



Using competition law to promote access to health technologies:

A supplement to the Guidebook for
low- and middle-income countries

United Nations Development Programme



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Abbreviations and acronyms

ANDA	Abbreviated New Drug Application (FDA, USA)
API	Active pharmaceutical ingredient
ATC	Anatomical Therapeutic Chemical (classification system)
CADE	Conselho Administrativo de Defesa Econômica (Administrative Council for Economic Defense, Brazil)
CJEU	Court of Justice of the European Union
CMA	Competition and Markets Authority (UK)
COVID-19	Coronavirus disease 2019
EFTA	European Free Trade Association
EU	European Union
FDA	Food and Drug Administration (USA)
FTA	Free trade agreement
FTC	Federal Trade Commission (USA)
HIC	High-income country
IPR	Intellectual property rights
LLC	Limited liability company
LMIC	Low- and middle-income countries
NCA	National competition authority
OTC	Over the counter
PLC/plc	Public limited company
R&D	Research and development
RTA	Regional trade agreement
SAMR	State Administration for Market Regulation (China)
TFEU	Treaty on the Functioning of the European Union
TIA	Trade and Investment Agreements
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
WTO	World Trade Organization

Coronavirus disease 2019 (COVID-19) has demonstrated the strong and reciprocal relationship between health and sustainable development. The COVID-19 pandemic is an unprecedented health and development crisis; as of January 2022, it has killed over 5.5 million people and infected over 328 million. It has unleashed profound socio-economic impacts and is derailing hard-won progress towards the achievement of the Sustainable Development Goals (SDGs), triggering the first decline in human development in 30 years.

The challenge before us is to ensure that the pandemic responses, recovery efforts and future pandemic preparedness benefit and are inclusive of all countries and peoples, consistent with the 2030 Agenda for Sustainable Development and the pledge to leave no one behind. Closing the vaccine equity gap and efforts to build forward better must ensure equitable and affordable access to health technologies for all. Such access is vital for realizing the right to health and the achievement of universal health coverage, and, in turn, eradicating poverty and reducing inequalities. 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 promote equitable access to health technologies and achieve the right to health.

The United Nations Development Programme (UNDP) first drew attention to the utility of competition law in health care as a tool to facilitate and promote access to health technologies in 2014. It published 'Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries' (the Guidebook), with the aim of promoting greater understanding of competition law and providing practical guidance on its use to increase access to affordable health technologies in low- and middle-income countries (LMICs).

It is worth noting that the Guidebook drew on the experience of the AIDS pandemic. It is now well accepted that generic competition for antiretroviral medicines has been an indispensable part of the success in expanding access to life-saving HIV treatment. It is hoped that this publication, 'Using Competition Law to Promote Access to Health Technologies: A supplement to the Guidebook for low- and middle-income countries' (the Supplement), provides further guidance on using competition law and policy as a tool to increase equitable access to affordable health technologies in LMICs, which, in turn, can contribute to improving health, well-being and inclusive economic growth.

The main objective of this Supplement is to provide information on competition law and related developments since the publication of the Guidebook in 2014. While the Guidebook introduced the policies and approaches that inform competition law, the Supplement describes how competition law and policy have been used to improve access to health technologies, particularly through recent examples of the use of competition law.

The Supplement has benefited from the experience and insights from a range of experts drawn from competition authorities, academia and multilateral organizations with relevant expertise across a range of development settings. We are deeply grateful to all who have contributed.

We hope the Supplement will be a useful tool for governments, civil society and all other partners wishing to explore a range of strategies and tools to increase equitable access to health technologies for better health and development outcomes consistent with our common agenda to eradicate poverty and inequalities and deliver on the promise of the SDGs and the pledge to leave no one behind.

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As part of the research for this Supplement, UNDP conducted an online survey. The survey sought updates and insights on developments in competition law jurisprudence affecting health technologies, including recent use of competition law and policy to promote access to health technologies. A wide range of stakeholders, which included competition authorities in LMICs and a number of high-income countries (HICs), were invited to share their expertise. We are grateful to all who participated and provided valuable contributions.

Finally, Mandeep Dhaliwal, Tenu Avafia, Cecilia Oh and Judit Rius Sanjuan of UNDP are acknowledged for their work in the preparation of the Supplement.

The 2030 Agenda for Sustainable Development has set out the ambitious goal of health and well-being for all, with the interlinked targets of eliminating communicable and infectious diseases, and the achievement of universal health coverage. These bring to the fore the critical importance of ensuring affordable access to health technologies. Competition law can be used to restrict or regulate unfair business practices and anti-competitive behaviour to protect consumer welfare—and in the context of health, promote affordable access to health technologies.

In line with the UNDP Strategic Plan,¹ UNDP's HIV, Health and Development Strategy² focuses on three interconnected actions of relevance: reducing inequalities and social exclusion that drive poor health; promoting effective and inclusive governance for health; and building resilient and sustainable systems for health.

In 2014, UNDP published *Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle income countries* (the Guidebook) to enhance understanding and use of competition law to promote access to health technologies. Following the publication of the 2014 Guidebook, UNDP, together with partners, has been working with government agencies, civil society and other stakeholders on these issues.

Understanding that there have been important legal and policy developments since 2014, UNDP undertook the development of a supplement to the 2014 Guidebook. 'Using Competition Law to Promote Access to Health Technologies: A supplement to the Guidebook for low- and middle-income countries' (the Supplement) aims to reflect key legal and policy developments since 2014 that may have important consequences for the use of competition law and policy to improve access to health technologies in LMICs.

UNDP commissioned Professor Frederick Abbott, one of the authors of the 2014 UNDP Guidebook, to research and write this Supplement. In 2019, UNDP conducted an online survey to gather information on key developments in the field of competition law and policy as part of the preparation of the Supplement. The survey was widely distributed to competition authorities in LMICs and to a number of competition authorities in HICs. In addition to national competition authorities (NCAs), experts from academia and civil society were also invited to respond. Their responses, including information on cases, enforcement actions, market studies and changes in doctrinal approaches, have been included in this Supplement. Finally, the research and writing of this Supplement has also benefited from the inputs of experts who kindly reviewed a draft version.

1 UNDP, 'Strategic Plan, 2022–2025', New York, 2021. Available at: <http://strategicplan.undp.org/>.

2 UNDP, HIV, Health and Development, 'Connecting the Dots: Towards a More Equitable, Healthier and Sustainable Future: UNDP HIV and Health Strategy 2022-2025', New York, 2022. Available at: <https://www.undp.org/publications/connecting-dots-towards-more-equitable-healthier-and-sustainable-future-undp-hiv-and>.

A. Purpose and structure

The objective of this Supplement is to provide information regarding the use of competition and policy and related jurisprudential developments since the publication of the 2014 UNDP Guidebook. The Guidebook introduced policies and legal doctrines that inform and give shape to competition law as it is relevant to the pharmaceutical and health sectors. It remains relevant and useful to understanding competition law. This Supplement is not designed as a substitute for, or to replace, the Guidebook. It might instead be viewed as illustrating the Guidebook in action. By providing these illustrations, UNDP hopes that competition authorities and other stakeholders will find the Supplement useful to appreciate the various situations or contexts in which competition law may be effectively deployed to improve access to medicines and other health technologies in LMICs.

The Supplement is organized in line with the structure of the Guidebook, with the same chapter headings maintained.³ The materials in the various chapters are intended to update the substance of the corresponding chapters in the original Guidebook:

1 The interface between intellectual property and competition in LMICs:

In the 2014 Guidebook, this chapter explains the underlying economic and social rationales of competition law. In respect to health technology products protected by intellectual property rights (IPRs), the chapter discusses the role of governments in balancing incentives for innovation and affordable access. The chapter includes illustrative policy statements from the United States (US) and European Union (EU) competition authorities as well as a notable case from South Africa.

2 Intellectual property and competition—room to legislate under international law:

In the 2014 Guidebook, this chapter addresses the international legal framework for the development and implementation of competition law.

3 Anti-competitive behaviours and the remedies available for redress:

In the 2014 Guidebook, this chapter addresses the various types of behaviours that may be inconsistent with competition rules, the methodologies for applying those rules, and the remedies that may be applied after a violation has been determined. The chapter includes illustrative cases from different jurisdictions.

3 This Supplement does not include a separate chapter that updates the subject matter of Chapter 5 of the 2014 UNDP Guidebook ('Advancing competition frameworks in the low- and middle-income country context'). That chapter addresses the tools of competition advocacy and continues to be relevant.

4 **Market definition:**

In the 2014 Guidebook, this chapter addresses market definition as a matter of competition law analysis in the pharmaceutical sector. It focuses primarily on the use of Anatomical Therapeutic Chemical (ATC) classes as the mechanism for defining the market.

Additionally, the Supplement includes a preface discussing competition law and the COVID-19 pandemic, included as a new discussion topic with information on policy and legal developments in different countries.

B. Major trends

Since the publication of the 2014 Guidebook and over the past six years, probably the most active use of competition law in the health and pharmaceutical sector has involved enforcement action against the abuse of IPR, such as patents and regulatory market exclusivity grants to delay the entry of generic versions of patented health technologies onto markets.⁴ This is not a new phenomenon. As the pharmaceutical sector moves away from small molecule chemical medicines towards reliance on biologics, the nature of the relationship between IPR, regulatory exclusivities and market entry is changing, and these changes are being reflected in the evolution of competition law and policy.⁵

However, competition enforcement has by no means been limited to IPR-related actions. There have been enforcement actions initiated and/or completed involving anti-competitive activities in the generics sector, where companies in HICs and LMICs have engaged in coordinated efforts to fix prices, rig bidding and procurement processes, limit output and otherwise abuse the market and consumers.⁶ In addition, mergers and acquisitions have

4 See, for example, CADE (Brazil), 'Enforcement action against regulatory abuse and sham litigation', Box 3.C.2 ("Eli Lilly fined BRL 36 million"), *infra*; European Union, 'Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009–2017): European competition authorities working together for affordable and innovative medicines', Brussels, 2017. Available at: <https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf>, also published with document identification Brussels, 28.1.2019 COM(2019) 17 final. Available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf (hereinafter 'European Commission 2019 Enforcement Report'), pp. 11, 20–21.

5 For example, the Executive Order on Promoting Competition in the American Economy, issued by US President Biden on 9 July 2021, called for a plan "to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the Federal Government for such drugs, and to address the recurrent problem of price gouging". Available at: <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy>.

6 See, for example, description of US Department of Justice (including criminal) and US State Attorneys Generals actions against generics companies, *infra* at pp. 52–53; European Commission Enforcement Report, for example, at p. 10; CADE (Brazil), *infra*, Box 3.B.3 ("CADE investigates cartels in public tenders for medicines purchases").

been used to stifle market entry in ways that have had dramatic effects on prices and access to key medicines.⁷

One of the key areas of doctrinal development is taking place with respect to ‘excessive pricing’.⁸ Several notable enforcement actions have been taken against pharmaceutical companies for charging excessive prices ‘as such’; that is, using a dominant market position to charge a price that is unfair or unreasonable, and without justification. So far, these cases have involved market dominance that is not based on patents or other IPR exclusivities, but rather involved health technologies that are generic but that face limited competition for various reasons.

Another important new trend is that up until the past several years, many governments were reluctant to negotiate international rules on competition law beyond the recognition of competition law flexibility included in the World Trade Organization (WTO)’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).⁹ This is the result of several factors. While the EU has advocated for such negotiations, the US competition authorities resisted this to maintain flexibility with respect to domestic policy, and also out of concern over international ‘lowest common denominator’ solutions. Some US-based multinational companies were not interested in promoting competition enforcement abroad. For a number of LMICs, there was interest in maintaining flexibility, including to treat locally based enterprises on a different basis than foreign enterprises with respect to competition law scrutiny. Some LMICs only recently began to adopt and implement competition law and related enforcement, and this too may have limited their interest in joining external negotiating exercises.

Reluctance to entertain international rules may have diminished somewhat. One reason was a change of perspective in the United States, where concerns grew over more active enforcement by non-US competition authorities, with minimal legal basis for pushback.¹⁰ As US-based companies faced increasing attention from non-US competition authorities, these

7 See, for example, Markus M. Meier, Bradley S. Albert and Kara Monahan, ‘Overview of FTC Actions in Pharmaceutical Products and Distribution’, Health Care Division, Bureau of Competition Federal Trade Commission, Washington, DC, 2019, pp. 27–75. Available at: https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20190930_overview_pharma_final.pdf (hereinafter ‘FTC Actions 2019 Overview’); and European Commission Enforcement Report, pp. 11, 26–27.

8 See discussion of excessive pricing prosecutions, *infra* pp. 64–69, and the European Commission Enforcement Report, pp. 24–25.

9 See Frederick M. Abbott, ‘Are the Competition Rules in the WTO TRIPS Agreement Adequate?’, *Journal of International Economic Law*, Vol. 7, No. 3, pp. 687–703 (2004). Available at: <https://ssrn.com/abstract=917108>; Frederick M. Abbott, ‘Let International Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity’, *International Review of Intellectual Property and Competition Law*, Vol. 49, pp. 259–266 (2018). Available at: <https://doi.org/10.1007/s40319-018-0683-5>.

10 See, for example, US Chamber of Commerce, ‘Competing Interests in China’s Competition Law Enforcement: China’s Anti-Monopoly Law Application and the Role of Industrial Policy’, Washington, DC, 2014. Available at: https://www.uschamber.com/sites/default/files/aml_final_090814_final_locked.pdf.

companies were more inclined to view international rules as constraints on competition authorities, as opposed to threats to their own behaviour. But the United States was not alone. The willingness to entertain international competition rules has involved a fairly broad range of countries and regions, with such rules mainly embodied in competition chapters in preferential trade and investment agreements (TIAs).¹¹ The focus of the competition rules in TIAs has largely been on process or procedural matters, and strategies to facilitate cooperation among competition authorities, rather than on establishing detailed substantive rules and harmonization of legal norms. There remain reasons for LMICs to be cautious about accepting competition-related commitments in TIAs. LMIC competition authorities may ultimately face trade-based pressures that affect their independence and efficiency.¹² It is relatively early days for these TIA competition chapters in terms of assessing their utility and consequences.

11 See, for example, Box 2.1 (Overview of Existing Elements and Commitments in Regional Trade Agreements [RTAs]) *infra*.

12 See discussion of trade agreement-based pressures brought to bear against LMICs attempting to facilitate access to medicines in United Nations Secretary-General's High-Level Panel on Access to Medicines, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting innovation and access to health technologies', New York, 2016, pp. 8–9, 22, 25. Available at: <https://static1.squarespace.com/static/562094dee4bod00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

Competition law and the COVID-19 pandemic

In 2020, as this Supplement was being written, the world confronted a pandemic arising from a novel form of a pathogenic virus, SARS-CoV-2, cause of COVID-19. The COVID-19 pandemic very dramatically impacted health systems and economies around the world, creating large-scale unemployment, causing gross domestic products to decline, significantly reducing trade volumes and so forth.¹³ International and national government action, including the adoption of stay-at-home orders, helped to curtail the spread of the virus, but controlling the pandemic depended (and continues to depend) on the development and distribution of health technologies. The term ‘health technologies’ is used in this document to cover a range of health technologies and products, such as vaccines, treatments, diagnostics and medical devices, including personal protective equipment, face masks and ventilators.

Economically vulnerable individuals and groups are far more likely to be adversely affected by changes to the business environment than wealthier individuals and groups. Economically vulnerable individuals are more likely to lose their jobs, suffer from food shortages and face restricted access to health care, and are substantially more likely to be affected by pre-existing health conditions that increase the likelihood that COVID-19 infection will have more serious consequences. When thinking about competition law issues, it is important to bear in mind that economically vulnerable individuals are the most likely to be adversely affected by anti-competitive practices.¹⁴

The COVID-19 pandemic gave rise to abusive market conduct in areas beyond the health sector. For example, actual or anticipated shortages of food and personal care products

13 United Nations Department of Economic and Social Affairs, ‘World Economic Situation and Prospects 2021’, New York, 2021. Available at: <https://www.un.org/en/world-economic-situation-and-prospects-2021>.

14 See, for example, United Nations General Assembly Resolutions A/RES/74/306 and A/RES/74/307 of 11 September 2020, ‘Comprehensive and coordinated response to the coronavirus disease (COVID-19) pandemic’ (“Recognizing that the COVID-19 pandemic has a disproportionately heavy impact on women, older persons, youth and children, as well as the poor, vulnerable and marginalized segments of the population, and that responses to the COVID-19 pandemic need to take into account multiple and intersecting forms of violence, discrimination, stigmatization, exclusion and inequalities...”); and ‘United response against global health threats: combating COVID-19’ (“Calls upon the international community, regional and international organizations and relevant stakeholders to give high priority to people, particularly the elderly, women and girls, displaced persons and refugees and persons with disabilities, and areas that are most vulnerable, particularly developing and least developed countries, in order to mitigate any drawback towards achieving the Sustainable Development Goals, and highlights the need to address risks of debt vulnerabilities in developing countries, including least developed countries, landlocked developing countries, small island developing States and African countries, as well as middle-income countries, due to the pandemic...”). See also Independent Panel for Pandemic Preparedness and Response, ‘COVID-19: Make it the Last Pandemic’, Geneva, 2021, pp. 43. Available at: https://reliefweb.int/sites/reliefweb.int/files/resources/COVID-19-Make-it-the-Last-Pandemic_final.pdf.

created opportunities for suppliers and intermediaries to engage in excessive pricing. As businesses approach insolvency in a host of areas (e.g. air transport), mergers and acquisitions of distressed companies might have eliminated substantial competition. We focus discussion here on the health sector.

The COVID-19 pandemic gave rise to issues of allocation of health technologies between and within countries. Funders and producers of these products, whether private or public, were making decisions that discriminate for one reason or another in favour of certain geographies and groups. In some cases, this discrimination may result from governmental directives. Decisions regarding allocation may be based on factors such as the source of subsidization of research and development (R&D), the willingness of the prospective recipients to pay higher prices in exchange for preferential access, or the local production of relevant products. The effects may include reducing the ability of countries operating through national health system procurement mechanisms and the population paying out of pocket to obtain the essential technologies and supplies they need.¹⁵ Competition authorities should be attentive to supply shortages that may arise from allocation decisions with respect to scarce products, including decisions taken outside their home jurisdictions. In some cases, there may be anti-competitive behaviours underlying such decisions, and competition law remedies such as mandatory licensing might be considered.¹⁶

1. Price gouging

The COVID-19 pandemic has created a special situation with respect to competition law. Some aspects are common to emergencies caused by natural phenomena, such as typhoons, hurricanes and earthquakes, when supplies of goods and services are disrupted (or threatened with disruption). During a supply shortage, economic operators (sellers) may decide to raise prices far in excess of typical prices because consumers have limited or no choice regarding whether to buy (e.g. purchasing gasoline/petrol when an evacuation order is in effect). Such practice is often referred to as 'price gouging'. This practice may be addressed nationally or locally under consumer protection laws specifically directed towards the practice,

15 Madlen Davies, Ivan Ruiz, Jill Langlois and Rosa Furneaux, "Held to ransom": Pfizer plays hardball in Covid-19 vaccine negotiations with Latin American countries', *STAT Pharma*, 23 February 2021. Available at: <https://www.statnews.com/2021/02/23/pfizer-plays-hardball-in-covid19-vaccine-negotiations-in-latin-america/>; Christopher Rowland, Emily Rauhala and Miriam Berger, 'Drug companies defend vaccine monopolies in face of global outcry', *Washington Post*, 20 March 2021. Available at: <https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>; Stephanie Baker, Cynthia Koons and Vernon Silver, 'Inside Pfizer's Fast, Fraught, and Lucrative Vaccine Distribution', *Bloomberg Businessweek*, 4 March 2021. Available at: <https://www.bloomberg.com/news/features/2021-03-04/pfizer-pfe-has-a-moral-dilemma-deciding-where-the-vaccines-will-go>.

16 This Supplement does not attempt to identify specific corporate behaviours that may be anti-competitive, but rather points to generally observable features of certain markets that have been dominated by a small number of suppliers, limited product availability, limited substitutable alternatives and corresponding market power.

in part due to the recognition that price gouging usually involves a relatively ‘time-constrained’ event, and there is an obvious consumer harm. In-depth competition investigation (market analysis etc.) and prosecution may not be required. The competition authority or a separate consumer protection agency may be responsible for addressing the matter.

A wide range of competition authorities around the world reported a significant volume of complaints from consumers regarding price gouging during the COVID-19 pandemic.¹⁷ Competition law does not preclude economic operators from raising prices during an emergency to reflect increased costs. It is a question of the reasonableness of any price increase. When the price of a bottle of hand sanitizer goes from US\$5 to US\$50 overnight, this is price gouging. When the price goes from US\$5 to US\$6, this may reflect a reasonable increase due to the higher cost of running a business during an emergency.

In the United States, price gouging is generally addressed by state law, and the relevant statutes may be activated by a state declaration of emergency. Price gouging or excessive pricing in some cases is addressed by formulae—for example, establishing a baseline price based on a prior 30-day average, and an ‘excess’ price being 10 percent, 25 percent or some other percentage above that price. Typically, a presumption of price gouging may be rebutted by concrete evidence of additional costs associated with acquiring and/or distributing goods or services.

Price gouging may be addressed by issuing warning letters, and a responsive undertaking to refund excess charges. Civil and/or criminal prosecutions are also possible.

The EU does not have a special ‘price gouging’ regulation or directive, but competition authorities may rely on Article 102 (Abuse of dominant position), although this approach has certain limitations (e.g. a requirement to demonstrate the dominant market position). However, individual Member States may have consumer protection statutes (or may now be enacting them) under which an NCA or consumer protection agency may proceed against price gouging.

