows Members to use one pro-competitive measure: the application of the doctrine of ‘exhaustion of rights’ to admit parallel imports.⁴¹ The principle of ‘exhaustion of rights’ may be applied at the **national** level (the rights are deemed exhausted domestically; the commercialization in foreign countries is not deemed to have exhausted the IP holder’s rights), at the **regional** level (exhaustion is deemed to have occurred if commercialization took place in a country that is member of a regional agreement) or at the **international** level (exhaustion is deemed to have occurred if commercialization took place in a foreign country).

From a public health perspective, international exhaustion of rights is the best option, since health technologies or active pharmaceutical ingredients (APIs) may be purchased in any country on the basis of pricing or other favourable conditions. The importance of the principle of exhaustion of rights to improve access to health technologies was highlighted by paragraph 5 of the Doha Declaration on the TRIPS Agreement and Public Health, which confirmed the space available to WTO Members to decide the scope of the principle. Paragraph 5 stated:

“Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

...

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.”

Parallel imports under the principle of exhaustion of rights take place in relation to IP-protected products on which the right-holder holds rights both in the exporting and importing countries. The TRIPS Agreement leaves open the question of the conditions under which the products were commercialized in the exporting country. Some national laws stipulate that, for parallel imports to be admissible, the product must have been put on the market in the foreign country by or with the consent of the patent owner. However, a WTO Member may consider that the supply of a protected product by a compulsory licensee, or by a voluntary licensee which is not authorized to export, is a legitimate source of parallel imports. If the product is sold by a licensee, either voluntary or compulsory, the right-holder would have been entitled to receive remuneration for the exploitation of its protected technology, generally in the form of a royalty payment. Hence, the patent owner would be compensated for its intellectual contribution, whether it has consented or not to the commercialization of the products subject to parallel importation.

40. 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.”

41. The principle of exhaustion has also been recognized (in relation to trademarks) by the UN RBP Principles, Section D(4)(e).



A controversial question is whether parallel imports would be admissible in cases where there is no IP protection in the exporting country, such as when patent protection was not available or was not sought and/or obtained there by the right-holder, or when protection has expired in the exporting country while it is still in force in the importing country. Some decisions by the European Court of Justice have permitted parallel imports originating from a country where no IP protection was available.⁴² In this case, there would be, *stricto sensu*, no exhaustion of rights (because they do not exist), but there would be no logical basis to reject parallel imports if the imported product was put on the foreign market by the right-holder.

Given that the international organization of companies is complex, and that a company may have been incorporated under different national laws, or be subject to the control of 'holding' societies, the concept of 'right-holder' needs to be broadly considered in implementing parallel imports policies. For instance, Section D(4)(e) of the already mentioned UN RBP Principles refers to abuse of trademarks of 'the same origin', meaning cases where the trademarks 'belong to the same owner or are used by enterprises between which there is economic, organizational, managerial or legal interdependence.'⁴³

Article 8.2: abuses of IP rights

Article 8 confirms WTO Members' discretion to adopt measures that may affect the availability or exercise of IP, when necessary for certain public purposes, including control of abuses of IP. This provision constitutes—jointly with Article 7—a central element for the interpretation and implementation of the TRIPS Agreement, particularly with regard to those provisions that leave flexibilities to legislate at the national level.⁴⁴ Thus, a WTO panel stated in 'Canada – Patent Protection for Pharmaceutical Products', in connection with the interpretation of Article 30 of the TRIPS Agreement:

"Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes."⁴⁵

42. See, for example, the *Merck v. Primacrown and Beecham Group v. Europharm* cases, ECJ, 5 December 1996, joined cases C-267/95 and C-268/95.

43. Under the Andean Community Decision 486, the consent to commercialize a product in the exporting country may have been given "by the owner or another person authorized by the right holder or with economic ties to that patent owner... [t]wo persons shall be considered to have economic ties when one of the persons is able to exercise a decisive influence on the other, either directly or indirectly, with respect to the exploitation of the patent or when a third party is able to exert that influence over both persons" (Article 54).

44. On the TRIPS flexibilities relevant to access to health technologies, see, for example, UNDP, 'Good Practice Guide: Improving access to treatment by utilizing flexibilities in WTO TRIPS Agreement', UNDP, New York, 2009, <http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf>.

45. World Trade Organization, 'Canada – Patent Protection for Pharmaceutical Products', WTO, Geneva, 2000, http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf.



Moreover, paragraph 5(a) of the Doha Declaration on the TRIPS Agreement and Public Health (the 'Doha Declaration') stated:

"In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."

In accordance with Article 8.2 of the TRIPS Agreement, "[A]ppropriate 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."

This 'principle' of the Agreement makes it clear that measures can be adopted by WTO Members to prevent or remedy abuses of IP and restrictive practices in contractual arrangements. Article 8.2 refers to three types of behaviour by IP right-holders:

(a) abuse of IP rights

Abuses of IP rights may be subject to competition laws such as in cases of tying clauses in licensing agreements (obliging the purchase of certain products),⁴⁶ the refusal to grant a licence on reasonable commercial terms⁴⁷ or excessive pricing.⁴⁸

Notably, Article 8.2 of the TRIPS Agreement does not indicate that the concept of 'abuse' needs to be considered in the context of competition laws only, which often require, as a premise for their application, the determination of the existence of a dominant position. The abuse of IP rights may or may not constitute an anti-competitive practice as defined under such laws. The Paris Convention, for instance, refers to the failure to work a patented invention as an 'abuse' (Article 5.A) independently of whether the patent owner enjoys or not a dominant position. In the United States, the doctrine of 'patent misuse' has developed in parallel to the application of antitrust law to address the use of patents in a manner that leverages them beyond the scope of rights and the term of protection granted by the law. Although the application of this doctrine is statutorily limited,⁴⁹ a number of specific practices by which a patentee may extend their patent right beyond its statutory limits may be considered by the courts as a misuse, notably to mitigate damages following a finding of infringement.⁵⁰

46. On restrictive practices in licensing agreements, see the analysis of Article 40 of the TRIPS Agreement below.

47. On 'refusal to deal' and the doctrine of 'essential facilities', see Chapter 3.

48. See, for example, Article 21(XXIV) of Brazilian Law No. 8.884/94, which considers "to impose excessive prices" as an abuse of economic power; Article 8 of the South African Competition Act which prohibits a dominant firm to "charge an excessive price to the detriment of consumers". See also http://ec.europa.eu/competition/consumers/abuse_en.html.

49. See 35 U.S.C. § 271(d).

50. See, for example, J. Mueller, 'Patent Misuse Through the Capture of Industry Standards', *Berkeley Technology Law Journal*, 2002, Vol. 17: 623, <http://ssrn.com/abstract=1346546>.



The abuse of patent rights (including the acquisition and exercise of rights) to block generic competition has raised growing concerns in the area of public health.⁵¹ The WTO, WIPO and WHO report on IP and public health notes “[S]everal potentially anti-competitive strategies in relation to IP rights involving medical technology have been observed and documented. These strategies mostly are designed to extend patent protection for originator drugs and to prevent market entry by generic competitors after patent expiry.”⁵² For instance, an investigation conducted by the European Commission on the pharmaceutical industry concluded, inter alia, that:

- filing numerous patent applications for the same medicine (forming so-called ‘patent clusters’ or ‘patent thickets’) is a common practice to delay or block the market entry of generic health technologies;
- individual health technologies are protected by up to nearly 100 product-specific patent families, which can lead to up to 1300 patents and/or pending patent applications across the Member States;
- patent litigation cases increased by a factor of four between 2000 and 2007; generic companies prevailed in 62 percent of 149 litigated cases that lasted from six months to more than six years; and
- European governments and consumers paid around €3 billion in excess between 2000 and 2007 (in relation to 219 drugs) due to abuses in the exercise of patent rights.⁵³

The possibility of requesting an indemnification in case of abuse in the enforcement of IP rights is specifically addressed in Article 48.1 of the TRIPS Agreement, according to which the judicial authorities shall have the authority to order the right-holder payment of an ‘adequate compensation’ for the injury suffered because of abuse of enforcement procedures, including the defendant’s expenses, which may include attorneys’ fees. This provision may be particularly important in cases of ‘strategic’ or ‘sham’ litigation.⁵⁴

(b) practices which unreasonably restrain trade

The wording of Article 8.2 is also broad in connection with measures that WTO Members may take in relation to “practices which unreasonably restrain trade”. The TRIPS Agreement does not define what these practices could be and leaves Members the capacity to determine when a restraint of trade may be deemed unreasonable, subject, however, to the ‘consistency test’ discussed below.

51. See also Chapter 3.

52. WHO/WIPO/WTO, ‘Promoting Access to Medical Technologies and Innovation. Intersections between public health, intellectual property and trade’, WHO/WIPO/WTO, Geneva, 2012: 198, http://www.who.int/phi/promoting_access_medical_innovation/en/index.html.

53. See European Commission, ‘Pharmaceutical Sector Enquiry. Final Report’, European Commission, Brussels, 2009, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

54. See L. Salgado and G. Ferrero Zucoloto, ‘Study on The Anti-Competitive. Enforcement. Of Intellectual Property Rights: Sham Litigation’, IPEA, Brasília, 2011, http://www.wipo.int/meetings/en/2011/wipo_ip_ge_11/docs/study.pdf.



It is worth noting that the Preamble of the TRIPS Agreement stresses the desire “to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade”, and that Article 41.1 stipulates that enforcement procedures “shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse”.

Importantly, the “practices which unreasonably restrain trade” mentioned in Article 8.1 are not limited to practices in licensing agreements, specifically addressed in Article 40 of the Agreement,⁵⁵ but to any behaviour that may (unreasonably) restrain trade, such as legally baseless litigation aimed at delaying the entry of generic health technologies.

(c) practices which adversely affect the international transfer of technology

Transfer of technology ranks high in the priorities of LMICs, such as those seeking to expand the local production of pharmaceuticals. Although Article 8.2 addresses the right of WTO Members to adopt measures aimed at eliminating certain practices adversely affecting the international transfer of technology, the provision is not limited to the control of restrictive practices in voluntary licensing agreements, as stipulated in Article 40, or to other practices condemnable under competition laws. Unreasonably high royalties may deter the transfer of technology as well. As done in the past by a number of LMICs,⁵⁶ WTO Members may establish policies to deal with technology pricing and other aspects of transfer of technology transactions.

The wording of Article 8.2 (“[A]ppropriate measures... may be needed to prevent...”) suggests that this is an “enabling provision: Members agree that there are such practices and that they have to be remedied”.⁵⁷ However, the recognition of Members’ authority to act against the referred to abuses and practices is subject to a double test: the measure must be “appropriate” (that is, subject to a proportionality test)⁵⁸ and “consistent with the provisions of this Agreement”. The implications of this latter test are difficult to establish, since the object of many of the measures that could be taken to address abuses and restrictive practices would fall outside the matters specifically regulated by the TRIPS Agreement. The rights recognized under the Agreement are negative in nature; they do not provide a specific right to use the protected subject matter.⁵⁹ Given the broad powers recognized for Members under Article 8.2, a Member challenging a measure adopted by another Member to prevent or eliminate abuses or restrictive practices would have the initial burden of proof of inconsistency with the provisions of the TRIPS Agreement.

55. See below.

56. See, for example, C. Correa, ‘Innovation and Technology Transfer in Latin America: a Review of Recent Trends and Policies’, *International Journal of Technology Management*, 1995, Vol. 10: 815.

57. UNCTAD–ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press, Cambridge, 2005: 546.

58. *Ibid.*: 553.

59. Whether there is or not of an implied right to use under the TRIPS Agreement has become an issue of particular relevance in relation to the challenge in WTO to restrictions applied by Australia on the use of trademarks for cigarettes. See, for example, M. Davison, ‘The Legitimacy of Plain Packaging Under International Intellectual Property Law: Why There is No Right to Use a Trademark Under Either the Paris Convention or the Trips Agreement’, in A. Mitchell, T. Voon and J. Liberman (eds), *Public Health and Plain Packaging of Cigarettes: Legal Issues*, Edward Elgar, 2012, <http://ssrn.com/abstract=2009115>.



Questions may arise as to the possible threat posed by 'non-violation' complaints in the case of measures addressing abuses or restrictive practices that cannot be considered in direct violation of the TRIPS Agreement provisions. The admissibility of such complaints in the context of the TRIPS Agreement is still under a moratorium, last renewed at the 2011 WTO Geneva Ministerial Conference.⁶⁰ Moreover, there are solid arguments to exclude such complaints altogether from the TRIPS framework.⁶¹

Interestingly, in *Microsoft v. Commission*, the Court of First Instance (CFI) of the EU recognized the policy space left by the TRIPS Agreement to implement competition laws in cases involving IP rights. It held:

"In any event, there is nothing in the provisions of TRIPS Agreement to prevent the competition authorities of the members of the WTO from imposing remedies which limit or regulate the exploitation of intellectual property rights held by an undertaking in a dominant position where that undertaking exercises those rights in an anti-competitive manner. Thus, as the Commission correctly observes, it follows expressly from Article 40(2) of TRIPS Agreement that the members of the WTO are entitled to regulate the abusive use of such rights in order to avoid effects which harm competition."⁶²

Although this decision refers to Article 40(2) and suggests certain conditions (valid for the EU) for the imposition of remedies, it does acknowledge the policy space left to WTO Members to apply competition laws to anti-competitive behaviour. This may be particularly relevant in the case of pharmaceuticals, where the proliferation of 'secondary' patents on minor developments (for example, polymorphs, salts, ethers, isomers etc.) is often used to block generic competition.

Article 31(k): compulsory licences to remedy anti-competitive practices

Compulsory licences have been used by competition authorities in some countries, notably in the United States,⁶³ to restore competition in cases involving the exercise of IP rights.⁶⁴ Although US patent law does not expressly provide for the grant of compulsory licences, this is probably the country with the largest experience in granting such licences to remedy anti-competitive practices.⁶⁵ They have included both present and future patents and have been granted against a reasonable royalty, generally determined on the basis of the 'willing-buyer, willing-seller' formulation; however,

60. See http://www.wto.org/english/tratop_e/trips_e/nonviolation_background_e.htm.

61. See, for example, F. Abbott, 'Non-Violation Nullification or Impairment Causes of Action under the TRIPS Agreement and the Fifth Ministerial Conference: A Warning and Reminder', *QUINO Occasional Paper*, No. 11, Quaker United Nations Office, Geneva, 2002, <http://www.geneva.quino.info/pdf/QP11-nv.pdf>.

62. CFI, Case T-201/04, *Microsoft v. Commission*, [2007] ECR II-3601, para. 1192 (emphasis added).

63. See, for example, J. Reichman and C. Hasenzahl, 'Non-voluntary Licensing of Patented Inventions. Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA', ICTSD-UNCTAD, Geneva, 2003, <http://www.iprsonline.org/resources/docs/Reichman%20-%20Non-voluntary%20Licensing%20-%20Blue%205.pdf>.

64. For some cases of use of compulsory licences to remedy anti-competitive practices in Europe, see C. Correa, 'Intellectual property and competition law: exploring some issues of relevance to developing countries', ICTSD, Geneva, 2007.

65. See, for example, F. Scherer, 'Comments' in R. Anderson and N. Gallini (eds), *Competition policy and intellectual property rights in the knowledge-based economy*, University of Calgary Press, Calgary, 1998.



in some cases the compulsory licences were conferred royalty-free, and the patentee was required to make the results of its research readily available to other industry members or to transfer the know-how actually used in production.⁶⁶

Article 31(k) of the TRIPS Agreement confirmed the right to use such licences as anti-competitive remedies. Largely inspired by the US experience, this provision allows for the granting of a compulsory licence 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 licence: 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.

The only condition required by Article 31(k) for the grant of this type of compulsory licence is of a procedural nature: the anti-competitive practice needs to have been determined through a judicial or administrative process. While many national laws establish that the competition authority is competent for such determination, WTO Members may choose other authorities, notably in cases where a competition authority has not been established or is not operative in the country.

A survey conducted by WIPO, to which 34 countries responded, noted that “compulsory licenses are generally aimed at achieving objectives other than remedying, repressing, correcting or preventing anti-competitive uses of IP rights”, but that “[I]t can be assumed that some of those legal grounds such as a non-use of patented inventions, or a failure to work or insufficient working of patented inventions, or public interest of extreme importance can be linked to competition, even if national statutory provisions do not clearly stipulate it.”⁶⁷ The UK observed in its response that “the fact that the Intellectual Property Office receives so few applications for the grant of compulsory licenses could indicate that the legislation in this area acted in itself as a deterrent. It ensured that IP rights owners entered into negotiations with each other to come to voluntary agreements on licensing IP rights.”⁶⁸

66. See, for example, C. Correa, ‘Intellectual property rights and the use of compulsory licenses: options for developing countries’, *Trade-Related Agenda, Development and Equity Working Papers*, South Centre, Geneva, 1999.

67. See WIPO, ‘Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses of Intellectual Property Rights’, WIPO, Geneva, 2011: 6, http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_5.pdf.

68. *Ibid.*: 24.



Article 40: control of anti-competitive practices in contractual licences

While abuses of IP rights may take various forms,⁶⁹ Article 40, the only operative provision in the TRIPS Agreement that specifically refers to the application of competition law, only relates to restrictive practices in contractual licences of IP.

On the one hand, Article 40 recognizes that the TRIPS Agreement does not prevent WTO 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”. It also recognizes that “...a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices...”. The reference to “practices or conditions” suggests that the provision covers not only **clauses** in licensing agreements, but “all conduct surrounding the grant and the execution of licenses. Thus, refusals to license, discriminatory grant of licenses as well as discriminatory license terms, and restrictive clauses in general, all fall within the scope of the provision.”⁷⁰

On the other hand, this provision includes some **examples** of restrictive business practices in licensing agreements: exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing. The illustrative nature of this part of this provision makes it clear that national authorities can consider other practices as restrictive. In addition, national laws may stipulate that certain practices constitute *per se* anti-competitive restrictions, without the need for an authority to determine the anti-competitive effects that it may have in the particular circumstances of the case. The identification of *per se* condemnable restrictions was, in fact, the main policy approach followed by the US antitrust authority until the 1980s. It is also reflected in the EU regulations on ‘block exemptions’ relating to technology transfer agreements.⁷¹

Although in the initial proposal for this provision LMICs sought to obtain a broader concept for restrictive practices,⁷² Article 40.2 of the TRIPS Agreement seems to be based on a competition test inspired by the ‘rule of reason’ developed under US law (“...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”). WTO Members are bound to respect measures that other Members may take in relation to licensing practices or conditions which “restrain competition” and that may have “adverse effects on trade and may impede the transfer and dissemination of technology”. These qualifications were probably introduced to prevent governments in LMICs from applying a ‘development test’ to assess practices in licensing agreements, as proposed by such countries during the unsuccessful negotiations of an International Code of Conduct on Transfer of Technology.

69. See Chapter 3.

70. H. Ullrich (ed.), *Comparative competition law: approaching an international system of antitrust law*, Nomos Verlagsgesellschaft, Baden-Baden, 1998: 556.

71. See Commission Regulation (EC) No. 772/2004 of 7 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:123:0011:0017:EN:PDF>.

72. See P. Roffe, ‘Control of anti-competitive practices in contractual licenses under the TRIPS Agreement’, in C. Correa and A. Yusuf (eds), *Intellectual Property and International Trade. The TRIPS Agreement*, Kluwer Law International, London, 2008.



However, Members are not confined to apply a competition test in dealing with licensing agreements. They may take measures based on other criteria and with objectives different from those of competition law—for instance, to reduce royalty payments or to ensure licensees the possibility of exporting to various territories. As noted by Ullrich, “Article 40.1 enshrines a competition approach to the regulation of technology transfer, albeit not to the exclusion of other approaches.”⁷³

Like Article IX of GATS, Article 40.3 of the TRIPS Agreement provides for the principle of ‘positive comity’. A Member may request consultations with any other Member in cases where it believes that an IP right owner that is a national or domiciliary of the other Member “is undertaking practices in violation of the requesting Member’s laws and regulations on the subject matter of this Section”. However, the Member to which a request of consultation is addressed is not obliged to take measures to prevent or sanction the abuses that affect the requesting Member; it preserves “full freedom of an ultimate decision” on the action to be taken, if any. The only obligations imposed on the Member to which the request is addressed are to “accord full and sympathetic consideration” to it, to “afford adequate opportunity for consultations” and to “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”.

There is no record of the concrete application of the consultation system established under Article 40 of the TRIPS Agreement. One explanation for this, in relation to LMICs, may be the fact that most of those countries dismantled the ‘transfer of technology laws’ they had implemented in the 1970s and part of the 1980s to control restrictive practices, level of payments and other conditions of transfer of technology agreements.⁷⁴ No policies or regulations have been established thereafter in such countries to effectively apply competition laws or other legislation⁷⁵ to control such practices.

Restrictive practices are common in licensing agreements relating to health technologies, including grant-back provisions, the obligation to purchase APIs from the licensor, use of field restrictions, and limitations to export outside a given territory. Some of these restrictions may be subject to competition rules, but, as noted, laws on the matter generally require that the abuse of a dominant position be determined as a pre-condition to consider whether the licensor’s behaviour is anti-competitive. As noted, restrictive practices that are not condemnable under a ‘competition test’ may, however, be subject to other regulations.

73. Ullrich, *op cit.*: 557.

74. See C. Correa, ‘A decade of control of transfer of technology in Latin America’, *Journal of World Trade Law*, 1981, Vol. 15, No. 5, Sept–Oct.

75. An exception is Chapter IV of Decision 291 (1991) of the Andean Community, ‘Common Regime for the Treatment of Foreign Capital and on Trademarks, Patents, Licenses and Royalties’ and Article 58 of the Decision 486 (2000) ‘Common Intellectual Property Regime’. Some IP laws contain provisions relating to restrictive practices in licensing agreements, such as Article 39 of the Argentine patent law No. 24.481 (1995).



Competition provisions in FTAs

As examined above, LMICs, including Members of the WTO, have preserved a significant degree of policy space to define and implement competition laws at the national level to control abuses and restrictive practices.

LMICs can choose their own model of competition law, though the influence of those applied in high-income countries is generally significant. Many countries have adopted competition laws on the basis of 'normative persuasion' rather than coercion (as has been the case with IP rights legislation)—that is, they learned and accepted the idea of competition laws but tailored them to their particular conditions.⁷⁶

FTAs generally contain chapters on competition law. Box 2.1 enumerates the most common clauses relating to competition law found in FTAs.

BOX 2.1: Competition provisions commonly found in FTAs

1. Measures relating to the adoption, maintenance and application of competition law
2. Provisions relating to the cooperation and coordination of activities by competition law enforcement bodies
3. Provisions relating to anti-competitive acts and measures to be taken against them
4. Provisions relating to non-discrimination, due process and transparency in the statement and application of competition law
5. Provisions to exclude the use of anti-dumping measures against the commerce of signatories
6. Provisions concerning the circumstances and conditions under which recourse to trade remedies (such as anti-dumping measures, countervailing duties and safeguards) are permitted
7. Provisions relating to the application of dispute settlement procedures in competition policy-related matters
8. Provisions relating to flexibility and progressivity, sometimes referred to as special and differential treatment provisions.

Source: OECD, 'Competition Provisions in Regional Trade Agreements. Part I. Secretariat Paper', COM/DAF/TD(2003)3, prepared for the Joint Group on Trade and Competition, Organisation for Economic Cooperation and Development, Paris, 1 February 2005.

Unlike other components of FTAs, the rules on competition law introduced in such agreements contain few binding commitments. Notably, the Parties agree to apply competition laws to certain types of anti-competitive behaviour and to cooperate to address anti-competitive practices.

76. S. Sell, *Power and Ideas. North-South politics of intellectual property and antitrust*, State University of New York Press, New York, 1998: 198 and 211.



Some evolution in the competition law content of FTAs may be observed. The EU, for instance, sought in some FTAs to export to its trade partners its own model on competition law, as set out in the EU Treaty. For instance, Article 53 of the EU–Jordan Euro-Mediterranean Agreement, signed in November 1997, partially reproduced Articles 101, 102 and 107 of the Treaty on the Functioning of the European Union (TFEU). Interestingly, however, the FTA did not contain the exceptions to the general rules spelled out in Articles 101⁷⁷ and 107⁷⁸ of the TFEU. In addition, the Agreement established that practices had to be assessed “on the basis of the criteria resulting from the application of the rules contained” in the Articles of the TFEU referred to—that is, in accordance with European legal standards. This not only means that such standards would prevail over or replace any standards developed to suit Jordan’s circumstances, but that EU firms would enjoy a considerable advantage in invoking the Agreement’s competition provisions against Jordanian competitors.⁷⁹

More recent FTAs signed by the EU recognize the applicability of the domestic law of the respective trade partners to determine the existence or not of anti-competitive conduct. The Trade, Development and Cooperation Agreement between EU and South Africa, for instance, defines conduct incompatible with the Agreement (Article 35), but an Annex stipulates that it will be assessed in accordance with criteria arising from the application of the rules of each Party’s domestic legislation. In the case of the EU FTA with Colombia and Peru, the Parties similarly agreed that certain behaviour is inconsistent with the FTA “to the extent that such practices may affect trade and investment between the Parties”, but the determination of the behaviour’s anti-competitive nature would be made in accordance with the Parties’ respective competition laws.⁸⁰ This FTA also provides for cooperation and coordination of the respective competition authorities, including the possibility of requesting the other Party “to initiate the enforcement activities established under its legislation” if the requesting Party considers that an anti-competitive practice “carried out within the territory of another Party has an adverse effect within the territory of both Parties or on trade relations between those Parties” (Article 261.5). This provision, however, would not apply in cases where a practice carried out within the territory of the EU has an adverse effect in Peru or Colombia, and vice versa.

Interestingly, in the case of the EU CARIFORUM (Forum of the Caribbean Group of African, Caribbean and Pacific States) Economic Partnership Agreement⁸¹ a provision with wording seemingly inspired by Article 40 of the TRIPS Agreement creates an obligation on the Parties to take anti-competitive measures. It stipulates:

77. The exception refers to agreements, decisions or practices that contribute “to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit” provided that they do not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives; or (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

78. Article 107.2 enumerates cases where aid “shall be compatible with the internal market”, and Article 107.3 situations where aid “may be considered to be compatible with the internal market” (emphasis added).

79. See ActionAid, Christian Aid, Oxfam International, ‘The EU’s approach to Free Trade Agreements Competition. Intellectual property’, *EU FTA Manual Briefing*, No. 8, http://aprodev.eu/files/Trade/EU%20FTA%20Manual%20fta8_ip.pdf.

80. Article 259.2.

81. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:289:0003:1955:EN:PDF>.



“The EC Party and the Signatory CARIFORUM States shall take measures, as appropriate, to prevent or control licensing practices or conditions pertaining to intellectual property rights which may adversely affect the international transfer of technology and that constitute an abuse of intellectual property rights by right holders or an abuse of obvious information asymmetries in the negotiation of licenses (Article 142.2).”

While this provision provides for an interesting precedent, the obligation is established in general terms, and it is unclear, for instance, whether the EU competition authority would take measures in cases of conduct by European enterprises that affect one of its trade partners.

FTAs signed by the United States also contain specific chapters on competition. NAFTA, for instance, obliged the Parties to “adopt or maintain measures to proscribe anti-competitive business conduct and take appropriate action with respect thereto” (Article 1501.1) and provided for cooperation and coordination among their authorities. However, NAFTA explicitly stipulated “[N]o Party may have recourse to dispute settlement under this Agreement for any matter arising under this Article” (Article 1501.3).

The more recent FTA between the United States and Colombia binds the Parties to apply their respective competition laws “that proscribe anti-competitive business conduct and promote economic efficiency and consumer welfare” and to “take appropriate action with respect to such conduct”.⁸² The FTA also provides for non-discrimination based on nationality, some procedural guarantees (the right to be heard and provide evidence and of judicial review) and cooperation between the competition authorities.

While competition-related rules in FTAs do not significantly limit the way in which the trade partners can apply their own legislation, they do not strengthen or amplify the capacity of the Parties to deal with anti-competitive behaviour. In particular, the cooperation between competition authorities does not go as far as obliging the authority of one Party to make a determination on behaviour solely affecting another Party. This means that competition rules in FTAs may be of limited help to LMICs with weak competition regimes, or in cases where they are affected by restrictive practices or other behaviour (e.g. mergers) that take place in the territory of another Party.

Conclusions: utilizing the policy space in competition law

As a result of the implementation of the TRIPS Agreement, legislative changes in response to demands by developed countries, or commitments made in FTAs, the IP rights protection in LMICs has been raised in the last two decades to levels comparable to those applied in developed countries. There is an important asymmetry, though, in the process of elevating such protection. While competition regimes are well established and can be effectively used to remedy anti-competitive

82. Article 13.2.1 of the US–Colombia FTA.



practices related to IP rights in developed countries, not all LMICs have competition regimes in force, and, where they exist, serious enforcement problems remain. Hence, most LMICs lack the capacity to use competition law to counterbalance the market power conferred under IP rights and protect public health.⁸³ LMICs have, in fact, only rarely used the flexibilities concerning competition law under the TRIPS Agreement to address IP rights-related anti-competitive practices.⁸⁴

As noted, there are important differences in the way national laws define and control anti-competitive practices, even among developed countries. In the absence of international rules on the matter—after the failed attempt to develop a set of disciplines in the WTO—LMICs can use the policy space available to them to implement competition law and policies consistent with their national development needs.

The domestic reach of competition laws vis-à-vis the growing global nature of anti-competitive practices calls for more cooperation in the enforcement of such laws. However, this would not be an automatic result of an international harmonization of the rules on the matter, if this still were a realistic option in the context of multilateral relations.

The competition-related provisions of the TRIPS Agreement provisions are weak and general in comparison to the obligations requiring the protection of IP rights under very specific minimum standards. They do not contain precise obligations regarding the way in which WTO Members can intervene to protect competitors and consumers. While the ‘consistency test’ in Article 8.2 and the ‘competition test’ suggested in Article 40.2 of the Agreement may be read as limiting the space for such intervention, they do not prevent Members from determining the type of abuses and practices that may be subject to control, nor the remedies to be applied.

The possible use of compulsory licences to deal with anti-competitive practices, as explicitly recognized in Article 31(k) of the TRIPS Agreement, might be of particular importance to protect public health in cases, for instance, of excessive pricing of health technologies or refusal to grant a licence on reasonable commercial terms. WTO Members enjoy great latitude to determine the reasons for the grant of a compulsory licence for public health purposes. They should ensure that the procedures are simple and effective enough to provide timely responses to public health needs.⁸⁵

83. The need for such a counterbalance was noted by the European Commission in ‘An Industrial Property Rights Strategy for Europe. Communication from the Commissions to the European Parliament, the Council and the European Economic and Social Committee’, COM(2008) 465 final, European Commission, Brussels, 16 July 2008 (para. 3.4: “Strong protection of industrial property rights should be accompanied by rigorous application of competition rules.”).

84. See Chapter 4 (reference to the decision on ARVs by the South African Competition Commission).

85. See in the Annex some model provisions that may be incorporated into national legislation to make use of the TRIPS flexibilities examined above.