The summaries below provide illustrative examples of how competition authorities responded to price gouging:

¹⁷ See Independent Panel for Pandemic Preparedness and Response, ‘COVID-19: Make it the Last Pandemic’, Geneva, 2021, p. 33. Available at: https://reliefweb.int/sites/reliefweb.int/files/resources/COVID-19-Make-it-the-Last-Pandemic_final.pdf; OECD, ‘Exploitative pricing in the time of COVID-19’, Paris, 26 May 2020, at Box 3. Available at: <https://www.oecd.org/daf/competition/Exploitative-pricing-in-the-time-of-COVID-19.pdf>; and examples from Italy, the United Kingdom and South Africa in this section, *infra*.

The Italian competition authority, Autorità Garante della Concorrenza e del Mercato (AGCM), initiated several investigations with respect to abusive practices associated with the COVID-19 pandemic. They included the following.

BOX P.1: Coronavirus emergency, inquiry launched following reports by the Lazio Region against Roman private health facilities and testing laboratories advertising COVID-19 antibody tests

As part of its institutional activity of monitoring the price trends of the goods and services most affected by the COVID-19 emergency, the Italian competition authority sent a request for information to Roman health facilities and testing laboratories that publicized an offer of serological tests for the identification of antibodies against the SARS-Co-V-2 virus.

The authority's initiative followed a communication received from the Lazio Region in which the Administration stated it had received reports about an offer 'at exorbitant prices', made by private facilities, of such serological tests. The authority requested the health facilities concerned to indicate, in particular: the type of tests performed; the ways in which clients are informed of the characteristics and limits of the above-mentioned tests; the way in which the services are performed (at their premises and/or at home); and the prices at which the tests are offered.

In this regard, in a communication of 9 April 2020, the Region also provided an estimate of the prices that customers would have to pay for this type of test, hoping that private facilities would not apply dissimilar prices: (i) rapid capillary blood test EUR 20 (against costs incurred by the provider of EUR 15); (ii) serological test with venous sampling EUR 45 (against costs incurred by the provider of EUR 30). In case of discrepancies between the prices indicated by the Lazio Region and the prices charged by private facilities for the same tests, justifications to support the difference were requested.

Source: AGCM, 'DC9877 – ICA: coronavirus emergency, inquiry launched following reports by the Lazio Region against Roman private health facilities and testing laboratories advertising Covid-19 antibody tests', press release, Rome, 17 April 2020.

BOX P.2: Coronavirus emergency, investigation launched into price increases for food and detergents, disinfectants and gloves

The Italian competition authority launched a preliminary investigation by sending requests for information to numerous operators in the large-scale retail sector to acquire data on the dynamics of retail prices and wholesale purchase prices of basic foodstuffs, cleansers, disinfectants and disposable gloves, to identify any phenomena exploiting the health emergency based on increasing prices.

The requests for information concern over 3,800 sales outlets for about 85 percent of the total recorded by the data analytics company Nielsen in the provinces that could be concerned by the above-mentioned phenomena.

Specifically, the preliminary analysis carried out by the Authority on Italian National Institute of Statistics (ISTAT) data showed increases in the prices of food products in March 2020, compared to the prices in previous months, differentiated at provincial level.

The largest increases were found in areas that were not affected by 'red zones' or by strengthened measures to contain mobility. The authority could not rule out the possibility that these higher increases were also due to speculative phenomena.

In fact, not all the recorded increases appeared to be immediately attributable to structural reasons, such as the greater weight of purchases in neighbourhood shops, less competition between sales outlets due to restrictions on consumer mobility, supply tensions caused by the sharp increase in demand for certain goods during the lockdown and the limitations on production and transport induced by the measures to contain the epidemic.

See also: AGCM, 'PS11736 – ICA: promotion and sales suspended on the tigershop.it site of masks that differ from the ones advertised and are not available for delivery within the specified time frame', press release, Rome, 10 April 2020. Available at <https://en.agcm.it/en/media/press-releases/2020/4/PS11736>; and AGCM, 'PS11746 – ICA: Authority asks the operators of the major search engines and browsers to take action against unauthorized online sales of COVID-19 drugs', press release, Rome, 21 April 2020. Available at <https://en.agcm.it/en/media/press-releases/2020/4/PS11746>.

Source: AGCM, 'DC9877 – DS2620 – ICA: Coronavirus emergency, investigation launched into price increases for food and detergents, disinfectants and gloves', press release, Rome, 7 May 2020.

The United Kingdom's Competition and Markets Authority (CMA) established a COVID-19 taskforce to investigate the significant volume of consumer complaints regarding excessive pricing.

BOX P.3: CMA COVID-19 taskforce

The press release that launched the taskforce highlighted the following:

“The outbreak of COVID-19 is an unprecedented and rapidly evolving challenge that has prompted many concerns that businesses might exploit the situation to take advantage of people, for example by charging excessive prices or making misleading claims about their products.

The COVID-19 virus, and the measures taken to suppress its impact on public health, are likely to have a substantial impact on competition, with the risk of an increase in consumer detriment. That is why the Competition and Markets Authority (CMA) is establishing a dedicated COVID-19 taskforce (the ‘taskforce’).

Key areas of focus.

The taskforce will:

- Scrutinise market developments to identify harmful sales and pricing practices as they emerge.
- Warn firms suspected of exploiting these exceptional circumstances — and people’s vulnerability — through unjustifiable prices or misleading claims.
- Take enforcement action if there is evidence that firms may have breached competition or consumer protection law and fail to respond to warnings.
- Equip the CMA to advise government on emergency legislation if there are negative impacts for people which cannot be addressed through existing powers.
- Advise government on how to ensure competition law does not stand in the way of legitimate measures that protect public health and support the supply of essential goods and services. It will also advise on further policy and legislative measures to ensure markets function as well as possible in the coming months.

The COVID-19 taskforce is monitoring market developments to enable us to intervene as quickly as possible, where required. The CMA has a range of options at our disposal, including warnings, enforcement action and seeking emergency powers.

We will do whatever is required to stop a small minority of businesses that may seek to exploit the present situation.”

Source: UK Competition & Markets Authority, ‘CMA COVID-19 taskforce’, London, 20 March 2020.
Available at <https://www.gov.uk/government/publications/covid-19-cma-taskforce/cma-covid-19-taskforce>.

BOX P.4: CMA publishes update on COVID-19 taskforce

“As part of the taskforce’s work, it asked the public for information about businesses behaving unfairly – for example, retailers charging unjustifiably high prices or making misleading claims about their products or services.

Some of the highlights in the update include:

- As of 19 April 2020, the CMA had received just under 21,000 COVID related complaints, of which 14,000 have come via its dedicated online form.
- The CMA has written to 187 firms accounting for over 2,500 complaints about large price rises for personal hygiene products, such as hand sanitiser and food products.
- Complaints relating to cancellations and refunds now account for four out of every five complaints being received.

The number of businesses complained about is smaller than the number of complaints. The 14,000 complaints received via the CMA’s online form refer to just 6,000 individual businesses – around one in every thousand of the private-sector businesses operating in the UK.

The taskforce is continuing to collect evidence, including about unjustifiable price rises further up the supply chain.”

Source: UK Competition & Markets Authority, ‘CMA published updates on COVID-19 Taskforce’, London, 24 April 2020. Available at <https://www.gov.uk/government/news/cma-publishes-update-on-covid-19-taskforce>.

The South African Competition Authority and the National Consumer Commission launched investigations against retailers regarding excessive price hikes on hand sanitizer and face masks, among other products. Substantial penalties up to 10 percent of a firm’s annual turnover may be imposed if the accused party is found guilty of price gouging.¹⁸

¹⁸ SAnews.gov.za, “Thirty companies investigated for excessive price hikes”, 26 March 2020. Available at <https://www.sanews.gov.za/south-africa/thirty-companies-investigated-excessive-price-hikes>.

BOX P.5: South African authorities investigate retailers during COVID-19

“The Competition Commission (Commission) welcomes the decision of the Competition Tribunal for finding Dis-Chem Pharmacies Limited (Dis-Chem), a national wholesale distributor and retailer of pharmaceutical products, guilty of excessive pricing of surgical face masks during the state of national disaster as declared by President Cyril Ramaphosa.

The Tribunal has ordered Dis-Chem to pay an administrative penalty of ZAR1.2 million. This follows an investigation by the Commission which found that that Dis-Chem has charged excessive prices on essential hygienic goods to the detriment of customers and consumers, in contravention of Section 8(1)(a) of the Competition Act read together with Regulation 4 of the Consumer Protection Regulations.

These essential items are surgical face masks blue 50PC, surgical face masks 5PC and surgical face masks folio dress blue. From at least 28 March 2020, the Commission received several complaints from the public against several retail stores owned by Dis-Chem for engaging in excessive pricing of face masks, specifically dust and surgical masks.

The Commission’s investigation established that prior to the declaration of a national state of disaster, Dis-Chem was selling the three types of masks, namely, surgical face masks blue 50PC, surgical face masks 5PC and surgical face masks folio dress blue at far lower prices.

For surgical face mask blue 50PC, the average price was inflated from ZAR43.47 (excluding value-added tax [VAT]) per unit (50 masks) in February 2020 to ZAR156.95 (excl. VAT) per unit (50 masks) in March 2020, a price increase of 261%.

‘This judgment reaffirms our work as the Commission on price gouging. It sends a strong message that the Commission will spare no efforts to protect the South African consumers against abusive pricing behaviour by firms whether small or large,’ says Competition Commissioner Tembinkosi Bonakele.”

Source: Competition Commission South Africa (2020). ‘Competition Tribunal Finds Dis-chem Guilty of Inflating Mask Prices during COVID-19 Disaster’, media statement, Pretoria, 2020.

The Brazilian competition authority (CADE), by way of counterpoint, has opposed legislation to limit or penalize price gouging, including during the COVID-19 pandemic, because, in its view, price gouging has positive resource allocation effects, and anti-price gouging policies reduce supplier incentives.¹⁹

¹⁹ See CADE, ‘Technical Note No. 15/2020/DEE/CADE’, Brasilia, 2020; and ‘Technical Note No. 16/2020/DEE/CADE’, Brasilia, 2020.

2. Waiver for cooperative undertakings during emergency situations

The research, development and distribution of health technologies typically involves multiple stages and economic actors. When economic actors compete to supply goods and services, the competition rules regarding cooperation can be complex.

The COVID-19 pandemic has placed significant pressure on pharmaceutical supply markets, as priority needs for certain health technologies have increased, while the need for other health technologies has remained stable or even decreased. There has been a similar dramatic increase in terms of demand for complex medical equipment such as ventilators and oxygen-related technology, and for less-complex equipment such as face masks and shields. Ordinarily, competitors in the market to supply health technologies are prohibited from sharing information regarding customer demand and their own supply capacity. This is because such information would facilitate coordination (and limitation) of output and supply that would place upward pressure on prices.²⁰

Because of the rapid shifts in demand for specific products created by the COVID-19 pandemic, governments encouraged producers to rationalize production by increasing the output of health technologies in short supply and, where appropriate, to consolidate and limit the production of health technologies for which demand may have fallen or remained stable.²¹ The same was encouraged for active pharmaceutical ingredients (APIs), where sharing information about supplies and capacity may help rationalize and increase production of those health technologies with increased demand. The competition authorities may decide to waive rules that would ordinarily prohibit sharing among competitors of information about supply and demand, to improve public health outcomes. This generally would not entail allowing producers to share information about pricing.

The EU adopted a ‘Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak’ that seeks to address the special circumstances of enterprises during the pandemic.²²

20 See, for example, European Commission Communication, Box P.6 *infra*, explaining that “Measures to adapt production, stock management and, potentially, distribution in the industry may require exchanges of commercially sensitive information and a certain coordination of which site produces which medicines, so that not all undertakings focus on one or a few medicines, while others remain in under-production. Such exchanges and coordination between undertakings are in normal circumstances problematic under EU competition rules” (at para. 15).

21 See generally OECD, ‘Co-operation between competitors in the time of COVID-19’, Paris, 26 May 2020. Available at: <https://www.oecd.org/competition/Co-operation-between-competitors-in-the-time-of-COVID-19.pdf>, including reference to announcement by Mexico’s Federal Economic Competition Commission (COFECE) of 27 March 2020 (at Box 2).

22 European Commission, ‘Communication from the Commission, C(2020) 3200 final’, Brussels, 8 April 2020. Available at: https://ec.europa.eu/info/sites/default/files/framework_communication_antitrust_issues_related_to_cooperation_between_competitors_in_covid-19.pdf.

BOX P.6: European Commission Communication on the supply and distribution of products and services during the COVID-19 outbreak

The communication highlights the following:

- “The present Communication covers possible forms of cooperation between undertakings in order to ensure the supply and adequate distribution of essential scarce products and services during the COVID-19 outbreak and thus address the shortages of such essential products and services resulting first and foremost from the rapid and exponential growth of demand. This includes notably medicines and medical equipment that are used to test and treat COVID-19 patients or are necessary to mitigate and possibly overcome the outbreak. Such cooperation could take place among undertakings active within the relevant sector to overcome this shortage, as well as between undertakings active in other sectors (e.g. certain undertakings converting part of their production lines to start producing scarce products). Depending on the evolution of the crisis, the Commission might amend or supplement this Communication in order to cover other forms of cooperation ...
- Different measures may contribute to bridging the gap between demand and supply. It might require a very significant, rapid increase of production for products that are needed but are in short supply. This may lead to a reduction in the production of other products. It might also require the reallocation of stocks, which would require that undertakings agree to exchange/communicate information on sales and stocks. To increase production, undertakings might need to switch their production lines for some non-essential/non-shortage medicines (or other products) to medicines (or other products) necessary to address the outbreak. In addition, output could be increased further and more efficiently if, at a certain site, only one medicine was produced (as opposed to switching production between different products, which requires time-consuming cleaning of machinery, etc.), balancing economies of scale with the need to avoid excessive reliance on any particular production site ...
- Measures to adapt production, stock management and, potentially, distribution in the industry may require exchanges of commercially sensitive information and a certain coordination of which site produces which medicines, so that not all undertakings focus on one or a few medicines, while others remain in under-production. Such exchanges and coordination between undertakings are in normal circumstances problematic under EU competition rules. Nevertheless, in the current exceptional circumstances, such measures would not be problematic under EU competition law or—in view of the emergency situation and temporary nature—they would not give rise to an enforcement priority for the Commission, to the extent that such measures would be: (i) designed and objectively necessary to actually increase output in the most efficient way to address or avoid a shortage of supply of essential products or services, such as those that are used to treat COVID-19 patients; (ii) temporary in nature (i.e. to be applied only as long there is a risk of shortage or in any event during the COVID-19 outbreak); and (iii) not exceeding what is strictly necessary to achieve the objective of addressing or avoiding the shortage of supply. Undertakings should document all exchanges and agreements between them and make them available to the Commission on request. The fact that a cooperation is encouraged and/or coordinated by a public authority (or carried out within a framework set up by the latter) is also a relevant factor to be taken into account to conclude that

continued...

BOX P.6 ...continued

such cooperation would not be problematic under EU competition law or would not be an enforcement priority for the Commission.”

See also, for example, European Commission, ‘Comfort letter: coordination in the pharmaceutical industry to increase production and to improve supply of urgently needed critical hospital medicines to treat COVID-19 patients, issued to Medicines for Europe, Brussels, 08/04/2020, COMP/OG – D(2020/044003)’, Brussels, 8 April 2020.

The Italian Competition Authority approved a joint purchase procedure for surgical masks and the subsequent distribution of the same among distributors at the unit purchase price negotiated with suppliers. See AGCM, ‘COV1-DC9901 – Verified the competitive compatibility of the cooperation agreements between companies for the distribution of masks’, press release, Rome, 1 June 2020 (original in Italian). Available at: <https://www.agcm.it/media/comunicati-stampa/2020/6/COV1-DC9901>.

Source: European Commission, ‘Communication from the Commission, C(2020) 3200 final’, Brussels, 8 April 2020.

3. Research and development and access to health technologies, including intellectual property pooling arrangements

The COVID-19 pandemic encouraged sharing of resources among innovators across the spectrum of health technologies. Some of the proposals and developments involve research and development (R&D) joint ventures among enterprises,²³ groups and individuals, in both the private and public sectors.²⁴ Competition law has experience with assessing potential anti-competitive agreements and conduct among those involved in R&D, including through the promulgation of guidelines regarding licensing of technology (including intellectual property) and regarding technology pooling arrangements.²⁵ Competition law authorities

23 See, for example, Pfizer, ‘Press Release: Pfizer and Biontech to Co-Develop Potential Covid-19 Vaccine’, 17 March 2020. Available at: <https://investors.pfizer.com/investor-news/press-release-details/2020/Pfizer-and-BioNTech-to-Co-Develop-Potential-COVID-19-Vaccine/default.aspx>.

24 See, for example, Oxford University, ‘Press Release: Oxford University announces landmark partnership with AstraZeneca for the development and potential large-scale distribution of COVID-19 vaccine candidate’, Oxford, 30 April 2020. Available at: <https://www.ox.ac.uk/news/2020-04-30-oxford-university-announces-landmark-partnership-astrazeneca-development-and>; and US Department of Health and Human Services, ‘Press Release: HHS Launches First Venture Capital Partnership to Develop Transformative Technologies to Combat Future Pandemics, Other Health Emergencies’, Washington, DC, 1 June 2021. Available at: <https://www.hhs.gov/about/news/2021/06/01/hhs-launches-first-venture-capital-partnership-develop-transformative-technologies-combat-future-pandemic.html>.

25 See, for example, US Department of Justice and Federal Trade Commission, ‘Antitrust Guidelines for the Licensing of Intellectual Property’, Washington, DC, 2017 (DOJ–FTC Licensing Guideline). Available at: <https://www.justice.gov/atr/IPguidelines/download>; and European Commission, ‘Communication from the Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2014/C 89/03)’, Brussels, 2014.

tend to view technology licensing arrangements as presumptively pro-competitive because they are intended to promote innovation and the introduction of new technologies into the stream of commerce, while recognizing that such licensing arrangements may also be anti-competitive or include anti-competitive elements. The US and EU competition authorities each establish market share thresholds such that licensing arrangements between firms that do not hold more than a certain share of the market are presumed not to raise competition concerns. Typically, if firms in a relevant technology market do and will not control more than 20 percent of the market, competition concerns are not raised.²⁶ In innovation markets if there are four or more firms in addition to the firms involved in the licensing arrangement, anti-competitive concerns are not raised.²⁷

Technology pooling arrangements are a form of licensing arrangement in which two or more entities contribute their intellectual property and/or technology into a common entity (i.e. the pool) with a view to sharing (i.e. licensing out and receiving additional contributions to) the pooled technology. Pooling arrangements can be, but are not necessarily, used as a vehicle for promoting joint R&D efforts in which enterprises contribute the results of R&D back into the pool with an arrangement for use by the other members. But the structure of pooling arrangements can vary quite widely. Whether a pooling arrangement will raise competition law concerns depends on the structure of the relevant market and whether the combination is likely to exacerbate market concentration. Factors such as the openness of the pool to entry by additional parties, the terms of any out-licensing arrangements, and the mechanism by which the pool is governed can all be relevant to assessment.²⁸

From a competition law standpoint, it is not clear that the COVID-19 pandemic created a special situation that should affect the assessment undertaken by competition authorities of a technology pooling arrangement, except that the authorities might be more tolerant of potential market concentration if the objective is to rapidly make available a needed treatment, vaccine etc., and depending on the level of access that the public will have to the resulting health technologies.

4. Mergers and acquisitions

The 2014 UNDP Guidebook discusses competition aspects of mergers and acquisitions, and this Supplement includes a number of illustrative actions undertaken by competition authorities with respect to assessment and remedies associated with merger and acquisition

26 See, for example, EU Commission Guidelines, *id.*, at para 85; US DOJ–FTC Licensing Guideline, *id.*, at sec. 4.3.

27 See, for example, EU Commission Guidelines, *id.*, at para 157; US DOJ–FTC, *id.*, at sec. 4.3.

28 See, for example, EU Commission Guidelines, *id.*, at sec. 4.4 (Technology Pools); US DOJ–FTC, *id.*, at sec. 5.5.

activity. There has been concern among legislators in various jurisdictions about the vulnerability of firms in weakened financial positions, because of the pandemic, to takeovers by better-capitalized enterprises. This may lead to a general consolidation of firms across industry sectors, with the resulting global economic environment more susceptible to anti-competitive conduct than before the pandemic.²⁹ There have been suggestions that merger and acquisition activity should be closely scrutinized during this difficult economic period.³⁰ These observations are not specific to the health sector.

In jurisdictions where hospitals and other health care facilities are private, the intense demands placed by the inflow of COVID-19 patients, combined with the necessity to limit visits by non-emergency patients, has had substantially negative financial effects. For example, in the United States, hospitals and other health care facilities have suffered significant financial harm during the pandemic.³¹ It may be that as the pandemic wanes, there will be a perceived need for consolidation among hospitals and other health care facilities, and ultimately this might result in unwelcome market concentration.³² Unless governments step in to shore up the financing of private hospitals and other health care facilities, the competition authorities may not be able to prevent this consolidation because of a lack of viable alternatives. In jurisdictions where hospitals and other health care facilities are publicly financed and operated, it is more difficult to see a new basis for consolidation.

It is not clear that the COVID-19 pandemic created some type of ‘special situation’ with respect to the pharmaceutical industry in terms of mergers and acquisitions. Both the originator and generic sectors of the industry have been undergoing consolidation for a number of years, and COVID-19 may not have substantial impact going forward. At this stage, the consequences can be difficult to foresee.

29 See, for example, OECD, ‘Merger control in the time of COVID-19’, Paris, 25 May 2020 (“One of the many consequences of the COVID-19 crisis is the risk that many firms will find themselves in financial distress and forced to exit the market or merge”, at p. 1).