Anti-competitive behaviours and the remedies available for redress

Frederick M. Abbott

KEY MESSAGES

- ▶ There are a variety of anti-competitive practices that may affect pricing and access in the pharmaceutical sector, some illegal per se, and others to be assessed under a rule of reason balancing approach.
- ▶ Anti-competitive conduct may affect health technologies as well as technology markets, including research and development.
- ▶ Patent-owning pharmaceutical companies may be in a position to abuse monopoly or dominant position, such as by refusing to supply or charging excessive prices.
- ▶ Mergers and acquisitions may create or exacerbate anti-competitive conditions.
- ▶ There are a wide range of remedies available to address anti-competitive conduct, including injunctions, damages, criminal penalties, orders of compulsory licensing, divestitures and other equitable remedies.
- ▶ Specific rules addressing conduct that delays entry of generic competition through abuse of patents or related conduct may be useful.

1. The typology of anti-competitive practices as they relate to access to health technologies

This chapter addresses anti-competitive conduct relating to markets for health technologies. This contribution starts with a brief background concerning the typology of anti-competitive behaviour. It then narrows its focus to anti-competitive conduct likely to affect markets both for the delivery of affordable, quality health care in general and for health technologies in particular.



a) Horizontal restraints, vertical restraints and abuse of dominant position

Competition law generally differentiates between two classes of unlawful behaviour. The first concerns activities engaged in by independent enterprises that are competitors in the production and/or distribution of the relevant goods or services. This is the 'horizontal' class of competitors that are able to influence markets by acting in concert. Horizontal anti-competitive conduct typically involves two or more independent enterprises.

The second class of unlawful behaviour concerns the supply and distribution chain from a single producer, such as the chain moving from manufacturing to supply of wholesalers and distributors to retail sellers. This chain of supply from the producer through the retail distribution network is referred to as 'vertical'.

The types of anti-competitive conduct engaged in by enterprises in horizontal and vertical relationships tend to be different, although the objectives may be the same. The unlawful objective of anti-competitive behaviour is to obtain prices above those that would be paid by purchasers/consumers in a competitive market, or otherwise to secure sales (i.e. market share) above that which would be obtained in a competitive market.

Competition laws tend to differentiate between conduct involving unlawful contracts or agreements between undertakings, on the one hand, and conduct involving unlawful monopolization or abuse of dominant position, on the other. Competition law needs to maintain a distinct place for 'monopoly' or 'dominant position' because enterprises that control markets may not need to enter into agreements or contracts to accomplish their objectives. Monopoly control over the market allows the single enterprise to dictate pricing and terms of supply. Abuse of dominant position is usually confined to a single enterprise, although there are situations in which several enterprises combine to establish a dominant position in the market. Abuse of dominant position may affect horizontal competition or the vertical distribution chain.

b) Conduct considered straightforward, hard-core or *per se* anti-competitive and conduct

The fundamental objective of competition law is to protect the integrity of competitive markets against abusive conduct, and to protect consumers from the effects of such conduct. There are many types of agreements between undertakings that are not necessarily anti-competitive, including among competitors in the same markets. In circumstances in which there are potentially pro-competitive or neutral reasons for entering into agreements, competition authorities and courts must balance these reasons with potentially restrictive elements and decide whether the agreements are, on the whole, anti-competitive. In the United States this type of balancing is often referred to as 'rule of reason' analysis, but the way this doctrine of balancing is named varies from country to country.

Some types of agreement or conduct have been considered so inherently anti-competitive that they are not subject to a balancing test. These types of arrangements or agreements are considered illegal *per se* (using terminology originating with the US Supreme Court) or hard-core restraints



(using terminology developed in the EU). Examples of conduct considered *per se* illegal in both the United States and EU are price-fixing and output restraints among horizontal competitors.

Not all national jurisdictions separate anti-competitive acts into those that are *per se* unlawful and those as to which a rule-of-reason-type analysis applies.

2. Horizontal restraints

As noted above, horizontal restraints involve agreements between independent economic actors that are the primary producers or distributors of goods or services. Such producers seek to maximize profits. Ways to pursue market advantage over horizontal competitors, without resorting to anticompetitive measures, include: (1) reducing costs of production and prices so as to attract a larger proportion of buyers or consumers than the competition; (2) developing improved or innovative products that shift buyers' consumption preferences; (3) increasing advertising expenditures (or improving the quality of advertising) to attract a larger proportion of consumers than the competition; and (4) improving the quality of after-sales service for consumers.

There are various reasons why independent economic actors may decide to choose instead to engage in behaviour that is anti-competitive. A group of enterprises may have collectively constructed production facilities with the potential to 'oversupply' consumer demand. To maintain prices sufficient to cover production costs plus a reasonable profit, these economic actors may agree to limit production so as to maintain profitable (or even higher than normal profit) production. For enterprises in the natural resources production sector, or in the agricultural production sector, 'natural factors' may give rise to a supply situation that exceeds buyer/consumer demand at prices sufficiently high for all of them to remain in the market. Or a group of enterprises may collectively decide that because of various factors they do not face threats from alternative or substitute products and that they may improve their individual and collective profitability by forgoing competition based on price.

These and other reasons may induce enterprises to reach agreement on horizontal restraints that are anti-competitive, allowing them to secure prices above competitive market prices. By doing this, they allocate to themselves a larger portion of national wealth than that to which they are legitimately entitled, depriving consumers of goods or services, and depriving other industry sectors of revenues.

a) Restraints among horizontal competitors

i. Price-fixing

A typical form of anti-competitive behaviour is price-fixing among horizontal competitors. The price-fixing arrangement is one in which the potential competitors agree not to sell their product(s) below a set price. In other words, the enterprises agree that they will not seek to attract



marginal buyers by offering prices lower than other members of the group (see Boxes 3.1 and 3.2 for examples). There is typically nothing to prevent the enterprises from selling at higher prices than the fixed minimum.

BOX 3.1: US antitrust actions in health care services and products

The complaint alleges that Cooperativa de Farmacias Puertorriqueñas (Coopharma), a Puerto Rico cooperative of approximately 300 pharmacy-owners, has violated federal antitrust laws by negotiating, entering into, and implementing agreements among its member pharmacies to fix prices in their contracts with insurers and pharmacy benefit managers.

Coopharma members own more than 350 pharmacies in Puerto Rico. Its members represent at least one-third of all of the pharmacies in Puerto Rico, and they have a significant presence on the western side of the island.

According to the complaint, since at least 2007 Coopharma has negotiated with more than 10 payers over reimbursement rates and signed “single-signature” master contracts on behalf of its member pharmacies. In addition, the threat of collective action by Coopharma members led two payers to pay higher rates to the group’s members through their individual pharmacy contracts.

The order prohibits Coopharma from entering into or facilitating agreements between or among any pharmacies to, among other things, negotiate on behalf of any pharmacy with any payer and refuse to deal with any payer. The order also prohibits Coopharma from facilitating information exchanges between pharmacies regarding whether to contract with a payer and inducing anyone to engage in the prohibited conduct.

Under the order, payers are allowed to terminate their contracts with Coopharma without penalty, and Coopharma must notify each pharmacy providing services under the contract of the termination.

Source: US Federal Trade Commission, ‘2013 Overview of Antitrust Actions in Health Care Services and Products’, US Federal Trade Commission, Washington, DC, 2013: 23–24.

Price-fixing among horizontal competitors is widely considered *per se* illegal—meaning that it cannot be justified by alleged pro-competitive benefits.

Generic health technologies may be sold with low profit margins in markets that are comparatively open to competition. As a consequence, there may be substantial pressure among generic producers to fix prices to preclude selling at near or below cost, particularly when making sales to government purchasers that may be less willing to pay premium prices for ‘branded’ generic products. As discussed below, such price-fixing may take the form of bid-rigging with respect to government procurement.



Patented health technologies enjoy a form of built-in market exclusivity because potential competitors may not make and sell the same product as the patent owner. This might appear to remove the incentive for price-fixing, since the patent owner is a single source supplier and can charge the price it self-determines (assuming the absence of government price controls). However, this pricing autonomy and power depends on the extent to which substitutes are available in a particular therapeutic class of a patented drug. If there are several patented drugs that may treat the same condition, the patent owners may collectively have an incentive to fix prices and compete on other grounds, such as through advertising and promotion with physicians.

ii. Output restraints

A related way to maintain prices at an 'above competitive market' level is for enterprises to fix the total aggregate supply of the product on the market, and to allocate shares of that supply among the colluding enterprises. Assuming that demand can be held stable, the participating companies are able to maintain their pricing without concern that they will be undercut by their competitors, because their competitors have restricted the amount of product they can provide.

Output restraints among horizontal competitors are widely considered *per se* illegal—meaning that they cannot be justified by alleged pro-competitive benefits.

Competitors in an industry, including the pharmaceutical industry, may understandably want to restrict output in a situation of oversupply, since low prices may drive one or more of them out of business. But competition law is not intended to preserve the market position or viability of individual enterprises. It is, in fact, a function of competitive markets to allow companies to fail. It is through the process of failure or the threat of failure that resources are efficiently allocated within an industry and the economy as a whole. Without the prospect of failure, an industry is likely to become inefficient.

iii. Allocation of geographic territories or alternative market segmentation

Horizontal competitors may seek to inhibit price competition by allocating geographic territories among themselves. This practice may be used to segment regional, national or subnational markets. Geographic allocation may be accomplished through a variety of mechanisms. In a 'hard' form, potential competitors may agree not to sell or supply product into each other's allocated territory. In a somewhat softer form, potential competitors may agree not to actively pursue sales into each other's allocated territory but leave it open to respond to unsolicited inquiries (i.e. passive sales). Geographic allocation may be accomplished by agreement not to market within each other's territory, not to appoint local distributors or service representatives, and other means of making products less available or attractive.

As discussed below, bid-rigging is a common vehicle for giving effect to anti-competitive arrangements. Bids can be allocated along geographic lines to restrain competition, such that potential competitors agree they will not submit bids within certain geographic territories or that their bids will be priced non-competitively within those territories.



It is not uncommon for allocation of geographic territories, output restraints and price-fixing to form part of the same collusive arrangement (see Box 3.2 for an example).

BOX 3.2: Example of the practice of allocation by geographic territories **US Department of Justice**

In 1999 the US government assessed a \$500 million criminal penalty against the Swiss pharmaceutical firm Hoffman-La Roche (pursuant to a plea agreement) “for leading a worldwide conspiracy to raise and fix prices and allocate market shares for certain vitamins sold in the United States and elsewhere”, and sentenced a Swiss executive of the firm to four months imprisonment in the USA for his part in directing the conspiracy.

The US Department of Justice press release regarding the criminal plea agreement stated:

“According to the charges, Hoffmann-La Roche and BASF agreed with the world’s other major vitamin manufacturers to suppress and eliminate competition in the U.S. and elsewhere. The criminal cases charge that Hoffmann-La Roche, BASF, and Sommer [the Swiss executive], with unnamed co-conspirators:

- Agreed to fix and raise prices on Vitamins A, B2, B5, C, E, Beta Carotene and vitamin premixes;
- Agreed to allocate the volume of sales and market shares of such vitamins;
- Agreed to divide contracts to supply vitamin premixes to customers in the U.S. by rigging the bids for those contracts; and,
- Participated in meetings and conversations to monitor and enforce adherence to the agreed-upon prices and market shares.

The two-count criminal case against Sommer charges him with participating in the same vitamin conspiracy and lying to the Department of Justice by providing false, fictitious and fraudulent information to investigators when he was questioned about the vitamin conspiracy.”

iv. Secretive practices, including disguised industry group cooperative activities

Unlawful price-fixing, output restraints and similar horizontal anti-competitive behaviour requires an agreement among the participating enterprises. To protect against risk of prosecution by competition authorities, the participating enterprises and their employees may avoid committing an agreement to writing, and may instead rely on oral agreement. To further protect against detection, participating enterprises may go out of their way to discuss arrangements in ‘secret’ locations to make detection by authorities difficult. This is one of the reasons why competition authorities sometimes are reliant on ‘whistleblowers’ (i.e. company employees or former employees) to detect and report this type of anti-competitive conduct.



Enterprises doing business in the same industry or sector may have a variety of reasons for forming cooperative networks or associations. Such industry groups may be used to advocate common positions with the government (i.e. lobbying), may provide forums for working toward common production or process standards, and may provide a forum for vendors to offer their products and services to a collected group of prospective purchasers (e.g. the industry group tradeshow).

At the same time, while executives within the same industry are gathered at a single location for a bona fide reason (e.g. to discuss prospective regulatory standards), the risk is raised that these same executives will discuss and agree on anti-competitive arrangements. Historically, industry group forums have proven a fertile ground for organizing anti-competitive activity.

v. Bid-rigging, corrupt payments and related practices in procurement (government and private sector)¹

Particularly in LMICs, the government may be one of the largest procurers of goods and services. Governments often undertake procurement through competitive bidding, typically conducted through secret bids. With some variation, the government agency issuing the tender is required to accept the lowest priced bid that meets the relevant specifications. While favourable to the government, this type of procurement practice poses serious difficulties for businesses, which must anticipate and underbid competitors. On the one hand, a particular enterprise may fail to be the lowest bidder. On the other hand, to secure the procurement contract, it may bid at a price which is the unattractive from the standpoint of earning a profit. This creates a temptation among potential bidders on a procurement contract to agree on a price that will be offered by the lowest price bidder, further agreeing that no other enterprise will submit a bid at or below that price. There will then be an ancillary agreement among the potential bidders either to allocate the tender award among themselves or to allocate among themselves the lowest bid on future tenders. In this way, the group of undertakings will have fixed the price to the government.

Collusive bidding arrangements are not infrequently accompanied by corrupt payments to government officials. This is to help assure that evidence of bid-rigging is not explored or reported. There are various ways that a government employee with inside knowledge and/or decision-making authority can facilitate the award of a procurement contract to a particular supplier.

Examples from Mexico and Peru provide illustrations of bid-rigging in the health care sector (see Box 3.3 for examples).

1. See, for example, OECD, 'Guidelines for Fighting Bid Rigging in Public Procurement', OECD, Paris, 2009.



BOX 3.3: Bid-rigging in the health care market in Argentina, Mexico and Peru

MEXICO—Grupo Sutinmex vs Internacional Farmacéutica and others

The Federal Competition Commission (FCC) initiated an investigation regarding collusion in public auctions of medical equipment. The companies involved were Grupo Sutinmex, Internacional Farmacéutica, Serral, Le Mare Internacional de México and Matur. During the investigation the public auctions summoned by The General Hospital of Mexico and the Institute for Social Security for State Workers were analysed. In both cases, a behaviour pattern among the bidders could be set.

One of the most important pieces of evidence considered in the investigation, was the tight difference among the bids, which differed in all cases only by few pesos. During the investigation, the companies involved confessed to the existence of collusive practices. Therefore, the FCC decided to impose a fine to each of the implicated companies and to issue a warning to refrain from acting contrary to the FLEC in the future.

Source: OECD, 'Annual Report 2000, Mexico', OECD, Paris, 2000: 3

PERU

In the case of oxygen for medical use (2008), the Comisión de Defensa de las Libre Competencia [Defense of Free Competition Commission] sanctioned companies that provided this product to Peru's public health system after it was found that between 1999 and 2004 these companies had distributed geographically the bids for purchase of the product, demand for which is inelastic because it is indispensable for sustaining the life and health of persons that do not have access to private establishments. (See: Resolution 051-2010/CLC-INDECOPI of 13 August 2010, at: http://www.indecopi.gob.pe/RepositorioAPS/0/2/par/RES_051_2010_CLC/Res051-2010.pdf.)

...It is also important to point out that in 2010 two cases were opened that are still in process. The second case is a sanctioning action against several pharmacy chains for allegedly colluding to fix prices of some medications and supplements that are consumed on a massive scale. (The brief note at the start of this proceeding can be found at: http://www.indecopi.gob.pe/repositorioaps/0/2/jer/notas_interes_clc/NotasInicioProc/Nota017-2010-STCLC-INDECOPI.pdf.)

Source: OECD, 'Competition Forum, Latin America', OECD, Paris, 2012: 4–5

vi. Horizontal IP-related restraints

A. Buyouts of generic patent challenge

When generic producers undertake to challenge the validity of patents, the patent owners may decide that it is in their better financial interest to 'buy out' the generic challengers than to risk a court decision invalidating their patents. There are many potential variations to the buyout (see Box 3.4). The patent owner may make a direct cash payment to the generic producer. The patent owner may offer a licence to the generic producer to market other products in its line.



The patent owner may agree to allow the generic producer to market and sell the patented product under licence in some markets. The intent of all of these arrangements is to allow the patent owner to continue to sell its drug product under patent protection for as long as possible, generally until the patent expires by its own terms (see Box 3.5).

BOX 3.4: Example of settlements between originator and generic companies in the EU European Commission Competition Directorate

Patent Settlements

The inquiry established that between 2000 and June 2008, more than 200 settlement agreements were concluded between originator and generic companies. They covered some 49 medicines, of which 31 (i.e. 63%) were best-selling medicines that lost exclusivity between 2000 and 2007. The vast majority of the settlements were reached in the context of litigation cases, the remaining settlements were concluded in out of court disputes and/or in the framework of opposition proceedings.

In approximately half of the settlements in question the generic company's ability to market its medicine was restricted. A significant proportion of these settlements contained—in addition to the restriction—a value transfer from the originator company to the generic company, either in the form of a direct payment or in the form of a licence, distribution agreement or a 'side-deal'. Direct payments occurred in more than 20 settlement agreements and the total amount of these direct payments from originator companies to generic companies exceeded €200 million. The latter type of agreement has attracted antitrust scrutiny in the USA.

Source: European Commission Competition Directorate, 'Executive Summary of the Pharmaceutical Sector Inquiry Report', European Commission, Brussels, 2009: 13.

Generic producers may also have incentives to enter into these types of buyout agreements because there is uncertainty or risk, along with considerable expense, associated with patent litigation. Also, the payment (in whatever form) being offered by the originator patent owner may be greater than the profit the generic producer would be able to make when it offers a lower priced version of the specific medicine. (In the United States there is a special 180-day marketing exclusivity incentive for generic producers to initiate patent challenges, which in principle reduces the incentive to enter into buyout agreements, but such incentive has not proved adequate to inhibit the practice.)

In June 2013 the US Supreme Court decided that buyout settlements of generic producer patent challenges by patent owners are subject to 'rule of reason' assessment under the antitrust laws.³ The Court rejected the view of certain lower courts that such buyouts were essentially immunized from antitrust scrutiny, provided that the settlements were within the ordinary zone of exclusion of the challenged patents, stating:

"Given these factors, it would be incongruous to determine antitrust legality by measuring the settlement's anti-competitive effects solely against patent law policy,

3. US Supreme Court, *Federal Trade Commission (FTC) v. Actavis*, Sup. Ct., 526 U. S. 756, US Supreme Court, Washington, DC, 2013.



rather than by measuring them against procompetitive antitrust policies as well. And indeed, contrary to the Circuit’s view that the only pertinent question is whether ‘the settlement agreement ... fall[s] within’ the legitimate ‘scope’ of the patent’s ‘exclusionary potential’, ... this Court has indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.”⁴

The Court specifically focused on ‘reverse payment’ settlements in which patent owners pay generic challengers (in cash or some other form of consideration) to drop patent validity challenges, suggesting that such payments are evidence that the patent owners have doubts about the validity of their patents. The Court said “An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival. And that fact, in turn, suggests that the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anti-competitive consequence that underlies the claim of antitrust unlawfulness.”⁵ The Court noted that both the patent owner and the generic challenger may benefit from a reverse payment settlement—the patent owner maintaining its monopoly (and pricing power) and the generic producer receiving valuable consideration (i.e. a share of those monopoly profits)—but that consumers lose because of the delay in initiation of generic competition.

BOX 3.5: Example of pay for delay arrangements

Press release: European Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines

The European Commission has imposed a fine of €93.8 million on Danish pharmaceutical company Lundbeck and fines totalling €52.2 million on several producers of generic medicines. In 2002, Lundbeck agreed with each of these companies to delay the market entry of cheaper generic versions of Lundbeck’s branded citalopram, a blockbuster antidepressant. These agreements violated EU antitrust rules that prohibit anti-competitive agreements (Article 101 of the Treaty on the Functioning of the European Union—TFEU). These generic companies were notably Alphanova (now part of Zoetis), Merck KGaA/Generics UK (Generics UK is now part of Mylan), Arrow (now part of Actavis), and Ranbaxy.

Commission Vice-President Joaquín Almunia, in charge of competition policy, said: “It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anti-competitive practices.”

Citalopram is a blockbuster antidepressant medicine and was Lundbeck’s best-selling product at the time. After Lundbeck’s basic patent for the citalopram molecule had expired, it only held a number of related process patents which provided a more limited protection.

4. Ibid.: 8–9.

5. Ibid.: 19.



BOX 3.5 (continued)

Producers of cheaper, generic versions of citalopram therefore had the possibility to enter the market. Indeed, one of them had actually started selling its own generic version of citalopram and several other producers had made serious preparations to do so.

Experience shows that effective generic competition drives prices down significantly, reducing dramatically the profits of the producer of the branded product and bringing large benefits to patients. For example, prices of generic citalopram dropped on average by 90% in the UK compared to Lundbeck's previous price level once wide-spread generic market entry took place following the discontinuation of the agreements.

But instead of competing, the generic producers agreed with Lundbeck in 2002 not to enter the market in return for substantial payments and other inducements from Lundbeck amounting to tens of millions of euros. Internal documents refer to a "club" being formed and money to be shared among the participants. Lundbeck paid significant lump sums, purchased generics' stock for the sole purpose of destroying it, and offered guaranteed profits in a distribution agreement. The agreements gave Lundbeck the certainty that the generics producers would stay out of the market for the duration of the agreements without giving the generic producers any guarantee of market entry thereafter. These agreements are very different from other settlements of patent disputes where generic companies are not simply paid off to stay out of the market.

Background

The Commission's competition inquiry into the pharmaceutical sector indicated a number of structural issues and problems in companies' practices that could delay entry of cheaper medicines into the EU market. It also emphasised the importance of stronger competition law enforcement (see IP/09/1098, MEMO/09/321 and MEMO/13/56)...

Action for damages

Any person or firm affected by anti-competitive behaviour as described in this case may bring the matter before the courts of the Member States and seek damages. The case law of the Court and Council Regulation 1/2003 both confirm that in cases before national courts, a Commission decision is binding proof that the behaviour took place and was illegal. Even though the Commission has fined the companies concerned, damages may be awarded without these being reduced on account of the Commission fine.

In June 2013, the Commission has adopted a proposal for a Directive that aims at making it easier for victims of anti-competitive practices to obtain such damages (see IP/13/525 and MEMO/13/531). More information on antitrust damages actions, including a practical guide on how to quantify the harm typically caused by antitrust infringements, the public consultation and a citizens' summary, is available at: <http://ec.europa.eu/comm/competition/antitrust/actionsdamages/documents.html>.

Source: European Commission, 'Press Release: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines', European Commission, Brussels, 19 June 2013



B. Patent pools

Two or more companies in the same sector may decide to pool their resources to undertake R&D activities with a view towards sharing costs and the resulting products of R&D. In principle, joint venture R&D arrangements may enhance the possibilities for the introduction of innovative products that benefit consumers. However, when enterprises that control significant parts of the innovation market and/or the resulting product market combine to develop new products, this may give them a significant and unfair advantage over potential competitors. This, in turn, may lead to increased concentration in the producer market and establish pricing power and market control for the combining enterprises. In this regard, competition authorities usually look at R&D joint ventures on a case-specific basis, asking whether the particular enterprises are likely to capture an unreasonably large share of the market at the expense of potential competitors. Both the competition authorities of the United States and the EU establish safe harbour market share thresholds pursuant to which it is assumed that R&D joint ventures will not be anti-competitive.

A related type of innovation agreement involves contributions by enterprises of existing or future innovation (typically in the form of patents) into a 'pool' from which the participating enterprises may draw technology. Patent pooling arrangements may take many forms. They may involve a small or large number of companies, they may require that royalties be paid into the pool for use of the technology, they may establish conditions regarding development of new technologies based on the pooled technologies, and they may use various types of management structures.

As a broad proposition, the more 'open' a patent pool is to enterprises wishing to make use of the contributed technology, the less likely it is that the pool will be used for anti-competitive purposes. Patent pooling arrangements may serve beneficial public health purposes. The Medicines Patent Pool (MPP), for example, negotiates licences for the use of patented antiretroviral medicines from various originator pharmaceutical companies and makes licences from the MPP available to generic producers from LMICs for distribution of medicines in defined geographic territories.⁶

While the MPP aims to promote competition, and by consequence more affordable treatment access, patents on health technologies may, on the other hand, be pooled in a manner that is anti-competitive. Assume that a particular type of HIV 'combination therapy' can be based on a number of combinations of antiretroviral health technologies, at least some of which are under patent, but that one particular patented component is needed for any form of the combination. Two or more enterprises agree to contribute their patents to a pool (or joint venture), allowing each of them to produce a combination therapy using the patent of the other, and that one of these enterprises owns the patent for the single necessary component. If this pool is limited, other enterprises that may (or may not) own patents and wish to produce a combination may be unable to do so because they lack access to the single necessary component.

6. The Medicines Patent Pool (MPP) offers a public-health driven business model that facilitates the production of low-cost versions of existing medicines as well as the development of needed new formulations, such as "fixed-dose combinations" – one pill comprised of several medicines that increase treatment adherence – and formulations suitable for children. It does this through voluntary licensing of key HIV medicines patents. See more: <http://www.medicinespatentpool.org/about/>



This would allow the enterprises that are party to the pool to gain a significant marketplace advantage over those that are not. Depending on the structure of the market (e.g., if it is highly concentrated), this may give them an unfair competitive advantage over other patent-owning (or generic) producers.

vii. Issues related to merger and acquisition

Enterprises frequently seek to increase market share and pricing power by acquiring competitors or potential competitors. The extent to which an acquisition may affect competition in a relevant market will depend on a number of factors, including the general level of concentration in that market. The risk to consumers is that a particular market participant will acquire sufficient power to control pricing and supply in the absence of effective competition. Relevant markets include product markets and geographic markets. With respect to geographic markets, for some health-sector services the relevant market may be rather small. For example, consumers may find it very difficult to travel for hospital services, and may be limited to seeking services within a relatively small geographic area.

Mergers and acquisitions play a substantial role in the health care industries, including with respect to the health technologies sector, and there is considerable enforcement activity worldwide in this area.

It is not uncommon that when two pharmaceutical companies (either originator or generic) combine, there will be a therapeutic overlap among the products they are offering for sale. If the two suppliers are replaced by a single supplier, and depending on the presence (or absence) of other participants in the relevant market, that single supplier may be able to raise prices without providing any additional public health benefit. For this reason, it is not unusual for competition authorities to require the divestiture of particular pharmaceutical product lines to third parties as a condition for allowing a merger or acquisition to proceed (see Box 3.6 for examples).

BOX 3.6: US antitrust actions in health care services and products

Sanofi-Synthelabo/Aventis, 138 F.T.C. 478 (2004) (consent order) (<http://www.ftc.gov/os/decisions/docs/Volume138.pdf#page=483>)

The complaint alleged that the merger of two large French pharmaceutical companies would lessen competition in three pharmaceutical markets in the United States and increase the likelihood that consumers would be forced to pay higher prices:

- Factor Xa Inhibitors. Factor Xa inhibitors are anticoagulant products used to treat conditions related to excessive blood clot formation. Sanofi and Aventis were the only two companies positioned to successfully compete in the market for factor Xa inhibitors. Lovenox, manufactured by Aventis, accounted for 92% of factor Xa inhibitor sales in the U.S. Sanofi manufactured Arixtra, a recent entrant to the market. A successful complaint



BOX 3.6 (continued)

resulted in an order which requires that Sanofi: 1) divest Arixtra to Glaxo, 2) transfer Manufacturing facilities used to produce Arixtra to Glaxo, 3) contract manufacture certain ingredients until Glaxo can obtain the necessary regulatory approvals and supply sources to make the ingredients, and 4) help Glaxo complete three clinical trials.

- **Cytotoxic Colorectal Cancer Drugs.** Cytotoxic drugs are used in the treatment of colorectal cancer. Sanofi's Eloxatin and Camptosar (irinotecan), which was manufactured by Yakult Honsha and marketed in the U.S. by Pfizer, accounted for over 80% of the U.S. market. Aventis did not market a similar drug in the U.S., but licensed irinotecan under the brand name Campto from Yakult for sale in other territories. In addition, through contractual relationships with Pfizer, Aventis shared the results of key clinical trials with Pfizer, and possessed a number of U.S. patents relating to Camptosar. According to the complaint, the merger gave Sanofi access to Camptosar's pricing, forecasts, and marketing strategy, which would result in diluted competition between Sanofi and Pfizer. The complaint was successful and the subsequent order includes provisions that require the parties to divest to Pfizer key clinical studies for Campto that Aventis is currently conducting, certain U.S. patents and other assets related to areas where Pfizer markets Camptosar.
- **Prescription Insomnia Treatments.** Sanofi's Ambien accounted for over 85% of the U.S. market for prescription insomnia treatments. Sepracor planned to enter this market within nine months as a competitor to Sanofi with its product Estorra, which is licensed to Sepracor from Aventis. Under the licensing agreement, Aventis is entitled to royalty payments based on Estorra sales. After the acquisition Sanofi would control the leading product in the market and have a financial stake in what is likely to be its main competitor. The order requires the parties to divest Aventis' contractual rights to Estorra, either to Sepracor or a third party approved by the FTC.

Source: US Federal Trade Commission, '2013 Overview of Antitrust Actions in Health Care Services and Products', US Federal Trade Commission, Washington, DC, 2013: 96–97.

A potential adverse consequence from a competition standpoint of mergers and acquisitions in the originator pharmaceutical sector is that combined companies may seek to reduce costs by eliminating R&D projects and staff. Over time, an increased concentration of originator enterprises may significantly diminish overall R&D in the pharmaceutical sector. A reduction in the number of corporate R&D groups may also reduce competition in the innovation market, as upstream (e.g. basic) researchers are presented with fewer potential acquirers/licensees of their research efforts (see Box 3.7). Because of the transnational character of the originator industry, it is difficult for competition authorities in a single country to address the problem of industry consolidation as it affects R&D.



BOX 3.7: US antitrust actions in health care services and products

Ciba-Geigy, Ltd., 123 F.T.C. 842 (1997) (consent order) (<http://www.ftc.gov/os/caselist/9610055.shtm>)

The complaint alleged that the merger of Ciba-Geigy and Sandoz would result in an anti-competitive impact on the innovation of gene therapies.