30 See, for example, Bill Baer, ‘Why we need antitrust enforcement during the COVID-19 pandemic’, Brookings Techtank blog, 22 April 2020. Available at: <https://www.brookings.edu/blog/techtank/2020/04/22/why-we-need-antitrust-enforcement-during-the-covid-19-pandemic/#:~:text=we%20need%20antitrust%20enforcement%20during%20the%20COVID-19%20pandemic.>

31 See, for example, Michael L. Barnett, Ateev Mehrotra and Bruce E. Landon, ‘Covid-19 and the Upcoming Financial Crisis in Health Care’, NEJM Catalyst Innovations in Care Delivery, Vol. 1, No. 2 (2020), doi: 10.1056/CAT.20.0153. Available at: <https://catalyst.nejm.org/doi/pdf/10.1056/CAT.20.0153>; and American Hospital Association, ‘Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID-19’, Chicago, IL, 5 May 2020. Available at: <https://www.aha.org/guidesreports/2020-05-05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due>.

32 See, for example, Laura Tollen and Elizabeth Keating, ‘COVID-19, Market Consolidation, and Price Growth’, Health Affairs blog, 3 August 2020. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20200728.592180/full/>.

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

Chapter 1 of the 2014 UNDP Guidebook discusses the balance between the granting of IPR protection and the maintenance of competitive markets operating in the interests of consumers. IPR are generally intended to promote innovation—in the pharmaceutical arena through, for example, the development of new therapeutic treatments—by offering a reward to the innovator in the form of exclusive rights for a limited duration. By their nature, IPR are exclusionary and tend to limit access because they provide the basis for maintaining supra-competitive prices. The policymaker is called on to balance the level of protection needed to induce innovation (and to bring products to market) while assuring that the public enjoys access to the successfully developed products. The main way that policymakers achieve this balance is by subsidizing in one way or another the purchase by consumers (including government procurement agencies, pharmaceutical benefit plans and individuals) of health technologies that are high-priced based on IPR effects. Achieving this balance is difficult in LMICs because the funds that may be needed to subsidize purchases may not be there. Thus, alternative mechanisms to establish access are needed. This may be through mechanisms that allow for differential pricing among geographic and/or internal market segments (including, for example, through mechanisms such as the Medicines Patent Pool which offers low-cost licensing for LMIC markets on a country-specific basis), through measures that address IPR obstacles to competition (e.g. patent oppositions and compulsory licensing of patents), or through international funding organizations (e.g. the Global Fund to Fight AIDS, Tuberculosis and Malaria) or national foreign assistance programmes (e.g. the United States President's Emergency Plan For AIDS Relief [PEPFAR]).³³

Patents also function as a means of identifying innovative technologies for purposes other than creating exclusive pharmaceutical marketing positions. For example, they facilitate licensing among entities at different stages in the research continuum. Foundations and non-profit entities may patent and otherwise protect health technologies that are intended to be sold at affordable prices in low-income markets. 'Defensive patenting' is used to prevent third parties from claiming rights in innovations that are not their own. Patents can also serve as assets underlying secured lending and other collateralized transactions.

33 PEPFAR, for example, is authorized to procure or support the procurement of generic versions of HIV medicines for use outside the United States even though the medicines remain patented or protected by regulatory market exclusivity in the United States. See Harinder Singh Chahal and others, 'Impact of the US Food and Drug Administration registration of antiretroviral drugs on global access to HIV treatment', *BMJ Global Health* 3, e000651 (2018), doi:10.1136/bmjgh-2017-000651.

Debate concerning the proper balance between the protection of IPRs and access to medicines has gone on for a long time, and the push and pull in favour of one preference or another appears likely to continue for the indefinite future. National governments are torn between interests in pursuing industrial policies (e.g. championing home-based pharmaceutical originators) and ensuring equitable access to medicines for individuals at home and abroad.

Competition law is not intended to solve the policymakers' dilemma of balancing the interest in promoting innovation, on one side, and establishing access, on the other. What competition law is intended to do is make sure that the ground rules established for participating in the pharmaceutical market are not abused. In other words, it is not the role of competition law to decide whether the term of a patent should be 10, 20 or 30 years or, more fundamentally, if patents should be used as an incentive for innovation. That is for the legislator to decide. The role of competition law is to ensure that the owner of the patent does not secure it through abusive conduct *vis-à-vis* the patent office, and that the owner is not exercising its rights of exclusion in ways that take unfair advantage of competitors or consumers. Competition law acts as a balancing mechanism seeking to ensure that the scope and function of IPR are not exceeded, and it includes strong remedial measures for use in appropriate cases, such as compulsory patent licensing. Exactly what constitutes abusive conduct or conduct taking unfair advantage is not answered the same way across national (or regional) jurisdictions, nor is it prescribed in a specific way by international law. On the other hand, international law does mandate, mainly through rules established at the WTO (including the TRIPS Agreement), but increasingly also through rules incorporated in more geographically limited TIAs, that national jurisdictions allow for the granting of pharmaceutical patents and comply with certain minimum standards regarding those grants, subject to various balancing limitations and exceptions such as compulsory licensing. In addition, the TRIPS Agreement requires that WTO members provide certain assurances regarding potential unfair commercial use of certain regulatory data submitted to authorities, and such requirements also appear in various forms in TIAs.

Since the publication of the 2014 Guidebook, the basic policy issues underlying the tensions between IPR and access to health technologies have not changed. However, there have been some notable trends in terms of policy concerns and ways to address them. One such issue involves increasing demands for 'transparency' regarding the way the pharmaceutical market works. This interest in transparency is wide-ranging, including demands for better information regarding the costs of R&D for new health technologies and delivery devices, and the way that prices are established taking account of those costs.³⁴

34 United Nations Secretary-General's High-Level Panel on Access to Medicines, 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting innovation and access to health technologies', New York, 2016. Available at: <http://www.unsgaccessmeds.org/>.

In addition, there is interest in ‘transparency’ with regards to the role that intermediaries play in the process of taking health technologies from the manufacturer (originator and generic) and providing them to the patient, whether that be through wholesalers, pharmaceutical benefit managers or others. The growing interest in transparency, or greater access to information, is entirely consistent with the policies underlying competition law. Traditionally, one of the principal tasks of the competition authority is conducting investigations that bring to light the way that prices are established in the marketplace. The movement towards greater transparency should help in the work of the competition authority. Likewise, competition authorities can support efforts to increase transparency by governments and other interested stakeholders.

“ A major challenge is the paucity of public data on R&D costs. Increasing cost transparency is likely to require government action. This has been proposed in many public forums and expert reports.” – Suerie Moon and colleagues³⁵

BOX 1.1: World Health Organization Resolution on improving the transparency of markets for medicines, vaccines, and other health products

“The Seventy-second World Health Assembly ... Agreeing that policies that influence the pricing of health products and that reduce barriers to access can be better formulated and evaluated when there are reliable, comparable, transparent and sufficiently detailed data across the value chain,

- URGES Member States in accordance with their national and regional legal frameworks and contexts:
 - 1 To take appropriate measures to publicly share information on the net prices of health products;
 - 2 To take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality;
 - 3 To work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;
 - 4 To facilitate improved public reporting of patent status information and the marketing approval status of health products;

continued...

35 Suerie Moon and others, ‘Defining the concept of fair pricing for medicines’, *BMJ* 368:l4726 (2020). doi: 10.1136/bmj.l4726.

BOX 1.1 ...continued

- 5 To improve national capacities, including through international cooperation and open and collaborative research and development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including health products for the diseases that primarily affect them, as well as for product selection, cost-effective procurement, quality assurance, and supply chain management.”

Source: World Health Organization, ‘Seventy-Second World Health Assembly’, WHA72.8, Agenda item 11.7, Geneva, 28 May 2019.

The originator pharmaceutical industry typically justifies high prices by reference to the costs and risks associated with innovation, and the need to recoup investment and fund future innovation.³⁶ A November 2017 report from the US Government Accountability Office (Box 1.2 below) raised questions regarding the extent to which spending on innovation justifies high prices.

BOX 1.2: US Government Accountability Office report on innovation and prices

What the US Government Accountability Office (GAO) found:

The GAO’s analysis of revenue, profit margin, and merger and acquisition deals within the worldwide drug industry from 2006 through 2015 identified key trends:

- Estimated pharmaceutical and biotechnology sales revenue increased from US\$534 billion to US\$775 billion in 2015 dollars.
- About 67 percent of all drug companies saw an increase in their annual average profit margins from 2006 to 2015. Among the largest 25 companies, annual average profit margins fluctuated between 15 and 20 percent. For comparison, the annual average profit margin across non-drug companies among the largest 500 globally fluctuated between 4 and 9 percent.
- The number of reported mergers and acquisitions generally held steady during this period, but the median disclosed deal value increased.

The largest 10 companies had about 38 percent of the drug industry’s sales revenue in 2014. However, concentration was higher for narrower markets, such as for certain drugs in the

continued...

36 See also discussion of divergent estimates of cost of R&D for medical technologies, including pharmaceuticals, in World Health Organization, World Intellectual Property Organization and World Trade Organization, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, 2nd ed., Geneva, 2020, pp. 142–43.

BOX 1.2 ...continued

same therapeutic class. In addition, experts noted that market pressures such as rising R&D costs, fewer medicines in development, and competition from generic medicines, have driven structural changes in the industry such as increased use of acquisition by large drug companies to obtain access to new research.

From 2008 through 2014, worldwide company-reported R&D spending, most of which went to development (rather than research), increased slightly from US\$82 billion to US\$89 billion in 2015 dollars. During the same period, US federal spending, which funded a greater amount of basic research relative to industry, remained stable at around US\$28 billion. In addition to grants, several federal tax provisions provided incentives for industry R&D spending, including the orphan drug credit, available for companies developing medicines intended to treat rare diseases, which increased more than five-fold from 2005 through 2014.

Pertaining to medicine approvals, the total number of new medicines approved for marketing in the United States fluctuated between 2005 and 2016, ranging from 179 to 263 approvals annually. Novel drugs—innovative products that serve previously unmet medical need or help advance patient care—accounted for about 13 percent of all approvals each year. Biologics—health technologies derived from living rather than chemical sources—and orphan drugs accounted for growing shares of approvals, reflecting market and policy incentives to invest in these areas, according to experts interviewed by the GAO.

Research reviewed by the GAO indicates that fewer competitors in the pharmaceutical industry are associated with higher prices, particularly for generics. Research also suggests that pharmaceutical company mergers can have varied impacts on innovation as measured by R&D spending, patent approvals and regulatory approvals. Certain retrospective studies of mergers have found a negative impact on innovation.

Source: United States Government Accountability Office, 'Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals', Washington, DC, November 2017.

A report prepared by the Drugs for Neglected Diseases initiative (DNDi) based on its experience in R&D suggests that there may be substantial opportunity for reducing the level of expenditures typically reported by the originator industry.

Another recent trend shifting the balance between IPR and access to health technologies involves an expansion of trade secret protection. Trade secret protection has been invoked by pharmaceutical companies to deny public access to pricing information,³⁷ and this has hindered better understanding of pharmaceutical markets. A more recent trend involves

37 See, for example, Maeve Allsup, 'Trade Secret Protection Limited for California Drug Price Data', *Bloomberg Health Law & Business*, 20 April 2020 (discussing a California case recognizing circumstances in which purported pricing trade secrecy protection lost: *Amgen Inc. v. Health Care Servs.*, 47 Cal.App.5th 716, (App. 2d Dist. 2020), Court Opinion).

BOX 1.3: Drugs for Neglected Diseases initiative report on research and development of new medicines

“[I]n order to estimate how much the development and registration by DNDi of a new drug may cost, the DNDi out-of-pocket costs ... have been adjusted to account for the cost of failure, by applying these average attrition rates per phase of development, for PDPs [product development partnerships] in the field of anti-infectives. This method allows DNDi to estimate that it can develop and register new treatments based on existing drugs at a cost of EUR 4 to 32 million, and new chemical entities for EUR 60 to 190 million, attrition included. These figures do not include post-registration additional studies and access costs, nor in-kind contributions from pharmaceutical partners.”

Source: DNDi, ‘15 Years of Needs-Driven Innovation for Access: Key lessons, challenges, and opportunities for the future’, Geneva, October 2019, p. 18.

Available at: https://dndi.org/wp-content/uploads/2019/10/DNDi_ModelPaper_2019.pdf.

the use of trade secret protection to inhibit access to processes used in the production of biologic medicines (and vaccines), including by denying access to samples of biological materials that may be important to creating generic biological health technologies.³⁸ Enhanced protection for trade secrets is being embedded in new TIAs, and this may raise additional obstacles for competition authorities.

Trade secret protection may be the basis for anti-competitive abuse. Chapter 3 refers to the *FTC v. Mallinkrodt* case which involved the purchase by a large pharmaceutical company of a potential competitor with a generic medicine the competitive production of which was limited by trade secret-protected technology. The remedies imposed in that case involved mandating the grant of a third-party licence to exploit that technology.

38 Manufacturing process technologies are important in the vaccine sector, and many of these processes are patented. See, for example, VaxPaL, ‘COVID-19 vaccines patent landscape’. Available at: <https://medicinespatentpool.org/what-we-do/vaxpal/>; M. Gaviria and B. Kilic, ‘A network analysis of COVID-19 mRNA vaccine patents’, *Nature Biotechnology* 39, 546–548 (2021). Available at: <https://doi.org/10.1038/s41587-021-00912-9>; and World Intellectual Property Organization, ‘Patent Landscape Report on Vaccines for Selected Infectious Diseases’, Geneva, 2012. Available at: <https://www.wipo.int/publications/en/details.jsp?id=264>.

See also US Food and Drug Administration and Federal Trade Commission, ‘Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace’, Washington, DC, 3 February, 2020, stating: “FDA and FTC will work together to deter behavior that impedes access to samples needed for the development of biologics, including biosimilars.

- FDA and FTC will collaborate to identify and deter tactics used to prevent or impede access to samples of the reference product that the prospective biosimilar applicant needs for testing to be licensed as a biosimilar or interchangeable biosimilar.
- To facilitate such collaboration, FDA and FTC will evaluate whether additional information sharing arrangements are warranted.” Available at: https://www.ftc.gov/system/files/documents/public_statements/1565273/v190003fdaftcbiologics_statement.pdf.

Much of the protection against competition in the pharmaceutical sector is based on exclusive marketing rights granted on the basis of commercial marketing approvals from regulatory authorities. Again, as with patents, it is not the role of competition law to establish the appropriate form or period of regulatory market exclusivity (or data exclusivity). That is the role of the legislator. On the other hand, anti-competitive abuse takes place in connection with drug regulatory approval processes, including by the filing of frivolous objections that slow down the work of regulators. In the United States, for example, originator companies have used ‘citizen petitions’ that were designed to allow the public to bring information to the attention of the US Food and Drug Administration (FDA) as a way to delay decisions by the FDA; in several cases, the companies have been found to have abused that mechanism.³⁹ See a description of these cases in Chapter 3.

The world of biologic health technologies brings new potential avenues of anti-competitive abuse. The regulatory pathway for the introduction of biologics and follow-on biogenerics is complex. When companies actively seek to improperly impede the pathway, the introduction of biogenerics may be pushed back for years.

The COVID-19 pandemic reminds us that the vaccine sector operates in a substantially different way than the pharmaceutical treatment sector, and that the shortage of vaccine manufacturing facilities and related supplies (including, for example, glass vials) may provide fertile ground for abusive business practices during the ramp-up to globally adequate production.⁴⁰

During the period covered by this Supplement, several competition authorities have conducted pharmaceutical market studies. Two summaries follow:

39 See, for example, Box 3.11, *infra*.

40 See, for example, AGCM, ‘IC50 – Investigation into human vaccines: “A more transparent market on drug costs and prices”’, press release, Rome, 25 May 2016. Available at: <https://en.agcm.it/en/media/press-releases/2016/5/alias-2331>.

BOX 1.4: Chilean competition authority pharmaceutical market study

On 30 August 2016, the Law No. 20.945 on the Improvement of the Competition Law Regime was published and thus came into force. The 2016 Legal Reform introduced several changes to the Chilean competition law. For instance, it empowered the Fiscalía Nacional Económica (FNE), the Chilean NCA, to ask private undertakings for information to allow it to conduct market studies, and introduced the possibility of imposing administrative sanctions for infringements to the duty of collaboration with the FNE.⁴¹

On 20 November 2019, the FNE published the preliminary report of its pharmaceutical market study.⁴² The study included all the operations of the pharmaceutical industry in Chile from the production of medicines to their sale by different market players to the consumers.

Information collected:

- Detailed information of 27 laboratories (those that account for 70 percent of sales by value in pharmacies).
- Detailed information of pharmacy chains.
- Survey conducted by IPSOS with 1,600 consumers in 300 pharmacies.
- Survey conducted by IPSOS with 320 physicians.
- Survey conducted by FNE with 380 visiting physicians.
- Data and information held by the Ministry of Health, Public Health Institute,⁴³ Chile Compra⁴⁴ and CENABAST.
- Expert review by Claudio Agostini (Universidad Adolfo Ibáñez, Chile) and Claudio Lucarelli (Wharton School of Business, USA).
- Detailed information on the way private hospitals buy medicines.

Main findings:

- The therapeutic equivalence policy has not been effective. Thus, 80 percent of the medicines registered in Chile still do not have therapeutically equivalent alternatives.
- The market works as a brand-driven one, in the same way as any other mass consumer markets (cars, beers, cookies etc.). Simply put, laboratories promote brands to doctors, doctors prescribe brands to their patients, patients buy brands at pharmacies, and pharmacies are forced to buy these brands from laboratories.⁴⁵
- One effect of this is that large pharmacy chains pay an average of 70 percent more than the public sector for the same products, and 60 percent more than private hospitals.
- A public policy that really aims at price competition necessarily implies structural reform of this market.

continued...

41 The following market studies have been concluded: annuities, notaries, school textbooks and the pharmaceutical market. Available at: <https://www.fne.gob.cl/estudios-de-mercado/estudios/estudios-de-mercados-actuales/>.

42 Fiscalía Nacional Económica, 'Final Report of the Pharmaceutical Market Study', Santiago, 2019, p. 12. Available at: <https://www.fne.gob.cl/wp-content/uploads/2020/01/Informe-Final.pdf>.

43 An entity created in 1980 to regulate and monitor the quality of the pharmaceutical and health care industries in Chile.

44 The Chilean central purchasing body that manages the electronic procurement system and runs procurement procedures.

45 Laboratories are investing over US\$200 million a year to promote their brands among doctors, who prescribe these products to their patients, rather than other technically equivalent and cheaper alternatives.

The FNE's conclusions are reflected in a package of 15 measures that have the purpose of increasing competition in the market:⁴⁶

- 1 Modify the procedures before the Public Health Institute to obtain market authorization and the bioequivalence certification. This measure implies that regulation should be clear about the different stages and deadlines involved in both processes.
- 2 Establish a faster procedure to grant market authorization to medicines that are already authorized in other countries that meet an adequate safety standard.
- 3 Establish that all applicants or current patent holders of an invention that contains or consists of an active ingredient included in a pharmaceutical product must inform to the National Institute of Industrial Property the international nonproprietary name (INN). In addition, it is necessary that applicants or current holders of a sanitary registry of a pharmaceutical product individualize all the patents (primary or secondary) associated with each market authorization before the Public Health Institute. This information should be part of a public database.
- 4 Grant a reward to the first generic to enter the market. This should be a period between 180 and 365 days of exclusivity.
- 5 Implement measures to increase the number of health technologies that are therapeutically equivalent.
- 6 Establish a policy of continuous production and dissemination of information among medical staff, pharmacies and other relevant market players. The Institute of Public Health should maintain on its website a database of marketing authorizations, duly updated and easy to use. Also, it should periodically inform the different actors involved in this market about new medicines and the availability of alternative generics of existing medicines.
- 7 The Institute of Public Health should apply data protection regulations effectively. Chilean intellectual property law establishes data protection about the clinical studies used to prove the safety and efficacy of original medicines. However, this protection is not admissible when the medicine is not marketed in Chile within 12 months from the date of the market registration or when the application for the marketing authorization was submitted 12 months after obtaining the first market authorization abroad. The Institute of Public Health is not applying these two exemptions correctly, and there are medicines that should have lost data protection, or the protection should have not been granted at all.
- 8 Strengthen the National Drugs Agency. This will allow more expedited processes for the registration of medicines and the certification of bioequivalence. In addition, this measure is also important to improve duties of control and pharmacovigilance.
- 9 Implementation of a transparent system that shows the financial relationship of the pharmaceutical industry with different subjects of interest.

continued...

46 Fiscalía Nacional Económica, 'Final Report of the Pharmaceutical Market Study', Santiago, 2019, p. 230. <https://www.fne.gob.cl/wp-content/uploads/2020/01/Informe-Final.pdf>.

BOX 1.4 ...continued

- 10 Create a single national platform for practitioners which requires them to prescribe by the International Common Denomination (DCI).
- 11 Regulate the dispensing and payment method of pharmacies.
- 12 Create insurance with coverage for health technologies after all the measures above are working. The implementation of a universal insurance with coverage for health technologies will allow insurers to negotiate directly with laboratories or pharmacies to obtain better prices.
- 13 Allow the sale of over-the-counter (OTC) health technologies in establishments other than pharmacies.
- 14 Regulate and allow the sale of health technologies online.⁴⁷
- 15 Regulate the functioning of pharmacy committees that decide which health technologies the State should buy.

Source: Fiscalía Nacional Económica, 'Final Report of the Pharmaceutical Market Study', Santiago, 2019. <https://www.fne.gob.cl/wp-content/uploads/2020/01/Informe-Final.pdf>.

BOX 1.5: Malaysia Competition Commission Market Review on Pharmaceutical Sector

"With the lack of substitutability, competition is only enabled when generic medicines enter the market—prices often drop dramatically, by up to 90 percent, as seen in the case of HIV medicines (generic competition also often results in significant lowering of originator prices.) While patents are accepted as one form of incentive and reward for innovation, competition law is increasingly used to remedy misuse of the patent regime when such conduct adversely impacts on the fostering of competition in, and growth of, the domestic industry as well as consumer welfare and public health. In Malaysia, many medicines treating non-communicable diseases, such as cardiovascular illnesses and cancer, remain high even where patent rights in relation to these medicines have expired in other parts of the world. Experience shows that prolonged patent terms can be one reason for the continued high price of these medicines.