The firms' combined position in gene therapy research was so dominant that other firms doing research in this area needed to enter into joint ventures or contract with either Ciba-Geigy or Sandoz in order to have any hope of commercializing their own research efforts. Without competition, the combined entity could appropriate much of the value of other firms' research, leading to a substantial decrease in such research. In addition, there was direct competition between the two companies with respect to specific therapeutic products. At the time of the merger, no gene therapy product was on the market, but potential treatments were in clinical trials. The complaint noted that the first products would not be available until the year 2000, but that the market could grow to \$45 billion by the year 2010. The complaint identified five relevant product markets, all of which were located in the United States. The first relevant market encompassed the technology and research and development for gene therapy overall. The other markets each involved the research and development, manufacture, and sale of a specific type of gene therapy: cancer; graft-versus-host disease (GVHD); hemophilia; and chemoresistance. In the market for overall gene therapy, the complaint alleged that Ciba and Sandoz controlled the key intellectual property rights necessary to commercialize gene therapy products. For each of the four specific gene therapy markets, the complaint asserted that the relevant market was highly concentrated and that Ciba and Sandoz were the two leading commercial developers of the gene therapy product. Moreover, entry into the gene therapy markets was difficult and time-consuming because any entrant would need patent rights, significant human and capital resources, and FDA approvals.

The order centered on the intellectual property rights. The new company, Novartis, was required to grant to all requesters a non-exclusive license to certain patented technologies essential for development and commercialization of gene therapy products. Depending on the patent, Novartis could receive an up-front payment of \$10,000 and royalties of one to three percent of net sales. Novartis also was required to grant a non-exclusive license of certain technology and patent rights related to specific therapies for cancer, GVHD, and hemophilia to a Commission-approved licensee. Novartis could request from the licensee consideration in the form of royalties and/or an equivalent cross-license. Further, the merged company could not acquire exclusive rights in certain intellectual property and technology related to chemoresistance gene therapy.

Source: US Federal Trade Commission, '2013 Overview of Antitrust Actions in Health Care Services and Products'; US Federal Trade Commission, Washington, DC, 2013: 114.



Health-sector issues relating to mergers and acquisitions are by no means limited to pharmaceuticals. Combinations among hospital providers, physician services groups, health insurance providers, medical device manufacturers, testing services and others may raise concerns as concentration in the relevant market increases.

3. Vertical restraints

Vertical arrangements from a competition law standpoint refer to the chain of production, distribution, retail sales and servicing of goods or services. By way of contrast, horizontal arrangements refer to those among independent producers of competing (or potentially competing) goods or services, each of which may have its own vertical distribution network or chain.

Some firms maintain internal ownership and control over the entire chain from production through retail sale of products. However, in most situations, through various permutations, the producer is selling goods or services through to distributors and/or wholesalers that are reselling to retail outlets, with retail outlets selling to the ultimate consumer. Electronic commerce is influencing the types of distribution chains that are more commonly used.

a. Vertical restraints in the goods and services market

With respect to health technologies and health goods and services more generally, there are different types of products and markets involved. For health technologies, the typical product used by the consumer is a physical good, a combination of chemicals, biological materials, excipients and so forth, delivered through some means (tablets, capsules, injectables etc.). That product may be manufactured in a facility located within the country where it is distributed and consumed, or it may be manufactured in a facility in a foreign country and imported.

There are a number of vertical steps in the production and distribution of health technologies, and anti-competitive conduct might be present at one or more of those steps. For the different types of health technologies (e.g. small molecule or biological), the steps are different. In respect to small molecule pharmaceuticals, a sector of manufacturers produces basic chemicals that are subsequently combined to yield APIs, which are subsequently formulated with excipients and transformed into finished forms.

It is possible that the producer and vendor of an API will seek to impose conditions on downstream formulators of finished products, such as restrictions on selling the formulated products for particular markets, including for export. If an API is unpatented, and there are multiple suppliers, it may be difficult for the producer to exercise downstream control. However, if the API is patented, and there is essentially a single source supplier, the producer is more likely to be able to impose restrictive conditions on downstream purchasers and resellers.

The finished form is packaged and enters the vertical distribution chain, which may involve a wholesale purchaser or distributor and a pharmacy or other retail point-of-sale. There are a number of



restrictive conditions that the formulator may impose on retailers, including a restriction on selling below a defined price. This latter practice is referred to as ‘resale price maintenance’. If independent retailers are allowed to set their own prices, they are likely to enter into competition with each other, driving them down. This benefits consumers but may also exert pricing pressure on the producer/supplier. In some jurisdictions, resale price maintenance is *per se* anti-competitive (or a hard-core prohibited restraint). In others, it is evaluated under the rule of reason or balancing approach. That is, the court or administrative authority inquires whether the benefit to the producer and its distribution network is sufficiently great (e.g. by allowing it to continue producing) to offset the harm to consumers (i.e. through payment of higher prices).

Producers of finished health technologies may seek to require distributors and/or retailers to purchase a line of products, rather than allowing them to purchase only specific products (i.e. ‘tying’ or ‘package selling’). Producers may demand that distributors/retailers purchase from them exclusively, rather than from a variety of sellers (i.e. ‘exclusive dealing’). Producers may refuse to do business with particular resellers for a number of reasons including, for example, dissatisfaction with previous pricing practices (i.e. ‘refusal to deal’). Producers may offer different prices to similarly situated resellers without market-based justification, with the intent or effect of reducing competition in a line of commerce (i.e. ‘unlawful price discrimination’). Whether particular product tying arrangements, exclusive dealing arrangements, refusals to deal or price discrimination are anti-competitive will depend on the characteristics of the market. For example, if there are a number of alternative producers/sellers of comparable products, the distributor/retailer may have sufficient alternatives that a particular producer cannot compel or dictate the terms of purchase.

Producers may seek to restrict wholesalers and distributors to selling in particular geographic territories or to selling actively only in particular territories. Restricting resellers in this manner reduces so-called ‘intra-brand’ competition and tends to prevent price competition. Some jurisdictions have considered the imposition of geographic restraints on resellers anti-competitive for this reason. Other jurisdictions have allowed such geographic restraints on grounds that reducing competition among resellers may allow them to invest more heavily in promotion and service. The theory is that as long as there are other producers supplying competitive products (so-called ‘inter-brand’ competition), the consumer should not be adversely affected.

Parallel trade takes place as a consequence of different prices for the same product being charged in different markets. Parallel traders move health technologies (and other products) from lower priced to higher priced markets, engaging in a form of arbitrage. Parallel trade is prohibited in some countries which allow IP right holders to restrict importation based on locally held IP rights. For countries or regions where parallel trade in health technologies is allowed, producer-imposed restriction on this practice is generally considered anti-competitive.

b. Vertical restraints in the technology market

Pharmaceutical technologies are the product of science and technology. The technology component of health technologies, including health technologies production, may be covered by different forms of IP right. Patents protect innovative health technologies that meet certain criteria (pat-



entable subject matter, novelty, inventive step, utility and sufficient disclosure). Other forms of IP are relevant to health technologies production and distribution, including trademark, trade secret, copyright and regulatory data protection (insofar as the latter is considered a form of IP).

i. Patents and anti-competitive measures

A patent gives its owner the right to prevent others from making, using, selling, offering for sale or importing for these purposes the patented invention, which may include a medicine. The basic function of the patent is anti-competitive in that it prevents identical (or equivalent in a patent sense) versions of the same product from being made and placed on the market. However, patents are thought to induce innovation and new products, and this innovation-inducing function is seen as promoting competition by promoting new entrants into a market (or creating new markets). In theory, this provides an adequate social offset to the anti-competitive function.

The patent owner may license all or a portion of its exclusive rights to a third party—i.e. the licensee. When a licence is granted to a horizontal competitor, this may be to create a joint venture of some kind. Several patent owners may contribute their technologies to create a single product (such as a triple-combination antiretroviral medicine).

The patent owner may license its invention to a third-party manufacturer, wholly or for a specific purpose. For example, a manufacturer may be licensed to sell in a particular geographic territory or to a defined class of purchasers (e.g. government health systems).

Originator medicine patent owners tend to avoid licensing their patented products to third parties, preferring to manufacture and market through their own distribution networks. However, in those instances where third-party manufacturing and distribution licences are granted, there may be anti-competitive licensing conditions imposed. For example, a patent licensor may require that the licensee grant back to the licensor an exclusive right to patent and make use of an improvement to the licensed invention (i.e. an 'exclusive grant-back'). In some jurisdictions exclusive grant-back conditions are *per se* anti-competitive. A patent owner may require as a condition to obtaining a licence for a desired product that the licensee also take and pay for a licence on an unwanted product (i.e. 'package licensing' or 'tying'). A patent owner/licensor may insert a clause that precludes the licensee from challenging the validity of the patent (i.e. a 'no-challenge clause'). This means that the licensee must pay for the technology even if the licensee rightly concludes that the licensor was not entitled to secure exclusive rights in the invention. In some jurisdictions no-challenge causes are unenforceable as anti-competitive.

Just as goods licences that restrict the territorial distribution of health technologies may be anti-competitive, patent licences that limit the territorial distribution may be anti-competitive. However, because patents generally allow their owners to prevent third-party manufacturing and sale of products, geographic restrictions in patent licences may be less likely to raise competition law concerns. That is, because the patent owner can restrict all sales of the relevant product, it may also restrict sales to specific territories. But a patent licence with geographic restrictions might include 'ancillary restraints' such as pricing controls that are anti-competitive.



ii. Other forms of IP

Manufacturers of health technologies, originator and generic, may find it useful to obtain technologies that are not under patent but may be held in secret by a producer. Confidential commercial information is usually referred to as 'trade secret'. Patent licences may be accompanied by trade secret licences that assist the licensee to make use of the patented technology; and in the generic sector, trade secrets may be licensed independently.

Licences of unpatented but secret technology may be accompanied by anti-competitive conditions, such as conditions that require the licensee to make payment even if the formerly secret technology is publicly disclosed by the licensor.

4. Unlawful monopolization/abuse of dominant position

a. Defining the market and establishing intent

The term 'monopoly' was used in the early development of antitrust law in the United States to describe a single firm that dominated its relevant market. The term 'dominant position' was adopted in European competition law to describe the same phenomenon. In both contexts, it is possible for a monopoly or dominant position to be shared by more than one enterprise, though this is perhaps the exception.

For a firm to be considered to hold a monopoly position it must have sufficient power in its relevant market to raise prices above competitive market prices and maintain those prices for a substantial period of time. Such capacity typically reflects an absence of concern that potential competitors will be drawn into the market so as to undermine the monopolist's market power.

Competition/antitrust laws usually distinguish between unlawful monopolization and abuse of dominant position, on the one hand, and conduct involving contracts in restraint of trade and unlawful agreements between undertakings, on the other. Abuse of dominant position does not require a consensual contractual relationship between the dominant enterprise and those with which it is doing business. Other forms of competition law violation typically require some form of consensual agreement among the parties, such as an agreement to fix prices or restrict output.

A predicate to determining that a monopoly position exists is defining the relevant market. It may be fairly commonplace for individual firms to dominate sales in a very narrow product line but not be able to raise prices (above competitive market prices) because of the availability of substitute products offered by competitors. A monopoly is threatening to consumer welfare when there are not readily available substitutes such that the monopolist may dictate price and availability of supply in the relevant market.

It is generally not unlawful for a firm to be a monopoly provided that it has obtained that position by lawful means, such as by producing a better product that consumers have preferred over those of competitors. Likewise, it is not unlawful for a firm to be dominant in a relevant market. However, it is unlawful for a firm to acquire or seek to acquire a monopoly through anti-competitive means or to abuse a dominant position once it has been acquired.



b. Abusive practices generally

There are various types of abusive practices in which firms may engage with the objective of obtaining monopoly or dominant position. These include establishing conditions in supply contracts that preclude purchasers from dealing with third-party suppliers (i.e. 'exclusive dealing arrangements'), pricing products below the cost of production with the intent of driving competitors from the market (i.e. 'predatory pricing'), establishing technical standards or requirements that preclude third-party products from interoperating with devices or networks, imposing volume and other purchase conditions that effectively foreclose competition, refusing to license under conditions where the refusal is unreasonable, and others.

A monopolist may unlawfully acquire its position by forcing competitors out of business. It may also unlawfully acquire its position by merger or acquisition. A merger or acquisition may be predatory in that the acquiring firm is attempting to secure a dominant position to raise prices above competitive market prices.

c. Issues relating to patents

Patented health technologies present complex issues in respect to monopoly and/or dominant position. The patent by its nature confers on its owner the right to exclude third parties from introducing an identical or equivalent (i.e. infringing) product onto the market. When it adopts patent protection for health technologies, a national government elects to confer monopolies on particular innovators. Each patent owner (assuming a drug is introduced onto the market) possesses a monopoly for that specific product but does not necessarily enjoy monopoly in a therapeutic class. That is, there may be acceptable substitutes.

The fact that a patent owner enjoys a legislated monopoly does not mean that this monopoly position may not be abused. For example, the owner might require purchasers of its patented medicine to purchase a full product line as a condition of purchasing the patented medicine. Such a condition will substantially leverage the power of the patent owner. The patent owner may be unlawfully extending the power of the patent to foreclose competitors from pursuing the same customers. As discussed above, the US Supreme Court recently observed in *FTC v. Actavis* that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent."⁷

i. Abusive or excessive pricing

A monopoly established through a patent gives its owner the ability to set its price without concern over direct competition from an identical or equivalent (from a patent standpoint) product. If the particular medicine is unique in its therapeutic class, consumers/patients may not have an alternative. They are effectively required to purchase the patented product regardless of its price (assuming, of course, they can afford it). Competition authorities may take action against a pharmaceutical patent holder when they conclude that there is not a reasonable relationship between the price being charged for a medicine and the expenses of the patent

7. US Supreme Court, *Federal Trade Commission (FTC) v. Actavis*, Sup. Ct., 526 U. S. 756, US Supreme Court, Washington, DC, 2013.



holder in developing and supplying it (see Box 3.9). This lack of reasonable relationship is a form of abuse of the patent right or dominant position, given that the patient/consumer has no viable alternative. The challenge to competition authorities in such context is to establish what the reasonable price of a medicine should be, given what is often a lack of reliable information from the patent holder/producer regarding the costs of development and production.

The refusal of the patent owner to provide cost information may itself be a form of abuse of monopoly or dominant position. Competition authorities may use their subpoena power to compel the provision of such information.⁸ A model standard regarding excessive pricing included in this guidebook suggests that competition law may employ a presumption that pharmaceutical prices that are unaffordable to the relevant public are excessive, shifting the burden to pharmaceutical suppliers to justify the prices on the basis of demonstrated cost.

Resource restraints aside, one reason why competition law actions involving pharmaceutical pricing are not commonplace is that government price control systems may function as a form of substitute for addressing abusive pricing, and many governments operate pharmaceutical price control systems. Some of these operate within the framework of a competition commission.

BOX 3.8: Canada: Patented Medicine Prices Review Board

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body established by Parliament in 1987 under the Patent Act (Act).

The PMPRB protects the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. It does this by reviewing the prices that patentees charge for each individual patented drug product in Canadian markets. If a price is found to be excessive, the Board can hold public hearings and order price reductions and/or the offset of excess revenues. The PMPRB regulates the 'factory gate' prices and does not have jurisdiction over prices charged by wholesalers or pharmacies, or over pharmacists' professional fees.

The PMPRB is also responsible for reporting on trends in pharmaceutical sales and pricing for all medicines and for reporting research and development spending by patentees.

The first step in the PMPRB's regulatory process is a scientific review, which assesses the level of therapeutic improvement of a new patented drug product. A committee of experts known as the Human Drug Advisory Panel also recommends appropriate drug products to be used for comparison. The level of therapeutic improvement of a patented drug is used to determine a ceiling price, known as the Maximum Average Potential Price, at introduction.

Decisions of the PMPRB that establish maximum prices for patented pharmaceuticals can be found at 'Decisions and Orders' (<http://www.pmprb-cepmb.gc.ca/english/View.asp?x=254>). Proceedings may also result in Voluntary Compliance Undertakings by the patent owner. For example: Patented Medicine Prices Review Board Communique: Price Reduction for Remicade:

8. Originator pharmaceutical companies may assert that R&D cost information is proprietary commercial information that must be protected against disclosure. An administrative authority or court may decide that such information should be examined under confidentiality constraints as appropriate to the circumstances.



BOX 3.8 (continued)

Ottawa, April 1, 2003: The Patented Medicine Prices Review Board has accepted a Voluntary Compliance Undertaking (VCU) agreed to by Schering Canada Inc. (Schering) and Board Staff that will have the effect of lowering the price of the medicine Remicade.

Upon releasing its decision to accept the VCU, the Board indicated that the VCU benefits patients with an immediate price reduction of approximately 20%, bringing the price of Remicade within the Board's Price Guidelines.

Source: Patented Medicine Prices Review Board (<http://www.pmprb-cepmb.gc.ca/english>)

Colombia: Reference prices and price controls in Colombia

Colombia's National Medicines Pricing Commission fixes reference prices for all medicines commercialized in the country's public sector at least once a year. To do so, it takes into account the average price in the domestic market for a group of homogenous health technologies, i.e. products with identical composition, doses and formulas. If the price applied for such a medicine is above the reference price for homogenous products, direct price controls are applied and a maximum retail price is fixed by the Commission.

Direct price controls are also applied if there are less than three homogenous products on the market. In such cases, the Commission establishes an international reference price (IRP) by comparing the price applied for the same product in at least three of eight selected countries from the region (Argentina, Brazil, Chile, Ecuador, Mexico, Panama, Peru and Uruguay) and in Organisation for Economic Co-operation and Development (OECD) countries. The lowest price found in any of these countries is fixed as the maximum retail price for Colombia.

The application of price controls has played a prominent role in the case of lopinavir and ritonavir provided to HIV/ AIDS patients in Colombia. In 2009, the Colombian Ministry of Health rejected a 2008 application for a compulsory licence on the grounds of lack of public interest. As this medicine was listed on the national EML, its supply by insurers to patients was mandatory, and therefore the price applied by the right holder would not block access. At the same time, the Commission decided to regulate the price of the medicine concerned. The prices were fixed at US\$1,067 for the public sector and US\$ 1,591 for the private sector, representing an average reduction of between 54 per cent and 68 per cent per person per year (Brazilian Interdisciplinary AIDS Association, 2009). The right holder's appeal against the decision was rejected. In 2010, the originator company agreed to sell the medicine at the price fixed by the Commission.

Source: WHO, WIPO and WTO, 'Promoting Access to Medical Technologies and Innovation: Intersections public health, intellectual property and trade', WHO, WIPO and WTO, Geneva, 2012: 158, Box 4.4.

On February 26, 2014, the Superintendent of Industry and Commerce of Colombia imposed a fine of 3,080,000 Colombian pesos (more than US\$1,500,000) on the originator company (Abbvie, formerly Abbott Laboratories) for having charged prices in Colombia for the above-referenced drug combination (lopinavir and ritonavir) above the reference price established by the National Medicines Pricing Commission (Resolution No. 11990 of February 26, 2014, Director of Investigations for the Control and Verification of Technical Regulations and Legal Measures, available at <http://www.citizen.org/actions-colombia>).



ii. Public interest distinguished

The situation in which the government intervenes to require that a patent owner make a drug available at a lower price (such as by issuing a government use or compulsory licence) because it is unaffordable to patients and necessary to protect public health is different from the competition ground discussed above. There may be situations in which a patent holder is not pricing unreasonably from the standpoint of a conventional business model but where the interests of the public are not being adequately served. In such circumstances, a government may decide that the interests of the public will take precedence over the commercial interests of the patent owner, even if that means that the patent owner will not recover its costs as rapidly as it might otherwise. A government issuing a government use or compulsory licence in this context need not make a finding that the patent holder has engaged in an abusive practice. The laws of many countries allow the granting of government use or compulsory patent licences on grounds of public interest/public health.

iii. Prevention of market entry by competitors

As noted above, a pharmaceutical patent holder may enjoy a period of market exclusivity for a product as a legislative consequence of the grant of the patent. However, patents are granted for a limited period of time; generally, 20 years from the filing date, but potentially extended for some years, depending on a country's national legislation. When the patent expires, off-patent or generic producers may enter the market with the same or equivalent drug. This typically results in a substantial reduction in prices. In addition to the "natural expiration" of patents, generic producers may challenge the validity of patents that have been granted in order to expedite entry into the market. A patent conveys only a presumption of validity; that presumption may be challenged. Generic challengers are often successful in demonstrating that patents should not have been granted in the first place.

Pharmaceutical patent holders face significant falloff in revenue when patents expire and/or are in successfully challenged. In order to forestall or delay the entry of generic competitors, patent holders may file new applications for minor modifications to existing health technologies that complicate the potential entry of generics. Even if it is not clear that the new patents prevent the making and selling of a generic product, the mere presence of those patents may create sufficient uncertainty for generic producers that they are unwilling to go ahead until the legal situation is clarified. In jurisdictions where there is a link between the system under which health technologies are approved for marketing health technologies and the system under which patents are granted, generic producers may be precluded from obtaining marketing approval until a court rules on the patent situation.

It is not unlawful or anti-competitive for an originator pharmaceutical firm to file a patent application for an improvement to an existing drug in circumstances in which the claimed innovation should ordinarily satisfy the criteria of patentability. And, in principle, an application covering a specific improvement or modification should not preclude a generic company from obtaining marketing approval and selling a version of the drug that is not covered by a new patent. The issue from a competition law standpoint is when does the filing of a patent application constitute abuse of the patent and/or health technologies regulatory system? The firm



filing a patent application may lack a good faith belief that the claimed invention should be entitled to patent protection. Filing an application solely for the purpose of inhibiting generic entry may be abusive (see Box 3.9 for an example, recognizing this). The firm that has secured a new patent, whether or not obtained in good faith, may initiate litigation knowing that the proposed activities of the generic producer would not infringe the new patent because, for example, the generic producer is acting within the scope of an expired patent. Such conduct by a patent owner may be anti-competitive and abusive. Such conduct may fall under the heading of “sham litigation” from a competition law standpoint, meaning that the litigation is initiated without a good faith or reasonable belief that it may be successful, and is brought for the purpose of harassing or unjustifiably inhibiting potential competitors.

BOX 3.9: A case study of pay for delay tactics
Press Release: European Commission welcomes Court of Justice judgment in the AstraZeneca case

19 June 2013: The European Commission welcomes today’s judgment by the Court of Justice of the European Union (Case C-457/10 P) dismissing an appeal brought by AstraZeneca against the judgment by the General Court of 2010 which had upheld—to a very large extent—a Commission’s decision from 2005. The Commission had fined AstraZeneca €60 million for abusing its dominant position relating to its best-selling anti-ulcer medicine Losec. The Court of Justice ruled for the first time on a Commission decision on the abuse of a dominant market position in the pharmaceutical sector. Today’s judgment is significant as it clarifies a number of issues of principle in relation to market definition, dominance and the concept of an abuse in the meaning of Article 102 TFEU. In particular, it confirms that misuses of regulatory procedures can in certain circumstances constitute abuses of a dominant position within the meaning of EU antitrust rules (Article 102 of the Treaty on the Functioning of the European Union). The judgment also confirms the Commission’s method to define the relevant product market and existence of a dominant position in the pharmaceutical sector.

In June 2005 the Commission adopted a decision fining AstraZeneca €60 million due to its infringements of Article 102 TFEU and Article 54 of the European Economic Area (EEA) Agreement (IP/05/737). The two infringements involved misuses by AZ of public procedures and regulations in a number of EEA states aimed at excluding generic firms and parallel traders from competing against AZ’s anti-ulcer product Losec.

In July 2010 the General Court (Case T-321/05: MEMO/10/294) very largely dismissed the appeal by AstraZeneca, upholding the Commission’s decision. The General Court annulled part of the Commission’s decision in respect of the second abuse, resulting in a lowering of the fine from 60 to 52.5 million euros.

The judgment concerns two types of misuses of regulatory procedures and systems. It does not concern abuses or misuses of patents or other intellectual property rights. The first abuse upheld by the Court today involved the provision of misleading information to national patent offices with the aim of preventing or delaying market entry of competing generic



BOX 3.9 (continued)

products. On the first abuse the Court found that the assessment whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be made in concreto and may vary according to the specific circumstances of each case.

The second abuse involved the deregistration of the market authorisation for AstraZeneca's bestselling ulcer medicine Losec in selected countries with the aim of raising barriers against generic entry and parallel trade. The Court stated that an undertaking which holds a dominant position has a special responsibility under Article 102 and that it cannot therefore use regulatory procedures in such a way as to prevent or make more difficult entry of competitors on the market, in the absence of grounds relating to the defence of legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.

The Court found that the illegality of abusive conduct under Article 102 is unrelated to the compliance or non-compliance by an undertaking of other legal rules and that, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.

The Court's judgment also clarifies many issues in relation to the product market definition. The judgment also confirms that IPRs constitute a factor relevant to the determination of dominance. The Court's judgment finds that a dominant position is not prohibited, only its abuse and a finding that an undertaking has such a position is not in itself a criticism of abusive conduct under Article 102 is unrelated to the compliance or non-compliance by an undertaking of other legal rules and that, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.

The Commission decision

On 15 June 2005 the Commission adopted a decision by which it found that AstraZeneca AB and AstraZeneca plc had committed two abuses of a dominant position. The first abuse consisted mainly of a pattern of allegedly misleading representations made before the patent offices in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom. The second abuse consisted of the submission of requests for deregistration of the marketing authorisations for Losec capsules in Denmark, Norway and Sweden combined with the withdrawal from the market of Losec capsules and the launch of a new version of that product (Losec MUPS tablets) in those three countries. The abuses found constituted abuses of regulatory proceedings. They did not involve abuse of patents or intellectual property rights.

The Commission imposed on AstraZeneca AB and AstraZeneca plc jointly and severally a fine of EUR 46 million and on AstraZeneca AB a fine of EUR 14 million.

Source: European Commission, 'Press Release: Commission welcomes Court of Justice judgment in the AstraZeneca case', European Commission, Brussels, 6 December 2012.



iv. Restricting access to essential facilities

A good, service or technology developed by a private-sector (or public-sector) firm may become so widely adopted that third-party access to it becomes necessary as a condition of doing business. In the technology area, this phenomenon is sometimes referred to as the 'network effect' in the sense that the more widely adopted a technology becomes, the more important it becomes to doing business. To illustrate, if there is only a single Internet service provider (ISP) covering a particular geographic region, third-party providers of Internet-based services are reliant on access to that ISP's network to pursue customers and conduct business. The ISP may be privately owned, but its facilities have become 'essential'. The ISP may unilaterally determine the conditions of service, including by threat (or act) of denying access to third-party users. There are different doctrinal approaches to determining the circumstances under which a facility is 'essential', and what may constitute anti-competitive denial of access to such facility. But it would appear that most competition law jurisdictions accept some form of essential facilities doctrine.

There are certain types of arrangements that may be essential to competition in the field of health technologies. For example, assume that there is a single pharmaceutical benefits firm and/or plan covering a given geographic territory.⁹ If that single pharmaceutical benefits firm and/or plan refused to allow bidding on contracts by a particular company (or companies) or established bidding conditions that were unusually onerous, such conduct might constitute anti-competitive restriction of access to an essential facility.

As discussed in Annex,¹⁰ South Africa's Competition Commission found, in a proceeding under the Competition Act initiated by Treatment Action Campaign and others, that two pharmaceutical-patent-owning companies (GlaxoSmithKline and Boehringer Ingelheim) had refused to give a competitor access to an essential facility (in this case patents on HIV medicines) when it was economically feasible to do so. The Commission proposed to request that the Competition Tribunal issue an order for compulsory licensing of the patents on payment of a reasonable royalty. The proceeding was terminated following the decision by the patent-owning companies to grant voluntary licences to a number of generic pharmaceutical companies (see Chapter 4).¹¹

v. Refusal to license

Competition law generally recognizes that patent and other IP right owners have discretion whether to license or refrain from licensing their IP rights to third parties. Generally speaking, there is no affirmative duty to license.

However, a refusal to license an IP right may be anti-competitive under certain conditions. Article 31(l) of the WTO TRIPS Agreement, by way of illustration, specifically authorizes a government to grant a compulsory patent licence in circumstances where a patent on an important technical advance (the 'second patent') over an existing patented invention (the 'first patent')

9.. A pharmaceutical benefit plan may be operated by a governmental or quasi-governmental authority. Potential anti-competitive conduct by government authorities is assessed differently from private conduct and is not addressed in this paper.

10. At Section 5.

11. At [text at notes 122–34].



cannot be exploited without infringing the first patent.¹² Under such circumstances, a refusal by the owner of the first patent to license it to the owner of the second patent is effectively presumed anti-competitive in the sense of unreasonably preventing the emergence of the new technological solution.

Where a patent is used to block a significant industrial or technical development, this may have a substantial anti-competitive effect by eliminating the possibility for dynamic change to the market that may occur through the introduction of the important new technology. A refusal to license on reasonable terms and conditions may thus be anti-competitive depending on the context.

As described in Chapter 1(a), the South African Competition Commission determined that refusal by patent-owning pharmaceutical companies to grant licences to generic companies on patents needed to produce HIV antiretroviral medicines constituted anti-competitive refusals to license. The patent-owning companies were found to have a dominant position on the relevant market, and the refusals to license prevented the introduction of low-priced treatments necessary to satisfy public health requirements.

The factors used to assess whether refusal to license is anti-competitive should take into account the characteristics of the relevant local market. The refusal to license a particular patent in the market of a highly industrialized country may have some anti-competitive effects, but those effects may be more than offset by the overall dynamism of the local R&D infrastructure or by the availability of alternative technical solutions. The refusal to license the same patent in the market of an LMIC may have anti-competitive effects that are not similarly offset, and may have an adverse effect on consumer welfare.

5. Remedies for anti-competitive practices relating to access to health technologies

Remedial actions to address anti-competitive behaviour may be initiated by public authorities or private parties. In many jurisdictions, government agencies responsible for competition law enforcement are the principal enforcers, with private-sector actors playing a minimal role. Among the reasons for this are that investigations of anti-competitive conduct are typically fact-intensive, and in many jurisdictions private-sector litigants may have difficulty compelling discovery and production of evidence. Also, conducting a competition enforcement action against a large enterprise may involve substantial expenditure of resources, and government agencies may be better situated to undertake such expenditures than private-sector companies. The United States appears to be unique in permitting private-sector actors to collect triple damages for harm caused by anti-competitive conduct. This provides an incentive for private plaintiffs and their attorneys to pursue anti-competitive conduct that may be absent in other jurisdictions where recovery is limited to actual damages.

12. In this situation, Article 31(l)(ii) of the TRIPS Agreement requires that a cross-licence on reasonable terms and conditions be made available to the owner of the first patent.



a. Settlement

Probably the most common form of remedy to anti-competitive conduct takes the form of an agreement between the government and the subject of investigation setting forth an undertaking by the subject to cease the alleged anti-competitive conduct. Such an undertaking may (or may not) include an admission of wrongful conduct by the accused. Such an undertaking may include conditions of various kinds reflecting the nature of the anti-competitive conduct and an appropriate remedy (see Box 3.10 for an example). Such a settlement may also include a payment by the subject party to the government to cover the cost of the investigation, damages caused by the anti-competitive conduct and/or as a penalty. A settlement usually defines the conditions under which government action against the subject would be re-initiated, and potentially defines undertakings regarding cooperation by the subject with a future investigation.