Patent and product life-cycle management strategies are employed by originator companies to extend the monopoly over blockbuster medicines in the form of patent clusters or thickets where multiple patents are filed on, for example, methods, formulations and salts. These lead to many secondary patents and follow-on products which do not necessarily have added therapeutic benefits. For this reason, the European Commission, upon completing its inquiry into competition in the pharmaceutical sector in 2009, now monitors patent settlement

continued...

47 On 7 May 2020, this measure was implemented by the Ministry of Health. See <https://www.diariooficial.interior.gob.cl/publicaciones/2020/05/07/42649/01/1759228.pdf>.

BOX 1.5 ...continued

agreements on a regular basis as one major action. Competition authorities can play a critical role in promoting greater access to medicines. Some countries have used competition law to improve the price, availability and transfer of health technologies. The MyCC [Malaysia Competition Commission] and the Malaysian Ministry of Health (MOH) have started to engage with United Nations agencies such as the United Nations Development Programme on the use of competition law to deal with abuse of patents and other intellectual property rights in order to increase availability and affordability of medicines. (...)

Data exclusivity is another aspect of product registration that is known to cause delay of generics and thus higher costs to consumers and public health budgets. The protection of clinical test data of an originator medicine for a number of years prevents drug regulatory authorities from registering a generic by relying on those test data. There is no international obligation to provide such market exclusivity. In adopting the Data Exclusivity Directive 2011, Malaysia has explicitly taken into account public health, and has achieved a balance between originator and generic companies whilst meeting requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO). (...)

It is recommended that the Patents Act currently under review should be aligned with national competition and public health objectives; the scope of patentability be revisited in light of the characteristics of pharmaceuticals and updating of patentability criteria in other countries; linking patent status to product registration be treated with caution; patent transparency be enhanced; and all TRIPS flexibilities be included. There should be closer cooperation among the MOH, MyIPO [Intellectual Property Corporation of Malaysia], the Ministry of Domestic Trade, Co-operatives and Consumerism (MDTCC) and the Ministry of International Trade and Industry (MITI) in dealing with patent and trade-related issues that impact on public health.

In terms of product registration, the requirement for retrospective bioequivalence for 'grandfather' products should be reconsidered. Regulations on 'biosimilars', a class of medicines that is growing in importance (e.g. for cancer, diabetes, etc.), also need to be attuned to the latest developments and experiences in other countries. The Guideline on Good Pharmaceutical Trade Practice is currently voluntary. The MyCC and MOH can continue the collaboration on this and other areas for potential guidance or regulation vis-à-vis industry players.

There is a need for a coherent price policy to be part of the National Medicines Policy. There should be price transparency at all levels of the supply chain. Malaysia should study examples from other countries like South Africa in regulating medicine prices and like the Philippines, which mandates that prescriptions to patients must include a choice of at least two generic medicines. Price regulation is a complex task and will need to balance between market forces and timely non-market intervention to ensure access to affordable medicines. There should be systematic price monitoring with better use of publicly available information from other countries; and the government should work towards sharing of government procurement prices."

Source: Malaysia Competition Commission (MyCC), 'Market Review on Priority Sector Under Competition Act 2010, Pharmaceutical Sector', Executive Summary, Kuala Lumpur, 27 December 2017.

Intellectual property and competition: room to legislate under international law

The 2014 UNDP Guidebook stressed the flexibility available to LMICs in the adoption and implementation of competition law in substantial part because the international legal system did not prescribe many substantive rules addressing competition. As explained in the 2014 Guidebook, while the WTO's TRIPS Agreement includes some rules relevant to competition, these rules largely confirm the flexibility of pre-existing competition law. Otherwise, for many years competition authorities and the business community in the United States resisted efforts largely championed by the EU to negotiate international competition norms, including at the WTO.⁴⁸ While efforts at the multilateral level have largely remained dormant, the past decade has nonetheless witnessed a proliferation of competition chapters and/or individual provisions in preferential TIAs, also known as regional trade agreements (RTAs), free trade agreements (FTAs), economic cooperation (or partnership) agreements, and so forth.⁴⁹

Many of the provisions in TIAs negotiated to date are focused on procedural matters or 'process', and are not directed towards harmonizing or requiring specific substantive norms beyond the broad category of anti-competitive agreements and abuse of dominant position.⁵⁰ However, the EU has concluded a number of agreements which specifically list certain types of anti-competitive practices that parties are expected to regulate.⁵¹ In addition to procedural matters, many TIAs include general or specific provisions regarding cooperation among competition authorities.⁵²

Although, in principle, minimum standards regarding procedures are unobjectionable, it is important for competition authorities, trade negotiators and health officials in LMICs to appreciate that it is typically multinational and export-orientated enterprises that motivate trade authorities from HICs to pursue international economic agreements. Commitments to follow certain procedural standards may be the basis for trade authorities to threaten sanctions or to withdraw benefits under economic agreements, and such threats may well have a chilling effect on the pursuit of anti-competitive behaviour by competition authorities. An analogy may be drawn to the field of pharmaceutical regulation, where rules of TIAs and the WTO

48 See Frederick M. Abbott, 'Are the Competition Rules in the WTO TRIPS Agreement Adequate?', *Journal of International Economic Law* (Oxford), 2004, Vol. 7, No. 3, pp. 687–703. Available at: <https://ssrn.com/abstract=917108>.

49 See Box 2.1, *infra*.

50 *Id.*, at para. 56.

51 *Id.*, at para. 53.

52 *Id.*, at para. 51.

TRIPS Agreement are regularly invoked by HIC trade authorities to exert pressure on LMIC (and HIC) medicines regulatory authorities. This argues for approaching the incorporation in TIAs of competition commitments—even the seemingly benign procedural ones—with a caution that reflects historical experience in other areas of international regulation.⁵³ This is not to suggest that LMICs should neglect to provide adequate process safeguards, but is rather to suggest that LMICs are perfectly capable of implementing such safeguards without making that implementation the object of trade agreement requirements that may affect the independence of the competition authorities and their ability to carry out their duties efficiently and effectively.⁵⁴ Competition authorities already share good practices through informal networks such as the International Competition Network (ICN). Information-sharing and cooperation among national and regional authorities, often undertaken through self-standing agreements between and among competition authorities, is an important means by which competition law and enforcement practices are evolving.

53 Frederick M. Abbott, 'Let International Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity', *IIC (Max Planck)* (2018) 49:259–266. Available at: <https://doi.org/10.1007/s40319-018-0683-5>.

54 Chapter 3 of the EU's ECN+ Directive stresses the importance of the independence of competition authorities. See European Union, 'Directive (EU) 2019/1 of the European Parliament and of the Council of 11 December 2018 to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market', Brussels, 11 December 2018. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0001&from=EN>.

BOX 2.1: Elements and commitments in regional trade agreements⁵⁵

A recent study by the WTO provides an overview of specific competition policy provisions in RTAs, including the following highlights:

164 RTAs (around 55 percent of the total 296 RTAs notified to the WTO and analysed by the WTO Secretariat) have dedicated chapters or provisions on competition policy.

1 Importance of adopting/maintaining competition laws and establishing competition authorities

- Most of the RTAs with dedicated competition chapters stipulate which anti-competitive practices are to be regulated and/or the measures which are to be implemented to address them (82 percent of such RTAs include provisions on anti-competitive agreements and abuse of dominance, while the issue of merger control is included in around 26 percent of such RTAs, increasingly in recent ones). Most of the RTAs with dedicated competition chapters (68 percent) provide for cooperation on competition policy, and are designed to facilitate the establishment and further development of competition principles. The adoption or maintenance of competition laws (57 percent) and the establishment of competition authorities (around 32 percent) are often required in competition chapters and further contribute to the above-mentioned objectives. Recently concluded RTAs increasingly include ‘horizontal principles’ such as transparency (51 percent), non-discrimination and procedural fairness (35 percent). Most RTAs address the regulation of State-owned enterprises (SOEs) and designated monopolies (59 percent of the RTAs with dedicated competition chapters).
- More than half of the RTAs with dedicated competition provisions include a requirement to adopt or maintain laws, legislation, or reference to parties’ already established legislation.
- Generally, RTAs inspired by the North American Free Trade Agreement (NAFTA) not only contain the requirement to “adopt or maintain competition laws that prescribe anti-competitive business conducts”, but also require the parties to “take appropriate action with respect to such conduct”. Most RTAs involving the EU or European Free Trade Association (EFTA) countries incorporate an obligation to adopt or maintain competition laws. In addition to the general requirement to “adopt or maintain in force comprehensive competition laws”, these RTAs refer to the requirement that these laws “shall effectively address anti-competitive practices”. Some of the EU’s RTAs, mainly with potential EU accession candidates, include an obligation for the latter to not only adopt a competition law, but also to ensure the compatibility of their legislation with EU competition law.
- Around 30 percent of the RTAs include an express requirement for parties to establish competition authorities. This is inherent to RTAs following the NAFTA or EU model, as well as RTAs by Asian and Latin American countries. A much lower share—only 7 percent—of the RTAs specify that such authorities are to be independent. Where present, such a requirement is usually included in the EU’s RTAs with potential EU candidates. On the other

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55 WTO TRIPS Agreement provisions relevant to competition law are described in Chapter 2 of the 2014 Guidebook.

hand, cases where there is no requirement to adopt or maintain competition laws and/or a competition authority usually reflect the fact that the parties to these agreements have already adopted competition laws and established competition authorities.

2 Anti-competitive practices and ‘horizontal’ principles addressed in RTAs

- With the exception of NAFTA-inspired RTAs and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), most agreements surveyed address which anti-competitive practices are to be regulated and/or which measures are to be implemented to that effect. Almost all of the RTAs with dedicated competition chapters specifically mention anti-competitive agreements (82 percent) and abuses of market power (80 percent). In contrast, only around 26 percent of these RTAs mention anti-competitive mergers. An express reference to merger control is a particular characteristic of RTAs involving Asian countries (49 percent of their RTAs include provisions on mergers); and the EU and EFTA countries (45 percent). Australia and New Zealand have adopted advanced provisions on anti-competitive mergers in the framework of the Australia–New Zealand Closer Economic Relations Trade Agreement (ANZCERTA) by adopting a Cooperation Protocol for Merger Review in 2006, aimed at formalizing relevant practices of their competition authorities.
- Also, half of the RTAs with the dedicated competition provisions recognize that any measures proscribing anti-competitive business conduct should be consistent with principles of transparency. Furthermore, some of these RTAs explicitly refer to transparency in relation to the application of competition laws and exclusions from competition law. Other requirements to follow ‘horizontal’ principles in competition policy enforcement, such as principles of non-discrimination, along with requirements of procedural fairness are referenced in around one third of the RTAs. Such requirements are found in RTAs involving the EU, EFTA, Canada, Asian economies (Japan and Singapore), and some Latin American countries (Peru and Chile). The CPTPP is among the most progressive RTAs in that regard, including reaching and detailed provisions on procedural fairness (such as the right to counsel, and the right to offer expert analysis, among others) drawn from the work of the International Competition Network (ICN) and the Organisation for Economic Co-operation and Development (OECD).

3 Regional cooperation on competition policy issues

- Most RTAs with dedicated competition chapters include different provisions on cooperation, though the envisaged scope and extent varies. Around 70 percent of such RTAs explicitly mention cooperation in their texts and refer to information-sharing and consultation (including both consultations in the implementation of the competition provisions or chapters of the agreements and consultations in specific cases of anti-competitive practices). Around half refer to notification and confidentiality requirements; and only about a third of RTAs include provisions on technical assistance on competition policy. Interestingly, the CPTPP envisages activities such as the exchange of information and experiences on competition advocacy with a view to promote a culture of competition.

continued...

4 Enforceability of competition policy chapters in RTAs

- Only around 34 percent of RTAs with dedicated competition chapters subject competition policies to full RTA dispute settlement procedures. These often involve the EU or EFTA, as well as some RTAs among countries in the Commonwealth of Independent States and MERCOSUR. Other RTAs, though exempting competition chapters from dispute settlement, still provide consultations. This is the case for more than half of RTAs with detailed competition chapters (60 percent).
- Few RTAs with a dedicated competition chapter (only 3 percent and only those involving Australia or New Zealand, Chinese Taipei, some Latin American countries and the CPTPP) include a direct reference to private rights of enforcement. For instance, the RTA between New Zealand and Chinese Taipei recognises that “a private right of action is an important supplement to the public enforcement of a Party’s competition laws” and sets an obligation for the RTA parties to “ensure that a right [...] is available to persons of the other Party on terms that are no less favourable than those available to its own persons”.

4 Regulating designated monopolies/State-owned enterprises

- Around 74 percent of all RTAs with dedicated provisions on competition policy make reference to SOEs and designated monopolies either in their competition chapters (around 60 percent of RTAs with dedicated chapters) or in separate provisions outside the chapter on competition. In many cases, separate chapters on SOEs contain more enforceable language than SOE provisions in chapters on competition policy. NAFTA-inspired RTAs usually recognize that “state enterprises/designated monopolies should not operate in a manner that creates obstacles to trade and investment”. In contrast, RTAs following the EU approach typically establish concrete obligations for public enterprises to follow general competition laws and not to engage in anti-competitive practices.
- Notably, the CPTPP’s chapter on SOEs (Chapter 17) establishes ambitious comprehensive standards on SOE management, aimed at disciplining SOEs policies. While in many respects the chapter on SOEs in the US–Mexico–Canada Agreement (USMCA) incorporates similar considerations as are included in the CPTPP, certain aspects of the USMCA text go even further. In particular, the USMCA chapter, in addition to defining SOEs on the basis of government ownership or government control through ownership interests, also covers situations of control through minority shareholding. Importantly, the SOEs chapters in the USMCA and in the CPTPP are subject to the RTA’s dispute settlement mechanism.

Source: Robert D. Anderson, William E. Kovacic, Anna Caroline Müller and Nadezhda Sporysheva, ‘Competition policy, trade and the global economy: Existing WTO elements, commitments in regional trade agreements, current challenges and issues for reflection’, World Trade Organization, Geneva, 5 December 2019.

The following text box is an example from the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), a 2018 trade agreement between 11 countries in the Asia-Pacific region. The provision addresses ‘procedural fairness’ or process. Competition authorities in LMICs and HICs have long confronted teams of lawyers representing corporate interests who are effective in making the prosecution of competition enforcement actions expensive, time-consuming and difficult. With the introduction of TIA chapters, such as Chapter 16 of the CPTTP, competition authorities face the prospect of confronting not only private-sector lawyers, but also trade officials from the host country of the firm raising concerns about procedure.⁵⁶ Considering the level of detail in the CPTPP provisions and the obligations placed on the competition authorities, it remains to be seen in practice how these new competition chapters influence competition authorities and practices.

BOX 2.2: CPTPP provisions on procedural fairness and non-application of dispute settlement

“Article 16.2: Procedural Fairness in Competition Law Enforcement

- 1 Each Party shall ensure that before it imposes a sanction or remedy against a person for violating its national competition laws, it affords that person:
 - a information about the national competition authority’s competition concerns;
 - b a reasonable opportunity to be represented by counsel; and
 - c a reasonable opportunity to be heard and present evidence in its defence, except that a Party may provide for the person to be heard and present evidence within a reasonable time after it imposes an interim sanction or remedy.In particular, each Party shall afford that person a reasonable opportunity to present evidence or testimony in its defence, including: if applicable, to offer the analysis of a properly qualified expert, to cross-examine any testifying witness; and to review and rebut the evidence introduced in the enforcement proceeding.
- 2 Each Party shall adopt or maintain written procedures pursuant to which its national competition law investigations are conducted. If these investigations are not subject to definitive deadlines, each Party’s national competition authorities shall endeavour to conduct their investigations within a reasonable time frame.
- 3 Each Party shall adopt or maintain rules of procedure and evidence that apply to enforcement proceedings concerning alleged violations of its national competition laws and the determination of sanctions and remedies thereunder.
- 4 These rules shall include procedures for introducing evidence, including expert evidence if applicable, and shall apply equally to all parties to a proceeding.
- 5 Each Party shall provide a person that is subject to the imposition of a sanction or remedy for violation of its national competition laws with the opportunity to seek review of the

continued...

⁵⁶ Article 16.3 of the CPTPP encourages, but does not require, that its country parties make available private rights of action to enforce competition law. Alternatively, private parties must be permitted to request national competition authorities to initiate an investigation.

BOX 2.2 ...continued

sanction or remedy, including review of alleged substantive or procedural errors, in a court or other independent tribunal established under that Party's laws.

- 6 Each Party shall authorise its national competition authorities to resolve alleged violations voluntarily by consent of the authority and the person subject to the enforcement action. A Party may provide for such voluntary resolution to be subject to judicial or independent tribunal approval or a public comment period before becoming final.
- 7 If a Party's national competition authority issues a public notice that reveals the existence of a pending or ongoing investigation, that authority shall avoid implying in that notice that the person referred to in that notice has engaged in the alleged conduct or violated the Party's national competition laws.
- 8 If a Party's national competition authority alleges a violation of its national competition laws, that authority shall be responsible for establishing the legal and factual basis for the alleged violation in an enforcement proceeding.
- 9 Each Party shall provide for the protection of business confidential information, and other information treated as confidential under its law, obtained by its national competition authorities during the investigative process. If a Party's national competition authority uses or intends to use that information in an enforcement proceeding, the Party shall, if it is permissible under its law and as appropriate, provide a procedure to allow the person under investigation timely access to information that is necessary to prepare an adequate defence to the national competition authority's allegations.
- 10 Each Party shall ensure that its national competition authorities afford a person under investigation for possible violation of the national competition laws of that Party reasonable opportunity to consult with those competition authorities with respect to significant legal, factual or procedural issues that arise during the investigation. [footnotes omitted]

Article 16.9: Non-Application of Dispute Settlement

No Party shall have recourse to dispute settlement under Chapter 28 (Dispute Settlement) for any matter arising under this Chapter.”

Source: CPTTP, 'Competition Policy', Chapter 16.

Article 16.9 of the CPTPP, as quoted above, ameliorates the potential adverse effects of the agreement on implementation and enforcement of competition law. It precludes the parties from formally challenging each other in dispute settlement proceedings that might lead to the imposition of trade sanctions. This shows an awareness among government authorities involved in the negotiations of the risks associated with bringing competition procedures and investigations within the framework of the TIA. Yet exclusion from the formal trade dispute settlement mechanism only partially addresses potential threats to the independence of competition authorities because most trade disputes—even serious ones—are resolved through negotiation, and do not reach the stage of a dispute settlement panel decision with accompanying formal imposition of sanctions.

Anti-competitive behaviours and the remedies available for redress

A. Resource documents

Certain competition authorities have prepared reports regarding their enforcement activities in the pharmaceutical sector. The European Commission recently prepared a report for the Council and the European Parliament on Competition Enforcement in the Pharmaceutical Sector (2009–2017).⁵⁷ This report serves to illustrate the various types of enforcement actions explained in the 2014 UNDP Guidebook by reference to completed investigations and prosecutions, as well as certain ongoing matters.

Notably, the European Commission report indicates that:

“Since 2009, the authorities [EU and national competition authorities (NCAs)] have together adopted 29 antitrust decisions against pharmaceutical companies. These decisions have imposed sanctions (with fines totalling over EUR 1 billion) or made binding commitments to remedy anti-competitive behaviour. More importantly, some of these decisions addressed anti-competitive practices that had previously not been addressed under EU competition law. These precedents give broader guidance to industry players on how to ensure that they comply with the law.”

The European Commission makes available an important set of resources with respect to enforcement of EU (and its Member States’) competition laws on its competition website.⁵⁸ These resources include materials relating to conduct of investigations, cooperation among national regulatory authorities and the Commission, and the legislation, regulations and guidance applicable in this area, as well as a database of relevant cases.⁵⁹

Of particular note with respect to the European Union is a directive adopted in December 2018 “to empower the competition authorities of the Member States to be more effective enforcers and ensure the proper functioning of the internal market”.⁶⁰ The so-called ECN+

57 European Union, ‘Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009–2017): European competition authorities working together for affordable and innovative medicines’, Brussels, 2017. Available at <https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf>. Also published with document identification Brussels, 28.1.2019 COM(2019) 17 final. Available at https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf (hereinafter ‘European Commission 2019 Enforcement Report’).

58 See https://ec.europa.eu/competition/antitrust/overview_en.html.

59 See, for example, European Union, ‘EU Competition Law, Rules Applicable to Antitrust Enforcement’, Volume I: General Rules, Situation as at 1st July 2013, Brussels, 2013. Available at https://ec.europa.eu/competition/antitrust/legislation/handbook_vol_1_en.pdf.

directive is designed to assure that NCAs in EU Member States have adequate powers to investigate and enforce competition law.⁶¹ Another important aspect involves assurances that competition authorities will not be subject to political pressures in the performance of their duties (i.e. they will enjoy independence).⁶²

The United States Federal Trade Commission (FTC) Health Care Division, Bureau of Competition, recently published its ‘Overview of FTC Actions in Pharmaceutical Products and Distribution’ (September 2019).⁶³ Two important resources with respect to US practice in regard to anti-trust/competition law enforcement relevant to the pharmaceutical sector are the Department of Justice/FTC ‘Antitrust Guidelines for International Enforcement and Cooperation’ (2017)⁶⁴ and the Department of Justice/FTC ‘Antitrust Guidelines for the Licensing of Intellectual Property’ (2017).⁶⁵

60 Directive (EU) 2019/1 of the European Parliament and of the Council of 11 December 2018 to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0001&from=EN>.

61 ECN+, id., Chapter IV, Powers, Article 6: Power to inspect business premises.

- 1 Member States shall ensure that national administrative competition authorities are able to conduct all necessary unannounced inspections of undertakings and associations of undertakings for the application of Articles 101 and 102 of the TFEU. Member States shall ensure that the officials and other accompanying persons authorised or appointed by national competition authorities to conduct such inspections are, at a minimum, empowered:
 - (A) to enter any premises, land, and means of transport of undertakings and associations of undertakings;
 - (B) to examine the books and other records related to the business irrespective of the medium on which they are stored, and to have the right to access any information which is accessible to the entity subject to the inspection;
 - (C) to take or obtain, in any form, copies of or extracts from such books or records and, where they consider it appropriate, to continue making such searches for information and the selection of copies or extracts at the premises of the national competition authorities or at any other designated premises;
 - (D) to seal any business premises and books or records for the period and to the extent necessary for the inspection;
 - (E) to ask any representative or member of staff of the undertaking or association of undertakings for explanations on facts or documents relating to the subject matter and purpose of the inspection and to record the answers.
- 2 Member States shall ensure that undertakings and associations of undertakings are required to submit to the inspections referred to in paragraph 1. Member States shall also ensure that, where an undertaking or association of undertakings opposes an inspection that has been ordered by a national administrative competition authority and/or that has been authorised by a national judicial authority, national competition authorities are able to obtain the necessary assistance of the police or of an equivalent enforcement authority so as to enable them to conduct the inspection. Such assistance may also be obtained as a precautionary measure.

This Article is without prejudice to requirements under national law for the prior authorisation of such inspections by a national judicial authority.

62 ECN+, id., Chapter 3.

63 Markus M. Meier, Bradley S. Albert and Kara Monahan, ‘Overview of FTC Actions in Pharmaceutical Products and Distribution’, Health Care Division, Bureau of Competition, Federal Trade Commission, Washington, DC, 2019. Available at: https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20190930_overview_pharma_final.pdf (hereinafter ‘FTC Actions 2019 Overview’).

64 US Department of Justice and Federal Trade Commission, ‘Antitrust Guidelines for International Enforcement and Cooperation’, Washington, DC, 2017). Available at <https://www.justice.gov/atr/internationalguidelines/download>.

65 US Department of Justice and Federal Trade Commission, ‘Antitrust Guidelines for the Licensing of Intellectual Property’, Washington, DC, 2017. Available at <https://www.justice.gov/atr/IPguidelines/download>.

In the following sections, the Supplement provides examples of competition enforcement actions initiated and/or concluded by competition authorities of various countries with respect to anti-competitive abuses in the pharmaceutical and health sectors, as well as some examples of civil competition actions initiated by civil society or other interested stakeholders.

B. Enforcement actions regarding agreements between undertakings/contracts in restraint of trade

In this section, there are examples of competition law actions in the pharmaceutical and health sectors involving ‘agreements between undertakings’ or ‘contracts in restraint of trade’ between independent entities.

1. Brazil

BOX 3.B.1: CADE investigates orthoses and prostheses and implantable cardiac pacemakers

In 2014, CADE (Brazil’s NCA) convicted the Associação Brasileira de Ortopedia Técnica (Abotec) [Brazilian Association of Technical Orthopedics] and 11 companies for price fixing in the orthopaedic orthoses and prostheses market. In total, BRL2.2 million was issued in fines. Nowadays, CADE is investigating illicit conduct (cartels) in the market of implantable cardiac pacemakers (implantable cardioverter-defibrillator—ICD, resynchronizer and pacemaker) and accessory items that include electrodes, sets of introducers and catheters (Administrative Proceeding 08700.003699/2017-31). Four companies are responsible for supplying all implantable cardiac pacemakers in Brazil, as well as 29 individuals and 2 associations in the sector: the Brazilian Association of the Medical and Dental Equipment and Supplies Industry (Abimo) and the Brazilian Association of High Technology Industry Products (Abimed). The representative entities are being accused of facilitating and promoting the adoption of anti-competitive practices, serving as a forum for the exchange of competitively sensitive information among cartel members, enabling the formation and monitoring of agreements, including through the preparation of price lists.

Another Administrative Proceeding (08700.003709/2017-38), opened in 2017, investigates a cartel on the national distribution market for orthoses and prostheses, which includes implantable and non-implantable health technologies. In this case, 46 companies, 80 individuals and the Brazilian Association of Importers and Implant Distributors (Abraidi) are being investigated for anti-competitive practices, serving as a forum for the exchange of competitively sensitive information among cartel members, enabling the formation and monitoring of agreements, including through the preparation of price lists.

Source: CADE, ‘CADE’s Office of the General Superintendent recommends the conviction of cartel members in tenders of orthoses, prostheses, and medical devices’, Brasilia, 2021. Available at: <https://www.gov.br/cade/en/matters/news/cades-office-of-the-general-superintendent-recommends-the-conviction-of-cartel-members-in-tenders-of-orthoses-prostheses-and-medical-devices>. Original (2014) with updates (2021) refers at end to earlier fines imposed; CADE, ‘General superintendence initiates administrative proceeding to investigate a cartel in the market of orthoses, prostheses and special medical supplies’, press release, Brasilia, 2017. Available at: <https://www.gov.br/cade/en/matters/news/cade2019s-general-superintendence-initiates-administrative-proceeding-to-investigate-a-cartel-in-the-market-of-orthoses-prostheses-and-special-medical-supplies>.

BOX 3.B.2: CADE condemns antiretroviral drugs manufacturers

On 20 January 2016, CADE condemned some companies, such as Aurobindo Pharma Indústria Farmacêutica Ltda. Brasvit Indústria e Comércio Ltda., and four individuals for cartelizing public tenders in the manufacture of antiretroviral drugs (Administrative Proceeding 08012.008821/2008-22). The fines imposed totalled approximately BRL 6 million.

Source: CADE response to UNDP survey.

BOX 3.B.3: CADE investigates cartels in public tenders for medicines purchases

CADE's General Superintendence is investigating, through the Administrative Proceeding 08012.002222/2011-09, the existence of an alleged cartel practice in public tenders for the purchase of medicines, such as antidepressants, anxiolytics, analgesics, sedatives and anticoagulants, in addition to medications for hypertension, reflux and cough. The evidence indicates that 15 companies would have maintained frequent communication to coordinate setting prices and combine conditions and advantages in bids, to restrict the competition and the competitive nature of the events. The practice would have occurred at least from 2007 to 2011 in some Brazilian states, such as Minas Gerais, São Paulo, Bahia and Pernambuco.

According to CADE's General Superintendence, managers and representatives of these companies monitored the bidding to determine the winners in advance and the values to be offered by each one. They also colluded in how the market should be divided; which companies would submit proposals or coverage bids; and which ones would withdraw their proposals or would not bid.

By investigating and punishing cartels, CADE helps to prevent this kind of practice and to decrease the price of medicines, hospital services, health plans, orthoses and prostheses. By decreasing the price of such services and products, the Brazilian antitrust authority helps to achieve public health outcomes, making health services more accessible.

Besides CADE, other actors are working to create a more competitive environment in the public health sector. The Brazilian Federal Police and the Public Prosecution Office worked on an investigation called 'Prosthesis Mafia', which arrested a number of physicians who were colluding with enterprises responsible for the manufacture of medical inputs. Several physicians were accused of administering very expensive medical inputs and prescribing unnecessary surgeries to patients, in exchange for bribes.

Source: CADE response to UNDP survey.

2. China

Prior to 2018, the implementation and enforcement of competition law in China was spread among three government agencies: the National Development and Reform Commission (NDRC), the State Administration for Industry and Commerce (SAIC) and the Ministry of Commerce (MOFCOM). In 2018, competition law administration was consolidated in a new agency, the State Administration for Market Regulation (SAMR).⁶⁶ Since the three agencies that were previously involved in competition oversight had issued a variety of regulations and guidance documents, consolidation under SAMR also required integration of these relevant regulatory instruments, including through the adoption of new policies, rules and regulations.

Chinese competition authorities have prosecuted several complaints against producers of pharmaceutical products since the publication of the 2014 Guidebook.

BOX 3.B.4: Chongqing AIC fines company in the Allopurinol API abuse case

In 2015, the Chongqing Administration for Industry and Commerce (AIC) fined Chongqing Qingyang for abuse of dominance for allopurinol API in the Allopurinol API abuse case (Administrative Penalty Decision of Chongqing Administration for Industry and Commerce (2015) No. 15, 28 October 2015), and then in 2016 the NDRC fined the same company for price fixing and dividing the sales market for allopurinol tablets in the Allopurinol Tablets cartel case (Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 1, 15 January 2016).

In the Allopurinol Tablets cartel case, the NDRC found that the three allopurinol tablet manufacturers and two distributors held four meetings between April 2014 and September 2015 to reach and implement agreements to increase the price of allopurinol tablets. Additionally, the three manufacturers agreed to divide the sales market for allopurinol tablets by limiting their respective tendering activities to within the sales area allocated to each manufacturer.

Source: Yong Bai and Richard Blewitt. 'The Application of the Anti-Monopoly Law to the Pharmaceutical Sector in China'. *China Antitrust Law Journal*, Vol 1, Issue 1 (2017). Available at <https://www.cliffordchance.com/content/dam/cliffordchance/PDFDocuments/the-application-of-the-anti-monopoly-law-to-the-pharmaceutical-sector-in-china.pdf>.

In 2016, the NDRC imposed penalties against three API manufacturers that control the market for estazolam, a psychotropic drug.⁶⁷ The API manufacturers also formulate the finished pharmaceutical and acted in concert to refuse supply to competing tablet manufacturers and to fix prices. Although only two of the companies actively participated in the conspiracy, the third did not initially object, and later followed their lead. Evidence included records of meetings, calls

⁶⁶ The agency's website is available at <http://www.samr.gov.cn/>.

⁶⁷ In the matter of Huazhong Pharmaceutical, et al. Facts based on Michael Gu, AnJie Law Firm, 'Annual Review of Public Enforcement of China's Anti-Monopoly Law (2016)', 29 March 2016.

and text messages. The NRDC demonstrated that the companies followed uniform practices, and rejected a defence that the companies had acted in response to market conditions. As a consequence of the concerted action, a substantial number of tablet manufacturers ceased producing the formulated medicine.

At the end of 2018, the newly consolidated SAMR published two additional decisions regarding APIs. The first involved glacial acetic acid APIs and a horizontal agreement to increase API prices by approximately 300 percent. The second case involved clorphenamine APIs and abuse of dominant position by Hunan Erkang Pharmaceutical Management Co. Ltd. SAMR found that the dominant actor in this case had implemented unfair prices, and engaged in tying and bundling and refusal to deal. According to commentators, Chinese authorities have focused on the API market because of strict government controls regarding market authorizations and a resulting dependence of downstream operators.⁶⁸

BOX 3.B.5: Three new antitrust regulations in China

The most notable legislative achievement in 2019 was the SAMR's promulgation of three new antitrust regulations, which took effect on 1 September 2019:

- The Interim Provisions on the Prohibition of Monopoly Agreements (the Monopoly Agreement Regulation)
- The Interim Provisions on the Prohibition of Abuse of Dominant Market Positions (the Abuse of Market Dominance Regulation)
- The Interim Provisions on the Prohibition of Abuse of Administrative Power in Eliminating or Restricting Competition (the Administrative Abuse Regulation).

The new regulations aim to:

- unify rules which were fragmented prior to the reorganization of China's antitrust agencies;
- provide clear guidance to business operators on compliance with China's antitrust rules and enforcement agencies for undertaking enforcement actions in a standardized manner.

The new regulations are more self-contained than the previous rules, in that they combine both substantive and procedural provisions. Before the reorganization, the previous antitrust agencies (i.e. the NDRC and SAIC) issued separate regulations to deal with substantive and procedural issues, respectively.

Further, based on experience accumulated from past enforcement actions, the new regulations have clarified the SAMR's position on a few outstanding issues. For example, the Monopoly Agreement Regulation implicitly clarifies that the *per se* approach is to be taken for the five types of horizontal monopoly agreement and resale price maintenance, which

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68 Michael Gu, AnJie Law Firm, 'China', *The Public Competition Enforcement Review*, Edition 11, The Law Reviews, London, 2020.

BOX 3.B.5 ...continued

are explicitly enumerated in the Anti-monopoly Law, and the rule of reason approach for other types of monopoly agreement which are not enumerated in the Anti-monopoly Law. Further, it is made clear that the commitment regime is inapplicable to certain hardcore restrictions, including price fixing, the restriction of sales and market partitioning between competitors. Detailed rules on the leniency regime have also been added in the Monopoly Agreement Regulation.

In addition, the new regulations demonstrate the SAMR's increased focus on a few emerging issues. For instance, there is a provision in the Abuse of Market Dominance Regulation that specifically addresses determination of market dominance in the internet sector and another provision pertaining solely to assessing market dominance in intellectual property. The Abuse of Market Dominance Regulation also outlines factors the agencies will take into consideration in determining collective dominance, such as market structure, market transparency, product homogeneity and behaviour uniformity.

Source: Michael Gu, AnJie Law Firm, 'China', *The Public Competition Enforcement Review*, 11th Edition The Law Reviews, London, 2020.

3. European Union

a. Pay for delay

As discussed in the 2014 Guidebook, pay for delay agreements involve originator patent owners that contract with potential generic market entrants usually (though not always) to settle/dismiss patent claims that might otherwise result in early entry of generics onto the market. This has been a common type of arrangement that both the European Commission and the US FTC have been working to curtail, as it results in injury to consumers and health care payers for whom medicine prices remain high. The European Commission generally assesses pay for delay agreements as potential violations of Article 101 of the Treaty on the Functioning of the European Union (TFEU) because they involve agreements between independent undertakings (i.e. the originator and the generic producer.) However, pay for delay agreements have also been addressed in the context of abuse of dominant position (Article 102, TFEU).

[Generics \(UK\) v CMA, CJEU Judgment \(Fourth Chamber\), Case C-307/18, 30 January 2020.](#)

This important decision of the Court of Justice of the European Union (CJEU) addresses whether the owners of patents protecting pharmaceutical products and/or processes are immune from prosecution under Articles 101 and 102 of the TFEU by virtue of their IPR. The context involves pay for delay agreements entered into by the owner of a patent, GlaxoSmithKline (GSK), with three generic producers that intended to enter the market with

competitive medicines, and two of which had pursued invalidity claims with respect to the patent. A product patent on the subject pharmaceutical, paroxetine (a selective serotonin reuptake inhibitor), had expired before the pay for delay agreements were reached, but GSK maintained a process patent which it asserted would be infringed by market entry of the generic versions.

The decision of the CJEU, which largely followed the recommendation/opinion of Advocate General Kokott, held that the presumption of validity conferred on the owner of a patent as a matter of law does not establish that the patent subject matter is insulated from competition law scrutiny. The CJEU decision noted that the outcome of invalidity proceedings is inherently uncertain, and such uncertainty is characteristic of the pharmaceutical sector and patent law.

With respect to Article 101, the CJEU held that where pay for delay agreements involve a transfer of commercial value from the patent owner to potential generic competitors that cannot be explained other than by the commercial interests of the parties not to engage in competition, this has as its 'object' a restriction of competition. If such an object is identified then, under Article 101 (1) of the TFEU, the prosecutor does not need to also demonstrate anti-competitive effects. However, this may not be the case if the settlement agreement "is accompanied by proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition". The CJEU said that such doubt is neither established by indeterminacy with respect to the validity of a patent, nor by some showing that the pay for delay agreements resulted in a reduction in the price.

In cases where the prosecutor must demonstrate anti-competitive effect, this does not presuppose a showing that the generic producer/s would succeed in a patent challenge, or would have concluded a less restrictive agreement but for the conclusion of the subject agreement.

The CJEU held that Article 101 (agreement between undertakings) and Article 102 (abuse of dominant position) may be applied to the same factual subject matter, and that an abuse of dominant position can be based on a patent owner holding market power entering into restrictive agreements with several potential competitors.

This decision by the CJEU has obvious parallels to the decision in 2013 by the US Supreme Court in *FTC v. Actavis*, 570 US 136 (2013), which rejected the notion that pay for delay agreements within the scope of the patent owner's exclusive rights are insulated from antitrust prosecution, holding that a large unexplained payment from a patent owner to a generic challenger (i.e. reverse payment) raises a presumption of anti-competitive abuse. In *Generics (UK) v. CMA*, the CJEU, like the Supreme Court in *Actavis*, observes that the patent owner and potential generic competitors all may gain financially from their arrangement at the expense of the consumer.

BOX 3.B.6: European Commission imposes fines for protecting perindopril from price competition by generics

Commission Decision of 9 July 2014 in case COMP/AT.39612 – Servier, and Judgment of the General Court of 12 December 2018, Servier SAS, Servier Laboratories Limited and Les Laboratoires Servier v European Commission, T-691/14

In addition to infringing Article 101 TFEU, pay for delay agreements can also infringe Article 102 TFEU. This may be the case when the originator holds a dominant position and the agreements are part of a strategy to delay generic entry. In 2014, the Commission imposed fines totalling EUR427.7 million on the French pharmaceutical company Servier and five producers of generic medicines (Niche/Unichem, Matrix/Mylan, Teva, Krka and Lupin) for concluding a series of deals aimed to protect Servier's bestselling blood pressure medicine, perindopril, from price competition by generics in the EU.

Servier paid several tens of millions of euros to the generics amounting to “buy [them] out” from the perindopril market. Servier's strategy of delaying generic entry included acquiring a competing technology and consecutively concluding the patent settlement agreements. On 12 December 2018, the General Court confirmed the Commission's findings under Article 101 (with the exception of the Krka agreement) but rejected the Commission's market definition and consequently annulled the conclusion that Servier's conduct also infringed Article 102 TFEU. As a consequence, the Court reduced the total fines to EUR315 million. [The judgments are on appeal to the CJEU.]

Source: European Commission 2019 Enforcement Report.

b. Coordination as a means to achieve higher prices

BOX 3.B.7: Example of cases from the European Commission 2019 Enforcement Report

Decision of the Autorità Garante della Concorrenza e del Mercato of 27 February 2014

Collusion in tenders, price fixing and other types of coordination between competitors belong to the well-known, and at the same time most reprehensible, violations of competition law. In 2014, the Italian NCA found that Hoffmann-La Roche and Novartis had entered into an anti-competitive agreement aiming to discourage and limit off-label use of Hoffmann-La Roche's oncology medicine Avastin for the treatment of Age-related Macular Degeneration (AMD). AMD is the main cause of age-related blindness in developed countries. Avastin (authorized for the treatment of tumorous diseases) and Lucentis (authorized for the treatment of eye diseases) are medicines developed by Genentech, a company which belongs to the Hoffmann-La Roche group. Genentech entrusted the commercial exploitation of Lucentis to the Novartis group by way of a licensing agreement, whereas Hoffmann-La Roche markets Avastin for cancer treatments.

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Nonetheless, the active ingredient in both medicines being similar (though developed in different ways), Avastin was frequently used off-label to treat eye diseases instead of Lucentis because of its significantly lower price.

The NCA established that Novartis and Hoffmann-La Roche had put in place an arrangement designed to artificially differentiate Avastin from Lucentis whereas, according to the NCA, Avastin and Lucentis are equivalent in all respects for the treatment of eye diseases. The arrangement was intended to disseminate information raising concerns about the safety of Avastin used in ophthalmology to shift demand towards the more expensive Lucentis. An internal Novartis presentation explained: “Leverage safety data and regulator’s statements against unlicensed intraocular use of bevacizumab for wet AMD to avoid off-label erosion”. According to the NCA, this illicit collusion was capable of hindering access to treatment for many patients and caused the Italian health care system additional expenses estimated at EUR45 million in 2012 alone.

The fine imposed on Hoffmann-La Roche amounted to EUR90.6 million, and the fine imposed on Novartis amounted to EUR92 million.

Judgment of the Court of Justice of 23 January 2018, *F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato*, C-179/16

In the second-instance appeal procedure against the NCA’s decision, the Italian State Council sent a preliminary reference to the CJEU on several questions concerning the interpretation of Article 101 TFEU. In its response, the CJEU clarified, among other things, that (i) in principle, a medicine used off-label for the same therapeutic indications as another product used on-label can be included in the same market; and that (ii) communication of misleading information regarding the safety of an off-label medicine to the authorities, medical professionals and general public may constitute a restriction of competition by object.

Other examples

Also included in the European Commission 2019 Enforcement Report: “In another case, the Spanish NCA established that an agreement between an association of pharmacists in Castilla-La Mancha and the region’s health service amounted to market sharing, as it introduced a rotation between pharmacies for the supply of medicines to health care centres (Decision of the Comisión Nacional de los Mercados y la Competencia of 14 April 2009). The Court of Appeal (Decision of the Audiencia Nacional of 6 June 2012) and the Supreme Court (Decision of the Tribunal Supremo of 9 March 2015) upheld the NCA’s decision in its entirety.

Other examples of interventions against collusive behaviour include decisions by the Hungarian NCA in 2015 (bid rigging in hospital tenders) (Decision of the Gazdasági Versenyhivatal of 14 September 2015), the Slovenian NCA in 2013 (bid rigging, price fixing between wholesalers and distributors, market sharing and exchange of information related to prices and sale) (Decision of the Javna agencija Republike Slovenije za varstvo konkurence of 14 October 2013), the Danish NCA in 2014 (coordination between wholesalers of fees and other trading conditions) (Decision of the Konkurrence- og Forbrugerstyrelsen of 24 November 2014), and

continued...

BOX 3.B.7 ...continued

the German NCA in 2017 (exchange of sensitive information between wholesalers via a common IT system) (Decision of the Bundeskartellamt of 27 April 2017). In 2015 the Italian NCA adopted a commitment decision requiring Novartis and Italfarmaco to adjust their market behaviour and make amendments to their co-marketing agreement (Decision of the Autorità Garante della Concorrenza e del Mercato of 4 June 2015). The binding commitments alleviated the NCA's concerns regarding the exchange of sensitive information and cooperation in tendering in regional public procurements.