The settlement agreement may take the form of a judicially approved order (sometimes referred to as a 'consent decree'). A judicial order typically follows the initiation by the government of proceedings against an accused competition law violator. The advantage of such a judicial order from the standpoint of the government is that its terms are enforceable by subsequent judicial decree that does not necessitate initiating a new case. In some circumstances, the judge may exercise continuing supervision over the implementation of the terms of the court order or consent decree. This may require the accused party to submit periodic reports to the judge. A consent decree may include built-in financial (or other) penalties for violating its terms.

BOX 3.10: US antitrust actions in health care services and products

Mylan Laboratories, et al., 62 F. Supp. 2d 25 (D.D.C. 1999) (<http://www.ftc.gov/os/caselist/x990015ddc.htm>)

In a complaint seeking injunctive and other relief filed in U.S. District Court for the District of Columbia, the Commission charged Mylan Laboratories and three other companies, Profarmaco S.R.L., Cambrex Corporation, and Gyma Laboratories, with restraint of trade and conspiracy to monopolize the markets for two generic anti-anxiety drugs, lorazepam and clorazepate. The complaint also charged Mylan with monopolization and attempted monopolization of those markets. Thirty four state Attorneys General filed a similar complaint in U.S. District Court. According to the FTC's complaint, Mylan, the nation's second largest generic drug manufacturer, sought to restrain competition through exclusive licensing arrangements for the supply of the raw material necessary to produce the lorazepam and clorazepate tablets, thereby allowing Mylan to dramatically increase the price of lorazepam and clorazepate tablets. On July 7, 1999, the court denied defendants' motions to dismiss the FTC complaint, finding that § 13(b) of the FTC Act allows the Commission to seek permanent injunctive relief for violations of "any provision of law" enforced by the FTC, and allows the Commission to seek monetary remedies such as the disgorgement of profits.

On November 29, 2000, the Commission approved a proposed settlement, subject to approval by the federal district court, under which Mylan agreed to pay \$100 million for



BOX 3.10 (continued)

distribution to injured consumers and state agencies. The defendants also agreed to an injunction barring them from entering into similar unlawful conduct in the future. Fifty states and the District of Columbia also approved the agreement. On February 9, 2001, the court entered the Stipulated Permanent Injunction agreed to by the parties. On February 1, 2002, the court granted final approval of the settlement agreement and distribution plan under which Mylan was required to place \$100 million into an escrow account for disbursement to purchasers of lorazepam and/or clorazepate during the time period covered by the settlement.

Source: US Federal Trade Commission, '2013 Overview of Antitrust Actions in Health Care Services and Products', US Federal Trade Commission, Washington, DC, 2013: 15–16.

b. Injunctions

Whether a proceeding has been initiated by the government or a private complainant, the remedy against anti-competitive conduct ordinarily will include an **injunction** directing that the accused cease the anti-competitive conduct and refrain from further anti-competitive acts (see Box 3.9). Such an injunction or order may direct the accused to restore certain conditions that may have existed prior to the anti-competitive conduct.

Although an injunction customarily refers to an order directing a party to refrain from certain conduct, a judge (or relevant administrative authority) may also direct a violator to undertake affirmative acts intended to remedy the damage it has caused. One such type of order, discussed further below, is to provide a licence to a third party or parties to use certain technologies. However, there are a wide variety of judicial orders or directives that may be issued as remedy. For example, if a judge were to determine that a pharmaceutical company had anti-competitively charged excessive prices for its health technologies, the judge could order the company to supply products at a defined lower price (i.e. 'price controls') for some period of time (as an alternative to, or in conjunction with, a compulsory licence).

c. Technology remedies

One government or judicial remedy for anti-competitive behaviour involving patented technology is the order of a compulsory licence (see Box 3.11 for an example). Pursuant to a compulsory patent licence, a party other than the patent owner is authorized to use the patented technology to manufacture the subject product, or import the subject product, and place it on the market in competition with the patent owner. As discussed above in Chapter 2, the TRIPS Agreement establishes certain limitations with respect to the issuance of compulsory licences. However, when such licences are issued to remedy competition law violations, several important limitations are waived. There need not be prior negotiation with the patent owner, there need be no royalty or compensation paid to the patent owner, and products produced on the basis of the patent can be exported without restriction (regarding predominant supply of the domestic market). Each of these waiver



conditions was initially established to take account of the competition law of the United States, where there are broad judicial powers and discretion in mandating compulsory patent licences as a competition law remedy. The TRIPS Agreement incorporates broad judicial and administrative flexibility to issue compulsory patent licences to remedy anti-competitive conduct, and some countries have incorporated this option into national law.

BOX 3.11: The Italian Competition Authority

A364—Merck—Active Ingredients (Conclusion of Investigation)

Pharmaceuticals: Antitrust Authority Rules Merck Must Grant Free Licences for the Active Ingredient Finasteride

The Authority accepts and renders obligatory a commitment presented by the companies Merck & Co. Inc. and Merck Sharp & Dohme (Italia) in order to conclude the investigation launched in February 2005 into possible abuse of a dominant position. Expected price reductions for the drug to benefit consumers and the National Health System.

The Merck group will be obliged to grant free licences to allow the manufacture and sale in Italy of the active ingredient Finasteride and related generic drugs two years before the 2009 expiration of the Complementary Protection Certificate. This was decided by the Italian Competition Authority when, at its meeting on 21 March 2007, it accepted and made obligatory the commitment presented by the multinational itself, thus bringing to a close without penalty the proceeding relating to abuse of a dominant position. The corporation's commitment to remove an obstacle to the production in Italy of Finasteride and a generic version of related pharmaceuticals, among the most important drugs used in the treatment of hypertrophy of the prostate, will encourage greater competition in this market and may lead to significant reductions in retail prices and in costs for the National Health System in Italy and in other European countries.

This ruling needs to be seen in the wider context of the Authority's efforts to encourage businesses to adopt commitments aimed at improving market conditions, competition and consumer choice. In the pharmaceuticals sector in particular the Antitrust Authority's initiative is aimed at encouraging more widespread use of generic products, taking advantage of notifications from the Italian Office of Patents and Trademarks within the Ministry of Economic Development which are based on regulations governing patents in this sector. In February 2006, the Antitrust Authority had already obtained the opening up of licensing from another multinational, Glaxo, which paved the way for the manufacture of generic forms of a powerful migraine medicine, sumatriptan succinate. In this recently concluded investigation, the Authority had also obliged the Merck group, by way of an injunction, to grant licences for the manufacture of the active ingredient imipenem cilastatina which is used in the treatment of serious hospital infections.



BOX 3.11 (continued)

These were cases in which the Authority had to assess the abusive nature of unjustified refusals to grant licences that were indispensable for the production of active ingredients in quantities sufficient to allow wide distribution of generic drugs, to the benefit of competition and consequently of consumers.

Rome, 26 March 2007

Source: Autorità Garante della Concorrenza e del Mercato (AGCM), 'Press Release: Pharmaceuticals: Antitrust Authority Rules Merck Must Grant Free Licences for the Active Ingredient Finasteride', AGCM, Rome, 2007, <http://www.agcm.it/en/news-room/press-releases/1096-a364-merck-active-ingredients-conclusion-of-investigation.html>

Abusive conduct based on patents is not limited to excessive pricing or similar actions with respect to health technologies. As discussed above, a patent pool may be established or implemented to accomplish anti-competitive objectives (such as to concentrate technology-based market power in a limited number of firms). Judicial or administrative remedies with respect to a patent pool might involve modifying the terms of access to the pool, such as opening up licences to additional parties or reducing royalty payment requirements.

d. Damages

Anti-competitive conduct imposes a cost on consumers and on the firms injured by that conduct. Those costs can be calculated and assessed as **damages** awarded against the violator. In jurisdictions where private competition law actions take place, damages are typically awarded in favour of the injured party that has prosecuted the legal action. The injured party must demonstrate to the court or judge the actual damages it has suffered using some reasonable basis. In the United States, the amount of actual damages suffered by a private party (or the US government) is tripled (or 'trebled') without a requirement to demonstrate some additional form of bad intent (such as willfulness). Damages may also include the forfeiture of property wrongly obtained as the result of anti-competitive acts.

A number of countries take issue with US competition law, insofar as it provides for the tripling of damages. However, as discussed above, because private prosecution of competition law complaints is an expensive and difficult undertaking, a significant financial incentive may be needed to encourage such private prosecution.

e. Merger and acquisition controls (e.g. blocking orders and divestment orders)

Mergers and acquisitions in the health sector, including with respect to pharmaceutical producers, raise concerns with respect to concentration of pricing power and control of availability. In many jurisdictions, mergers and acquisitions above a threshold size require notification to competition authorities (i.e. 'pre-merger notification') and are subject to review and approval by those authorities. Denials of approval may typically be appealed to the courts.



Competition law authorities may take into account a variety of factors in deciding whether or not a particular merger or acquisition will be anti-competitive. These include the level of concentration of firms in the relevant industry, as well as the implications for competition in particular markets (and submarkets). In the context of mergers and acquisitions of originator and generic pharmaceutical companies, competition law authorities may consider the resulting situation as regards specific therapeutic classes of health technologies and whether there is a risk that the combined firm will exercise undue control over a specific therapeutic class. Competition authorities might also take into account whether the combined firms would create a risk of reduced competition in R&D in the development of new health technologies. In a number of jurisdictions the competition authorities have issued guidelines that should allow proposed combining firms to determine whether a combination is likely to be approved.

In terms of pre-merger review, competition authorities may establish as a condition of approval that the combining firms divest themselves of certain properties or product lines. Thus, for example, if competition authorities determine that there is a risk of reduced competition for a particular therapeutic class of health technologies, they might require that a particular medicine line be transferred to a third party whose products will compete with comparable products of the combining firm.

If competition authorities determine that a particular merger or acquisition would unduly reduce competition and should not be approved, depending on the national law, they might issue a blocking order or request such an order from judicial authorities. As noted above, such an order would be subject to challenge by the proposed combining firms. As a consequence of a challenge, the judge might modify the order, for example, authorizing the combination to proceed but under defined conditions (including, for example, with a divestiture).

f. Criminal penalties (fines and/or imprisonment)

Anti-competitive conduct is subject to criminal penalty (in addition to civil prosecution) in many jurisdictions (see Box 3.2 above for an example). Individuals and business entities may be subject to prosecution. Culpable individuals may be subject to imprisonment, and individuals and business entities subject to criminal fines. By way of illustration, sections 1 and 2 of the Sherman Act in the United States each provide that the prohibited acts shall constitute felonies, that corporations may be fined \$100 million for a violation of each section, that individuals may be fined \$1 million, and that individuals may be imprisoned for up to 10 years. The maximum fine may be increased to twice the amount the conspirators gained from the illegal acts or twice the money lost by the victims of the crime, if either of those amounts is over \$100 million.

g. Remedies for patent and related abuse

i. Current trends in enforcement

This chapter has described various practices by which patents and other forms of IP can be abused so as to hinder competition. Traditionally, competition law remedial actions are initiated by government regulatory authorities or private parties to prevent further injury to the public and to recover damages (and, in appropriate cases, penalties) for the injuries that may



have been caused. However, there is a type of anti-competitive practice that pharmaceutical enterprises have engaged in that, up until recently, has not often been appropriately or commonly addressed. This is when patents have been abused to prevent entry of generic products onto the market in suspect or abusive circumstances, such as when a pharmaceutical company applies for and secures a patent with the knowledge that it has made an invalid claim. For a number of reasons, patent offices may grant patents without adequate assessment, and it is left to third parties to challenge those patents to gain market entry (including by defending against an unwarranted infringement claim).

If a suspect patent is eventually determined by a court or administrative authority to be invalid, and if it has been invoked by a pharmaceutical company patent owner to prevent generic competition from entering the market, the pharmaceutical company may well have abused the patent system for anti-competitive purposes. But if the only potential means by which the pharmaceutical company patent owner is penalized is through private competition lawsuits by generic companies, effective remedy may be infrequent. It is expensive and time-consuming for a private generic company to initiate and pursue a competition law cause of action. Government regulatory authorities are typically in a better position to pursue such actions because they should maintain sufficient staffing for such purposes; they have a longer time horizon (e.g. shareholders are not demanding immediate financial returns); and in the case of governments which procure large amounts of health technologies for their citizens, they will often have a significant financial incentive to do so. By pursuing competition enforcement against patent abuse and related practices, they are protecting the broad public interest.

Recently government competition authorities have been more assertive in bringing actions against pharmaceutical-patent-owning companies that have abused their position to prevent or forestall generic market entry. This includes imposing substantial fines for so-called 'pay for delay' deals pursuant to which patent owners buy off patent challenges by prospective generic market entrants (see Box 3.5 above), and by imposing fines for using related tactics such as negative advertising campaigns against generic companies (for example, that impugn the quality of generic products without justification) (see Box 3.12).

BOX 3.12: France: The Autorité de la Concurrence fines Sanofi-Aventis € 40 600 000 for denigrating generic versions of branded drug Plavix

On 14 May 2013, following a complaint from the generics manufacturer Teva Santé, the Autorité de la concurrence (the Autorité) imposed a fine of € 40 600 000 on Sanofi-Aventis for having implemented a strategy of denigrating the generic versions of its branded drug, Plavix, vis-à-vis pharmacists and doctors, with the goal of limiting their entry on the market and favoring Sanofi-Aventis' Plavix as well as its own generic version Clopidogrel Winthrop. It found that Sanofi-Aventis had abused its dominant position, thereby infringing Article 102 TFEU as well as the corresponding French provision.

Source: http://ec.europa.eu/competition/ecn/brief/03_2013/fr_sanofi.pdf.



Government regulatory authorities may be aided in efforts to address patent abuse by specific legislation that provides a cause of action and a pathway for obtaining damages and/or penalties from the party undertaking the abusive conduct. As an example, Australia adopted legislation that requires pharmaceutical patent owners that initiate legal actions under its patent/regulatory approval 'linkage' mechanism (i.e. that allows patent owners to block regulatory approval by invoking patents), to certify that they are proceeding in good faith against the generic company applying for market entry. If a court or administrative authority later determines that the patent claim was not brought in good faith, the patent owner is subject to a substantial fine and to the recovery by the government of the cost to the public health system of the delayed market entry. Requiring the abusive patent owner to repay the economic losses caused to the public health system may serve as a substantial deterrent to future abuse, although the harm to an individual patient who may have been denied drug benefit coverage because of high costs might not be adequately addressed.

BOX 3.13: Australia's defence against abuse in patent linkage mechanisms

Article 17.10.4 of the US–Australia FTA obliges Australia to have measures in its marketing approval process to prevent a generic company from marketing a product where that product is claimed in a patent.

Some key features of Australia's so called Anti-evergreening provisions, adopted to prevent abuse of the linkage mechanism, are:

- Certification by patent owner under Subsection 26C(3) of the Therapeutic Goods Act 1989 (TGA): If the brand company wishes to take legal action against the generic company it must certify that the proceedings:
 - (a) are to be commenced in good faith; and
 - (b) have reasonable prospects of success; and
 - (c) will be conducted without unreasonable delay.

The test for reasonable prospects of success is an objective test that takes into account circumstances beyond the mere grant of the patent (see Paragraphs 26C(4)(a) and (b) of TGA).

- A false or misleading certificate under s26C will lead to a fine to a maximum of \$10 Million (Subsection 26C(5A) of the TGA)
- The Court may order patent owner to pay compensation to Commonwealth or State Government for losses suffered from grant of interlocutory injunction (for example, losses under Pharmaceutical Benefits Scheme) (Subsection 26C(8) and Section 26D of TGA).

Source: Peter Drahos, 'Negotiating FTAs and Public Health: The Australian Experience' (PowerPoint), Bangkok, 16 February 2007.



In addition to the route for discouraging ever-greening prescribed in Australia's patent-regulatory approval linkage mechanism described above, another more 'conventional' Australian litigation mechanism is currently being used by the Australian government in attempting to recover the economic losses the Pharmaceutical Benefits Scheme (PBS) sustained as a consequence of invalidation of certain patents that had been invoked by their owners to block entry of generic products onto the market. Under Australian law, when a party requests a preliminary or interlocutory injunction pending the outcome of a dispute, including a patent infringement action, it must provide an undertaking to compensate injured persons in the event it is not successful.¹³ Both Sanofi-Aventis (regarding a patent on clopidogrel) and Wyeth/Pfizer (regarding a patent on an extended release version of venlafaxine) had initiated infringement actions against generic producers (Apotex¹⁴ and Sigma¹⁵), respectively, and obtained preliminary/interlocutory injunctions. But the result of these infringement actions was invalidation of the patents. The government has initiated proceedings to collect the damages that resulted from delayed entry of the generic products based on the preliminary/interlocutory injunctions. This type of action provides a potential model for other countries looking for mechanisms to dissuade pharmaceutical patent owners from initiating weak or suspect infringement actions against generic producers seeking to enter the market. The patent owner must carefully evaluate the risks associated with pursuing a claim, and this may help reduce the burden of infringement actions on public health budgets and consumers.

ii. Proactive approaches

Remedies generally available in competition law enforcement, both to government authorities and private claimants, include the award of 'equitable relief' as a court or administrative authority may consider appropriate. As discussed above, the abuse of patent rights or related practices may result in substantial delays to the introduction of generic health technologies. Such practices may cause substantial harm to the public in the form of higher prices and reduced access to health technologies, and they may cause substantial harm to prospective generic competitors that are blocked from entering the market.

Once a finding of patent or related abuse is made, a court or administrative authority should broadly consider how the adverse effect on the public and/or generic competitors from that abuse can be remedied. If the objective is to bring generic products onto the market as rapidly as possible, the court or administrative authority might issue an order requiring the patent owner (originator) to assist prospective generic competitors to enter the market. Such an order might require the patent owner to consent to the use by generic competitors of a confidential drug regulatory file maintained by the drug regulatory authority so that approval of the competing generic drug can be accelerated. Another order might direct the patent owner (originator) to transfer technology to prospective generic competitors, such as by providing access to production processes or methods that may be difficult for generic competitors to replicate in the absence of technical assistance. Such technology transfer might be accomplished pursuant to a court or administratively ordered licensing arrangement.

13. This is a judge-made rule deriving from equity jurisprudence in Australia, and is today applied by the courts in granting interlocutory or preliminary injunctions. Per email from Luigi Palombi, LLB, BSc, PhD (Australia).

14. See *Apotex Pty Ltd ACN 096 916 148 v Sanofi-Aventis*, Federal Court of Australia, New South Wales Registry, filed 16 August 2007.

15. See *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2011) FCAFC 132.



Individual patients that have been denied access to necessary health technologies as a consequence of delayed introduction of generic products may not directly benefit from remedial orders that accelerate future introduction of generic products. There remains the possibility for some type of private ‘class’ financial compensation, such as through the creation of a fund to provide compensation to a patient group that has suffered injury. While the administration of such a private compensation arrangement may be difficult, the cost to the abusive patent owner may serve as a further deterrent to future abusive conduct.

It is difficult to foresee all of the circumstances in which patent and related abuse will cause anti-competitive harm to the public and generic competitors. In this regard, courts and administrative authorities should keep an open mind regarding potential equitable remedies that address specific circumstances. However, a fundamental and overarching principle to determining anti-competitive behaviour and finding remedies should be that pharmaceutical companies should not be permitted to engage in practices that abuse the patent system to unfairly prevent or hinder generic competition from entering the market. If the only remedy is invalidation of the patent (potentially after prolonged litigation), the pharmaceutical-patent-owning company retains its ‘ill-gotten gains’ (that is, the profits it made prior to invalidation of the patent) and is encouraged to repeat the behaviour. The only way to protect the public over the longer term is to establish penalties for abusive conduct sufficient to deter such behaviour.

6. International aspects: anti-competitive activities taking place abroad, and extraterritorial application of competition law

Although the focus of this guidebook is on strengthening national capacity to regulate anti-competitive behaviour within national borders, in many instances it is important to take into account the often important—albeit more difficult to control—implications of international dealings which affect the competitiveness of a marketplace. The health technologies market within a country may well be affected by actions or events taking place outside the territory of the country. Particularly in light of the significant role that international trade plays in the development, manufacture and distribution of health technologies, it is probably the exceptional case in which some aspect of the process has not taken place abroad. In terms of development and application of competition law, consideration must be given to how administrative authorities, courts and private parties will address the domestic or local effect of anti-competitive activities taking place outside the country.

There are several elements to addressing so-called ‘extraterritorial’ conduct. One issue is whether administrative authorities, courts and private parties have jurisdiction over the person (including a corporate entity) engaged in the relevant conduct abroad. Generally speaking, to exercise jurisdiction over a person, government authorities should provide notice of proceedings involving that person, and the opportunity to participate in the proceedings.¹⁶ The key thing is that for a decision, judgement or ruling to be enforceable in a domestic and/or foreign court, it is important that rules

16. Issues regarding jurisdiction over the person are common to the application of domestic rules to persons situated outside the country, and competition law is not especially unique in this regard.



regarding proper securing of jurisdiction over the person are observed.

More specific to the area of competition law enforcement is the question of when and whether conduct taking place outside a country can and should be addressed within the country. Generally speaking, as a matter of customary international law, the authorities of a country may exercise 'subject matter' jurisdiction over activities outside the country (or extraterritorial activities) when those activities have a direct and substantial effect within the country. This is a general rule designed to minimize competing or overlapping claims to exercise subject matter jurisdiction over the same conduct. Otherwise, the same activities would be governed by the law of the place where the activity takes place (i.e. the local jurisdiction), as well as by the law of the 'foreign' place which decides to exercise extraterritorial jurisdiction. This would frequently lead to conflicts between local regulation and foreign regulation, and would make conducting business rather difficult.

To make matters somewhat more confusing, international law also allows countries to regulate the conduct of their own nationals, wherever they may be located. This can (and does) lead to conflicts in regulation, though governments try to take into account the potential for such conflicts when adopting business regulations addressed to their nationals abroad.

It is certainly possible that the internal pharmaceutical market of a country will be affected by anti-competitive activities taking place outside the country. As a straightforward example, several independent pharmaceutical companies with products in the same therapeutic class may decide to fix prices for these products, expecting that this 'price-fixing' will affect import markets around the world. The pharmaceutical companies may not be 'doing business' within the territory of most of the countries where their products are sold. They may be selling to distributors that import the products into these countries from outside. In such cases, the anti-competitive price-fixing activity may be preponderantly 'extraterritorial', but it may have a direct and substantial effect within the territory of the importing countries in the form of higher prices than would prevail in competitive markets.

Though at first glance the possibilities for taking enforcement action against such extraterritorial conduct may seem straightforward, the reality may be rather complicated and difficult. There is first the issue of gathering sufficient evidence to prosecute an enforcement action, and that is likely to mean gathering evidence in a foreign jurisdiction. The rules for such evidence-gathering differ from country to country but often involve securing the cooperation of a magistrate or judicial authority in the foreign country to supervise evidence-gathering. The subject of the investigation is very likely to resist. Second, there must be some type of jurisdiction over the person within the country where the competition enforcement action is initiated, and local rules must anticipate proceedings against a person that may choose not to enter an appearance. Third, the administrative authority or court before which an action is brought must be satisfied that the requirements for exercising subject matter jurisdiction over extraterritorial activities are met. Fourth, the case must be successfully prosecuted in terms of proving that the anti-competitive activity took place. Fifth, if and when an award or judgement is rendered against a person doing business abroad, there is the matter of enforcing the judgement in the foreign jurisdiction. That is a rather complex matter in itself.

Because of the complexities inherent in bringing enforcement actions against anti-competitive



activities that take place abroad, competition enforcement authorities have placed a high premium on improving cooperation. In an ideal world, competition authorities in a country that believe the local market is being affected by anti-competitive activity in a foreign jurisdiction will notify and provide the basis for their suspicion to the competition authorities in that foreign jurisdiction. They will request the foreign competition authority to aid in the investigation by pursuing evidence, and may even encourage the foreign authority to initiate an enforcement action in the foreign country (which may be easiest if the anti-competitive activity is also affecting that foreign country). The foreign competition authority may at least be asked to provide evidence in a proceeding initiated within the requesting country.

Sometimes, anti-competitive activity is only directed to export markets. Some countries, such as the United States, do not make it illegal for their domestic companies to engage in anti-competitive activity that only affects export markets. Under US statute, a group of pharmaceutical companies within the country can agree to fix prices for the export market, and this is perfectly lawful (if not somewhat shocking).¹⁷

17. Pursuant to the Foreign Trade Antitrust Improvements Act of 1982 (FTAIA), as confirmed by the Supreme Court in *Hoffman-La Roche v. Empagran*, 542 U.S. 155 (2004).



Market definition

Jonathan Berger

KEY MESSAGES

- ▶ Defining the relevant market may be critical to an assessment of whether conduct is anti-competitive.
- ▶ Whether particular health technologies are competitors in a relevant market depends on a variety of factors which are likely to be case specific, including the extent to which the products are interchangeable from a treatment standpoint.
- ▶ Narrow product market definition enhances the likelihood that findings of anti-competitive conduct will be made.

What is market definition and why is it important?

In 'Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP', Mark Lemley and Mark McKenna explain:¹

"[Competition law]² is about market relationships. It is designed to promote competition. Competition doesn't occur in a vacuum; a company must compete with others in some market. As a result, the first step in virtually any [competition] case is the definition of the market in which the competitive harm is alleged. This is true of mergers and monopolization cases, which generally require some quantum of market share as an element of the offense—you can't measure market share without having a market in which to have that share."

Put differently, market definition is about determining the size of the playing field, as well as the number and type of players on it.³ Thus if the relevant geographic market is defined as the soccer field and the relevant product market is composed of the two teams playing each other on that

1. Mark A. Lemley and Mark P. McKenna, 'Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP', *Georgetown Law Journal*, 2012, 100(2055): 2077 (footnotes omitted).
2. Writing in the US context, Lemley and McKenna refer to antitrust (instead of competition law).
3. The size of the field refers to the relevant geographic market; the number and type of players refers to the relevant product market.



field, a third team playing on a second field cannot complain about the conduct of any particular team on the first field. But if the market is defined more broadly, to include all teams in the relevant league, then the third team would be able to pursue a complaint that relates to the impact of the result of the match between teams one and two on its league prospects.

This shows why the breadth or narrowness of a market may be determinative of an issue, without any consideration of the substantive merits. As Hovenkamp explains:⁴

“In many cases, courts have defined differentiated markets too broadly,⁵ ignoring the fact that many of the goods that were included were not capable of holding the defendant’s prices to cost. But there are other cases in which differentiated markets were defined too narrowly. A good, recent example is the *Lundbeck* decision,⁶ in which the [US Court of Appeals for the] Eighth Circuit held that the only two drugs that treated a particular condition, but which were not bioequivalents,⁷ were in different markets. As a result, the merger that united them under a single firm was lawful.”

The importance of market definition was explained by the European Commission in its ‘Commission Notice on the definition of relevant market for the purposes of Community competition law’.⁸ Published “to provide guidance as to how the Commission applies the concept of relevant product and geographic market in its ongoing enforcement of Community competition law”;⁹ the Commission Notice sees market definition as “a tool to identify and define the boundaries of competition between firms... to establish the framework within which competition policy is applied.”¹⁰ It explains:

“The main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face. The objective of defining a market in both its product and geographic dimension is to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings’ behaviour and of preventing them from behaving independently of effective competitive pressure. It is from this perspective that the market definition makes it possible *inter alia* to calculate market shares that would convey meaningful information regarding market power for the purposes of assessing dominance or for the purposes of applying Article 85 [of the Treaty establishing the European Community (TEC) dealing with Commission investigations of potential infringements of Articles 81 and 82].”¹¹

4. Herbert Hovenkamp, ‘Response: Markets in IP and Antitrust’, *Georgetown Law Journal*, 2012, 100(2133): 2146–2147 (footnotes omitted).

5. A differentiated market is one wherein the products falling within that market are differentiated from each other—while competitors in many respects, they are not carbon copies.

6. *Lundbeck* is discussed in some detail below.

7. The Merriam-Webster Dictionary defines bioequivalence as “the property wherein two drugs with identical active ingredients or two different dosage forms of the same drug possess similar bioavailability and produce the same effect at the site of physiological activity”.

8. European Commission, ‘Notice 97/C 372/03’, *Official Journal of the European Communities*, 1997, 372/5.

9. *Ibid.*: para. 1.

10. *Ibid.*: para. 2 (footnote omitted).

11. *Ibid.* Articles 81, 82 and 85 of the TEC are now articles 101, 102 and 105 of the Treaty on the Functioning of the European Union (TFEU), respectively. The TEC was amended—and renamed as the TFEU—in 2007.



The United Kingdom’s Office of Fair Trading (OFT) recognizes that market definition “is not an end in itself”.¹² Instead, it notes that market definition merely “provides a framework for competition analysis”,¹³ being “important in the process of establishing whether or not particular agreements or conduct fall within the scope of the competition rules”.¹⁴

So when would the relevant market have to be defined? It will be necessary to do this, for example, when considering whether:

- an agreement between firms has the effect of limiting competition, whether dealing with licensing (with or without technology transfer) or any other relevant matter;
- a company has a dominant position and is, therefore, subject to controls dealing with abuse of dominance; and
- a merger between companies would limit effective competition, in particular by creating or strengthening a dominant position.¹⁵

In an abuse of dominance investigation, for example, defining the market enables a determination of whether the firm in question is indeed dominant and, therefore, subject to the law’s regulation. The broader the definition, the more difficult it is to establish dominance; conversely, the narrower the definition, the easier it is to establish dominance. In practice, this translates into complainants seeking to define the market narrowly, with firms whose conduct is under investigation seeking to define the market as broadly as is reasonably possible.¹⁶

In various jurisdictions, courts, tribunals and competition authorities have developed a range of legal tests to provide guidance on how to define the relevant market in any particular case. Of course, the facts differ from case to case, so court decisions and policy guidelines have to be understood in their respective contexts. While a useful starting point, these generic approaches have to be supplemented with a specific focus on what distinguishes the pharmaceutical sector and why it may often be more helpful to return to first principles than to apply standard tests (which may be more appropriate in other sectors).

Body of the chapter

As indicated above, determining market definition may be important in a range of competition law contexts, including—but not limited to—an assessment of the lawfulness of an agreement

12. OFT, ‘Market Definition: Understanding competition law’, OFT, London, 2004: para. 2.1.

13. Ibid.

14. Ibid.: para. 2.2.

15. Richard Whish and David Bailey, *Competition Law*, 7th ed., Oxford University Press, Oxford, 2012: 28–29.

16. In merger control, however, the opposite is ordinarily the case, with the merging parties ordinarily defining markets as narrowly as is possible in the circumstances. The narrower the markets of the merging parties are defined, the less likely the proposed merger is to raise competition concerns (because the product and/or geographic overlaps giving rise to such concerns simply disappear).



between firms. For instance, at the time of entering into an agreement, the firms in question may or may not yet be rivals. As the 'Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements' recognize,¹⁷ "[i]n general, agreements between competitors pose a greater risk to competition than agreements between non-competitors."¹⁸ Such firms can only be considered competitors for this purpose if they operate within the same relevant market(s).

A recent decision of the Competition Commission of India (CCI) shows the importance of market definition in adjudicating complaints relating to the alleged anti-competitive effects of agreements between rival firms. In *Manoj Hirasingh Pardeshi v Gilead Sciences Inc., USA*,¹⁹ the informant (complainant) alleged that Gilead had violated sections 3 and 4 of the Competition Act, 2002 by entering into certain licensing agreements with Indian generics manufacturers for the production and distribution of certain antiretroviral medicines on certain restrictive terms.²⁰ At the time, Gilead was seeking patent protection in India in respect of the ARV medicines in question.

Central to the CCI's decision was its approach to the issue of market definition. In dealing with the abuse of dominance aspect of the complaint, the CCI concluded that "the relevant product market... was the production/manufacture of ARV drugs."²¹ While the decision does not expressly deal with the relevant market in respect of the alleged anti-competitive agreements, it is clear from the CCI's reasoning that the same broad market—all ARV medicines and not just Gilead's drugs or the therapeutic classes into which they fall—was identified. With such a broad product market in mind, the CCI could not find any "appreciable adverse effect on competition... due to the alleged agreements."²²

The analysis in this chapter, however, is limited to two other areas of competition law in which market definition is important: abuse of dominance and mergers. This is not because these two areas are more important, but rather because they are more likely to form the focus of litigation or other forms of legal action in an LMIC context. Furthermore, many of the principles and concepts that are used in establishing the relevant product market in these contexts—such as the fine-tuning of therapeutic class determinations—will be relevant in other contexts.

This chapter continues by examining what it is about health technologies and how they are used to prevent, treat or cure that may require a more nuanced approach to market definition than what may ordinarily be adopted in relation to other products or sectors. Among other issues, the relationship between patents and product market definition is considered, with a particular focus on

17. European Commission, 'Notice 2004/C 101/02', *Official Journal of the European Communities*, 2004, 372/5, which deals expressly with market definition at paragraphs 19–25.

18. *Ibid.*: para. 26.

19. Competition Commission of India, 'Case No. 41/2012', Competition Commission of India, New Delhi, 5 March 2013, <http://www.cci.gov.in/May2011/OrderOfCommission/412012.pdf>.

20. Section 3 deals with anti-competitive agreements; Section 4 deals with abuse of dominance.

21. Competition Commission of India, 'Case No. 41/2012', Competition Commission of India, New Delhi, 5 March 2013: para. 24, <http://www.cci.gov.in/May2011/OrderOfCommission/412012.pdf>.

22. *Ibid.*: para. 23.



whether and in what circumstances patent protection helps to define the product market. Put differently, when does patent protection result in a product constituting its very own market?

This is followed by a focus on how courts in two jurisdictions—the EU and the United States—have approached market definition in the pharmaceutical sector. Thereafter we move from theory to practice, looking at how the science of HIV treatment was used in South Africa to define the product market in an abuse of dominance case dealing with three excessively priced ARV medicines. This chapter concludes with some observations on what an access-friendly approach to market definition might entail.

Importantly, this chapter does not focus in any detail on competition law and policy dealing with market definition more broadly. Wherever useful, examples are cited in this chapter to assist in understanding why it may be more appropriate to adopt a particular approach in the context of health technologies.

Why are health technologies different?

The European Court of Justice (ECJ) makes it plain that “the definition of the market is essentially a matter of interchangeability.”²³ Whish and Bailey expand on what appears, at first glance, to be a simple concept:

“In practice, however, the measurement of interchangeability can give rise to considerable problems for a variety of reasons: for example there may be no data available on the issue, or the data that exist may be unreliable, incomplete or deficient in some other way. A further problem is that, in many cases, the data will be open to (at least) two interpretations. It is often the case therefore that market definition is extremely difficult; this is why the EU Courts have conducted a fairly “light touch” review of the Commission’s conclusions on market definition, recognising that this involves a ‘complex economic assessment.’”²⁴

At a conceptual level, this is no different in the pharmaceutical sector. Consider the following example. The antiretroviral medicine lamivudine (3TC)—a nucleoside reverse transcriptase inhibitor (NRTI)—is used to prevent and treat HIV infection.²⁵ For this indication, it is always used in combination with at least two other ARVs, one of which must ordinarily not be an NRTI (i.e. it must come from another therapeutic class).

As a stand-alone drug,²⁶ 3TC is ordinarily available in the following different dosage forms: 100 mg tablets (for hepatitis B); 150 mg and 300 mg tablets (for adult HIV); and oral solution containing

23. Richard Whish and David Bailey, *Competition Law*, 7th ed., Oxford University Press, Oxford, 2012: 30.

24. *Ibid.* (footnote omitted).

25. 3TC is also used to treat chronic hepatitis B, but at a lower dose than when used to treat HIV.

26. 3TC is also available in various two- and three-drug combinations of ARVs.



10 mg of 3TC for every mL of liquid (for paediatric HIV). Adults take 300 mg of 3TC per day, either 150 mg twice daily or 300 mg once daily. Paediatric dosing varies according to weight and height; the liquid format adequately caters for this.

In terms of the Anatomical Therapeutic Chemical (ATC) Classification System,²⁷ 3TC falls into the following five categories:

- Level 1: J—anti-infectives for systemic use;
- Level 2: J05—antivirals for systemic use;
- Level 3: J05A—direct-acting antiviral drugs;
- Level 4: J05AF—nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs and NtRTIs); and
- Level 5: J05AF05—lamivudine.

The levels are organized in the following way:

- Level 1 indicates the anatomical main group. There are 14 main groups.
- Level 2 indicates the therapeutic main group.
- Level 3 indicates the therapeutic/pharmacological subgroup.
- Level 4 indicates the chemical/therapeutic/pharmacological subgroup.
- Level 5 indicates the chemical substance.

At level 4, 3TC is joined by 11 other chemical substances. Of these, five are used to prevent and/or treat HIV;²⁸ two are used to prevent and treat HIV and to treat hepatitis B;²⁹ one is used to treat hepatitis B and herpes simplex virus;³⁰ and three are used to treat hepatitis B.³¹

Assume that an abuse of dominance complaint in respect of 3TC oral solution—to treat HIV infection in children—has been lodged with a competition authority. Before the substantive complaint can be considered, the relevant product and geographic markets have to be defined. Using the ATC system to provide potential markets, the relevant product market might be one for:

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27. We consider the implications of the ATC system for market definition below. In the WHO-maintained ATC system, used for the classification of medicines, medicines are divided “into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties”. See http://www.whooc.no/atc/structure_and_principles/.
 28. J05AF01—zidovudine; J05AF02—didanosine; J05AF03—zalcitabine; J05AF04—stavudine; and J05AF06—abacavir.
 29. J05AF09—emtricitabine (although emtricitabine is not approved for the treatment of hepatitis B in the US) and J05AF07—tenofovir.
 30. J05AF08—adefovir.
 31. J05AF10—entecavir; J05AF11—telbivudine; and J05AF12—clevudine.



- anti-infectives for systemic use,³² which includes antivirals alongside antibacterials, antimycotics, antimycobacterials, vaccines, and immune sera and immunoglobulins;³³
- antivirals for systemic use,³⁴ which only includes direct-acting antiviral drugs;³⁵
- direct-acting antiviral drugs, which includes NRTIs and NtRTIs alongside—among others—protease inhibitors,³⁶ non-nucleoside reverse transcriptase inhibitors,³⁷ and neuraminidase inhibitors;³⁸
- NRTIs and NtRTIs,³⁹ which includes drugs to treat one or more of the following infections: HIV,⁴⁰ hepatitis B and herpes simplex virus;
- 3TC;⁴¹ or
- paediatric (oral solution) 3TC.

Or the relevant product market might be something else, such as the market for NRTIs and/or NtRTIs in oral solution form that are used to treat HIV. At some point, however, the breadth of the relevant product market will preclude the substantive complaint from being considered because dominance could not be achieved over such a broadly defined market.

What is clear from this degree of complexity is that it is difficult to rely on general categorization. Instead, the ATC system can be used as a broad guide, focusing in particular on first principles and their application to the facts of any particular case. Indeed, as shown below, this is the approach that has been adopted by the European Commission in its merger analysis.

What is the key concern that underpins market definition?

Competition law is primarily concerned “with the problems that occur where one or more firms possess, or will possess after a merger, market power.”⁴² Whish and Bailey explain:⁴³

“Market power presents undertakings with the possibility of profitably raising prices over a period of time; the expression ‘raising price’ here includes, and is a shorthand for, other ways in which competition can be restricted, for example by limiting out-

32. Level 1—J.

33. J01—J06.

34. Level 2—J05.

35. Level 3—J05A.

36. Level 4—J05AE.

37. Level 4—J05AG.

38. Level 4—J05AH.

39. Level 4—J05AF.

40. As already explained, some of the drugs used to treat HIV are also used to prevent infections.

41. Level 5—J05AF05.

42. Richard Whish and David Bailey, *Competition Law*, 7th ed., Oxford University Press, Oxford, 2012: 25.

43. *Ibid.* (footnote omitted).



put, suppressing innovation, reducing the variety or quality of goods or services or by depriving consumers of choice, all of which are clearly inimical to consumer welfare. In a perfectly competitive market no firm has market power; in a pure monopoly one firm has absolute control over it. There is a continuum between these two extremes, and many degrees of market power lie along it. Competition law attaches particular significance to ‘substantial market power’, often equated with ‘a dominant position’, since the prohibition of certain unilateral practices... applies only where an undertaking or undertakings have this amount of market power.”

Pharmaceutical technologies are unlike soft drinks or cell phones. A particular increase in the price of Coca Cola may see consumers switching either to Pepsi Cola or other soft drinks; similarly, an increase in the cost of the iPhone 5 (over the previous model) may result in consumers willing to give the BlackBerry Z10 a chance. But even a substantial increase in the price of a drug to treat breast cancer will not see patients switching to antifungal medication, or even to another drug that targets a different cancer. In the health technologies field, substitutability takes on a very particular flavour.

Factors influencing the definition of product market in the pharmaceutical sector

Over and above the ordinary considerations that apply across sectors, there are numerous factors specific to health technologies that potentially have an impact on market power and market definition. Many of them are addressed in the various cases that are still to be considered in this chapter. They include (but are not limited to):

- the identity of those who make decisions about which health technologies to use;
- the relevant domestic legislative framework;
- the science underpinning the prevention, treatment or cure of any specific condition, infection or illness;
- drug regulatory considerations; and
- where applicable, the nature and extent of patent protection.

These factors are now considered in some detail below.

Identity of decision makers

Considerations of interchangeability presuppose that (a) those deciding between competitive products are in a position to make informed choices and (b) the choices are made by consumers themselves. But in the case of health technologies, this is ordinarily not the case: consumers are usually not well informed about the health technologies in respect of which they are required to exercise a choice, and decisions in respect of prescription pharmaceutical technologies are mostly taken on their behalf by health care providers and/or funders. The asymmetry of information in the prescriber–user relationship means that the user is simply not in a



position to second-guess the prescriber. And all too often, the economic choices of funders—and unfortunately, at times, prescribers—are largely determinative of which medicine gets chosen.

Relevant domestic legislative framework

In many ways, a domestic legislative framework may influence the determination of the relevant product market. Laws which have the potential to do this include those dealing with price regulation and/or control, mandatory generic substitution following patent expiry, and restrictions on advertising (in particular those that prohibit direct-to-consumer advertising in respect of prescription health technologies). Thus while two health technologies may appear at face value to compete for market share, the impact of the regulatory framework may indeed be such so as to render the perceived competition merely illusory.

Science of prevention, treatment or cure

Not all conditions, infections or illnesses are dealt with in the same way. Thus while a simple headache—absent other complicating factors—may be treated with a couple of ibuprofen, aspirin or paracetamol tablets, the same cannot be said, for example, in respect of the prophylaxis of malaria. According to the US Centers for Disease Control and Prevention (CDC), “[r]ecommendations for drugs to prevent malaria differ by country of travel.”⁴⁴ Importantly, the CDC cautions to “consider the possibility of drug–drug interactions with other medicines that the person might be taking as well as other medical contraindications, such as drug allergies”.

So, for example, Mozambique—where the predominant (95 percent) species of malaria is chloroquine-resistant—is considered a high-risk destination for US travellers. In recommending atovaquone/proguanil, doxycycline or mefloquine as prophylaxis, the CDC notes that “[w]hen deciding which drug to use, consider specific itinerary, length of trip, cost of drug, previous adverse reactions to antimalarials, drug allergies, and current medical history.”⁴⁵

The ‘Guidelines for the Prevention of Malaria in South Africa’ note that “[i]n order to choose a safe and appropriate prophylactic agent for a person travelling to a malaria area, various clinical and drug-related factors need to be taken into account”. Among others, the following are listed:⁴⁶

- current or planned pregnancy;
- pre-existing medical conditions;
- taking other health technologies, whether prescription, over-the-counter or other;
- activities requiring fine coordination and ‘spatial discrimination’, such as piloting and scuba-diving;

44. See Centers for Disease Control and Prevention, ‘Choosing a Drug to Prevent Malaria’, Centers for Disease Control and Prevention, Atlanta, 2011, <http://www.cdc.gov/malaria/travelers/drugs.html>.

45. Centers for Disease Control and Prevention, ‘Malaria Information and Prophylaxis, by Country [M]’, Centers for Disease Control and Prevention, Atlanta, 2013, http://www.cdc.gov/malaria/travelers/country_table/m.html.

46. See Department of Health, ‘Guidelines for the Prevention of Malaria in South Africa’, Department of Health, Pretoria, 2009: 12, <http://www.kznhealth.gov.za/medicine/2009malariaguideline.pdf>.



- length of visit to the area, noting that the “long-term safety of some chemoprophylactic drugs has not been evaluated”; and
- the level of compliance expected with each of the options.

The Guidelines set out the benefits and risks of the prophylactic regimens recommended for travellers. The same three drugs that the CDC recommends for Mozambique are considered, based on the following seven aspects:⁴⁷

- prophylactic efficacy;
- most common side effects;
- contraindications;
- special precautions;
- dosage interval;
- time period needed before entering malaria area; and
- resistance.

So while each of the drugs is considered “highly effective in areas where it has been tested”, mefloquine is contraindicated for the first trimester of pregnancy, and doxycycline is contraindicated throughout pregnancy and breast-feeding. In other words, pregnant women in their first trimesters have no choice of prophylactic regimen—they have to use atovaquone/proguanil or take their chances with no chemoprophylaxis at all.

Drug regulatory considerations

Globally, drug regulators differ in the manner in which they regulate the ease with which health technologies may be purchased.

In the UK, for example, the Medicines Act 1968 governs the manufacture and supply of three categories of medicine: prescription-only medicines, which can be sold by a pharmacist if prescribed; pharmacy medicines, which may be sold by a pharmacist without prescription; and general sales list medicines, which may be sold without a prescription in any shop.

In Australia, the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)⁴⁸ recognises nine schedules of medicines and poisons.⁴⁹ The scheduling classification sets the level of control on the availability of medicines and poisons. For example:

- Schedule 2 deals with pharmacy medicines: “Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.”

47. Table 3 at page 28.

48. SUSMP is established under section 52D of the Therapeutic Goods Act 1989.

49. See Australian Government, ‘Poisons Standard 2012’, F2012L01200, Australian Government, Canberra, 2012, <http://www.com-law.gov.au/Details/F2012L01200>.



- Schedule 3 deals with pharmacist-only medicines: “Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.”
- Schedule 4 deals with prescription-only medicines and prescription animal remedies: “Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.”

In South Africa the Medicines and Related Substances Act 101 of 1965 recognises 10 schedules,⁵⁰ each with increasing levels of control. So, for example, Schedule 0 medicines “may be sold in an open shop”;⁵¹ whereas only certain registered medical practitioners may sell medicines in Schedules 2 through 6 to members of the public—without a prescription for Schedule 2 medicines, but with a prescription for medicines in Schedules 3 through 6.⁵²

Depending on its form and intended application, a medicine may be found in more than one schedule:

- The antiviral drug acyclovir is ordinarily a Schedule 4 medicine in South Africa. However, “when intended for application to the lips in the early treatment of recurrent herpes simplex virus infections”;⁵³ acyclovir—in the form of a topical cream—is to be found in Schedule 1; and
- Ranitidine, a histamine receptor antagonists (‘H2 blocker’)⁵⁴ that inhibits the production of stomach acid and is used to treat acid reflux, is listed in Schedule 2 “when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to... a maximum dose of 75 milligrams... , a maximum daily dose of 300 milligrams... [and] a maximum treatment period of two weeks.” Otherwise, ranitidine is a Schedule 3 medicine, requiring a prescription.

Put simply, scheduling status may well have implications for the definition of the relevant product market.

Nature and extent of patent protection

In the introduction to this chapter, the need to consider the relationship between patents and product market definition was identified. Given increasing harmonization in respect of national patent laws, in large part as a consequence of the WTO TRIPS Agreement, it is unlikely that the extent of variation in this area compares to what is seen in respect of medicines regulation. That said, national patent laws do vary, with potential consequences for product market definition.

On its own, the existence of a patent does not necessarily mean that a particular medicine constitutes its own market. What is needed is something more: the exclusion of generic alternatives plus

50. See section 22A.

51. Section 22A(3).

52. Section 22A(5).

53. Schedule 1 to the Medicines and Related Substances Act 101 of 1965.

54. See discussion below on the *AstraZeneca* case in the EU.



a scientific reason to exclude other chemical entities also indicated for the prevention, treatment or cure of the same infection, illness or condition.

Take the example of Emtriva® (emtricitabine or FTC), a patented ARV medicine used in combination with others to treat HIV infection. While ARVs may not ordinarily be considered as interchangeable,⁵⁵ emtricitabine and lamivudine are widely considered to be interchangeable.⁵⁶ While patent protection in respect of Emtriva® currently precludes the market entry of generic emtricitabine products in many countries, the patent on Epivir® (the patented version of lamivudine) has expired in such countries, and generic lamivudine products are widely available. At minimum, the relevant product market comprises, therefore, Emtriva®, Epivir® and the various generic versions of lamivudine.

Geographic market in the pharmaceutical sector

Given that patents are granted by a national authority, that health technologies are ordinarily regulated at the national sphere of government and that courier pharmacies are available to deliver health technologies anywhere in a particular country, the geographic market will ordinarily be the national market. However, the facts of a particular case may suggest otherwise: it may well be that the geographic market is limited to the public sector, or to hospitals, or to a particular state or province. Again, context is key.

How courts in the EU and the United States have approached the issue

This part of the chapter seeks to understand how various courts, tribunals and other institutions in the United States and Europe have approached the issue of market definition in relation to health technologies. Focus is limited to the EU and the United States because there is much more—from an access to health technologies perspective—to consider in the jurisprudence.

The EU

A discussion on relevant EU law begins with the recent ECJ decision in *AstraZeneca v Commission*.⁵⁷ In that case, which upheld the findings of the General Court,⁵⁸ the ECJ had to consider the relevant product market in dealing with the European Commission's findings of abuse of dominance in respect of a medicine used to treat gastrointestinal hyperacidity. At issue on this point was whether the product market was limited to proton pump inhibitors (PPIs), which act directly on the 'proton pump';⁵⁹ or whether it also included medicines which employ a different mechanism to treat the

55. See the discussion below on *Hazel Tau*.

56. 3TC is discussed in some detail above.

57. As yet unreported decision of the ECJ (First Chamber) in Case no. C-457/10 P (6 December 2012).

58. The ECJ hears appeals against decisions of the General Court.

59. The proton pump is an enzyme found in certain cells along the stomach wall that pumps acid into the stomach.



same condition. Histamine receptor antagonists ('H2 blockers'), for example, only act indirectly on the proton pump, blocking one of its stimulants.

The abusive conduct had nothing to do with H2 blockers. Two AstraZeneca companies—based in Sweden and the UK, respectively—had been fined €60 million by the Commission “for having abused the patent system and the procedures for marketing pharmaceutical products in order to prevent or delay the arrival of competing generic [PPIs] on the market and to impede parallel trade.”⁶⁰ In particular, the conduct related to attempts to delay the market entry of generic omeprazole, the active compound in AstraZeneca’s Losec® (omeprazole), following expiry of the relevant patent(s).⁶¹

AstraZeneca had sought to delay market entry in two ways:⁶²

- first, by making misleading representations to patent offices and before courts in various European countries, which resulted in the effective extension of patent protection for Losec® to which AstraZeneca was either not entitled or to which it was only entitled for a shorter duration; and
- second, by taking steps to deregister certain formulations of Losec® that would effectively delay market authorization (registration) of generic omeprazole products.

In addition to three other grounds of appeal, AstraZeneca sought to overturn the General Court’s decision on the basis that it had made an error of law in the way it determined the relevant product market. In short, it sought to overturn the finding that the market was limited to PPIs.

Before considering the ECJ’s reasoning, it is important to understand the ATC categorization of the drugs in question. As a class, PPIs are located at level 4.⁶³ So too are H2-blockers.⁶⁴ Together with prostaglandins,⁶⁵ combinations for the eradication of *Helicobacter pylori*⁶⁶ and other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD),⁶⁷ they both fall under ‘drugs for peptic ulcer and GORD’ at level 3.⁶⁸ Together with drugs such as antacids, medicines for peptic ulcer and GORD fall under ‘drugs for acid-related disorders’ at level 2.⁶⁹

At its most basic, the product market definition question was whether it should be defined with ref-

60. At para. 1

61. Losec was the first PPI to market.

62. At paras 18–19, read together with para. 8

63. A02BC.

64. A02BA.

65. A02BB.

66. A02BD.

67. A02BX.

68. A02B.

69. Drugs for acid-related disorders (A02—level 2) include antacids (A02A), drugs for peptic ulcer and GORD (A02B) and other drugs for acid-related disorders (A02X). A02 falls under alimentary tract and metabolism (A—level 1).



erence to ATC3 or ATC4 classes of drugs. The appellants essentially pushed for ATC3; the Commission, in contrast, pushed for ATC4. And the ECJ upheld the General Court's decision to accept the Commission's view. In doing so, it noted that the Commission had made a number of (uncontested) findings in respect of AstraZeneca's market share of PPIs during the period in question (1993–2000). Among others, these included the following:⁷⁰

- In Germany, AstraZeneca held a market share of 96 percent in 1993 and nearly 83 percent in 1994. Its market share, as well as the market shares of the two companies marketing other PPIs, fell considerably following the introduction of generic omeprazole during 1999.
- In Belgium, AstraZeneca's market share was 100 percent until 1993, remained above 90 percent between 1994 and 1996, fell slightly below 90 percent in 1997, and dropped to 81 percent in 1998 and 68 percent in 2000.
- In Denmark, AstraZeneca held 100 percent in 1993 and almost 97.5 percent of the market in 1994. From 1995 to 1997, it had between 85 percent and 75 percent of the market. That share increased in 1998, stabilizing at just below 75 percent in 1999.
- In the UK, AstraZeneca's market share varied between 100 percent and 88 percent from 1993 to 1996. In 1997 it fell to 78 percent, then to 68 percent in 1998, 63 percent in 1999 and 57 percent in 2000.

At the time it first received marketing approval in the EU,⁷¹ Losec was the only PPI on the market. That only changed six years later with the first marketing approval for lansoprazole (Prevacid®).⁷² The third PPI to enter the EU market was pantoprazole (Protonix®) a year later.⁷³ The first generic version of any PPI to enter the EU market was omeprazole in 1999.

So what considerations did the ECJ take into account in upholding the General Court's—and the Commission's—approach to market definition? According to the ECJ, the General Court—in making its determination on product market definition—considered an overall appraisal of the evidence on the basis of which the Commission had made its finding. Among others, these included:

- the greater efficacy of PPIs (compared to H2-blockers);
- the different therapeutic uses of PPIs and H2-blockers;
- “the trend of asymmetrical substitution that characterised the growth in sales of PPIs and the corresponding decrease or the stagnation in sales of H2 blockers”; and
- price indicators.

70. See para 246–252 of the General Court's decision.

71. April 1987 in France.

72. In June 1993.

73. In September 1994.



For the Commission, this evidence—as a whole—“was sufficient to substantiate the conclusion that H2 blockers did not exercise a significant competitive constraint on PPIs during the reference period between 1993 and 2000.”

For the ECJ, the following two considerations were central:

- first, the General Court’s finding that while PPIs and H2-blockers were used to treat the same conditions between 1991 and 2000, the former were “generally prescribed to treat severe forms of gastrointestinal conditions linked with hyperacidity”, while the latter “were generally prescribed more to treat their mild or less serious forms”;⁷⁴ and
- second, the ECJ’s understanding that “the gradual nature of the increase in sales of a new product being substituted for an existing product does not necessarily mean that that latter product exercised on the former a significant competitive constraint.” On this issue, the ECJ found it possible that, “even in the absence of an earlier product such as H2 blockers, the sales of PPIs as a new product would have evolved overall in the same gradual manner on account of the prescribing doctors’ fears as regards the possible carcinogenic effects of PPIs.”⁷⁵

It is not uncommon for European Commission authorities to define markets for pharmaceuticals very narrowly in abuse of dominance cases. In *Istitutio Chemioterapico Italiano S.p.A. and Commercial Solvents Corporation v Commission of the European Communities*,⁷⁶ for example, the ECJ was faced with a complaint by a pharmaceutical manufacturer that it was denied the supply of an active ingredient needed to create the anti-tuberculosis drug ethambutol. The Court affirmed the Commission’s findings that the relevant market was the “separate market in the raw material for the manufacture of this product”, in which the defendant was dominant, rather than the market for the end product itself.⁷⁷ It explained:

“Contrary to the arguments of the applicants it is in fact possible to distinguish the market in raw material necessary for the manufacture of a product from the market on which the product is sold. An abuse of a dominant position on the market in raw materials may thus have effects restricting competition in the market on which the derivatives of the raw material are sold and these effects must be taken into account in considering the effects of an infringement, even if the market for the derivative does not constitute a self-contained market.”

The Advocate General’s opinion in the case argued that the Commission should define the relevant market as that for ethambutol itself, despite the presence of other anti-tubercular medicines, “because it was used in combination with other anti-tubercular drugs and was a complement of them rather than their competitor.”⁷⁸ This line of thinking was adopted by the complainants in the

74. At para. 41.

75. At para. 50.

76. [1974] E.C.R. 223.

77. At para. 19.

78. Opinion of Mr Advocate General Warner, quoted in opinion of Mr Advocate General Jacobs (delivered on 28 May 1998) in *Oscar Bronner GmbH & Co. KG v Mediaprint*, [1998] ECR I-7791: para. 60.



Hazel Tau matter, an abuse of dominance complaint in South Africa that is discussed in some detail towards the end of this chapter.

AstraZeneca v Commission illustrates that while the ATC system is a helpful start, it is not able to answer the product market definition question fully. This is in line with Commission decisions in merger cases, which have expressly considered the value of the ATC system. Thus in *Takeda/Nycomed*,⁷⁹ the Commission explained as follows:⁸⁰

“ATC 3 is generally used by the Commission as a starting point for market definition. Products classified in one and the same ATC 3 class generally have the same therapeutic indication and, subject to exceptions, cannot be substituted by products belonging to other ATC 3 classes. **The Commission has previously departed from the ATC 3 class in cases where the market investigation indicated that another market definition was more appropriate, such as the ATC 4 class, the active pharmaceutical ingredient (‘API’) or galenic form (dosage, pharmaceutical form and route of administration).”**

In *Teva/Barr*,⁸¹ the Commission noted that the ATC3 level “is generally used as the starting point for investigating and defining relevant product markets in competition cases.”⁸² That said, it also noted that:

“it is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level and there are indications that ATC3 class does not lead to a correct market definition.”⁸³

In the specific context of the EU, *Teva/Barr* considers two factors relevant to the determination of the correct product market: the distinction between prescription and over-the-counter (OTC) pharmaceuticals; and the distinction between innovator and generic pharmaceuticals.

In respect of the first factor, the Commission’s investigation “largely confirmed that OTC and prescription pharmaceuticals constitute separate product markets.”⁸⁴ The Commission explained:⁸⁵

“In the past, the Commission has considered that [OTC] drugs... normally belong to a different product market than drugs available only on prescription. Medical indications, side effects, legal framework, distribution and marketing tend to differ between these drug categories, even if the active ingredients are sometimes identical. OTC pharmaceuticals may be advertised to the general public, whereas advertising of

79. Case No COMP/M.6278.

80. At para.19 (footnotes omitted and emphasis added).

81. Case No COMP/M.5295.

82. At para. 10.

83. At para. 11 (footnote omitted).

84. At para. 13.

85. At para. 12 (footnotes omitted).



prescription pharmaceuticals is restricted in most Member States. In most cases, consumers choose OTC pharmaceuticals themselves and purchases are not reimbursed. Prescription pharmaceuticals are prescribed by a doctor and part of the patient's purchase price is reimbursed by the public health-care system. Marketing of prescription pharmaceuticals is therefore targeted at the prescribers and not the patients."

In other words, OTC and prescription drugs do not effectively compete with each other, sometimes even in cases where they contain the same APIs. And while this part of the Commission's reasoning is limited to the distinction between prescription and OTC pharmaceuticals, its importance goes way beyond. *Teva/Barr* tells us that we should be mindful of a range of factors in our considerations of the relevant product market, whether or not such factors ordinarily flow from the prescription-OTC distinction.

Almost two years later, the Commission expanded in *Teva/Ratiopharm*.⁸⁶

"In numerous cases in the past, the Commission has defined separate relevant product markets for pharmaceuticals available without prescription (over-the-counter, 'OTC') and pharmaceuticals available only on prescription, because medical indications (including possible side-effects), the legal framework, marketing, distribution and rules on reimbursement all tend to differ between the two categories of medicines, even when the active ingredients are identical. Doctors do not directly play a role in the purchase of OTC pharmaceuticals, whereas pharmacists can suggest other (substitutable) products, and in most cases consumers bear the full cost. Prescription pharmaceuticals are prescribed by a doctor and part of the patient's purchase price is reimbursed or directly paid by health insurers. Marketing of prescription pharmaceuticals, if it takes place, is targeted at the prescribers and not the patients. Moreover, it may happen in certain markets that some variants of a drug with the same active ingredient or brand name are classified as OTC, whilst others are classified as prescription-only, depending on the package size, dosage or galenic form.⁸⁷

In respect of the second factor, the Commission noted—in line with previous decisions—"that originator drugs and their generic copies belong to the same relevant product market." It explained:⁸⁸

"It was found in previous decisions that generics can efficiently substitute originator drugs after patent expiry, especially if the regulatory system encourages switching. When assessing the competitive situation in a given product market, the Commission takes into account the fact that the originator drug is exposed to generic competition. Most off-patent drugs are available both in their original version and as generic copies. **Once a drug goes off-patent and generic producers enter the market, the originator tends to lose market share, unless he reduces his price.**"

86. Case No COMP/M.5865: para. 19.

87. Galenic form refers to the pharmaceutical dosage form of a medicine—such as whether oral (tablet, capsule or solution), topical or for intravenous injection.