In a commitment decision in 2011, the Lithuanian NCA addressed possible vertical price coordination in agreements between manufacturers and wholesalers (Decision of the Konkurencijos tarybą of 21 July 2011). These agreements included a provision requiring that the wholesalers and manufacturers coordinate retail prices of medicines, thus possibly resulting in prices of medicines being raised for the patients, and the "accepted commitments provided for such provisions to be deleted."

Source: European Commission 2019 Enforcement Report.

4. United States

a. Horizontal contracts in restraint of trade

Each state of the United States has its own Attorney General's office that is responsible for enforcing state law. In several related cases brought against a substantial number of generic pharmaceutical producers, 51 State (and US Territory) Attorneys General have alleged a wide-ranging pattern of concerted practices among generic pharmaceutical producers to raise prices, *inter alia*, by bid rigging and output restraints (see BOX 3.B.8 below). A number of the same companies and practices are subject to a criminal antitrust investigation by the US Department of Justice.⁶⁹ One aspect of the evidence laid out in the State Attorneys General's complaints is the extent to which the defendants went to disguise their unlawful conduct, though apparently not so successfully.

69 See David McLaughlin and Riley Griffin, 'Novartis' Sandoz Settles U.S. Drug Price-Fixing Charges', *Bloomberg Health Law and Business News*, 3 March 2020: "Novartis AG's Sandoz unit agreed to pay \$195 million to settle U.S. criminal charges that it conspired with other pharmaceutical companies to fix prices of generic drugs, the most significant settlement to come from a long-running Justice Department investigation ... Sandoz conspired with four of its competitors between 2013 and 2015 to rig drug prices, the Justice Department said Monday. The settlement marks the largest penalty obtained by the U.S. in a domestic cartel case, the government said. Sandoz agreed to cooperate with the antitrust division's continuing investigation ... Sandoz admitted that the sales affected by the conspiracies exceeded \$500 million and involved drugs for common skin conditions, high blood pressure and cystic fibrosis, according to the Justice Department."

BOX 3.B.8: Attorney General Tong leads coalition filing third complaint in ongoing antitrust price-fixing investigation into generic industry

“The United States Attorney General William Tong led a coalition of 51 states and territories today in filing the third lawsuit stemming from the ongoing antitrust investigation into a widespread conspiracy by generic manufacturers to artificially inflate and manipulate prices, reduce competition, and unreasonably restrain trade for generic drugs sold across the United States. This new Complaint, filed in the U.S. District Court for the District of Connecticut, focuses on 80 topical generics that account for billions of dollars of sales in the United States. The Complaint names 26 corporate Defendants and 10 individual Defendants. The lawsuit seeks damages, civil penalties, and actions by the court to restore competition to the generic market.

The topical medicines at the center of the Complaint include creams, gels, lotions, ointments, shampoos, and solutions used to treat a variety of skin conditions, pain, and allergies.

“These generic drug manufacturers perpetrated a multibillion-dollar fraud on the American public so systemic that it has touched nearly every single consumer of topical products. Through phone calls, text messages, emails, corporate conventions, and cozy dinner parties, generic pharmaceutical executives were in constant communication, colluding to fix prices and restrain competition as though it were a standard course of business. But they knew what they were doing was wrong, and they took steps to evade accountability, using code words and warning each other to avoid email and detection. Our case is built on hard evidence from multiple cooperating witnesses, millions of records, and contemporaneous notes that paint an undeniable picture of the largest domestic corporate cartel in our nation’s history. Our investigation is ongoing and expanding, and we will not rest until competition is restored and those responsible are held fully accountable,” said Attorney General Tong.

The Complaint stems from an ongoing investigation built on evidence from several cooperating witnesses at the core of the conspiracy, a massive document database of over 20 million documents, and a phone records database containing millions of call detail records and contact information for over 600 sales and pricing individuals in the generics industry. Among the records obtained by the States is a two-volume notebook containing the contemporaneous notes of one of the States’ cooperators that memorialized his discussions during phone calls with competitors and internal company meetings over a period of several years.

Between 2007 and 2014, three generic manufacturers, Taro, Perrigo, and Fougera (now Sandoz) sold nearly two-thirds of all generic topical products dispensed in the United States. The multistate investigation has uncovered comprehensive, direct evidence of unlawful agreements to minimize competition and raise prices on dozens of topical products. The Complaint alleges longstanding agreements among manufacturers to ensure a “fair share” of the market for each competitor, and to prevent “price erosion” due to competition.

The Complaint is the third to be filed in an ongoing, expanding investigation that the Connecticut Office of the Attorney General has referred to as possibly the largest domestic corporate cartel case in the history of the United States. The first Complaint, still pending in the U.S. District Court in the Eastern District of Pennsylvania, was filed in 2016 and now includes 18 corporate Defendants, two individual Defendants, and 15 generic medicines.

continued...

BOX 3.B.8 ...continued

Two former executives from Heritage Pharmaceuticals, Jeffery Glazer and Jason Malek, have entered into settlement agreements and are cooperating with the Attorneys General working group in that case. The second Complaint, also pending in the U.S. District Court in the Eastern District of Pennsylvania, was filed in 2019 against Teva Pharmaceuticals and 19 of the nation's largest generic manufacturers. The Complaint names 16 individual senior executive Defendants. The States are currently preparing for trial on that Complaint.

Corporate Defendants:

1 Sandoz, Inc.	14 Lannett Company, Inc.
2 Actavis Holdco U.S., Inc.	15 Lupin Pharmaceuticals, Inc.
3 Actavis Elizabeth LLC [limited liability company]	16 Mallinckrodt Inc.
4 Actavis Pharma, Inc.	17 Mallinckrodt plc [Public Limited Company]
5 Amneal Pharmaceuticals, Inc.	18 Mallinckrodt LLC
6 Amneal Pharmaceuticals, LLC	19 Mylan Inc.
7 Aurobindo Pharma USA, Inc.	20 Mylan Pharmaceuticals Inc.
8 Bausch Health Americas, Inc.	21 Perrigo New York, Inc.
9 Bausch Health, US LLC	22 Pfizer, Inc.
10 Fougera Pharmaceuticals, Inc.	23 Sun Pharmaceutical Industries, Inc.
11 G&W Laboratories, Inc.	24 Taro Pharmaceuticals USA, Inc.
12 Glenmark Pharmaceuticals Inc., USA	25 Teligent, Inc.
13 Greenstone LLC	26 Wockhardt USA, LLC

Attorney General Tong led the attorneys general of Alabama, Alaska, Arizona, Arkansas, Colorado, Delaware, District of Columbia, Florida, Georgia, Territory of Guam, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Northern Mariana Islands, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Utah, U.S. Virgin Islands, Vermont, Virginia, Washington, West Virginia and Wisconsin in filing the complaint.”

Source: Office of the Attorney General, Connecticut, ‘Press Release’, 10 June 2020.

b. Pay for delay

In the United States, the first filer of an FDA Abbreviated New Drug Application (ANDA) with a paragraph IV certification (i.e. certifying the patent is invalid or not infringed) is entitled to a 180-day period of generic market exclusivity upon approval of market entry. To reduce the extent to which the new generic entrant cuts into the originator market share, the originator often introduces an ‘authorized generic’ to compete with the newly entering generic. At least one of the pay for delay prosecutions undertaken by the FTC includes an agreement between the originator and the prospective generic entrant that the originator will refrain from introducing an authorized generic, thereby increasing the profitability of the new generic once introduced (i.e. during the 180-day exclusivity).

BOX 3.B.9: FTC actions against Par Pharmaceutical and Concordia Pharmaceuticals.

“The FTC complaint charged that Par and Concordia entered an unlawful agreement that Concordia would refrain from launching an “authorized generic” version of its brand-name medicine Kapvay in exchange for a share of the supra-competitive profits Par would earn as the sole seller of generic Kapvay. Kapvay is a non-stimulant medication for the treatment of attention deficit hyperactivity disorder. According to the complaint, a brand-name manufacturer is permitted to market a generic version of its branded product during the first filer’s exclusivity period. Such generics are commonly known as ‘authorized generics.’ Brand-name companies introduce authorized generics upon entry of the first generic to maintain some of the revenue it would otherwise lose to the generic competitor. By agreeing not to compete, the complaint charged that Par and Concordia, the only two firms permitted to market a generic Kapvay at the time, deprived consumers of the lower prices that occur with generic competition.

According to the complaint, Par filed an application seeking FDA approval to sell a generic version of Kapvay in March 2011. Concordia acquired the rights to Kapvay in May 2013. Par and Concordia entered into a ‘License Agreement’ approximately five weeks before the Kapvay patent’s October 2013 expiration date. Under the agreement, the complaint alleged that Concordia agreed not to market an authorized generic version of Kapvay for five years. Par in turn agreed to pay Concordia at least 35 percent (and as much as 50 percent) of the net profits from the sale of Par’s generic Kapvay product. The parties provided no evidence that Concordia held any rights that might have prevented Par from selling generic Kapvay after expiration of the patent.

The orders settling charges prohibit Par and Concordia from (1) enforcing the relevant provisions of their 2013 License Agreement and (2) entering into similar ‘no authorized generic’ agreements in the future. Specifically, the Par order prohibits Par from seeking to enforce any provision in its 2013 License Agreement with Concordia that restricts Concordia’s ability to market an authorized generic Kapvay product. In addition, Par may not enter into any agreement that (1) limits a brand-name drug manufacturer’s ability to market an authorized generic version of a drug product for which Par is seeking FDA approval to sell a generic counterpart; and (2) the limitation extends beyond the expiration of any Orange-Book listed patents for the medicine in question. The Concordia order requires Concordia to relinquish all rights to payment under the License Agreement. It also bars Concordia from entering any agreement with a generic applicant for a reference-listed medicine for which Concordia holds the NDA, if the agreement (1) limits marketing of an authorized generic version of that drug and (2) the limitation extends beyond the expiration of any Orange-Book-listed patents.”

Source: Federal Trade Commission, Par Pharmaceutical, Inc./ Concordia Pharmaceuticals Inc., FTC File no. 1510030 (final order issued 20 October 2015), ‘FTC Actions 2019 Overview’, Washington, DC, 2019. Available at <https://www.ftc.gov/enforcement/cases-proceedings/151-0030/concordia-healthcare-par-pharmaceutical>.

c. Enforcement actions regarding abuse of dominant position/monopolization

The previous section provided examples of competition law enforcement actions involving allegations of unlawful collusion among producers of pharmaceuticals and other health technologies. These are unlawful ‘agreements between undertakings’ or ‘contracts in restraint of trade’. This section includes examples of competition law actions in the pharmaceutical and health sectors involving ‘abuse of dominant position’ or ‘monopolization or attempted monopolization’ from various national and regional jurisdictions.

1. Brazil

a. Civil society complaint against Gilead

BOX 3.C.1: Complaint to the Brazilian NCA denounces abuse on hepatitis C medicine pricing

Nine civil society organizations, including Médecins Sans Frontières/Doctors Without Borders (MSF) and the Brazilian Institute of Consumer Protection (Idec), together with the Federal Public Defender’s Office, filed a complaint to the Brazilian NCA (CADE) on 21 October 2019, against the pharmaceutical company Gilead for the abuse of its dominant position in relation to the drug sofosbuvir. The action is groundbreaking, as it is the first one based on excessive prices of medicines and the first proposed by patient and consumer groups in CADE’s history. According to the organizations, abusive prices charged for medicines that include sofosbuvir in their composition have prevented thousands of people from accessing effective hepatitis C treatment.

The entities call on CADE to fine Gilead and to impose, through an injunction, the compulsory licensing of sofosbuvir. The measure would suspend Gilead’s patent and allow the production and commercialization of the medicine by other companies, increasing competition and thereby expanding access to the cure for hundreds of thousands of people suffering from the disease in Brazil. The Ministry of Health estimates that about 700,000 people need hepatitis C treatment in the country, but by June 2019, only 102,000 patients had been treated with the newest and most effective medicines, including sofosbuvir. Type C is the most prevalent and lethal kind of hepatitis in Brazil.

The complaint submitted to CADE is based on a study conducted by researchers of the Law and Poverty Group of the University of São Paulo, and coordinated by professors Calixto Salomão Filho and Carlos Portugal Gouvêa. The study concluded that since the launch of the medicine in Brazil, in 2015, Gilead has been systematically abusing its dominant market position, with severe economic and social consequences.

Between 2015 and 2018, the study points to a “*de facto* monopoly” period when Gilead supplied 99.96 percent of the sofosbuvir sold in the country. During this period, the average price charged ranged from BRL179.41 (US\$45) to BRL639.29 (US\$160) per pill of medicines containing sofosbuvir, resulting in a revenue of BRL1.4 billion (US\$350 million) for purchases made by the Brazilian Government alone.

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BOX 3.C.1 ...continued

In the same period, however, treatment was rationed because of high prices, preventing a huge contingent of people from being treated and cured.

Between 2015 and 2017, there were almost 6,000 deaths from hepatitis C in the country. Between July 2018 and January 2019, the researchers point to a brief period of competition, during which the amount charged by Gilead fell by 89.9 percent, to BRL64.84 (US\$16). After the patent was granted up until 22 June 2019 (the end of the period analysed by the study), the average price rose to BRL986.57, an increase of 1,421.5 percent per pill of medicines containing sofosbuvir. This is considered a period of a formal monopoly, in which “arbitrary price increases” were observed.

The text of the complaint explains that “the unlawful conduct carried out by Gilead is serious and clearly affects the public interest ... There are hundreds of thousands of people with poor access to treatment or totally deprived of it, disrespecting the principle of universal access.”

Source: Make Medicines Affordable, 23 October 2019; and CADE, ‘CADE supplemental note: Preparatory Procedure no. 08700.005149/2019-18 was opened by CADE’s General Superintendence in 2019/10/22 to investigate this complaint’, Brasilia, 2019.

b. Sham litigation

BOX 3.C.2: CADE—Eli Lilly fined BRL36.6 million

At its public hearing on 24 June 2015, CADE named the companies Eli Lilly do Brasil Ltda. and Eli Lilly & Co. as engaging in the practice known internationally as sham litigation (Administrative Proceeding no. 08012.011508/2007-91) and imposed a fine of BRL36.6 million.

By means of contradictory and misleading lawsuits filed in the Federal Courts of Rio de Janeiro, the Federal District and São Paulo, the company gained the exclusive rights to trade the medicine Gemzar, of which its active principle is gemcitabine hydrochloride, used in cancer treatment.

By analysing the judicial actions filed by Eli Lilly, CADE concluded that the company omitted a series of relevant information about the change of scope in the patent request, which was initially related exclusively to the active principle production process. The company also omitted information from the administrative process in the National Institute of Industrial Property.

In this sense, the company obtained a temporary monopoly for the medicine in July 2007, when the Regional Federal Court of the First Region ruled that the National Health Surveillance Agency (ANVISA) should not authorize other competitors to sell medicines similar to Gemzar for breast cancer treatment. The monopolistic protection remained in effect until March 2008, when the Superior Court of Justice understood that upholding the interlocutory injunction would cause serious harm to public health and the economy.

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BOX 3.C.2 ...continued

“The respondent practised sham litigation by filing a lawsuit against ANVISA in order to obtain the exclusive rights over the sales of Gemzar, being aware that the patent request was exclusively related to its production process. The company also did not inform the judge of the Federal District that the amendment to the original request had been denied in the lawsuit filed in Rio de Janeiro,” explained the Reporting Commissioner, Ana Frazão.

CADE also concluded that Eli Lilly infringed competition law by trying to unfairly extend the effects of the right of exclusivity to other therapeutic purposes not covered by the decision of the Regional Federal Court of the First Region, which was restricted to breast cancer treatment.

According to CADE’s Tribunal, by obtaining an undue monopoly of gemcitabine hydrochloride based on a judicial decision that was favourable due to strategies that involved the omission of relevant data, Eli Lilly’s conduct produced serious damages to competition.

From July 2007 to March 2008, the period in which the company held the monopoly for the active principle, its competitors were kept out of the market. Furthermore, for three months within that period, Sandoz was also forbidden to sell the Gemcit medicine, used for the treatment of any type of cancer, even though Eli Lilly’s monopoly was only related to the marketing of medicines used to treat breast cancer.

During the monopoly, Eli Lilly abused its dominant position. In a bid promoted within the period, in which Sandoz was forbidden to trade the Gemcit medicine, the charged price for Gemzar was BRL540. After the preliminary injunction that prohibited other competitors from selling the product was revoked, the price fell to BRL189.

Source: CADE, ‘Condemnation’, Brasillia, 25 June 2015.

BOX 3.C.3: CADE’s General Superintendence concludes investigation in the antidepressants market

CADE’s General Superintendence recommended an Administrative Proceeding (PA 08012.006377/2010-25) to investigate alleged anti-competitive conduct perpetrated by the Lundbeck group of companies in the market for antidepressants with escitalopram as the active ingredient.

The investigation was initiated based on a complaint filed by the Brazilian Association of Generic Medicine Industry (Pró-Genéricos). According to the association, Lundbeck is the leader in the national antidepressant market because of the sales of its medicine Lexapro (which has escitalopram as the active ingredient) and is applying efforts to artificially maintain its market exclusivity.

According to Pró-Genéricos, Lundbeck was taking a series of abusive judicial and extrajudicial actions against health and regulatory authorities, and against competing companies, distorting

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facts and misleading judges—a practice known as sham litigation. The main point of the complaint was Lundbeck’s judicial questioning of the procedures adopted by the Brazilian Health Regulatory Agency (ANVISA) regarding the grant of generic licences.

Analysis

After analysis of the judicial and extrajudicial actions taken by Lundbeck, the General Superintendence concluded that the elements verified were not sufficient to sustain a violation, according to parameters considered in the agency’s jurisprudence. The opinion pointed out, though, that the debate surrounding the proper protection of the data package covers divergent positions, which were broadly shown in the proceedings, and it is not CADE’s role to decide which thesis should prevail.

According to the General Superintendence, even the eventual disagreement on the thesis defended by Lundbeck (due to possible anti-competitive effects if the thesis prevailed) was not enough to categorize the conduct as sham litigation. As stated by Technical Note 16/2018, it was not possible to claim that the defendant made use of documents purposely unfounded, hid relevant information or showed contradictory positions that could mislead the judiciary authority. Neither could it be said with certainty that Lundbeck planned a series of anti-competitive actions with a low probability of favourable outcome and causing collateral damages.

Given this scenario, the General Superintendence submitted the process to CADE’s Administrative Tribunal, which is responsible for issuing the final decision about the case, recommending that the case be closed. The Administrative Tribunal subsequently closed the case.

Debate

The General Superintendence understood that the lack of antitrust violation does not prevent debate about the expiry date for data package protection, which has important competitive implications. However, it is the role of the judiciary system, and not CADE’s role, to deliberate on the merits of the issue.

According to the company, the fact that manufacturers of generic/similar medicines use the data package related to the reference medicine manufactured by Lundbeck to obtain health registration, without a previous licence, can be seen as unfair competition. In its opinion, either the laboratories create their own data package, or they should license Lundbeck’s for a period.

The General Superintendence recommended that, when deliberating on the matter, the judiciary should take into account that broader protection for the data package can be harmful to both competition and to the policies regarding generic medicines in the country.

Source: CADE, ‘Assessoria de comunicação’, Brasília, 27 April 2018 (updated June 2020).

2. Chile

a. Sham litigation

On 10 November 2016, the Tribunal de Defensa de la Libre Competencia (TDLC) approved the conciliatory agreement between the Chilean competition authority (FNE) and GD Searle LLC that encourages the participation of competitors in the market of medicines containing Celecoxib.

BOX 3.C.4: TDLC approves conciliatory agreement between FNE and GD Searle LLC

On 8 June 2016, the FNE accused GD Searle, a company linked to Pfizer Inc., of abusing its dominant position by executing a series of anti-competitive acts aimed at using an instrumental patent right, for the purpose of delaying, restricting and hindering the entry of competitors into the market for the marketing of medicines containing Celecoxib, where it participates with its medicine Celebra®.

The TDLC approved the conciliatory agreement signed with GD Searle, which obliges it to: (i) grant a free, non-exclusive, irrevocable and sub-licensable licence to any current or potential competitor within the territory of the Republic of Chile, for the elaboration, commercialization, distribution, use, offer of sale, sale or import for these purposes of, at least, the product, use and procedure object of the patent No. 49,960 (Secondary Patent) containing the active substance Celecoxib, without the possibility of revocation; as well as to (ii) inhibit themselves from carrying out promotional activities with medical professionals regarding their pharmaceutical products called 'secondary brands' of Celecoxib, such as Valdyne® and Capsure®, for a period of two years.

On the other hand, in relation to the actions against competitors denounced by the FNE in its requirement, GD Searle must: (i) be inhibited from taking any future administrative or judicial action on the occasion of the exercise of its industrial property rights related to the Secondary Patent; (ii) withdraw from the lawsuit filed against Synthon Chile Ltda. for unfair competition and patent infringement; and (iii) take all measures to terminate the contract with Laboratorios Saval SA, which authorized it to market medicines containing Celecoxib, in exchange for a royalty.

Likewise, GD Searle undertakes to communicate the content of the conciliatory agreement and its most relevant aspects, through publications in national newspapers, among others.

The TDLC said that GD Searle is subject to a series of benefits that tend to foster competition, since "it makes it easier for other laboratories to enter the market without the risk of being sued by Searle or their licences being revoked". In addition, it indicates that the commitments assumed "represent an improvement with respect to the conditions of competition in the market existing at the time the requirement was filed".

Within the framework of this process, the FNE had the specialist advice of a leading international expert in the field of free competition and intellectual property, who gave a favourable opinion on the terms of the agreement and the importance of the precedent that

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BOX 3.C.4 ...continued

was generated for the industry when signalling to the owners of industrial property rights that the exercise of the same must conform to free competition.