88. Para. 14 (footnote omitted and emphasis added).



Collectively, the EU cases provide a lengthy list of relevant considerations to be applied to the particular facts of any proposed merger or abuse of dominance complaint. What they show is that while the ATC system may provide a good starting point, helping to explain how the medicine in question relates to others used to prevent, treat or cure the same condition, much more needs to be considered in determining which products form the relevant product market under investigation. This chapter now considers US cases, which place no reliance directly on the ATC system.

The United States

In the 1962 case of *Brown Shoe Co., Inc. v. United States*, the US Supreme Court held that “[t]he outer boundaries of a product market are determined by the **reasonable interchangeability of use or the cross-elasticity of demand** between the product itself and substitutes for it.”⁸⁹ The Court expanded:

“[W]ithin this broad market, well defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes. The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.”⁹⁰

Two years later in *United States v. Continental Can Co.*,⁹¹ the Supreme Court made it plain that price is but one factor to consider. The case dealt with the proposed divestiture of certain assets acquired in an earlier merger between Continental Can Company (at the time the second largest producer of metal containers) and Hazel-Atlas Glass Company (at the time the third largest producer of glass containers). At the time of the merger, Continental Can Company did not produce glass containers; similarly, Hazel-Atlas Glass Company did not produce any metal containers. At issue was how the relevant product market should be defined:⁹²

“[P]rice is only one factor in a user's choice between one container or the other. That there are price differentials between the two products, or that the demand for one is not particularly or immediately responsive to changes in the price of the other, are relevant matters, but not determinative of the product market issue. Whether a packager will use glass or cans may depend not only on the price of the package, but also upon other equally important considerations. The consumer, for example, may begin to prefer one type of container over the other, and the manufacturer of baby food cans may therefore find that his problem is the housewife, rather than the packer or the price of his cans. This may not be price competition, but it is nevertheless meaningful competition between interchangeable containers.”⁹³

89. 370 U.S. 294 (1962): 325 (emphasis added).

90. Footnote omitted and emphasis added.

91. 378 U.S. 441 (1964).

92. *Ibid.*: 455–56.

93. Footnote omitted.



Before the District Court, the government had submitted that there were 10 product markets, including the can industry, the glass container industry and various lines of commerce defined by the end use rather than the type of containers. In respect of the 'end-use' markets, it identified "containers for the beer industry, containers for the soft drink industry, containers for the canning industry, containers for the toiletry and cosmetic industry, containers for the medicine and health industry, and containers for the household and chemical industry."⁹⁴

The District Court found only three product markets: metal containers, glass containers and metal and glass beer containers. In reversing that decision, the Supreme Court held as follows:⁹⁵

"It is quite true that glass and metal containers have different characteristics which may disqualify one or the other, at least in their present form, from this or that particular use; that the machinery necessary to pack in glass is different from that employed when cans are used; that a particular user of cans or glass may pack in only one or the other container, and does not shift back and forth from day to day as price and other factors might make desirable; and that the competition between metal and glass containers is different from the competition between the can companies themselves or between the products of the different glass companies. **These are relevant and important considerations, but they are not sufficient to obscure the competitive relationships which this record so compellingly reveals.**"

In abuse of dominance cases involving pharmaceuticals, US antitrust authorities almost always define markets as consisting of a single product (ATC level 5). These conclusions are often based on findings that other medicines in the same ATC3 or ATC4 therapeutic class are "different in terms of chemical composition, safety, efficacy, and side effects", as well as on evidence showing "little price sensitivity" between the potential substitute products.⁹⁶ The authorities sometimes define the market as consisting only of a specific formulation of a single product.⁹⁷

In *In the Matter of Biovail Corporation*, the Federal Trade Commission (FTC) defined the relevant product market as Tiazac[®]—or diltiazem hydrochloride, a prescription drug taken once daily to treat high blood pressure and chronic chest pain—and generic versions of diltiazem hydrochloride. While acknowledging therapeutic substitutes, the Commission argued that they did not constrain Biovail's pricing in the way generic competition would:

94. Ibid.: 447.

95. Ibid.: 450 (emphasis added).

96. See FTC complaint, *In the Matter of Abbott Laboratories and Geneva Pharmaceuticals, Inc.*, Docket No. C-3946, 2000, <http://www.ftc.gov/os/2000/03/abbottcmp.htm>; FTC complaint, *In the Matter of Hoechst Marion Rousell, Inc., Carderm Capital L.P., and Andrx Corporation*, Docket No. 9293, 2000, <http://www.ftc.gov/os/2000/03/hoechstandrxcplmt.htm>; and FTC Complaint, *In the Matter of Asahi Chemical Industry Co., Ltd.*, 2000, <http://www.ftc.gov/os/2000/12/fmcasahicplmt.htm>.

97. See FTC complaint, *FTC v. Mylan Laboratories, Inc., Cambrex Corporation, Profarmaco S.R.L., and Gyma Laboratories of America, Inc.*, FTC File No. X990015 (District for the District of Columbia), 1999, <http://www.ftc.gov/os/1999/02/mylanamencmp.htm>; and FTC complaint, *In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation*, Docket No. 9297, 2001, www.ftc.gov/os/2001/04/scheringpart3cmp.pdf.



“In addition to Tiazac®, other therapeutic agents can be used to treat high blood pressure and chronic chest pain, including several branded and generic formulations of once-a-day diltiazem, but these other therapeutic agents do not significantly constrain Tiazac®’s pricing. In contrast, entry of a generic bioequivalent version of Tiazac® likely would result in a significant, immediate decrease in the sales of branded Tiazac®, and lead to a significant reduction in the average market price paid for Tiazac® and its generic bioequivalents.”⁹⁸

In a case involving Bristol-Myers Squibb (BMS), the FTC defined the relevant product market as the market for buspirone products, which consists of BMS’s product BuSpar® and generic bioequivalents of buspirone hydrochloride. In reaching this determination, the FTC made parallel arguments to those adopted in the *Biovail* case:

“Entry of generic buspirone products significantly and immediately decreased BMS’s BuSpar sales and market share, and led to a substantial reduction in the average market price paid for buspirone products. Before generic entry, BMS’s U.S. BuSpar sales were over \$600 million. In the year after generic entry, BMS’s U.S. BuSpar sales declined by more than 50%. ...

Because of this competitive relationship between BuSpar and its generic bioequivalent drug rivals, such products comprise a distinct relevant product market for anti-trust purposes. Other therapeutic agents can be used to treat anxiety, but the presence of these therapeutic agents is not sufficient to prevent the anti-competitive effects from BMS’s conduct.”⁹⁹

In merger cases, US practice is to scrutinize closely overlapping markets between merging firms. Current trends require divestiture of overlapping products in narrowly defined product and geographic markets, where post-merger combinations would give the newly merged firm market power or expand the existing market power of one of the firms. The general approach has led the US antitrust authorities to assess markets in merger cases on a case-by-case basis, without presumptive reliance on therapeutic groups or other general product groupings. In practice, the authorities generally find product markets to be defined by therapeutic group, though whether this tracks ATC3 or ATC4 varies.¹⁰⁰

In some pharmaceutical merger cases, the US antitrust authorities have defined relevant product markets as consisting of a single product:

98. FTC complaint, *In the Matter of Biovail Corporation*, Docket No. C-4060, 2002: paras 19–20, <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>.

99. FTC complaint, *In the Matter of Bristol-Myers Squibb Company*, Docket No. C-4076, 2003: paras 65–66, <http://www.ftc.gov/os/caselist/bristolmyerscmp.pdf>.

100. See, for example, FTC complaint, *In the Matter of Amgen Inc. and Immunex Corporation*, Docket No. C-4056, 2002, <http://www.ftc.gov/os/2002/07/amgencomplaint.pdf>; FTC complaint, *In the Matter of Baxter International*, Docket No. C-3726, 1997, <http://www.ftc.gov/os/1997/03/c3726cmp.htm>; FTC complaint, *In the Matter of Baxter International Inc., and Wyeth*, Docket No. C-4068, 2002, http://www.ftc.gov/os/2002/12/baxter_wyethcomplaint.pdf; and FTC complaint, *In the Matter of Pfizer Inc., and Pharmacia Corporation*, Docket No. C-4075, 2002, <http://www.ftc.gov/os/2003/04/pfizercmp.htm>.



- In the Glaxo-Wellcome–SmithKline Beecham merger, for example, the FTC identified nine separate markets, varying across therapeutic categories, and in one instance composed of a single drug.¹⁰¹
- In the Ciba-Geigy–Sandoz-Novartis merger, the FTC defined relevant markets in the following three ways:¹⁰²
 - a specific gene therapy to meet a specific therapeutic purpose (analogous to defining a single drug as the product market);
 - all gene therapies to serve a particular therapeutic purpose (similar to defining the product market as a therapeutic class, though this definition is narrower than therapeutic class); and
 - all gene therapies.

The Supreme Court has not yet had the opportunity to consider product market definition in the pharmaceutical sector. A relatively recent decision of the Court of Appeals for the Eighth Circuit—*Federal Trade Commission v. Lundbeck, Inc.*¹⁰³—was to be appealed when the FTC announced that it did not intend to seek Supreme Court review, despite recognising:

“that the result in this case was profoundly wrong, reflecting a serious misunderstanding... of the dynamics of this market and of the competitive consequences of an acquisition that allowed one company to control the only two pharmaceutical treatments for a life-threatening medical condition and raise prices by nearly 1300 percent.”¹⁰⁴

At issue in *Lundbeck* was whether the only two approved drugs (at the time) for treating patent ductus arteriosus (PDA)—a congenital heart problem that sees abnormal blood flows between two of the major arteries connected to the heart in newborns—competed with each other in the same product market. The rights to the two drugs—Indocin IV® (indomethacin for injection) and NeoProfen® (ibuprofen lysine injection)—were purchased by Lundbeck in 2005 and 2006, respectively. From then until generics entered the market in 2010, Lundbeck controlled the PDA therapeutic market.¹⁰⁵

101. FTC complaint, *In the Matter of Glaxo Wellcome plc, and SmithKline Beecham plc*, Docket No. C-3990, 2000, <http://www.ftc.gov/os/2000/12/glaxosmithklinecmp.pdf>.

102. FTC complaint, *In the Matter of Ciba-Geigy Limited, Ciba-Geigy Corporation, Chiron Corporation, Sandoz Ltd., Sandoz Corporation, and Novartis AG*, Docket No. C-3725, 1997, <http://www.ftc.gov/os/1997/04/c3725cmp.htm>.

103. *FTC v. Lundbeck, Inc.*, 650 F.3d 1236 (8th Cir. 2011), affirming *FTC v. Lundbeck, Inc.*, 2010 U.S. Dist. LEXIS 95365 (D. Minn. Aug. 31, 2010).

104. See <http://www.ftc.gov/os/closings/publicltrs/120120lundbeck-jdl-brill-ramirez.pdf>. A majority of the FTC explained:

“The Court of Appeals’ opinion unfortunately upheld [the] result. But it did so on narrow grounds, emphasizing the narrow standard of review that it applies to issues it views as factual in nature. The decisions of both the Court of Appeals and the District Court are limited to the District Court’s assessment of the evidence, which Judge Kopf observed in his concurrence was ‘perplexing,’ ‘odd,’ and ‘strange.’ We therefore intend to forgo further review in this case, and turn our energies to other enforcement priorities.”

In a dissenting view, Commissioner Rosch explained why Supreme Court review should be pursued. In this regard, see <http://www.ftc.gov/os/closings/publicltrs/120120lundbeck-rosch.pdf>.

105. Majority decision of the Court of Appeals for the Eighth Circuit.



When Lundbeck purchased the rights to Indocin IV[®] from Merck & Co., the latter was charging \$77.77 per treatment. Lundbeck immediately raised the drug's price. Just two days after acquiring the rights to NeoProfen[®] from Abbott Laboratories the following year, Lundbeck raised the price of Indocin IV[®] by ± 1200 percent. By 2008, the price of Indocin IV had settled at \$1614.44 per treatment—a 1975 percent increase on Merck's original pricing. Unsurprisingly, this price compared favourably with the settled price of NeoProfen[®]—\$1,522.50.¹⁰⁶

The case arose when the FTC filed a complaint in federal court challenging the acquisition by Ovation Pharmaceuticals Inc.—subsequently bought by Lundbeck—of NeoProfen[®]. In its complaint, the FTC alleged that this acquisition eliminated Ovation's only competitor for the treatment of PDA, said to affect more than 30,000 babies born prematurely every year in the United States. The FTC press release explained:¹⁰⁷

“By acquiring its only competitor in the treatment of a serious heart condition affecting premature babies, Ovation has been able to charge dramatically higher prices for its drugs,’ said Acting FTC Bureau of Competition Director David P. Wales. ‘While Ovation is profiting from its illegal acquisition, hospitals and ultimately consumers and American taxpayers are forced to pay millions of dollars a year more for these life-saving medications. The action taken today is intended to restore the lost competition and require Ovation to give up its unlawful profits.’”

Following a trial, the district court held that the FTC failed to identify a relevant product market. The Court of Appeals approached its task mindful that “[t]he determination of the relevant market is an issue for the trier of fact.”¹⁰⁸ It stressed that it “reviews for clear error the district court’s fact-findings supporting its ultimate determination of the existence of a relevant market.”¹⁰⁹ Put differently, the appropriate standard of review was such that the Court of Appeals’ job was not to determine whether the district court had reached the correct decision:

“It is precisely the job of the district court to consider the evidence offered by both sides and render a judgment. . . . Whether this court would come to the same conclusion is irrelevant. The district court’s fact-finding was not clearly erroneous.”

Notwithstanding the narrow review powers, the decision has been subjected to much criticism.¹¹⁰ While recognising that the FTC and its commissioners were heavily invested in the case, it is nevertheless worthwhile to consider Commissioner J. Thomas Rosch’s statement in which he explains why seeking Supreme Court review would have been appropriate. In addition to exploring numerous errors of law that he identified, one of which is discussed below, Rosch noted that the Supreme Court had not reviewed a merger decision since the mid-1970s:¹¹¹

106. When Lundbeck introduced NeoProfen to the market in 2006, it charged \$1450 per treatment.

107. The FTC press release is available at <http://www.ftc.gov/opa/2008/12/ovation.shtm>.

108. *Ryko Mfg. Co. v. Eden Servs.*, 823 F.2d 1215 (8th Cir. 1987): 1232; *General Indus. Corp. v. Hartz Mountain Corp.*, 810 F.2d 795 (8th Cir. 1987): 805.

109. See *Community Publishers, Inc. v. DR Partners*, 139 F.3d 1180, 1183–84 (8th Cir. 1998).

110. See Commissioner Rosch’s statement, <http://www.ftc.gov/os/closings/publicltrs/120120lundbeck-rosch.pdf>.

111. *Ibid.*



“To the extent that the Court has been unclear as to what ‘reasonable interchangeability... or ...cross- elasticity of demand’ means in its merger case law, this case presents an excellent opportunity for the Court to make clear that **customers may switch from one product to another based on changes in non-price terms as well as price terms.**”

Central to Rosch’s substantive criticism of the Court of Appeals’ decision was its focus on “cross-price elasticity of demand”—“whether customers would switch from one product to the other based on **price** considerations alone”. In his view, which accords with the earlier Supreme Court decisions in—among others—*Brown Shoe Co.* and *Continental Can Co.*, the Court of Appeals “failed to embrace the basic legal (and economic) principle that cross-elasticity of demand includes non-price considerations as well.”

Bayer Schering Pharma AG v. Sandoz, Inc., a relatively recent district court judgment from New York, neatly summarises the law applicable to that court:¹¹²

- “The relevant market... is the ‘area of effective competition’ within which the defendant operates.”¹¹³
- “The goal in defining the relevant market is to identify market participants and competitive pressures that restrain an individual firm’s ability to raise prices or restrict output.”¹¹⁴
- “A relevant product market consists of ‘products that have reasonable interchangeability for the purposes for which they are produced—**price, use and qualities considered.**”¹¹⁵
- “The relevant market is defined as all products ‘reasonably interchangeable by consumers for the same purposes,’ because the ability of consumers to switch to a substitute restrains a firm’s ability to raise prices above the competitive level.”¹¹⁶
- “Every product that can be substituted for the same use or purpose should be included within a single product market.”¹¹⁷
- “The product market inquiry focuses on the range of products that actually compete in the disputed market, and that inquiry turns on the concepts of reasonable interchangeability and cross-elasticity of demand.”¹¹⁸

112. 813 F.Supp.2d 569 (S.D.N.Y. 2011). The case was decided by the District Court: Southern District of New York. That court falls within the jurisdiction of the Court of Appeals for the Second Circuit, which includes the states of Connecticut, New York and Vermont, and has appellate jurisdiction over district courts in the following districts: Connecticut, Eastern District of New York, Northern District of New York, Southern District of New York, Western District of New York and Vermont.

113. *AD/SAT, Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216 (2d Cir. 1999); 227, quoting *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320 (1961): 327–328.

114. *Geneva Pharma. Tech. Corp. v. Barr Laboratories, Inc.*, 386 F.3d 485 (2d Cir. 2004): 485.

115. *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101 (2d Cir. 2002): 105 (quoting *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956)) (emphasis added).

116. *Geneva Pharm. Tech. Corp.*, 386 F.3d: 496 (quoting *E.I. du Pont de Nemours & Co.*, 351 U.S.: 395)

117. *Intellective, Inc. v. Massachusetts Mut. Life Ins. Co.*, 190 F. Supp. 2d 600, 610 (S.D.N.Y. 2002).

118. *Mathias v. Daily News, L.P.*, 152 F. Supp. 2d 465, 480–81 (S.D.N.Y. 2001).



- “Interchangeability’ looks to the use or function of the given product as compared to other products.”¹¹⁹
- “Products will be considered to be reasonably interchangeable if consumers treat them as ‘acceptable substitutes.’”¹²⁰
- “‘Cross-elasticity’ is related to interchangeability, and requires a consideration of the extent to which a change in the price of one product will alter demand for another product.”¹²¹

The footnote to the final quote above states that “[a]pplication of this principle in the prescription drug context is complicated given that (1) patient choice is constrained by the physician’s prescribing authority, and (2) the impact of price variation may be blunted by the effect of health insurance.” These factors need to be borne in mind when dealing with prescription health technologies, something that the Court of Appeals for the Eighth Circuit arguably failed to do in *Lundbeck*.

While the tests of reasonable interchangeability and cross-elasticity of demand provide some guidance to defining the relevant product market, US case law also shows that these tests can be applied in ways that have very unpredictable outcomes. There appears to be much scope under US law to argue for a product market that suits a particular desired outcome in the circumstances of any case. Put differently, facts matter, as does convincing legal argument.

From theory to practice: Hazel Tau, market definition and access to treatment for HIV

In September 2002, legal and community activists in South Africa turned to the country’s competition authorities for assistance in their decade-long battle for access to treatment for HIV infection. In the complaint, Hazel Tau—a woman living openly with HIV—and her fellow activists focused on the prices of three patented ARV medicines. Jonathan Berger explains:¹²²

“Alleging that GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) were acting in violation of section 8(a) of the Competition Act 89 of 1998 by charging excessive prices for certain of their ARV medicines to the detriment of consumers, Hazel Tau and others argued—in a formal complaint lodged with the Competition Commission—that the prices charged by the two groups of pharmaceutical companies for their essential and life saving medicines were directly responsible for the premature, predictable and avoidable deaths of women, men and children living with HIV.

119. *Intellective, Inc.*, 190 F. Supp. 2d: 610.

120. *PepsiCo, Inc.*, 315 F.3d: 105 (citing *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 46 (D.D.C. 1998).

121. *Intellective, Inc.*, 190 F. Supp. 2d: 610.

122. Jonathan Berger, ‘Litigating for Social Justice in Post-Apartheid South Africa: a Focus on Health and Education’ in Varun Gauri and Daniel M. Brinks (eds), *Courting Social Justice: Judicial Enforcement of Social and Economic Rights in the Developing World*, Cambridge University Press, New York, 2008: 57–58 (footnotes omitted).



The complaint—which assembled the testimonies of people living with HIV and health care workers who treat people living with HIV, as well as the expert evidence of leading HIV clinicians, nurses, scientists, economists and actuaries—attempted to show that even when allowance was made for the costs of research and development, higher profits, licensing fees and the incentive to develop new drugs, the prices of these ARV medicines could not objectively be justified.”

The very first hurdle to be overcome was the identification of the relevant geographic and product markets within which the respondent companies were alleged to have abused their dominant positions. The complainants’ statement of complaint dispensed quickly with geographic market:¹²³

“It is clear that the relevant geographical market for each ARV that is the subject of this complaint is the national South African market. This follows from the fact that the registration of and the authorisation to use and sell medicines in South Africa, rests exclusively with the South African Medicines Control Council (MCC). Other factors supporting such a finding include the national regulation of the medical scheme industry which is currently responsible for financing the bulk of ARV sales in the country and the regulation of patent protection that also takes place at the national level.”¹²⁴

In respect of the relevant product market, the complainants first explained the impact of patent protection:¹²⁵

“As a result of the respondents’ reliance on patent protection, none of the ARVs that are the subject of this complaint can at present be sold in the South African market in the form of generics. In other words, the respondents’ branded ARVs are not substitutable by equivalent products in South Africa. For the purposes of establishing whether the respondents are dominant in a relevant market the remaining question is whether other ARVs that are available in South Africa can be substituted for the particular ARVs which are the subject of this complaint. In other words, for example, can a patient whose proper and effective treatment requires the use of zidovudine be satisfactorily treated by the substitution of another ARV available in South Africa.”

Thereafter, two arguments were advanced: first, each antiretroviral medicine constituted its own market; and second, in the alternative, each respondent was dominant with respect to the therapeutic class of antiretroviral medicine in question. The complaint concerned three ARVs: zidovudine, lamivudine and nevirapine. Both zidovudine and lamivudine fall within the therapeutic class of nucleoside analogue reverse transcriptase inhibitors (NRTIs), with nevirapine being a non-nucleoside reverse transcriptase inhibitor (NNRTI).¹²⁶ On either approach, the complainants argued, the

123. Para. 53. The statement of complaint is available at <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKevidenceAndLegalSubmissions.pdf>.

124. At the time the complaint was lodged, ARV treatment was not available in the public health sector.

125. Para. 54 (emphasis added).

126. Earlier in the complaint, these therapeutic classes were described in some detail.



firms were dominant and, therefore, subject to the prohibition on excessive pricing to the detriment of consumers.

To advance the first argument, the complainants relied on the expert testimony of Professor Robin Wood.¹²⁷ A summary of his affidavit evidence was included in the statement of complaint:¹²⁸

“In general, ARVs cannot be considered as substitutable for each other. In order to access HAART, a person living with HIV/AIDS must at a minimum be able to have access to all of the ARVs that are the subject of this complaint. This is because HAART requires the commencement of at least three ARVs simultaneously, with alternative regimens being necessary to meet specific requirements at initiation of treatment and to substitute for regimens in the case of unmanageable side effects or treatment failure.

...In the result, each ARV constitutes its own market both in respect of manufacturers and marketers. Coupled with patent protection, the relevant international respondent companies (as manufacturers and suppliers to South Africa) and the relevant South African respondent companies (as marketers within South Africa) are dominant in respect of the South African market for each particular ARV that is the subject of this complaint. In this case, therefore, dominance exists regardless of each firm’s share of the market for a particular therapeutic class of ARVs.”

To advance the second argument, the complainants relied on available information for the 2002 financial year in South Africa:¹²⁹

- GSK was responsible for 83.7 percent of the NRTI market,¹³⁰ “substantially in excess of the 45 percent threshold above which the abuse of dominance provisions are automatically triggered” under the Competition Act 89 of 1998; and
- BI was responsible for 48.3 percent of the NNRTI market,¹³¹ also in excess of the 45 percent threshold.

The Competition Commission—the body entrusted by law to investigate alleged infringements of the Competition Act—agreed that GSK and BI had abused their dominant positions.¹³² That said, the Commission’s decision to refer the matter to the Competition Tribunal for adjudication identified neither the relevant markets nor the basis on which it determined that the respondent compa-

127. At the time, Professor Wood held the position of the Principal Medical Specialist for the Provincial Administration of the Western Cape. In addition, he also held the following positions at that time: Associate Professor of Medicine, University of Cape Town; Head of the Department of Medicine, Somerset Hospital, Cape Town; and Director of the HIV Research Unit, Somerset Hospital.

128. Paras 55–56. Professor Wood’s full affidavit was submitted as part of the complaint.

129. Para. 57.

130. In terms of units sold, of a total market of 18,420 units, GSK sold 9060 (or 49 percent).

131. In terms of units sold, of a total market of 5260 units, BI sold 2500 units (or 47.5 percent).

132. The Commission investigates and ‘prosecutes’, the Tribunal adjudicates, and the Competition Appeal Court (CAC) hears appeals. In appropriate cases, CAC decisions may be taken on appeal.



nies were dominant.¹³³ As such, the argument about each patented medicine—in these circumstances—constituting its own market remains untested.

So how did the complaint get resolved? Berger described its outcome:¹³⁴

“As a result of its investigation, [the Competition Commission] had found sufficient evidence to support the referral on the basis of prohibited excessive pricing as well as two additional grounds, both of which dealt with the failure of GSK and BI to license generic manufacturers in the circumstances. By December 2003, within two months of the Commission’s announcement, GSK and BI entered into separate settlement agreements with the complainants and the Commission respectively, in terms of which the two groups of companies effectively agreed to open up the market for these drugs to generic competitors.”

Towards an access-friendly approach to market definition

So what would an access-friendly approach to market definition entail? Despite varying approaches in different jurisdictions, what is clear is that there are no simple tests to apply. Put differently, context is key; the facts really do matter.

What is also clear is that an approach that seeks to narrow the relevant product market to promote access in an abuse of dominance case might similarly be used to limit access in merger analysis. Just compare *Hazel Tau* to *Lundbeck*.¹³⁵ On the other hand, reliance on first principles—at the expense of rigid tests—might result in fairer, less formulaic outcomes.

Insofar as market definition in respect of health technologies is concerned, the current uncertain state of play globally could be understood by some as a barrier in the way of those seeking to use competition law to increase access to health technologies. But another way to consider the status quo is to see this uncertain state of affairs as providing opportunities to create new law, unencumbered by an old and (possibly) outdated body of law. The right set of facts, considered within the context of a progressive legal framework,¹³⁶ may very well pave the way to an access-friendly approach to market definition.

133. See <http://www.cptech.org/ip/health/sa/cc10162003.html>.

134. Jonathan Berger, ‘Litigating for Social Justice in Post-Apartheid South Africa: a Focus on Health and Education’ in Varun Gauri and Daniel M. Brinks (eds), *Courting Social Justice: Judicial Enforcement of Social and Economic Rights in the Developing World*, Cambridge University Press, New York, 2008: 58 (footnotes omitted).

135. In the one case, access was promoted by defining the product market narrowly—by bringing the respondent companies within the scope of the abuse of dominance provisions. In the other, access was undermined by defining the product market narrowly—by treating the parties as operating in separate product markets that could be merged without giving rise to any anti-competitive concerns.

136. Such as one that expressly recognises a right to have access to health care services.



Advancing competition frameworks in the low- and middle-income country context

Natasha Nyak

KEY MESSAGES

- ▶ In drafting competition laws, LMICs should avoid direct transposition of developed-country laws, but should rather adapt such laws to their own circumstances or create their own approaches.
- ▶ Competition authorities in LMICs may be hampered by human resource, financial and political economy constraints, but there are ways to overcome these constraints.
- ▶ Awareness among the public and business community of the potential benefits of competition law enforcement is needed to support the competition authorities.
- ▶ International cooperation is particularly important for competition authorities in LMICs that are engaged in a learning process.
- ▶ Civil society organizations can and should encourage coalition-building, networking and capacity-building in competition law enforcement.

Previous chapters have focused on how competition laws and policies can be used to promote access to health technologies, addressing the interface of the IP regime, relevant anti-competitive practices that inhibit access, and possible remedies. This chapter does not focus on these issues. The main issues for discussion here are: (i) how competition law has been adopted in LMICs; (ii) the implementation and enforcement challenges in these countries; and (iii) some recommendations on how these challenges could be addressed.



I. Evolution of competition regimes

It is not surprising to see that while countries have increasingly embraced trade liberalisation over the last decade, more countries have also adopted competition laws. At the start of the 1990s, there were approximately 30 countries with a competition law. However, at present, the number is over 130, with more in the pipeline.¹

A combination of factors may have contributed to the adoption of competition regimes in LMICs. The onset of privatization reforms and moves towards market economies have resulted in the need for a regulatory mechanism to check, *inter alia*, firms' behaviour; adverse cross-border impacts of anti-competitive practices (such as international cartels, mergers and acquisitions etc.); and commitments under FTAs etc.; along with a growing realisation by many that competition is good public policy for both developed and developing countries—these factors can be seen as some of the core reasons.²

Adoption of the law

Countries drafting competition laws in more recent years have the benefit of being able to observe the experiences of some of the more developed countries or communities such as the United States, Japan, Germany and the EU. In fact, the 20th century has seen several proactive efforts, especially by the United States and EU, to install their models of competition in LMICs that were just beginning to embrace this concept. International aid and development agencies such as the OECD, the World Bank and the United Nations Conference on Trade and Development (UNCTAD) have also been influential in this process, having provided assistance in the preparation, amendment and adoption of new competition laws in many countries.

There is no international consensus as such on what is the best model to follow for LMICs seeking to adopt competition law. However, some scholars have, to a large extent, rightly characterised the approach adopted by such countries into three generic models: the cut and paste model, the contextualised model and the tailor-made model.³ The following section discusses these three approaches with the help of examples from countries that have incorporated each of the models.

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1. P. Mehta, 'Towards a multilateral framework on competition policy', International Centre for Trade and Sustainable Development, Geneva, 2011, <http://ictsd.org/downloads/2012/02/pradeep-mehta-towards-a-multilateral-framework-on-competition-policy.pdf>.
 2. In the cases of India and Pakistan, high levels of concentration—i.e. production or trade being controlled by a handful of businesses—contributed to the adoption of competition law. In the former (Soviet bloc) and current (China and Viet Nam) Communist countries, it was to curb state monopolies and government policies that hindered competition. Guatemala, Singapore, Jordan etc. had to adopt competition law because of their commitment under an FTA with the USA. Cambodia and Nepal agreed to adopt a competition law under their commitment to the WTO when acceding to it, though to date, progress has been poor. See P. Mehta and S. Evenett, 'Evolution of Competition Policy and Law', Briefing Paper, CUTS International, Jaipur, 2006.
 3. H. Shahein, *New Jurisdictions and Competition Law: shaping policies and building institutions*, Edward Elgar, Cheltenham, 2012.