The National Economic Prosecutor, Felipe Irarrázabal, said that “this case allowed us to generate a discussion about respect for the right to free competition in the framework of the exercise of intellectual property rights. Thus, this agreement constitutes an important precedent that enables laboratories to participate in this market with bioequivalent medicines, through a free and irrevocable licence, without the risk of being sued, which generates immediate conditions for their entry, benefiting consumers.”

Source: FNE, ‘Press release’, Santiago, 11 November 2016 (translated).

b. Horizontal agreements between undertakings

On 8 November 2018, the TDLC⁷⁰ accepted the FNE’s claim and decided against Laboratorios Biosano, Sanderson and Fresenius Kabi Chile, declaring that they executed and entered into a unique agreement that was intended to affect the results of public bidding processes called by the National Supply Centre of the National System of Health Services (CENABAST) for the acquisition of medicines (generic injectables distributed in small volume containers) from 1999 until at least 2013. Afterwards, the Supreme Court confirmed partially the TDLC’s decision.⁷¹ The Court imposed on the laboratories the fines requested by the National Economic Prosecutor’s Office in its request, condemning the Sanderson laboratory to pay US\$13.5 million and Fresenius Kabi Chile to pay US\$1.5 million, lowering the amounts initially imposed by the TDLC. In addition, it ratified the exemption for Laboratorios Biosano, which used the leniency programme.

70 See https://www.tdlc.cl/nuevo_tdlc/tdlc-acoge-requerimiento-de-fne-en-causa-cn-312_16-respecto-de-laboratorios-biosano-s-a-sanderson-s-a-y-fresenius-kabi-chile-limitada/.

71 Fiscalía Nacional Económica, ‘Corte Suprema condena a laboratorios Sanderson y Fresenius por colusión en licitaciones públicas de medicamentos con multa total de US\$ 15 millones’, Blog article, 27 January 2020. Available at <https://www.fne.gob.cl/corte-suprema-condena-a-laboratorios-sanderson-y-fresenius-por-colusion-en-licitaciones-publicas-de-medicamentos-con-multa-total-de-us-15-millones/>.

3. European Union

This section includes examples of competition enforcement actions by the European Commission, European NCAs and European civil society involving three types of abuse of dominant position in the pharmaceutical sector: (a) pay for delay; (b) disparagement and other practices curbing demand; and (c) excessive pricing.

a. Pay for delay

See Section B.3.A above, **Generics (UK) v. CMA**.

b. Disparagement

BOX 3.C.5: European Commission 2019 Enforcement Report on disparagement practices

In the *Plavix* decision (Judgment of the Cour d'appel de Paris of 18 December 2014) from May 2013, the French NCA considered that Sanofi-Aventis had abused its dominant position on the French market for clopidogrel (the active ingredient of its leading medicine Plavix, used to prevent cardiac diseases). Sanofi-Aventis had a comprehensive communication strategy aimed at misleading physicians and pharmacists into stopping the mechanisms of generic substitution. The company's disparagement strategy promoted its products (both Plavix as the originator medicine and Clopidogrel Winthrop, Sanofi's own generic version of Plavix) and limited the market entry of competing generic medicines. In particular, the NCA found that Sanofi's sales representatives misled doctors and pharmacists about the quality and safety of competing generics, and tried to dissuade them from substituting generic versions of Plavix except with Sanofi's own generic, Clopidogrel Winthrop.

The French NCA imposed a fine of EUR40.6 million on Sanofi. The NCA's decision was confirmed by the Paris Court of Appeal (Judgment of the Cour d'appel de Paris of 18 December 2014) and the Supreme Court (Judgment of the Cour de cassation, 18 October 2016).

Much like pay for delay agreements, disparagement practices are often only a part of a broader strategy aimed at hindering generic competition. In December 2013, the French NCA fined the company Schering-Plough EUR15.3 million for having abusively hindered the entry of generic versions of buprenorphine (an opioid used for treating addiction and sold by Schering-Plough as Subutex). This consisted of (i) awarding dispensing chemists commercial advantages (particularly discounts) inducing brand loyalty, and (ii) disparaging the generic competitors. For example, Schering-Plough organized seminars and telephone meetings and briefed its sales teams and pharmaceutical representatives so that they could spread alarmist messages among doctors and pharmacists on the risks of prescribing or issuing Arrow Generique's generic product. This was despite Schering-Plough not having any specific medical studies at its disposal which could have justified its arguments. The NCA also imposed a fine of EUR414,000 on Schering-Plough's parent company, Merck & Co., for entering into an agreement aimed at implementing the abusive strategy with its supplier Reckitt Benckiser, which in turn was fined EUR318,000. The French NCA's decision was confirmed by the Paris Court of Appeal and the Supreme Court.

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BOX 3.C.5 ...continued

Another example of enforcement against disparagement practices is the Durogesic case which was also decided upon by the French NCA.

Also included in the European Commission 2019 Enforcement Report:

“The French Durogesic Case: Following a complaint by the company Ratiopharm France (Teva Santé), the French NCA adopted a decision imposing a fine of EUR 25 million on Janssen-Cilag and its parent company Johnson & Johnson for delaying the arrival to the market of a generic version of Durogesic and then blocking the market growth. Durogesic is a powerful opioid analgesic, with the active ingredient fentanyl. Janssen-Cilag was deemed to have been involved in two anti-competitive practices: Repeated unjustified approaches to the French agency for medical safety of health products, aiming to convince the authority to refuse to grant, at national level, generic status to competing medicine, even if this status was already obtained at EU level, and a major campaign disparaging the generic versions of Durogesic among office- and hospital-based health care professionals (doctors, pharmacists). Janssen-Cilag used misleading language to create doubts concerning the effectiveness and safety of these generics. This involved sending out numerous newsletters to medical practitioners, making statements in the press as well as Janssen-Cilag training a specialist team of 300 sales representatives called ‘*commandos*’. They were told to emphasize that generic alternatives have neither the same composition, nor the same quantity of the active ingredient fentanyl as its Durogesic patch, and could entail risks of adverse effects or recurrence of pain for certain patients. These practices delayed the market entry of generic medicines by several months and discredited the generic versions of Durogesic. The strategy implemented by Janssen-Cilag had large-scale effects targeting all the health care professionals likely to prescribe or dispense Durogesic. The NCA’s decision is currently under review by the Paris Court of Appeal.”

Source: European Commission 2019 Enforcement Report.

c. Excessive pricing

The competition law doctrine of excessive pricing is important in the pharmaceutical context in part because of the specific characteristics of the sector. Much of competition or antitrust law doctrine is directed towards identifying contractual or other restraints that impair competition between enterprises, or abuses of monopoly or dominant position to foreclose competitors from entering or staying in a market. A general premise of competition law is that by eliminating the artificial restraints that impair competition, or by precluding the abusive exercise of market power, the markets will reach or return to an equilibrium that will restore competitive pricing. That in turn will provide consumers with the benefit of lower prices and improved access to products.

As part of that doctrinal thesis, it is accepted that high prices may be evidence of underlying anti-competitive practices, and that by following the trail of high prices, competition authorities may identify abusive market restrictions.

However, there are situations in which removing horizontal restraints (e.g. price fixing) between suppliers or eliminating an abusive practice by a dominant actor (e.g. an exclusive dealing arrangement) may not provide the relief needed by consumers. For this reason, most competition laws and/or judicial interpretations permit actions against ‘excessive prices’ as such, without the requirement for demonstration of an underlying abusive market restraint. This is particularly important for the pharmaceutical sector, where suppliers may hold exclusive rights to put health technologies on the market either through patents or regulatory market exclusivity, and where those exclusive rights may have been lawfully obtained. Moreover, often (though not exclusively) because of complex regulatory environments, producers in generic markets are able to secure exclusive positions as the source of health technologies in the absence of horizontal arrangements with competitors. Here too, excessive prices may be extracted from consumers.

Even as of 2014, when the UNDP Guidebook was published, there were few cases brought by competition authorities alleging excessive pricing as such, where existing doctrine appeared to allow such cases. Since then there have been a number of notable pharmaceutical sector cases prosecuted based on excessive pricing doctrine, and there are important cases pending before the courts, particularly in Europe. As discussed below, in the United States there remains judicial and administrative reticence to employ excessive pricing doctrine, even though there has been some movement in that direction.

In the EU, the legislative underpinning for actions against excessive pricing is set forth in Article 102 of the TFEU, which provides:

Article 102

(ex Article 82 TEC) Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in:

(a) directly or indirectly *imposing unfair purchase or selling prices* or other unfair trading conditions.

This provision has been interpreted by the CJEU on several occasions, notably in the lead case *United Brands v. Commission* decided in 1978.⁷² In its *United Brands* decision the CJEU

72 Case 27/76, *United Brands Co. & United Brands Cont'l B.V. v. Commission of the European Community*, 1978 E.C.R. I-207.

established a two-step analytic approach to determining whether prices are excessive. First, the competition authority (or private litigant) must demonstrate that the price charged by the accused party is excessive—usually by determining the cost of production of the relevant product and comparing it to the price charged, and asking whether there is a reasonable relationship based on the economic value of the product. In the second step, the competition authority must demonstrate either that the price is ‘unfair in itself’ or that the price is unfair when compared with comparable products on other markets. Under CJEU jurisprudence, a price may be excessive, yet not unfair.

In its 2017 decision in the *Latvian Copyright* case,⁷³ the CJEU affirmed that it is acceptable to use methodologies other than cost-price comparison to assess the first step, since there may be circumstances, as in this copyright case, where the cost of the product (e.g. songwriting) is difficult to establish. In looking at cross-market comparisons of price under the second step, the CJEU declined to establish a minimum threshold for differences between markets as evidence of unfairness, saying that this should be done on a case-by-case basis.

Doctrine in this area as it applies to the pharmaceutical sector is evolving as competition authorities and courts appear to recognize that the characteristics of the pharmaceutical sector may raise obstacles to other approaches to prosecution. It should not be surprising that the industry is resisting this at every turn.

73 Autortiesību un komunikēšanās konsultāciju aģentūra/Latvijas Autoru apvienība v. Konkurences padome, CJEU, Case C-177/16, 14 September 2017.

BOX 3.C.6: Aspen Italia et al. v. Italian Competition and Market Authority—the Aspen case

In September 2016, the Italian NCA imposed a EUR5.2 million fine on the pharmaceutical company Aspen Pharmacare Holdings Limited (Aspen) for abusing its dominant position by setting unfair prices for important medicines in Italy (Decision of the Autorità Garante della Concorrenza e del Mercato of 29 September 2016). These off-patent medicines included Leukeran, Alkeran, Purinethol and Tioguanine, which were used to treat cancer. They had been included in a wider package of pharmaceutical products, for which Aspen purchased the marketing rights from the originator GlaxoSmithKline in 2009. The NCA found that Aspen abused its dominant position in Italy by imposing price increases of between 300 percent and 1,500 percent and by applying aggressive tactics towards the Italian Medicines Agency in negotiating these prices. Aspen even threatened to “initiate supply termination”—i.e. withdraw the medicines if the Agency did not accept the requested higher prices. Following the acceptance of price increases, Aspen’s consultant concluded: “I wouldn’t [have] expected to conclude the negotiation so favourably, but I remember when you told me in Rome that everywhere at the beginning it seems it was kind of ‘mission impossible’ and then the prices increase were always authorised ... Let’s celebrate!”

The NCA also ordered Aspen to put in place measures aimed at, among other things, setting new fair prices for the medicines concerned. Following the NCA’s order and after protracted negotiations, Aspen reached an agreement on pricing with the Italian Medicines Agency.

On 13 June 2018, the NCA determined that Aspen was compliant with its order and estimated that the concluded agreement would save the Italian National Health Service EUR8 million annually. The NCA decision was upheld by the Administrative Regional Court (Judgment of the Tribunale Amministrativo Regionale per il Lazio of 26 July 2017).

Update.

On 13 March 2020, the Council of State of Italy rendered its judgment on an appeal by Aspen pharmaceuticals against the decision by the Italian NCA.⁷⁴ The NCA had determined that Aspen abused its dominant position for certain generic anticancer medicines (the ‘Cosmos’ medicines) on the Italian market by threatening to cease supplying those medicines unless it was awarded a very significant price increase. The effect of the threatened withdrawal would have been to seriously impair access to life-saving treatments among particularly vulnerable parts of the Italian population. As a consequence, Aspen was authorized to raise prices to an ‘excessive’ level, but faced the action by the NCA as a consequence.

The Council of State affirmed the decision of the NCA to limit the relevant market to the specific medicines marketed by Aspen because there was no reasonable alternative treatment available for patients, and no prospect of market entry by competitors within a reasonable period. The Council of State also affirmed the cost benchmarking methodology used by the NCA under the first step of the United Brands test, as well as the right of the NCA to find the prices unfair in themselves given the lack of appropriate comparators in other European markets. The decision by the Council of State is meticulous and clear; the fine against Aspen sustained.

Source: European Commission 2019 Enforcement Report.

74 Aspen Italia et al. v. Italian Competition and Market Authority, Council of State (Italy), Section Six, N. 01832/2020 REG. PROV. COLL., N. 08447/2017 REG.RIC., 13/03/2020.

BOX 3.C.7: The Netherlands: The Pharmaceutical Accountability Foundation requests the Authority for Consumers and Markets to take action against medicines manufacturer Leadiant for abuse of its dominant market position

On 7 September 2018, the Dutch Pharmaceutical Accountability Foundation (Stichting Farma ter Verantwoording) submitted an enforcement request to the Authority for Consumers and Markets (ACM) asking it to take action against the manufacturer Leadiant Biosciences on account of the high price the company was asking for the medicine chenodeoxycholic acid (CDCA).

Leadiant was charging EUR140 per capsule in the Netherlands. This is equivalent to EUR 153,300 per treatment-year for each person using the medicine to treat the rare metabolic illness cerebrotendinous xanthomatosis (CTX). CDCA is inexpensive to produce and, from 1976 until as recently as 2008, it was available on the market in the Netherlands at the cost of EUR0.28 per capsule for the treatment of gallstones. Since 1999, the medicine had been prescribed off-label for the treatment of CTX at a cost of EUR308 per treatment-year. In 2017, Leadiant was granted exclusive rights to market the medicine in Europe for the treatment of CTX after the European Medicines Agency (EMA) approved Leadiant's CDCA for marketing and granted the medicine an orphan drug designation.

“By increasing the price by a factor of 500 for a medicine which has required only limited research by Leadiant, the company is abusing its dominant position in the market,” said Wilbert Bannenberg, Chairperson of the Pharmaceutical Accountability Foundation. “Our research shows that Leadiant has done everything it can to ensure that less expensive versions of the medicine produced by competitors have been taken off the European market. In this way, CTX patients have been made dependent on the availability of the overpriced Leadiant product.”

In its request for action, the Foundation stated that Leadiant's actions were in violation of Dutch competition law. The Foundation argued that Leadiant had pursued the strategy of developing a market monopoly position by obtaining the marketing rights to alternative CDCA medicines and cancelling existing CDCA registrations. By doing this, Leadiant had created the opportunity to increase enormously the price of the only effective medicine for the treatment of CTX. As a result of the company's actions and subsequent price hike, anyone purchasing the medicine will be exploited and the Dutch health care system will lose significant amounts of money. The Foundation asked the ACM to take measures and impose a fine on Leadiant citing article 24 of the Dutch Competition Law or to take other measures to control the actions of Leadiant.

Note that in October 2019, a similar investigation was launched in Italy. See AGCM, 'A524 – ICA: investigation launched into Leadiant medicine for the treatment of xanthomatosis', press release, Rome, 15 October 2019. Available at <https://en.agcm.it/en/media/press-releases/2019/10/A524>.

Source: Stichting Farma ter Verantwoording, 'press release', 7 September 2018.

continued...

Update

On 19 July 2021, it was announced that the ACM had imposed a fine on Leadiant for CDCA's excessive price. The ACM established that Leadiant had abused its dominant position and, therefore imposed a fine of EUR19,569,500.

The ACM's conclusions following the investigation were that, in the period from June 2017 through December 2019, Leadiant enjoyed a dominant position in the Netherlands for CDCA-based medicines for the treatment of CTX. During that period, there were no available alternatives to CDCA; therefore, CTX patients were dependent on it, and health insurers were required to continue funding the medicine. Leadiant charged and collected an excessive price for CDCA. According to the ACM, the price that Leadiant charged was too high and unfair. It was exorbitantly high because the price in combination with the low costs and the low risks resulted in an exorbitant return for Leadiant. And it was unfair because the medicine, under a different trade name, had already been on the market for years at a much lower price, while patients benefited very little from the registration as an orphan drug.

According to Leadiant, the company wanted to agree on a lower price in negotiations with health insurers and the Dutch Ministry of Health, Welfare and Sport. According to the ACM, however, Leadiant had a special responsibility, considering its dominant position, to negotiate actively and effectively with the aim of achieving an outcome at a price that is not excessive. The ACM is of the opinion that Leadiant did too little in this respect. By charging and collecting an excessive price, Leadiant abused its dominant position and violated competition rules.

Source: Netherlands Authority for Consumers and Markets, 'Publications', 19 July 2021.

BOX 3.C.8: CMA welcomes Court of Appeal judgment in Phenytoin case (UK)

In December 2016, following a thorough investigation, the UK CMA found that Pfizer and Flynn had breached competition law by charging unfairly high prices for phenytoin sodium capsules, an important anti-epilepsy medicine. The CMA had intervened to protect patients, the NHS and the taxpayers who fund it, because Pfizer and Flynn had imposed, overnight, a very large increase in the price of the phenytoin capsules in September 2012 despite there being no material change in the underlying costs.

A 2020 judgment from the Court of Appeal followed an earlier decision from the Competition Appeal Tribunal (CAT) in 2018, which the CMA appealed. Although the Court of Appeal did not uphold all aspects of the CMA's appeal, it dismissed Flynn's case in its entirety. Importantly, the Court of Appeal found that the CAT had made a number of fundamental legal errors in its 2018 judgment. The CAT was found to have misapplied seminal EU case law. Specifically, the CAT was wrong to require the CMA to go beyond a cost plus calculation in order to determine whether the prices charged by Pfizer and Flynn were excessive. In his judgment, the Rt Hon Sir Geoffrey Vos said of the CAT's decision: "It was quite easy to lose sight of a stark reality, which was that, literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between approximately 7 and 27, when they were in a dominant position in each of their markets."

In its 2016 decision, the CMA found Pfizer and Flynn's conduct to be a particularly serious breach of the law and imposed fines totalling GBP90 million. NHS expenditure on phenytoin sodium capsules rose from about GBP2 million a year in 2012 to about GBP50 million in 2013, with, for example, the price of 100-milligram packs of the medicine rising from GBP2.83 to GBP67.50. The prices charged in the UK were also many times higher than Pfizer's prices for the same medicine in every other European country it sold capsules in, and several Clinical Commissioning Groups complained about the impact on the services they would be able to offer patients. The significance of this case is further demonstrated by the European Commission's rare decision to intervene in a national proceeding.

The CMA's Chief Executive Andrea Coscelli said:

"Today's judgment is a good result. The CMA was right to appeal the CAT's judgment. We will now get on with the elements of the case against Pfizer and Flynn Pharma that the court has decided to refer back to us. The CMA also continues to have serious concerns about the very big price increases imposed by certain drug companies for several other generic drugs, which have cost the NHS hundreds of millions of pounds. The CMA remains committed to its work to robustly tackle any illegal behaviour by drug companies ripping off the NHS."

Source: Competition and Markets Authority, 'CMA welcomes Court of Appeal judgment in Phenytoin case', press release, London, 10 March 2020. United Kingdom (initiated while an EU Member State): Competition and Markets Authority v. Flynn and Pfizer. In the Court of Appeal (Civil Division), Case No: C3/2018/1847 & 1874, Neutral Citation Number: [2020] EWCA Civ 339, 10 March 2020.

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Update

On 5 August 2021, it was announced that the CMA had accused pharmaceutical companies of illegal pricing. The CMA provisionally found that Pfizer and Flynn abused their dominant positions to overcharge the NHS for vital anti-epilepsy medicines, after reassessing the case. It said: “Having gathered further evidence and after carefully assessing the facts, the Competition and Markets Authority (CMA) has reached a provisional view – known as a Statement of Objections – that Pfizer and Flynn broke competition law by charging unfairly high prices for phenytoin sodium capsules.”

The CMA provisionally found that the companies exploited a loophole by de-branding the medicine—known as Epanutin prior to September 2012—with the effect that it was not subject to price regulation in the way branded medicines are. As Pfizer and Flynn were the dominant suppliers of this vital medicine in the UK, the NHS had no choice but to pay unfairly high prices for it.

Following the overnight price increases by the companies, NHS spending on phenytoin sodium capsules rose from around GBP2 million a year in 2012 to about GBP50 million in 2013. For over four years, Pfizer’s prices were between 780 percent and 1,600 percent higher than it had previously charged. Pfizer then supplied the product to Flynn, which sold it to wholesalers and pharmacies at prices between 2,300 percent and 2,600 percent higher than those they had paid previously.

Source: Competition and Markets Authority. ‘CMA accuses pharma firms of illegal pricing’, press release, 5 August 2021.

Additional action by the CMA

On 15 July 2021, it was announced that the CMA found that pharmaceutical companies had overcharged the NHS and that the CMA had imposed fines totalling over GBP260 million for competition law breaches in relation to the supply of hydrocortisone tablets. It found that prices of life-saving hydrocortisone tablets rose by over 10,000 percent and that pharma firms bought off potential rivals to avoid them competing with their own versions of the medicine and preserve their ability to increase prices.

The fines were the result of a CMA investigation into the conduct of several pharmaceutical firms which found that Auden Mckenzie and Actavis UK (now known as Accord-UK) charged the NHS excessively high prices for hydrocortisone tablets for almost a decade.

Source: Competition and Markets Authority. ‘CMA finds drug companies overcharged NHS’, press release, 15 July 2021.