The **cut and paste model**, as the term suggests, is the importation either wholly or partially from established competition rules. This model follows Watson's theory⁴ most closely, which argues that laws in general could be transplanted from one country to fit into another's setting, regardless of the unique economic and political circumstances which influenced rule-making in the country from which they are taken/adopted in the first place.⁵ For instance, the last amendment of the Israeli competition law of 1998 added a new Article (29A) dealing with abuse of dominance, which reveals that Israel's decision makers followed a 'cut and paste' of Article 102 of the TFEU, inspired by its success in the EU. Scholars such as Rodrik, Owen and Sheth have raised serious concerns about this type of transplantation, suggesting that it would not be sympathetic to the realities of LMICs.⁶

By contrast, the **contextualised model**, adapts specific successful foreign competition law concepts and ideas to fit its specific needs. A country should, according to this model, adopt foreign law in a way that is sensitive to its current conditions by trying to contextualise the transplanted rules.⁷ For example, China's Antimonopoly Law blends common Chinese legislative practices with distinct principles and practices from foreign jurisdictions, relying on legislative provisions of the EU, United States, Japan, Germany and Korea. However, although the Antimonopoly Law incorporates ideas from foreign jurisdictions, it has amended them to fit China's unique institutions, cultures and policy constraints. A good example is the introduction of 'administrative monopoly' provisions⁸ in the Antimonopoly Law to regulate administrative abuse in China, a significant step in its economic reforms process. However, the enforcement of this regulation has been limited by adoption of some other provisions. For example, Article 7⁹ effectively exempts some state-owned enterprises from competition scrutiny under the Antimonopoly Law's administrative monopoly regulation such that it is the State and not competition agencies that continues to have the ultimate power over some of the most powerful state-owned enterprises which are present in China's strategic sectors.¹⁰

4. The concept of 'legal transplant' was coined by Scottish-American legal scholar Alan Watson in the 1970s, to describe the process whereby a rule of law is moved from one country to another. Watson was a proponent of the view that transplantation is the most fertile source of legal development. See A. Watson, *Legal Transplant: An Approach to Comparative Law*, University of Georgia Press, Athens, GA, 1993.

5. M. Gal, 'The "Cut and Paste" of Article 82 of the EU treaty in Israel: conditions for a successful Transplant', *European Journal of Law Reform*, 2008, 9(3): 467.

6. See D. Rodrik, 'Institutions for High-Quality Growth: What They Are and How to Acquire Them', NBER Working Paper, No. 7540, National Bureau of Economic Research, Cambridge, MA, 2000; B. Owen, 'Competition Policy in Latin America', paper presented at a Conference on Sectoral Reform in Latin America, 13 November 2003; and M. Sheth, 'Formulating Antitrust Policy in Emerging Economies', *Georgetown Law Journal*, 1986, 86: 451.

7. See P. Mehta and S. Evenett, 'Evolution of Competition Policy and Law', Briefing Paper, CUTS International, Jaipur, 2006.

8. Antimonopoly Law, Chapter V, Articles 32–37.

9. Article 7 provides in pertinent part that industries controlled by the state-owned economy and relied on by the national economy and national security or industries implementing exclusive operation and sales in accordance with the law shall be protected by the State to conduct lawful operation by the undertakings. The State shall supervise and control the price of commodities and services provided by these undertakings and the operation of these undertakings so as to protect the interests of the consumer and facilitate technological progress.

10. In one of her articles Professor Eleanor Fox argues that the exemption of state monopolies in strategic sectors could drive a huge hole in China's efforts to help the market work, and while China has privatized much of its business, monopolies in the key sectors, including telecommunications, banking, electricity, petroleum, railroads, aviation and insurance, remain under state control. See E.M. Fox, 'An Antimonopoly Law for China – Scaling the Walls of Government Restraints', *Antitrust Law Journal*, 2008, 75: 173.



The third model is a newly created structure. The **tailor-made model** creates a new model that specially addresses its unique realities and is ‘tailored’ to those needs. Examples of countries that have done this are South Africa and Indonesia. South Africa has been examined in previous chapters. Indonesia incorporates explicitly, under various articles of the law, as its main objectives: to protect people’s welfare, public interest and small business; to fight unfair dominance by large enterprises; equity among stakeholders; and prevention of corruption.¹¹

As mentioned earlier, the United States and EU have been very active in providing assistance to LMICs seeking support in drafting their laws. Primarily, the motivations for this might be traced to the creation of a web of countries sharing the same principles of competition law and enhancing their own competitiveness in export markets. On the other hand, there are several reasons why LMICs have sought to import the developed-country models of competition law. One of the obvious reasons is that the US and EU competition rules are highly evolved—both have experimented and created effective systems of competition regulation which might provide valuable insights into the process of competition law development for decision makers in new jurisdictions. Eleanor Fox argues that LMICs have, in the past, been induced into adopting Western designs of competition laws to attract much-needed Western investment, by making the environment familiar to these firms and instilling greater trust and confidence.¹² Another factor that has played a role are the FTAs (generally with some of these countries), which often give foreign States a stronger voice in the domestic competition laws of these countries. Beyond these factors, of course, there appears to be a general tendency towards transplanting and adopting Western competition laws from developed countries into reforming economies.¹³

Although LMICs certainly needed to look to their developed counterparts and donor agencies for support in this regard, this may be seen to have a negative impact in the long run, as seen in the implementation challenges that many of these countries are grappling with today. In a study conducted by CUTS International, a civil society organization, the findings revealed that in many instances, the adoption of competition policy has been a result of pressure from outside agencies and countries, rather than internal policy reforms. Having employed such a **reactive** approach to evolving competition regimes, governments in LMICs have failed to support the process of adopting competition law through concurrent policy measures and practices that support competition in the market.¹⁴ Therefore, many realities of the developing world continue to hamper any reform initiatives intended at meaningful enforcement of competition laws by LMICs, such as resource constraints and other competition enforcement challenges, political economy constraints, lack of regulatory independence, bureaucratic constraints and lack of a culture of competition. Mere adoption of competition law in the presence of such bottlenecks cannot yield the intended results.

11. See Republic of Indonesia, ‘Law of the Republic of Indonesia No. 5 of 1999, Concerning the Ban on Monopolistic Practices and Unfair Business Competition’, Republic of Indonesia, Jakarta, 1999: Articles 3, 20 and 50, http://www.wipo.int/wipolex/en/text.jsp?file_id=181117.

12. E.M. Fox, ‘Antitrust and Regulatory Federalism: Races up, Down, and Sideways’, *New York University Law Review*, 2000, 75: 1784.

13. See P. Mehta and S. Evenett, ‘Evolution of Competition Policy and Law’, Briefing Paper, CUTS International, Jaipur, 2006.

14. R. Sengupta and C. Dube, ‘Competition Policy Enforcement Experiences From Developing Countries and Implications for Investment’, presented at the ‘OECD Global Forum on International Investment’, 27–28 March 2008, Paris.



Scholars have often argued that competition law in LMICs adopts the language of Western models but frequently reflects little understanding of the economic objectives of modern Western antitrust enforcement policy. This may be largely true of the cut and paste model. While the foreign experience may provide much-needed guidance and contribute to the attainment of legal certainty, the failure to consider the political, commercial, cultural and structural nuances unique to each particular economy prior to the mere adoption of foreign legislation may actually stifle, rather than promote, competition therein.¹⁵ Owen¹⁶ notes that while the goal of competition law across the globe is constant, the content of the laws formulated uniformly for the rich and the poor will not be able to achieve the same goals. For example, the presumption that a relatively high market share automatically confers market power in developing economies could result in a misapplication of abuse of dominance provisions, penalising dominant firms unnecessarily. Inexperienced authorities may further fail to take account of the fact that positions of dominance may be attained by a single firm acting in isolation or by a group of firms acting in concert. Bill Kovacic,¹⁷ former FTC Commissioner, who has assisted in drafting many competition laws in Asia, Africa and Eastern Europe, stresses in his work that the law-drafting process should involve a collaboration between indigenous experts and external technical advisers. From his point of view, the strongest draft law is one where the principles emerge from the recommendations of local experts of the borrowing countries who have a command of the market's need, and is enriched by the experiences of other foreign competition laws. This is to ensure that the needs of the markets are appreciated while knowledge and experiences of developed competition rules are also addressed during the borrowing process.

Having observed the sources of assistance and types of models that have guided the drafting of competition laws for LMICs, one would conclude this section with a recommendation for those countries that are yet to adopt a competition law. It would be important here to reiterate that the effectiveness of competition law depends on the extent to which the law has actually evolved in a country in tandem with the socio-economic realities of that country. The law should be able to reflect the realities of a country with respect to its economic development, social and political realities, culture and constitution. Here context informs design, and blindly transplanting competition law from another developed country or an LMIC with a different history and context should be avoided. However, having said this, a tailored model is also often practically impossible to achieve. The proposed way to go is a combination of the contextualised and the tailored approach.

15. See P. Mehta and S. Evenett, 'Evolution of Competition Policy and Law', Briefing Paper, CUTS International, Jaipur, 2006.

16. B. Owen, 'Competition Policy in Latin America', paper presented at a Conference on Sectoral Reform in Latin America, 13 November 2003.

17. See W. Kovacic, 'Capitalism, Socialism, and Competition Policy in Vietnam', *Brooklyn Journal of International Law*, 1997, 13(57): 403; 'The Competition Policy Entrepreneur and Law Reform in Formerly Communist and Socialist Countries', *American University Journal Law and Policy*, 1996, 11: 437; 'Designing and Implementing Competition and Consumer Protection Reforms in Transitional Economies: Perspectives from Mongolia, Nepal, Ukraine and Zimbabwe', *DePaul Law Review*, 1995, 44: 1197; and 'Competition Policy, Economic Development, and the Transition to Free Markets in the Third World: The Case of Zimbabwe', *Antitrust Law Journal*, 1996, 16: 253.



II. Implementation challenges

After having adopted a competition law, the current challenge that most LMICs face, as mentioned earlier, pertains to implementation. Despite enactment, countries often fall short of implementing the law effectively for several reasons; therefore, it can be concluded that enacting a competition law may not necessarily translate into an effective competition regime.

CUTS International has been running a phased multi-country initiative on competition reforms targeting 19 countries since 2000, known as the 7-Up initiative. The project launched several competition advocacy initiatives in the select countries with the aim of building awareness and capacity among key stakeholders instrumental in bringing about competition reforms and building a culture of competition across parts of Asia and Africa. **A large part of this section on implementation challenges, and the following one on preparing an agenda for reform, derive their data and learnings from the findings of this project.**

One of the observations of the 7-Up initiative was clearly that competition regimes in most of the select countries were found to be ineffective after adopting competition law.¹⁸ Furthermore, while the growing realisation of the importance of competition law and policy has been felt, what continues to remain a challenge is the creation of the right institutional environment and adequate resources to enable effective implementation of competition law and policy. Most importantly, a culture of competition, engagement with stakeholders, civil society etc. is gravely missing in many LMICs that may have formally adopted competition regimes but have consistently failed to implement them.

While implementation challenges are several, this section identifies and focuses on a few major constraints: resource constraints of competition agencies, weaknesses in the draft/design of law, political economy challenges (such as lack of political will, vested interests, favourable treatment to state-owned enterprises) and absence of a culture of competition. The following section thereafter seeks to recommend the way forward and also includes some encouraging examples of how countries have successfully overcome the identified challenges.

1. Financial/budgetary resource constraints

Budgetary constraints are a pervasive problem with all competition agencies, more particularly those of LMICs. Insufficient operational funding and below par compensation levels are two key reasons why competition authorities have been unable to attract top-quality economists and lawyers. CUTS 7-Up studies have revealed that except in Zambia and South Africa, the salaries paid in other South Asian and African countries are considerably lower than the salaries paid in the private sector.

Competition agencies are often unable to raise their own resources and have to rely on government funds, which are often scarce and plagued by red tape. In some countries, there is limited budgetary support from the government, which is exacerbated by the fact that the Commission has no

18. CUTS International, 'Pulling Up Our Socks—A Study of Competition Regimes of Seven Developing Countries of Asia and Africa under the 7-Up Project', CUTS International, Jaipur, 2003.



authority to impose fines—only the courts can impose fines, and they are payable to the Crown. In other countries, a lack of human and financial resources is a big challenge, primarily because of red tape in bureaucratic procedures in transferring budgets from the Treasury.¹⁹

While financial constraints cannot be completely overcome, agencies have of late been exploring ways to work their ways around this problem. For example, it has now been proposed that certain commissions are considering charging fees for providing opinions to private firms, to help deal with the financial difficulties. Other competition agencies have found alternative means and innovative ways of addressing budgetary constraints, with some amount of success, which could serve as lessons for others (discussed in the subsequent section). An additional challenge here is to ensure that their independence is not compromised in this process.

- **Technical (capacity, personnel) constraints**

Competition is a fairly new concept for many LMICs; therefore, even after a law is adopted, many of the personnel struggle to enforce it due to capacity constraints. This stands as a big stumbling block in the implementation of a country's competition regime.

The financial and budgetary constraints have a direct impact on the type of personnel recruited at the agencies. As mentioned earlier, an inability to pay better makes recruitment and on-the-job capacity-building of professional and technical staff particularly challenging. Additionally, there is a general shortage of skilled personnel in relevant areas of study. This is because the vast majority of LMICs do not offer courses or continue with legal education programmes specific to competition law and its enforcement. Even for a country such as India, competition as a specialised area of expertise has only started to develop recently. Several universities and law schools still do not offer specialised courses in this area. Further, the officials at the agencies often struggle with the inability to handle so many cases at once. While it is extremely important that competition agencies allocate their limited resources effectively and prioritise their case work, they have very little experience in doing so. And if they end up taking on too many difficult cases at first, it is likely that their overall performance in case handling suffers. There are also few training programmes for agency officials. Determining how best to design technical assistance programmes to interact with nascent and financially constrained competition agencies is another difficult and complex matter.

2. Deficient legislation/weaknesses in drafting the law

As mentioned in the previous section, one of the factors contributing to implementation and enforcement challenges is transplantation of laws from advanced jurisdictions without being mindful of the socio-economic and political context of the borrowing country. There is no one-size-fits-all solution, which is why any such cut and paste approach can prove problematic subsequently. A number of countries also lack key safeguards against anti-competitive behaviour as a result previously adopted laws, for example, where there is a lack of a general merger control regime and no provisions on predatory conduct.

19. CUTS International, '7-Up4 Evaluation Report', CUTS International, Jaipur, 2011.



3. Political economy constraints

Access to adequate and appropriate resources is not the only factor preventing many countries—regardless of income level—from pursuing and sustaining strong competition frameworks. The state of the political economy, which encompasses a wider range of influences than those affecting simple supply-side capacity, also plays an important role.

CUTS, in its 7-Up initiative report, observed that political economy challenges were possibly the most significant of all in operationalizing national competition regimes. It found several examples of countries where such political economy constraints had deeply affected the adoption and implementation of competition regimes.

- **Political will**

The effectiveness of competition law in developed countries has clearly been dependent on the political climate. Therefore, to better understand economic policy reform outcomes in each country, it is necessary to study its political context. In LMICs, adoption and implementation of competition and regulatory laws is quite politically charged, as one of its core objectives is to constrain concentrated political and economic power and work towards the welfare of the poor.²⁰ Political will in adoption and implementation of the law can play a big role in how successful such reforms eventually are. For example, in countries where there is substantial national commitment towards market reforms, such as Chile and Mexico, agencies have shown signs of success.

- **Links between business and government**

In some countries, the distinction between public and private sectors and interests may be blurred. This has an impact on the actual or perceived relationship between vested private sector interests and a public sector competition authority. Concerns have often been raised that such proximity could influence the government while framing policies affecting the private sector, such as competition policy or law. Under the circumstances, adoption and implementation of a competition regime may easily fall prey to being captured or side-lined by powerful vested interests. Evidently, some countries have witnessed strong opposition to the introduction of competitive reforms. And even where the law has been adopted, countries struggle with limited implementation of the law because of the strong nexus of businesses with polity.

However, little effort has been made to identify potential gains for politicians out of promoting competition measures—i.e. how competition regime outcomes could help them retain/enhance their public image/support base. It might be the case that, so far, a great deal of effort has not been made in the right direction to sell competition reforms to politicians.

20. P. Mehta, M. Agarwal and V.V. Singh, 'Politics Trumps Economics—Lessons and experiences on competition and regulatory regimes from developing countries'. CIRC and CUTS C-CIER, Jaipur, 2007.



- **Favourable treatment to state-owned enterprises/creating regulatory entry barriers**

Competitive neutrality means that state-owned and private businesses compete on a level playing field. In practice, it is difficult to ensure competitive neutrality in sectors where government or its agencies retain control or insist on doing so, which is the case with many of the LMICs starting to undertake privatisation reforms. In certain LMICs, for example, the state-owned companies have been exempted from various taxes, where private companies enjoy no such exemptions. Exemptions such as these put private operators at a relative disadvantage when it comes to competing with the state-owned incumbent, ultimately restricting competition and maintaining high prices in the sector.

In some countries, certain sectors have low levels of regulation applied where state-owned companies are active. In the absence of competition, such sectors do not achieve the kinds of efficiencies and levels of production which competition might afford. In the mining sector, for instance, regulations might prohibit competitive bidding of an area considered for allocation to a government company, or vested interests might retain the power to choose prime contracts with the government companies, leaving less productive blocks for competitive bidding. Life insurance is another sector where state-owned enterprises may enjoy privilege, for example regulations might require that policies receive a sovereign guarantee against failure to pay, while the same might not be available to the private life insurance companies which have recently entered the market.

4. Lack of a culture of competition

Almost all young and new competition regimes experience a lack of a culture of competition to varying degrees—commonly defined as the desirable situation that exists within a country when the rules and benefits of competition are widely known and supported, and serious consideration of the likely impact of actions and regulations on competition forms a natural part of the background for decisions by firms and governments.

In other words, competition culture refers to the awareness of the general public, including the business community, politicians and civil servants about competition law and the benefits of competition. In some countries, however, this kind of understanding among the government and people appears to be insufficient, and this has often resulted in tacit resistance to reforms. For example, in the 7-Up studies, it was revealed that the competition agencies in several project countries not only face problems in implementing and enforcing the law with regard to international issues but also face opposition on the domestic front. Even when competition agencies are *de jure* independent, their independence is threatened and made obsolete if their decisions are overruled or not carried out by the government. In many LMICs, government intervention in the functioning of markets continues to be significant.

A survey on implementation constraints by the International Competition Network, an international informal (virtual) network/platform which seeks to facilitate cooperation between competition law authorities globally, observes the need for a culture of competition, because competition authorities depend on a continuous supply of evidential and supporting information in their investigations



with regard to the effect of certain business practices on domestic competition. Only a knowledgeable and aware community will demand and provide such cooperation.²¹

Creating a culture of competition is very important, therefore, and has unfortunately plagued many young competition jurisdictions. Efforts in this regard will involve broad advocacy work explaining the benefits of competition regulation in the face of liberalising markets to business, consumer communities, politicians and the media. A strong consumer movement is crucial in the creation and sustenance of a culture of competition. It is also useful to support and amplify the voice of small and medium-sized enterprises, which, at this stage, are crucial to the development prospects of many LMICs.

III. Reform agenda

Having discussed some of the core challenges in the previous section, this section highlights how some of those implementation challenges have been successfully addressed by countries, and attempts to set a future agenda for reform.

1. Addressing financial resource constraints

As mentioned earlier, competition agencies are coming up with innovative ways to raise funds and address the constraints posed by insufficient budgets. In South Africa, for example, the competition authorities have streamlined their processes within the enforcement and mergers areas to improve turnaround times for investigations. For instance, merger applications are divided by the Competition Commission into three phases, with phase 1 types requiring less extensive analysis than phase 3 types. In this manner, they manage to address both capacity and financial constraints. Importantly, agencies do not compromise on their independence in trying to procure funds, which is very important for them to be able to work efficiently.²²

A major challenge facing competition authorities is reliance on government funding. To address this, agencies can look at alternative sources of funding as well. Although increased government funding is a possibility, especially in countries where the authority's budget is a small percentage of the government's total budget, the 7-Up projects recommend international donors as a potential source to finance training and advocacy programmes. Donors could play a role in setting up and providing specific training programmes and finance advocacy activities to create a culture of competition. They could also provide resources to establish and maintain libraries and databases.

Care should be taken to align the interests of donors with national priorities to strengthen competitive market conditions. Investigations must be made to verify that any proposed funding will not raise any conflicts of interests vis-à-vis potentially affected corporate or industry interests. Building

21. International Competition Network (ICN), 'Lessons to be learnt from the experiences of young competition agencies', Competition Policy Implementation Working Group Report, ICN, Cape Town, 2006.

22. Ibid.



South–South institutions and expert resources and sharing information that would specialize in a ‘new’ developmental competition policy could be one way to avoid such conflicts.

Second, the competition agencies can raise financial resources through other means such as fees for notifications/complaints and charges for providing copies of publications/reports. Here again, South African agencies are a very good model to follow. The majority of their funds are obtained through notification and process fees from merger cases. The Competition Commission is, therefore, also financially quite independent. A third possibility for competition authorities to increase their financial resources while at the same time making them less dependent on government funds would be to grant them a percentage of the fines imposed on companies that violate competition laws. A problem with this is that the authorities would have a perverse incentive to impose excessive fines on these companies, which could potentially put their credibility as an independent regulator under question.

2. Addressing capacity constraints

Many countries have augmented their capacity with technical assistance from outside players, including foreign governments, international organisations and civil society. Technical assistance programmes might provide a supply of professionals through training not only in prioritization of tasks (as mentioned earlier) but also in rigorous legal and economic analysis. Technical assistance can also be provided by multilateral agencies. Various LMIC commissions have made use of such technical assistance from multilateral agencies. As stated above, when accepting such technical assistance, countries must be careful to avoid any real or perceived conflicts of interest. In the case of support from competition authorities from high-income countries, care must also be taken against pursuing a single-minded ‘cut and paste’ method without first making a full assessment of implications, to ensure that any laws or policies introduced are suitable to the level of development and in line with the developmental priorities of the country.

The South African Competition Commission has also spent considerable effort in increasing the skills base of existing staff through relevant training. Its commitment to a culture of continuous learning is reflected in the number of hours spent by its employees on training, as well as the percentage of the budget being invested in academic development.²³ The Commission has invested in the training of its staff through its collaboration with international organisations. South Africa has also had arrangements with foreign competition authorities such as the US Department of Justice, the US FTC, the Australian Consumer and Competition Commission and the Norwegian Competition Authority, in which staff from these agencies have been seconded to the South African Commission as mentors.

A recommendation on addressing capacity constraints as developed from the 7-Up findings²⁴ calls for cooperation with foreign competition authorities which is also required for dealing with

23. Ibid.

24. P. Mehta and R. Sengupta, ‘Did we make any difference? Reforming Competition Law Regimes in the Developing World through the 7Up Programme’, CUTS International, Jaipur, 2012.



cross-border issues. The findings suggest that whether countries have special provisions for extra-territorial jurisdiction or apply the ‘effects’ doctrine is not important when they have no means to enforce their decisions. (See more on extraterritorial application of competition laws in Chapter 3 and recommendations in Model 5).

Often the companies involved are beyond the reach of the competition agencies, which also causes problems in obtaining the information necessary to make a decision. Cooperation with foreign agencies could certainly help in this regard. Further, the project highlighted the need for exchange visits between LMICs competition agencies. The Zambian government offered this service to Botswana soon after Botswana finalised its competition law. (This may be a valuable way for LMIC competition authorities to share their experiences in this way with others. Courses can also be developed on competition to enhance the knowledge of students and young professionals. This would help address the problem of a lack of skilled personnel faced by competition agencies. Universities in Ethiopia, Bangladesh and Viet Nam have already started offering such courses.²⁵

Some countries have adopted this strategy while implementing their competition laws, wherein the first year has been spent in creating awareness in society, the second in checking anti-competitive practices, and the third in taking up structural issues or vertical restraints.

3. Addressing opportunities for law reform

In most cases countries have tried to address this problem of inadequate legislation by way of amendments through parliament, by insertions and corrections. For example, the Peruvian Congress is currently discussing a Bill that would introduce a general merger review regime for relevant transactions in the market which has been shaped and proposed by the Competition Agency, which has gained a lot of expertise working over the last two decades. The Bill follows international standards in the matter and establishes a mandatory *ex ante* merger review regime in which only mergers and acquisitions of companies with turnover exceeding \$1.387 billion would need to be notified (Article 5 of the Bill).²⁶ The proposal has not yet been adopted but is currently under debate.

Similarly, the Costa Rican Competition Commission has, thanks to the international cooperation agreements in recent years, prepared a Bill to amend the competition law to strengthen its facilities and expand its field of application.

For countries that are yet to adopt or are in the process of adopting a competition law, reliance on the cut and paste approach must be avoided and a more contextualised approach be followed.

4. Overcoming political economy challenges

While political economy factors can impose substantial constraints in the competition reform process, it is important to take lessons from countries such as Zambia, where implementation of the

25. Ibid.

26. International Competition Network (ICN), ‘Lessons to be learnt from the experiences of young competition agencies’, Competition Policy Implementation Working Group Report, ICN, Cape Town, 2006.



competition regime has been rather successful despite several political economy challenges. The main credit for overcoming these challenges goes to the way in which the competition agencies proactively worked within these constraints and tried their best to enforce the laws within the existing challenging environment. The key tool to success was strong advocacy and outreach with opinion leaders such as civil society, policymakers and bureaucrats/senior public servants.²⁷

- **Parliamentary outreach and sensitisation**

Members of the executive and legislature should be sensitised on the benefits of competition, and how to apply its principles to government decisions. This holds the key to a successful competition reform process. It has proved useful in the past to identify parliamentarians as friends of competition and sensitise them on its benefits. The Gambia is a good example here of the reforms process being fast-tracked to such initiatives and the interest generated among relevant ministers such as the Minister of Trade and Industry.²⁸ In India, after a lot of similar efforts, politicians have started appreciating the need for an effective competition regime. Clear-cut measures backed by policy decisions were undertaken to develop the present competition regime in the country (Competition Act 2002, as amended by the Competition (Amendment) Act 2007). A parallel process has also been envisaged by the policymakers (hosted by the Planning Commission, Government of India) to evolve the national competition policy for the country. To this effect, a working group of experts has also been constituted.

- **Engagement with businesses**

Competition helps to create an environment more conducive to doing business by lowering entry barriers, creating a level playing field for competing firms in the market and driving innovation/production of new products and services. Furthermore, competition helps boost investments by creating an enabling environment for businesses to operate. Unfortunately, business communities in many LMICs are not well versed on how they stand to gain from competition, and often oppose such reforms. Businesses are one of the key categories of stakeholders that competition advocacy efforts must target. Efforts to engage with them on the various benefits of competition should emphasize the gains that outweigh the costs they may bear from enhanced competition in markets.

5. Building a culture of competition

Flowing from the previous discussion, LMICs who may be newcomers to competition laws need to build awareness and capacity among relevant stakeholders through advocacy, outreach and networking initiatives. The stakeholders should include, among others, civil society groups, media, policymakers, businesses and consumers.

27. CUTS International, 'Political Economy Constraints in Competition and Regulatory Regimes', CUTS International, Jaipur, 2007.

28. International Competition Network (ICN), 'Lessons to be learnt from the experiences of young competition agencies', Competition Policy Implementation Working Group Report, ICN, Cape Town, 2006.



Generating awareness/sensitising stakeholders

Generating awareness and sensitisation are continuous processes, and necessary to gather public support for competition reforms. Multiple stakeholder initiatives and focus group discussions are helpful ways of doing so. It is important to note that awareness cannot be raised in a generic way and in isolation—i.e. without any cases studies. Until such time that a competition authority builds up its own armoury of case studies, it can rely on cases studies from other jurisdictions, particularly from other LMICs. Communicating with all the stakeholders on relevant issues pertaining to competition such as its benefits, the costs of competition distortions to the stakeholders etc. is a key—and this needs to be effectively managed by modern competition agencies in LMICs.

Public education on competition issues is very important to dispel some of the myths associated with it, such as that competition is bad for LMICs and only works for the rich, or that it is harmful for domestic industries, as well as to explain how consumers, producers and the government can gain from competition. All of this forms part of competition advocacy, which is a core component in building a culture of competition.

The Competition Commission of India has actively been pursuing competition advocacy efforts with the help of toolkits, booklets etc. Civil society organizations can also play an important role in addition to countries' competition agencies in terms of taking on such advocacy initiatives.

In its efforts to generate awareness and sensitisation, the Turkish Competition Authority organizes events such as panels, conferences and regional seminars to increase awareness of competition by the public and the business community. It has also extensively used media to inform the public and the business community about its practices and has produced a great number of publications on competition law and policy that are available as soft and hard copies. The agency is in close contact with law and economics faculties in universities to enable the students to have a course on competition law and economics. It can be argued that the Turkish Competition Authority has been quite successful in these endeavours.²⁹

The South African competition authorities have similarly managed to secure the buy-in and participation of specific stakeholders and are continuing their advocacy efforts aimed at raising public awareness through presentations, workshops and meetings with business entities, labour groups, consumer groups and other affected stakeholders. Its successful engagement with businesses can be seen now that most firms have an internal competition law compliance programme.

Advocacy and capacity-building on competition reforms through networks

Competition advocacy and capacity-building initiatives need not be confined to the domestic territories of countries. Building strong networks that go beyond borders can play a very effective role in this regard. For example, the African Competition Forum was launched in Nairobi in 2011. Its principal objective is to promote the adoption of competition principles in the implementation

29. International Competition Network (ICN), 'Lessons to be learnt from the experiences of young competition agencies', Competition Policy Implementation Working Group Report, ICN, Cape Town, 2006.



of national and regional economic policies of African countries. Specifically, the Forum assists in building the capacities of agencies in the region and promoting awareness and appreciation of competition principles among government and other stakeholders.

Another network that deserves mention here is made up of civil society organizations and called the International Network of Civil Society Organizations on Competition (INCSOC). The network intends to put civil society on the map of competition policy discussions at the international and domestic arena. Its main objective is to promote and maintain a healthy culture of competition among civil society and other interested organisations. The activities of the network revolve around the objectives of coalition-building, networking and capacity-building on competition issues, primarily of civil society organizations but also of other stakeholder groups, achieved by sharing experiences and through information dissemination projects. In working towards the long term goal of building an effective competition framework and competition culture, various stakeholders, organisations and regulatory bodies have a role to play – no one network or organisation should be considered isolation.



Access to health technologies is a fundamental human right that should be promoted using all of the means available. Making health technologies accessible and affordable to populations of LMICs requires resources and tools of various kinds. A robust competition framework and resources to effectively carry out its mandate is one of those means. While competition law does not provide the financial resources necessary to procure and supply health technologies, it may well be used to bring down prices and to help ensure that budget resources are used most efficiently. Competition law can also help spur the quicker introduction of novel and improved health technologies. This will promote the achievement of human rights objectives.

Competition law is an underused tool in the toolbox for LMICs. This guidebook has shown that in certain circumstances competition law has advantages over and complementaries with some of the flexibilities built into international IP and trade rules and, therefore, warrants further attention. In terms of advantages, competition law can be used to address 'market failures' and wrongful conduct in the health technologies sector, whether or not they are associated with the abuse of patents or other IP rights. For instance, anticompetitive activities undertaken in the context of government procurement processes, such as bid-rigging and price-fixing, are not necessarily associated with IP.

Competition law enforcement actions can be initiated by government authorities, or by affected persons or groups, without the need to demonstrate some type of infringing activity or without being the subject of an infringement claim by an IP right holder. Additionally, damages or penalties can be assessed on the basis of effects on the market, and need not be limited to individual claimants.

Unlike some other areas of law, there are no extensive overarching international agreements on competition law. As a consequence, there are few external constraints on the approaches that governments may legitimately adopt to address anticompetitive conduct, and governments, particularly those in the developed world, have adopted and employed substantially different approaches to competition law over time. Competition law is a part both of industrial policy management and consumer protection, and governments require flexibility to address changing needs and perspectives in each of these areas.

That said, LMICs face substantial challenges in effectively using competition law to promote affordable access to health technologies. While some have already built up competition law enforcement agencies, many are at early stages in this process.

Competition law enforcement typically involves investigation into private business practices, which often requires authorities being equipped to issue and execute demands for documents, testimony and so forth. A case must be built based on the evidence that has been assembled. For a competition law authority to undertake its mission effectively, adequate budget and staffing, accompanied by the political will for such an enabling legal and political environment, is core.



One way that LMICs can mitigate some of the potential burden of complex law enforcement is to make use of *per se* rules that do not require applying a balancing test (e.g. the rule of reason) in each case. For conduct such as horizontal price-fixing or bid-rigging, it is enough for the authorities to present evidence that the activity has occurred.

Another way that competition authorities in LMICs can reduce their operating burdens is to work with presumptions in areas such as assessment of market power. As discussed in Chapter 4, the holder of a patent on a therapeutic drug should be presumed to have market power in respect to that drug, shifting the burden to the patent owner to demonstrate (if it can) that alternative therapies act as effective substitutes. Similarly, when a merger or acquisition is proposed among pharmaceutical companies, there should be a presumption that drugs in the same broad ATC class are in competition with each other, and that the combination should not be permitted to eliminate that competition. The burden should shift to the combining companies to demonstrate that drugs in the same broad class do not compete.

The model provisions following this conclusion are intended to provide suggestions or guidance regarding potential *per se* rules and/or presumptions that may be used in competition legislation or regulations in LMICs.

There are also ways to simplify remedies under competition law. Usually, remedies include the assessment of damages caused by or related to the anticompetitive conduct, and the potential assessment of criminal fines and penalties, as well as imprisonment for individuals. To reduce the burdens of litigation, consent orders or agreements that put an end to the anticompetitive conduct might be used, and may also include monetary compensation. In addition, courts and administrative authorities may issue compulsory licences as a remedy for patent-related anticompetitive conduct. An advantage is that the TRIPS Agreement provides greater flexibility for compulsory licensing as a remedy for anticompetitive conduct than it does for some other contexts. For instance, a compulsory licence issued to remedy anticompetitive conduct need not require the payment of a royalty to the patent owner; prior negotiation with the patent owner is not required; and the licence may authorize exports as well as supply of the domestic market without employing specific WTO rules adopted for 'compulsory licensing for export'. At the same time that it is desirable to simplify some remedies to reduce adjudicative burdens, it might also be appropriate to consider new and broader remedies to address previously unaddressed harms to consumers, patients and payers, as well as to competitors.

While competition law authorities in LMICs may well lack experience as compared with their counterparts in developed countries, the only way to overcome that lack of experience is to get started. Once the competition law has been enacted, it may be necessary to put in place regulations and working procedures. It may also be useful to bear in mind the old adage, 'perfection can be the enemy of the good'. Regulatory structures take time to evolve, and are 'perfected' only through the experience gained from implementation. Competition authorities are policing the market in the interests of protecting the public, including the public health budget. There is no country or region where markets are functioning without some form of anticompetitive abuse, and there is plenty of



work to be done everywhere. If competition authorities in LMICs wait until they have developed perfect programmes, the delay may be contrary to the public interest.

Furthermore, there should be no reason for any LMIC competition authority to 'go it alone'. Competition authorities can share knowledge and experiences formally and informally. A number of the developed-country competition law authorities, along with international organizations and civil society organizations, are able to help with technical training and support. As in so many other areas, the Internet enables competition law authorities, and the public (including civil society organizations), to learn from the experience of others at very low cost and with few barriers. The laws, regulations and practices of competition law authorities across much of the world are available online, and in several languages.



Restrictive practices in licensing agreements

Restrictive practices in licensing agreements may have negative effects on the capacity of the licensee to produce and offer health technologies at competitive prices locally or internationally. They may also limit its ability to innovate or improve on the received technologies.

Restrictive practices may be enumerated in competition laws and subject to the control of competition authorities, or regulated under other pieces of legislation, such as industrial property laws. In some countries, industrial property offices have the competence to review the terms and conditions provided for in licensing agreements.

In cases where restrictive practices are found, remedies may include the non-registration of the licensing agreement (where required to produce certain effects or for fiscal purposes) or the invalidation of the agreement or of those clauses deemed contrary to the applicable laws and regulations. Where restrictive practices have caused injury to a licensee, the licensor may be held liable to pay damages to compensate the licensee.

One important aspect of the legislation regarding the control of restrictive practices is how the lawfulness or unlawfulness of a particular practice is determined. One approach (based on what is known as the 'rule of reason') is to investigate and establish in **each particular case** whether a practice has anti-competitive effects. This approach requires a case-by-case balancing analysis that may be difficult to conduct, particularly when the competent authorities have limited resources.

Another approach is to define a set of restrictive practices that may be considered unlawful *per se*—that is, without a specific analysis and evaluation of the circumstances of the particular case. This approach was extensively used by US antitrust authorities in the past, and continues to be used in the EU and other jurisdictions. Its implementation is more straightforward than the 'rule of reason' and could be the most suitable option for LMICs. The adoption of *per se* rules regarding the unlawfulness of certain practices may be undertaken through legislation. *Per se* rules may also be adopted through judicial or administrative decision. As discussed in Chapter 2, under the WTO TRIPS Agreement countries are free to regulate IP licensing agreements.

The following provisions in licensing agreements may be considered abusive or anti-competitive *per se*:

- (i) exclusive grant-back provisions and/or zero-royalty grant-backs; grant-backs of know-how and unrelated improvements;



- (ii) non-challenges to validity of industrial property rights;
- (iii) ineligibility to become a compulsory licensee;
- (iv) exclusive dealing;
- (v) restrictions on research;
- (vi) restrictions on use of personnel;
- (vii) price-fixing;
- (viii) restrictions on adaptations;
- (ix) exclusive sales or representation agreements;
- (x) tying arrangements;
- (xi) export restrictions, particularly for the supply to countries without a blocking patent;
- (xii) restrictions on publicity of licensed products;
- (xiii) payments and other obligations after expiration of industrial property rights;
- (xiv) restrictions after expiration of the licensing agreement.¹

Importantly, Article 40 of the TRIPS Agreement does not prevent WTO Members from defining which restrictive practices can be deemed abusive or anti-competitive *per se*.

1. This list is based on one of the proposals discussed during the negotiation of the TRIPS Agreement (Chairman's Draft of 23 November 1990 and the Brussels Draft).



Defining the relevant product market in access to health technologies cases

Using the ATC system as a starting point

The Anatomical Therapeutic Chemical Classification System (the “ATC system”), which is used for the classification of medicines, divides medicines into groups based on the organ or system on which they act and their therapeutic, pharmacological and chemical properties. There are five levels in the ATC system:

- ATC level 1: anatomical main group (14 main groups, such as dermatologicals, medicines that work on the cardiovascular system, and anti-infectives for systemic use);
- ATC level 2: therapeutic subgroup (dermatologicals, for example, are divided into 11 therapeutic subgroups, including antifungals for dermatological use, antiseptics and disinfectants, and anti-acne preparations);
- ATC level 3: pharmacological subgroup (antifungals for dermatological use are divided into two pharmacological subgroups: antifungals for topical use and antifungals for systemic use);
- ATC level 4: chemical subgroup (antifungals for topical use are divided into three chemical subgroups: imidazole and triazole derivatives, antibiotics and ‘other antifungals for topical use’; and
- ATC level 5: chemical substance (there are 21 imidazole and triazole derivatives that are recognised as antifungals for topical use, including clotrimazole, ketoconazole and fluconazole).

The European Commission recognises that medicines in the same ATC 3 class “generally have the same therapeutic indication and, subject to exceptions, cannot be substituted by products belonging to other ATC 3 classes”. That said, the appropriate ATC level must be identified on a case-by-case basis, with the circumstances of any particular case being considered to identify the relevant product market. In other words, the ATC system is only a guide; a starting point.

Abuse of dominance

When a health technology is patented, there should be a presumption that it has its own product market. If the drug in question is no longer patented (or is a generic version—a bioequivalent—of the originator drug), the presumption should be that the originator drug and all its bioequivalents constitute a single product market. This translates into using the ATC level 5 as a starting point for market definition in any abuse of dominance matter.



While it is ordinarily appropriate to start the assessment with the lowest ATC level and move upward to identify potential substitutes, there may be cases where the starting point of market definition should be even more specific than the ATC level 5—that is by first considering the galenic form of the drug. The galenic form refers to the pharmaceutical dosage form of a medicine—whether oral (tablet, capsule, solution or other), topical or for intravenous injection. It may be appropriate to use the galenic form as a starting point, for example, when dealing with a drug used to treat young children. In other cases, it may even be appropriate to distinguish between prescription and OTC markets involving the same active ingredient medicine.

The question that arises is who should have to show that the market should be defined more broadly—who bears the onus of rebutting the presumption regarding the relevant product market? An access-friendly approach would see the onus resting on the party which is alleged to have abused its dominance (the company under investigation) to make out a case why the relevant product market should be defined more broadly.

Merger control

In merger control, the objective is to prevent a decrease in market competition. This makes it appropriate to presume that drugs in the same therapeutic class can ordinarily be substituted for each other, which ordinarily translates into ATC 3. But depending on the condition, infection or illness that is the target of the drug(s) in question, either ATC level 2 or ATC level 3 should be used as a starting point. The following two examples explain why:

- In a proposed merger between two firms that market drugs to treat fungal infections of the skin, it may be appropriate to use ATC level 2 as a starting point. This is because, as indicated above, antifungals for dermatological use are located at the ATC 2 level; at the ATC 3 level, one finds both antifungals for topical use and antifungals for systemic use. A fungal infection of the skin may be treated either topically or systemically.
- In a proposed merger between firms that market drugs to prevent malaria, it may be more appropriate to use ATC level 3 as a starting point. This is because antimalarials are located at the ATC 3 level. Antiprotozoals, which are located at the ATC 2 level, include antimalarials as well as agents against amoebiasis and other protozoal diseases and agents against leishmaniasis and trypanosomiasis.

Who bears the onus of showing that the market should be defined differently? While an access-friendly approach should see the onus resting on the merging parties to prove that the relevant product market should be defined more narrowly, in jurisdictions where the competition authority is responsible for review of proposed mergers, it is that regulatory authority that should have the statutory mandate—acting in the public interest—to define the market appropriately.



Model interpretations: refusal to license

- A refusal to license an IP right in and of itself is not a violation of competition law.
- A refusal to license IP rights, including patents, data rights and know-how, by a dominant enterprise may violate competition law where the refusal has a substantial anticompetitive effect that outweighs its technological, efficiency or other pro-competitive gain.
- A refusal to license an IP right on reasonable commercial terms may be presumed to cause anti-competitive harm that outweighs any pro-competitive gain in the following situations:
 - i) The IP holder does not make the medicine available at reasonably affordable prices to the public, and the refusal to license involves an essential input such that the refusal to license prevents competition in the relevant market; or
 - ii) The refusal to license extends market power beyond the scope of the patent as defined by the patent law and its working requirements, such as where the refusal:
 - (1) prevents supply of a segment of the market that is not served by the IP owner on reasonable prices, terms and conditions; or
 - (2) forecloses access to, or anti-competitively raises the price of, an important input needed to supply a market other than that which is protected by the IP right, including by blocking R&D or marketing of new products for which the IP right is an essential input (for example, a rational fixed-dose combination medicine);or
 - iii) The refusal is in respect of an IP right that covers minimal creative contributions (considering, for example, the nature and funding of the R&D) compared to the anti-competitive effects of the refusal; or
 - iv) The refusal is motivated by anticompetitive animus, rather by a legitimate business justification.
- In determining a remedy for an illegal refusal to license, authorities should consider the availability of standard form licenses of right as may be available under the patent law and the possibility to license on reasonable and non-discriminatory terms through the Medicines Patent Pool or similar mechanism.



Model interpretations: excessive pricing

An excessive price of a needed medicine may be presumed where the price maintained by a dominant supplier of a medicine does not make the benefit of the patented invention available at reasonably affordable prices to the public.

The IP holder may rebut the presumption above by showing any of the following:

1. The owner of the IP has open licensed the technology to all potential competitors on reasonable and non-discriminatory terms, including at reasonable royalties determined in reference to the WHO/UNDP 'Remuneration Guidelines for Non-Voluntary use of a Patent' or as compared to average royalty rates in the industry for comparative goods; or
2. Competitive provision of the good is not economically feasible—for example, because of the relatively small size of the market, and the price is reasonable in the light of the demonstrated cost of production of the particular good plus a reasonable and proportionate reward for R&D, including a reasonable rate of return on invested capital.

A reasonable reward for R&D should be proportionate to the resources of the country—for example, as measured by GDP per capita.



Model approach to extraterritorial application of competition law

1. General international legal principles regarding jurisdiction

Under general principles of international law, each country typically exercises jurisdiction (or legal control) over activities taking place within its own territory (i.e. territorial jurisdiction) and over its nationals, wherever they may be located (i.e. nationality jurisdiction).¹ As part of territorial jurisdiction, it is also generally accepted that each country may extend jurisdiction to acts occurring outside its territory when those acts have a direct and substantial effect within the national territory (i.e. 'objective territoriality').²

2. Transnational anti-competitive conduct

When applying competition law, national enforcement authorities (and private complainants) are usually concerned with conduct that is taking place within the territory of the country. But, particularly in a highly integrated global economy, anti-competitive acts undertaken outside the national territory may have a direct and substantial effect within the country. For example, several enterprises exporting a particular product to a country may fix its export price such that all importers must pay the price established through an anti-competitive arrangement. Some exporting countries—for example, the United States—provide an exemption in their competition law allowing exporters to undertake this kind of anti-competitive conduct as long as the products are exported.³ As a consequence, importing countries and their consumers are denied the potential benefits of competition among exporters. There are a variety of other circumstances in which anti-competitive arrangements have both domestic (local) effects and foreign elements or causes. The executives of a group of suppliers may travel outside the country to discuss a bid-rigging arrangement for a government procurement contract; establishing their agreement outside the country and then carrying it out within the country.

Some anti-competitive conduct is intended to broadly affect the entire global market for a product, rather than being directed towards an individual importing country. Such conduct may nevertheless have an adverse impact on local consumers in each affected territory. Such conduct should not

1. There are other bases on which a country may exercise jurisdiction, but those are not relevant here.

2. Bernard H. Oxman, 'Jurisdiction of States', *Max Planck Encyclopedia of Public International Law*, MPEPIL 1436, Oxford, 2014.

3. Pursuant to the Foreign Trade Antitrust Improvements Act of 1982 (FTAIA), as confirmed by the Supreme Court in *Hoffman-La Roche v. Empagran*, 542 U.S. 155 (2004).



escape the application of competition law just because the perpetrators did not target a particular country. Such conduct might be considered to have a 'widespread' or 'diverse' direct effect.

3. General principle for applying competition law to extraterritorial conduct

Competition authorities, private complainants and courts should be empowered to take action against persons (including enterprises) whose anti-competitive conduct outside the national territory has a direct and substantial effect within the national territory. Jurisdiction may extend to anti-competitive conduct that is widespread or diverse (i.e. the country need not have been specifically 'targeted'), in the sense of that the anti-competitive conduct was intended to affect the global market for a product, with a resulting impact on local prices or availability.

4. Comity

Some governments (including their courts) have expressed concern that competition laws of other countries should not be extended so far as to interfere with their own local approach to formulating rules and enforcing competition law. Activity that is considered anti-competitive in one country may not be considered anti-competitive in another. Extraterritorial application of competition law might be so intrusive as to undermine or negate the sovereign authority of other countries to develop and apply their own approach. In applying domestic competition law to activities being carried out in other countries, competition authorities and courts should be attentive to the rules of those other countries insofar as this does not result in substantial adverse effects in the domestic market. Foreign comity concerns, however, should not be addressed at the expense of the local consumer.



Remedies to address generic pathway-related abuse

A number of countries have adopted legislation that ‘links’ approval by the drug regulatory authority (DRA) to market a generic drug to the claimed patent status of the originator version of such drug. Such legislation may allow a patent owner to block DRA marketing approval of a generic version pending a determination by a court or administrative body regarding whether a patent would be infringed by introduction of the generic.

As a consequence of such linkage, the entry to market of a generic medicine may be significantly delayed, including in circumstances where it is not clear whether the patent in question is valid or would be infringed. The litigation or administrative process that decides whether the patent is valid or invalid, or would be infringed, may last for well over a year, during which time the public is deprived of access to the lower-cost competitor products, and the generic producer is deprived of sales opportunities.

Aside from linkage, there are several other ways in which patent holders may unfairly obstruct entry to market of generic competitors. These are discussed in more detail in Chapter 3. Although the discussion that follows is primarily concerned with addressing anti-competitive abuses connected with linkage mechanisms, these remedial measures may also be relevant to other forms of anti-competitive activity.

1. Recovery of damages

To protect the public from overpaying and to deter patent owners from securing and seeking to enforce weak patents, if a linkage mechanism is adopted, it should include a means to recover from the patent owner the damages that are suffered by the public and the generic producer from delay occasioned by a wrongly invoked patent. Such a damage recovery system may take the form of an obligation imposed on the patent owner to pay any costs or losses that may have been sustained should the court or administrative body determine that such blocking was unwarranted. In the absence of such a damage recovery mechanism, pharmaceutical patent owners are encouraged to engage in the practice of ‘evergreening’.



2. Fines

In addition to such a mechanism, competition authorities should have the power to impose fines on pharmaceutical companies that abuse their patents or dominant position on the market to hinder the entry of generic products. Such fines should be sufficient to deter future abuses.

3. Equitable remedies, including access to regulatory data and technology

Courts and administrative authorities should have substantial discretion to impose equitable remedies to redress harms caused by anti-competitive conduct inhibiting the use of generic products. For example, as a remedy for abusive practices that block generic market entry, courts and administrative authorities may order pharmaceutical patent owners to allow generic producers to rely on confidential drug regulatory files for the purpose of accelerating DRA approval of generic drugs. Courts and administrative authorities may also order patent owners to provide access to manufacturing process technologies that will accelerate generic entry.

4. Preclusion of patent challenge buyouts

A linkage mechanism typically permits the generic producer seeking market entry to challenge the validity of a patent, or to assert non-infringement, to overcome the blocking of DRA approval. Linkage legislation should expressly preclude patent owners and generic producers from settling generic challenges to the validity or infringement of patents (sometimes known as 'pay for delay' or 'buyout' agreements). Such settlements enrich patent owners and generic producers at the expense of the public.



Model provisions of competition-related TRIPS flexibilities

Article 6: Exhaustion of rights

The principle of international exhaustion of rights may be incorporated into patent laws,¹ consistently with Article 6 of the TRIPS Agreement, with the following formulation:

- The rights conferred by a patent shall not extend to acts in respect of Articles which have been put on the market in any country by the patentee or with his consent, or by any other authorized party.

This formulation would allow parallel imports of products commercialized by the patentee or its voluntary licensees, as well as by compulsory licensees.²

Article 8: Measures to prevent abuses of IPRs

Abuses of IP rights would ordinarily be subject to competition laws. However, IP laws may contain provisions dealing with different types of misconduct, such as restrictive practices in licensing agreements, fraud in the prosecution of patent applications, legally baseless requests for interlocutory injunctions and other abuses of enforcement measures. Some examples of provisions to deal with IP abuses are the following:

- The clauses in licensing agreements that adversely affect the technological development of the licensee, impose exclusive grant-back conditions, prevent any challenge to validity or impose mandatory joint licences will be deemed null and void.³
- The omission or misrepresentation by the patent applicant of information known to him that would render one or more claims invalid will be deemed fraud and cause the patentee to lose the right to enforce the patent.⁴

1. Similar provisions may be included in other IP laws.

2. There are differing approaches among countries about whether the right owner's consent is required to consider that his rights have been exhausted. The TRIPS Agreement does not give a definitive position on the issue, thus leaving scope for countries to interpret exhaustion as set out in this model law. The implementation of the principle of exhaustion of rights is not subject to dispute settlement in accordance with Article 6 of the TRIPS Agreement.

3. Partially based on Article 38 of the Argentine Patent Law No. 24.481.

4. This proposal is in line with the 'inequitable conduct doctrine' developed in the United States. See, for example, C. Cotropia, 'Fraud Before the United States Patent and Trademark Office and the Copyright Office: Basic Elements and Recent Developments', American Intellectual Property Law Association, Arlington, VA, 2007, <http://www.aipla.org/learningcenter/library/papers/am/AM08Materials/Documents/Cotropia-paper.pdf>.



- An interlocutory injunction for the alleged violation of a patent related to pharmaceuticals shall not be granted unless the patentee has first notified the Attorney-General in writing of the application. The Attorney-General shall be deemed to be a party to the proceedings unless he gives written notice to the court that he does not desire to be a party.

If an interlocutory injunction is granted and:

- (a) the patentee subsequently discontinues the principal proceedings without the consent of the other parties thereto; or
- (b) the principal proceedings are dismissed; and in either case the court declares that: (i) the patentee did not have reasonable grounds, in all the circumstances known to the patentee or which ought reasonably have been known to the patentee to believe that it would be granted final relief, or that each of the claims, in respect of which infringement is alleged, would have a reasonable prospect of being held to be valid if challenged by the defendant; or (ii) that the application for the interlocutory injunction was otherwise vexatious or not reasonably made or pursued,

the court may, in addition to any other relief which it believes should be granted to any person, award a compensation to the defendant, to other affected parties and to the State for any damages sustained, or costs incurred, as a result of the grant of the interlocutory injunction.⁵ (Regarding this type of relief, see also Model 6 regarding potential remedies for wrongly invoked patents.)

- A party at whose request measures were taken and who has abused enforcement procedures shall provide to the party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse, including defendant expenses and appropriate attorneys' fees.⁶

Article 31 (k): Compulsory licences as remedy for IP abuses

Compulsory licences to remedy anti-competitive practices may be granted by competition authorities (even in the absence of specific provisions allowing for them) or by other authorities under IP or other legislation. The following is an example of a possible provision:

- The competent national authority shall, either *ex officio* or at the request of a party, grant compulsory licences where anti-competitive practices, including excessive pricing, are determined to exist, especially where they constitute an abuse by the right owner of a dominant position in the market. No prior negotiation with the right-holder will be required.

The need to correct anti-competitive practices shall be taken into account in determining the amount of remuneration to be paid in such cases.

The competent national office shall refuse termination of a compulsory licence if and when the conditions which led to the granting of the licence are likely to recur.

5. Based on Australia's Therapeutic Goods Act 1989, Section 26d, as amended.

6. Based on Article 48.1 of the TRIPS Agreement.



Examples of price reductions achieved through use of competition law and use of compulsory licensing

Table A.1: Examples of TRIPS flexibility (compulsory licensing) actions in the pharmaceutical sector

| Country and date of Issue | Type of licence | Type or name of medicine | Impact of compulsory licence |
|---------------------------|---|---|---|
| India February 2012 | Compulsory licence to manufacture generic version | Sorafenib (kidney cancer treatment) | Resulted in price reduction of 97% |
| Ecuador April 2010 | Compulsory licence to import and, if necessary, locally produce generic version | Ritonavir (ARV) | Resulted in patent holder reducing price of brand medicine by 70% |
| Thailand January 2008 | Government use licence to import generic version | Letrozole (Breast cancer treatment) | Projected price reductions of 97% expected |
| Brazil May 2007 | Compulsory licence to import generic version | Efavirenz (ARV) | Resulted in a 72% price reduction |
| Thailand January 2007 | Government use licence to import or locally produce generic version | Lopinavir/Ritonavir (ARV) | Projected price reductions of 80% expected |
| Indonesia October 2004 | Government use licence to locally produce generic version | Lamivudine/Nevirapine (ARV) | Resulted in price reduction of 53% |
| Malaysia November 2003 | Government use licence to locally produce generic version | Combination of Stavudine, Didanosine and Nevirapine (ARV) | Resulted in price reduction of 83% |



Table A.2: Examples of competition law actions in the pharmaceutical sector

| Country and date of action | Description of action | Pharmaceutical product | Impact |
|----------------------------|---|--|---|
| France 2013 | Following complaint by Teva, French Competition Authority found that Sanofi-Aventis abused dominant position with strategy to denigrate generic versions of its branded drug, Plavix | clopidogrel | Fine of €40.600 million imposed on Sanofi-Aventis |
| European Union 2012 | European Court of Justice affirmed Commission finding of abuse of dominant position by AstraZeneca by providing misleading information to patent offices and deregistering product to inhibit generic entry | Losec | Fine of €52.5 million imposed on AstraZeneca |
| Colombia 2009 | Finding less than three homogenous products on the market, the National Medicines Pricing Commission regulated price of medicine ¹ sold by Abbott Laboratories | Lopinavir and Ritonavir | Average reduction of price between 54% and 68% per person per year |
| Italy 2007 | Competition authority initiated investigation into abuse of dominant position by Merck | API Finasteride | Defendant agreed to grant free licences to allow manufacture and sale of API prior to expiration of patent term |
| South Africa 2003 | Finding by Competition Commission of excessive pricing and denying a competitor an essential facility against two pharmaceutical companies following complaint from activist groups | AZT, lamivudine and nevirapine and fixed dose combinations containing these ARVs | Led to voluntary settlement agreements with GlaxoSmithKline and Boehringer Ingelheim providing for licensing of patents to a total of seven generic companies based on 5% royalty |
| United States 2000 | Federal Trade Commission charged generic producers with restraint of trade and conspiracy to monopolize markets for two generic drugs; settlement agreed | Lorazepam and Clorazepate | Lead defendant (Mylan) placed \$100 million into escrow account for distribution to purchasers of relevant drugs during time period covered by settlement |

1. National Commission on the Price of Medicines, 'Circular No. 2', National Commission on the Price of Medicines, Bogotá, 2008.



Discussion—Competition law and compulsory licences: When might it be more useful to pursue one over the other; when are they useful when pursued in conjunction?

Compulsory licensing

A compulsory patent licence authorizes a party or parties other than the patent owner to make use of the technology covered by the relevant patent. A compulsory licence may be ordered as a remedy in a competition law proceeding. However, compulsory licensing is not limited to remedying anti-competitive practices. As confirmed by paragraph 5(b) of the Doha Declaration on the TRIPS Agreement on Public Health, “Each [WTO] Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.”

A compulsory licence, including a government use licence, may be issued on grounds such as ‘the public interest’. While the potential grounds for granting a compulsory licence are much broader than only to address anti-competitive practices, there are certain procedural steps that should be followed in granting such licences according to the TRIPS Agreement. Some of these steps—for example, prior negotiation with the patent holder—may be waived for government use licences or emergencies (TRIPS Agreement, art. 31(b)), and the requirement of prior negotiation is also waived when a compulsory licence is issued to remedy anti-competitive practices (TRIPS Agreement, art. 31(k)).

The objective of a compulsory patent licence is to remove or reduce the monopoly control that the patent owner otherwise exercises over the patented technology. In the health technologies context, on the grant of the compulsory licence the originator/patent owner no longer has the exclusive right to make and sell the specific pharmaceutical product. The generic licensee(s) may enter the market with the same product and compete with the patent owner. While the WTO TRIPS Agreement generally provides that compulsory licensees (that is, generic producers) should pay adequate remuneration in the circumstances of the case, there is an exception for compulsory licences issued as a remedy in competition law proceedings, where “[t]he need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases” (TRIPS Agreement, art. 31(k)). In addition, it is important to note that when compulsory licences are issued to address anti-competitive practices, there is no restriction on exporting the product made available under compulsory licence. Specifically, the restriction of Article 31(f) that otherwise limits compulsory licensing to predominantly supplying the domestic market does not apply, and there is no need to follow the procedures prescribed under the 30 August 2003 Waiver Decision authorizing compulsory licensing for export (or Article 31bis of the TRIPS Agreement when it enters into force).

It is well known that the introduction of generic competition, particularly when there are multiple generic competitors, typically results in very significant price reductions. It is not uncommon that the generic price for a medicine is only 20 percent or less of the previous patented price (i.e. price reductions of 80 percent or more) once several generic producers have entered the market. As Table A.1 indicates, substantial price reductions have followed compulsory licences issued in the pharmaceutical sector.



Competition law remedies

Competition law remedies are potentially much broader than the grant of compulsory patent licences. Courts and administrative authorities typically order the competition law violator to cease its offending conduct (that is, issue an injunction against the violator). Competition law remedies also typically include the assessment of damages for injuries that have already occurred. This may, for example, allow the government to recover excess payments that have been made in pharmaceutical procurement. Awards of damages may be quite substantial and may serve to deter future abusive conduct. Because competition law generally gives the courts broad powers to impose 'equitable remedies', the courts may impose specific pricing commitments on competition law violators. By issuing orders to prevent patent owners from 'buying out' patent challenges by generic producers, courts and administrative authorities may accelerate the entry of generic products onto the market. In the merger and acquisition context, courts may order that an acquiring company divest a portion of the portfolio of health technologies that would otherwise be controlled by the acquiring company, thereby enhancing competition. The courts may also order that research projects on certain new health technologies be divested, to promote competition in R&D.

Compulsory patent licensing standing alone may provide the most straightforward means for accelerating price reductions for specific patented health technologies. The grounds may be as straightforward as 'in the public interest', and, as noted above, for a government use licence the requirement of prior negotiation with the patent owner is waived. It may be worth considering, however, that the grant of compulsory licences on health technologies 'standing alone' has tended to generate political reaction from the home countries of the patent owners. Granting a compulsory licence after finding that the patent owner has engaged in anti-competitive conduct may well be less politically charged. The practice of remedying anti-competitive conduct is well accepted in the advanced economies that are usually the home of the patent owners.

Because of the substantially broad range of remedial actions that may be taken in competition law actions, it is difficult to compare the price and/or access effects of compulsory licensing standing alone, on the one side, and the remedies for competition law violations more broadly. Imposing a substantial financial penalty on a patent owner for inhibiting the introduction of generic competition may deter the patent owner from engaging in such conduct in the future, but it may be difficult to establish a direct correlation to the price of a particular medicine. Similarly, assessing damages for competition violations that affect procurement may aid the government in purchasing additional health technologies, but it may be difficult to correlate that to a particular pharmaceutical price. The foundation of competition law is the idea that creating and maintaining competitive market conditions will benefit consumers. It is not only the effect in an individual case that is important, but also in establishing the conditions for doing business more broadly.



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The authors of this report would like to warmly acknowledge the photographic contribution on the cover page, bottom row: Libeweb – Libération Société, Flickr, Taki Steve, 2009