On 29 July 2021, it was announced that the CMA had imposed over GBP100 million in fines after Advanz inflated the price of thyroid tablets, causing the NHS and patients to lose out. The CMA found that Advanz increased the price of thyroid tablet packs from GBP20 in 2009 to GBP248 in 2017—an increase of 1,110 percent—and stated that the latest CMA fine “sends

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BOX 3.C.8 ...continued

a clear message” to the pharma sector that breaking the law will not be tolerated. Following an investigation, the CMA found that from 2009 until 2017 the pharmaceutical company Advanz charged excessive and unfair prices for supplying liothyronine tablets which are used to treat thyroid hormone deficiency.

Source: Competition and Markets Authority. ‘CMA fines pharma firm over pricing of crucial thyroid drug’, press release, 29 July 2021.

The UK Court of Appeal in *CMA v. Pfizer/Flynn* decisively rejected the suggestion by the CAT that the competition authority is obliged to satisfy both elements of the second step of the United Brands test (unfair in itself, or unfair in comparison to comparable products on other markets), affirming that multiple methodologies are not required and that the tests are alternative. The Court of Appeal opined that the competition authority should investigate potential defences under one of the alternative elements if substantial relevant facts (not mere pleadings) have been brought forward by the defendant.

BOX 3.C.9: European Commission 2019 Enforcement Report on CD Pharma (Denmark)

By the decision from January 2018 (Decision of the Konkurrence- og Forbrugerstyrelsen of 31 January 2018), the Danish NCA found that CD Pharma (a pharmaceutical distributor) abused its dominant position in Denmark by charging Amgros (a wholesale buyer for public hospitals) unfair prices for Syntocinon. This medicine contains the active ingredient oxytocin, which is given to pregnant women during childbirth. From April to October 2014, CD Pharma increased the price of Syntocinon by 2,000 percent from DKK45 (EUR6) to DKK945 (EUR127). The NCA established that the difference between the costs actually incurred and the price charged by CD Pharma was excessive. In addition, the NCA compared CD Pharma’s price with the economic value of Syntocinon, historical prices for Syntocinon, prices charged by CD Pharma’s competitors and the prices charged outside Denmark. As a result, the NCA found that prices for Syntocinon were unfair and, therefore, CD Pharma had abused its dominant position. On 29 November 2018 (Judgment of the Konkurrenceankenævnet of 29 November 2018), the Danish Competition Appeal Tribunal upheld the decision made by the Danish NCA.

Source: European Commission 2019 Enforcement Report.

4. South Africa

The following information note from the South Africa Competition Commission illustrates that government regulatory procedures may themselves constitute market entry barriers when, for example, they are designed in a way that unjustifiably makes it difficult for generic producers and importers to enter the market. Such governmental regulatory barriers may reinforce the exclusive or dominant position of holders of registrations for health technologies. The note from the Commission suggests that it declined to prosecute private actor conduct because the regulatory framework was a significant factor impeding competition, and instead elected to pursue reform of the regulatory framework in cooperation with the health products regulatory authority (SAPHRA).

BOX 3.C.10: South Africa Competition Commission's interventions in the health technologies sector

- 1 “The Commission investigated the first case in 2018, involving a distributor and parallel importer of a medical device used for the vacuum extraction medical procedure. The Commission found that there is a sole authorized distributor of the medical device in South Africa. There was, however, a parallel importer of the medical device which is not authorized by the manufacturer to distribute the health technology. The regulations require distributors of medical devices to submit a letter of authorization from the manufacturer to the South African Health Products Regulatory Authority (‘SAHPRA’) as part of the application process to obtain a trading licence. SAHPRA is the health technologies (including medicines and medical devices) regulatory authority in South Africa.
- 2 The Commission found that the regulations pertaining to medical devices were only promulgated in 2016 and still in their infancy stage as they were not yet fully implemented by SAHPRA. Distributors of medical devices are thus permitted to operate in the market without a licence until such time that the regulations are fully implemented. The full implementation of the regulations will, however, mean that all importers, manufacturers, distributors and wholesalers will be compelled to apply for a trading licence from SAHPRA to operate in the market.
- 3 The second case was brought by a cancer generic medicine manufacturer to the Commission. The complaint was regarding the requirement that a comparative dissolution study between the generic medicine and the innovator medicine must be conducted before a new generic medicine is registered by SAHPRA. The study is to compare the safety, efficacy and quality of the generic and the innovator medicine. The generic manufacturer must, therefore, have obtained a sample of the medicine from the innovator manufacturer to conduct the study. The innovator medicine manufacturer refused to provide the sample to the generic manufacturer, which raised competition concerns in relation to refusal to supply scarce goods to a competitor when it is feasible to do so according to the Competition Act.
- 4 The regulations and registration process adopted by SAHPRA gave rise to several competition concerns. In the first case, the Commission found that should the regulations

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be fully applied by SAHPRA they would create barriers to entry and exclude current importers of various medical devices. These regulations could also have unintended consequences of creating monopolies in the relevant market to the detriment of consumers. The competition concerns were also not only limited to the specific medical device, as they could arise with other health technologies regulated by SAHPRA. In the second case, it was found that the design of the regulations themselves act as a stumbling block to market entry and innovation, by requiring new entrants to rely on incumbents to enter the market.

- 5 To address these concerns, the Commission decided not to prosecute and conducted advocacy through engagements with SAHPRA in 2019. The advocacy recommendations which SAHPRA committed to take on board included the following:
 - SAHPRA’s mandate must be broadened to consider competition principles when registering and licensing health technologies.
 - SAHPRA’s role must be strengthened to address intellectual property-related issues and consider preferential treatment of small and medium enterprises in the sector to promote market entry.
 - SAHPRA must be capacitated to have the technical expertise to conduct in-house evaluations of the efficacy and safety of health products without having to rely on incumbents to provide information that may allow or hinder the entry of a competitor.
 - A cooperation framework between the Commission and SAHPRA be established to ensure alignment between the competition rules and health products-related policies and regulations.”

Source: Competition Commission South Africa, ‘Information Note’, Pretoria, 30 June 2020.

5. United States

In reviewing the following cases, it is important to note that the US FTC pursues actions both in administrative tribunals at the FTC as well as in the federal courts. Issues concerning jurisdiction in specific cases and at different steps in the process are somewhat complex, particularly as the FTC shares authority to prosecute cases under the Sherman Act with the US Department of Justice—the FTC acting under section 5 of the FTC Act. Responsibility for criminal prosecution for antitrust violations is in the hands of the Department of Justice.

a. Cases

i. Product hopping and abuse of regulatory process

Product hopping is a mechanism through which the owner of a patent or regulatory marketing exclusivity that is scheduled to expire ‘transitions’ physicians and patients to a different health technology that will maintain exclusivity, often through some minor modification with

insubstantial therapeutic benefit compared to the original product. It is one of the mechanisms of ‘evergreening’. Product hopping may involve withdrawing marketing authorization for the original health technologies to force the shift.

In the United States, any interested party may file a ‘citizen petition’ at the FDA intended to provide information that may be important to its consideration of the approval of the commercial marketing of a health technology, and the FDA is obligated to consider the petition.⁷⁵ Because marketing approval is delayed pending review of these petitions, the submission mechanism has been abused through the filing of frivolous petitions intended only to delay the introduction of competitive products.

BOX 3.C.11: FTC action on product hopping and abuse of regulatory process

According to the FTC complaint, Reckitt Benckiser Group (Reckitt), the producer of the opioid addiction treatment Suboxone, violated the antitrust laws through a deceptive scheme to thwart lower-priced generic competition to Suboxone. The complaint charged that before generic versions of Suboxone tablets became available, Reckitt and its former subsidiary Reckitt Benckiser Pharmaceuticals, now known as Indivior, Inc. (Indivior), developed a dissolvable oral film version of Suboxone and worked to shift prescriptions to this patent-protected film. Worried that doctors and patients would not want to switch to Suboxone Film, Reckitt allegedly employed a ‘product hopping’ scheme where the company misrepresented that the film version of Suboxone was safer than Suboxone tablets because children are less likely to be accidentally exposed to the film product. The complaint further charged that to buy more time to move patients to the film version of Suboxone, Reckitt, through Indivior, filed a citizen petition with the FDA reciting the same unsupported safety claims and requesting that the agency reject any generic tablet application, effectively delaying the approval of generic competitors. In 2014, the FTC’s non-public investigation of Reckitt’s conduct was largely put on hold due to a parallel federal criminal investigation for related conduct that ultimately resulted in a 28-count indictment of Indivior by a grand jury in the Western District of Virginia.

The stipulated order for a permanent injunction and equitable monetary relief seeks to bar Reckitt from similar future conduct. If Reckitt introduces a reformulated version of an existing

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75 “A citizen petition is a vehicle that stakeholders outside of FDA can use to ask FDA ‘to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action’ (21 CFR 10.25(a) and 10.30). Under the governing regulations, petitioners can request, for example, that the Agency:

- Disapprove a drug product application;
- Add warnings to the labeling of a drug; and/or
- Change products from prescription to over-the-counter (OTC) status.

FDA regulations also provide for the submission of petitions for ‘stay of action’ to delay the effective date of an administrative action, such as the approval of certain drug applications (21 CFR 10.35).” US Department of Health and Human Services, Food and Drug Administration, ‘Seventh Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2014’, Washington, DC, 2015, p. 3. Available at <https://www.fda.gov/media/93664/download>.

BOX 3.C.11 ...continued

medicine, it must provide the FTC with information about that product and the reasons for its introduction. If generic companies file for FDA approval of competing versions of the branded medicine, the order requires Reckitt to leave the original medicine on the market on reasonable terms for a limited period so that doctors and patients can choose which formulation of the medicine they prefer. The order also requires that if Reckitt files a citizen petition, the company must simultaneously submit any data or information underlying that petition to the FDA and FTC. As part of the order, Reckitt agreed to pay US\$50 million in equitable monetary relief. The FTC settlement is part of a broader government settlement with Reckitt, which resolves criminal and civil fraud claims by the US Attorney's Office for the Western District of Virginia and the Department of Justice.

Source: Federal Trade Commission, Federal Trade Commission v. Reckitt Benckiser Group plc, Case No. 1:19-cv-00028, FTC File No. 1310036 (complaint filed 11 July 2019; stipulated order for permanent injunction and equitable monetary relief entered on 12 July 2019), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc>.

II. Maintaining monopoly/dominant position by purchasing and suppressing potentially competing health technologies

BOX 3.C.12: FTC action on maintaining monopoly by preventing competing health technologies

The FTC complaint alleged that, while benefiting from an existing monopoly over the only US adrenocorticotrophic hormone (ACTH) medicine, H.P. Acthar Gel, Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., illegally acquired the US rights to develop a competing medicine, Synacthen Depot. The acquisition stifled competition by preventing any other company from using the Synacthen assets to develop a synthetic ACTH medicine, preserving Mallinckrodt's monopoly and allowing it to maintain extremely high prices for Acthar. Acthar is a specialty medicine used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, and a medicine of last resort to treat several other serious medical conditions—including nephrotic syndrome, flare-ups of multiple sclerosis, and rheumatoid disorders. Since 2001, Mallinckrodt has raised the price of Acthar from US\$40 per vial to over US\$34,000 per vial—an 85,000 percent increase.

Under the stipulated court order, Mallinckrodt must make a US\$100 million monetary payment to the Commission. Mallinckrodt must also grant a licence to develop Synacthen Depot to treat infantile spasms and nephrotic syndrome to a licensee approved by the Commission.

Source: Federal Trade Commission, Federal Trade Commission, et al. v. Mallinckrodt ARD Inc., et al., Civil Action No. 1:17-cv-00120 (D.D.C.), FTC File No. 1310172 (stipulated order for permanent injunction and equitable monetary relief approved 30 January 2017), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/1310172/mallinckrodt-ard-inc-questcor-pharmaceuticals>.

III. Reverse payments

BOX 3.C.13: FTC action on reverse payments—Endo and Allergan case

The FTC complaint alleged that the defendants had entered into a reverse-payment agreement to eliminate the risk of lower-cost generic competition to Endo Pharmaceutical Inc.'s Lidoderm, a topical patch used to relieve pain associated with a complication of shingles known as post-herpetic neuralgia. Under the agreement, Watson Laboratories, Inc. agreed to forgo entry with a lower-cost generic version of Lidoderm for more than a year. In return, Endo agreed to refrain from competing with an authorized generic for up to the first 7½ months of Watson's generic sales. This no-authorized-generic commitment was worth hundreds of millions of dollars to Watson. Second, Endo agreed to provide Watson with branded Lidoderm patches valued at US\$96 million to US\$240 million at no cost. The complaint also named Allergan plc and Allergan Finance LLC, Watson's parent at the time of the settlement, which led the negotiations of the settlement and directly benefited from the reverse payments.

On 2 February 2017, the Court accepted an agreement between the Commission and Endo, effectively bringing litigation between the two parties to an end. Under the agreement, Endo and its subsidiaries are prohibited from entering into the type of anti-competitive agreements that the Commission had alleged that it had previously used to prevent generic entry. The order allows Endo to enter into supply agreements in connection with patent settlements if the agreements comply with certain requirements. The order authorizes the Commission to appoint a monitor with the authority to evaluate whether these supply agreements comply with the order's requirements.

On 19 February 2019, the Commission reached a global settlement with Watson's parent company, Teva, resolving pending claims in three separate federal court antitrust lawsuits, including the Lidoderm matter. The settlement agreement prohibits Teva from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced generic medicines. The order specifically prohibits Teva from entering into agreements that include reverse payments in the form of: (1) side deals, in which the generic receives compensation through a business transaction entered at the same time as a patent litigation settlement; or (2) a no-authorized-generic commitment, in which a brand company agrees not to compete with an authorized generic version of a medicine for a period of time. The global settlement ends this litigation.

Source: Federal Trade Commission, *Federal Trade Commission v. Allergan PLC, et al.*, Case No. 17-cv-00312 (N.D. Cal.), FTC File No. 1410004 (complaint filed 23 January 2017) (stipulated order for permanent injunction covering Endo defendants entered 2 February 2017; global settlement entered with Teva 19 February 2019), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0004/allergan-plc-watson-laboratories-inc-et-al>.

BOX 3.C.14: FTC action on reverse payments—Impax case

The FTC complaint alleged that Impax had entered into an anti-competitive reverse-payment agreement with Endo Pharmaceuticals Inc. in June 2010 to eliminate the risk of generic competition to Endo's Opana ER, an extended-release opioid indicated for the relief of moderate to severe pain. Under the agreement, Impax agreed to forgo entering the market with its lower-cost generic version of Opana ER for 2½ years until January 2013. In exchange, Endo agreed that it would refrain from offering an authorized generic Opana ER product during Impax's initial 180 days of marketing its own generic. If market conditions were to change to devalue this no-authorized-generic commitment, Endo further agreed to pay Impax a cash amount based on Impax's expected profits for that six-month period of generic exclusivity. Endo also agreed to pay Impax up to US\$40 million for a purportedly independent development and co-promotion deal.

The case went to trial on 24 October 2017, with Chief Administrative Law Judge D. Michael Chappell presiding. On 11 May 2018, Judge Chappell issued the initial decision, which found that Impax accepted a large reverse payment from Endo, but that the agreement was justified.

On 28 March 2019, the Commission unanimously reversed the initial decision. The Commission found that Complaint Counsel established a prima facie case because: (1) Endo possessed market power in the market for branded and generic oxymorphone ER; and (2) Impax received a large and unjustified payment. The Commission further determined that Impax failed to show a cognizable procompetitive rationale for its reverse payment, because it did not prove that the procompetitive benefits it identified were related to the restraint at issue. The Commission found, in the alternative, that a settlement agreement including the allegedly procompetitive terms without the large, unjustified payment provided a viable less restrictive option.

The Commission's final order bars Impax from entering into any type of reverse payment that defers or restricts generic entry, including no-authorized-generic commitments, as well as certain business transactions entered with the branded pharmaceutical manufacturer within 45 days of a patent settlement.

Source: Federal Trade Commission, Impax Laboratories, Inc., D-9373, FTC File No. 1410004 (complaint filed 19 January 2017; final order issued 29 March 2019), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0004/impax-laboratories-inc>.

BOX 3.C.15: FTC action on reverse payments—Endo case

The FTC complaint charged that Endo Pharmaceuticals Inc. entered anti-competitive reverse-payment settlements between 2010 and 2012 on its two bestselling branded health technologies, Opana ER and Lidoderm, and further that Endo used the settlements to unlawfully maintain its monopoly on each medicine. The complaint alleged that, in each case, Endo paid the generic company eligible for first-filer exclusivity and that the generic company agreed not to market its generic for a period of time in exchange for a no-authorized-generic commitment—in which Endo agreed not to sell an authorized generic for at least the first six months of generic sales—and other compensation. Other companies named in the complaint were Impax Laboratories, Inc. (the first generic on most dosages of Opana ER), Watson Laboratories, Inc./Allergan plc (the first generic for Lidoderm) and Teikoku Pharma USA, Inc./Teikoku Seiyaku Co., Ltd. (Endo’s partner for Lidoderm). The complaint also charged that the no-authorized-generic commitment on generic Lidoderm independently violated the antitrust laws and resulted in reduced competition and higher prices for generic Lidoderm. With the complaint, the Commission filed a settlement with the Teikoku entities, in which they agreed not to enter into similar reverse-payment agreements for a period of 20 years. Against the remaining defendants, the Commission sought injunctive and other equitable relief, including equitable monetary relief.

In October 2016, after the Judge severed the Lidoderm and Opana ER claims, the Commission dismissed this action. Subsequently, the Commission settled its claims with Endo by Endo agreeing not to enter into similar reverse-payment settlements for a period of 10 years. The Commission then filed a complaint against Watson/Allergan covering the Lidoderm claims in the Northern District of California (Federal Trade Commission v. Allergan PLC, et al. Case No. 17-cv-00312 (N.D. Cal.), FTC File No. 1410004) and an administrative complaint against Impax covering the Opana ER claims (Impax Laboratories, Inc., D-9373, FTC File No. 1410004).

Source: Federal Trade Commission, Federal Trade Commission v. Endo Pharmaceuticals Inc., et al., Case No. 2:16-cv-01440- PD (E.D. Pa.), FTC File No. 1410004 (complaint seeking a permanent injunction and other equitable relief filed 30 March 2016), ‘FTC Actions 2019 Overview’, Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0004/endo-pharmaceuticals-impax-labs>.

IV. Sham patent litigation

An originator may seek to suppress entry of generic competitors by initiating patent infringement litigation to accomplish that objective based on claims which it knows cannot succeed.

BOX 3.C.16: FTC action on sham patent litigation

The FTC complaint charged several pharmaceutical companies with illegally blocking consumers' access to lower-cost versions of the blockbuster medicine AndroGel, a brand-name testosterone replacement therapy for men with low testosterone. The complaint alleged that the AbbVie Defendants (AbbVie Inc., Unimed Pharmaceuticals, LLC (now a wholly owned subsidiary of AbbVie), Abbott Laboratories) and Besins Healthcare Inc., filed baseless patent infringement lawsuits against potential generic competitors Teva Pharmaceuticals USA, Inc. and Perrigo to unlawfully maintain and extend their monopoly power on AndroGel by delaying the introduction of lower-priced versions of the medicine. Under federal law, these lawsuits triggered an automatic 30-month stay of the FDA's authority to approve the generics' applications to market their testosterone gel, regardless of the merits of the infringement claims. The complaint further alleged that while the lawsuits were pending, the AbbVie Defendants entered into an anti-competitive settlement agreement with Teva to further delay generic competition. According to the complaint, Teva concluded that it would be better off by sharing in the AbbVie Defendants' monopoly profits from the sale of AndroGel than by competing. Thus, Teva settled the baseless infringement lawsuit by entering into an agreement with the AbbVie Defendants to delay launching its alternative to AndroGel. In return, the AbbVie Defendants paid Teva in the form of a highly profitable authorized-generic deal for another medicine, executed on the same day as the AndroGel patent litigation settlement.

In May 2015, the district court dismissed claims that the patent settlement agreement with Teva was an anti-competitive reverse payment.

On 15 September 2017, the district court awarded partial summary judgment to the FTC, ruling that the patent infringement lawsuits filed by the AbbVie Defendants and Besins were objectively baseless. In February 2018, the FTC tried its case to the court on the remaining issues: (1) whether the AbbVie Defendants and Besins used their objectively baseless lawsuits as anti-competitive weapons; (2) whether they had market power; and (3) the appropriate relief, if any.

On 29 June 2018, the court found in the FTC's favour and held that the AbbVie Defendants and Besins violated section 5(a) of the FTC Act. The court held that the FTC established that the Defendants illegally and wilfully maintained their monopoly power through the filing of sham litigation. The sham litigation delayed the entry of generic AndroGel to the detriment of consumers. The court awarded equitable monetary relief to the FTC in the amount of US\$448 million and also awarded US\$46 million in prejudgment interest. The Defendants appealed the district court's ruling to the Third Circuit. The FTC also appealed the district court's dismissal of the reverse-payment claim, as well as certain remedy issues.

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BOX 3.C.16 ...continued

On 19 February 2019, the Commission reached a global settlement with Teva, resolving pending claims in three separate federal court antitrust lawsuits, including the reverse-payment claim against Teva in the AbbVie matter. The settlement agreement prohibits Teva from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced generic medicines. The order specifically prohibits Teva from entering into agreements that include reverse payments in the form of: (1) side deals, in which the generic receives compensation through a business transaction entered into at the same time as a patent litigation settlement; or (2) a no-authorized-generic commitment, in which a brand company agrees not to compete with an authorized generic version of a medicine for a period of time. The FTC's appeal of the dismissal of the reverse-payments claim will continue.

Source: Federal Trade Commission, *Federal Trade Commission v. AbbVie Inc., et al.*, Case No. 2:14-cv-05151-HB, FTC File No. 121-0028 (complaint filed seeking a permanent injunction and other equitable relief on 8 September 2014; global settlement entered with Teva 19 February 2019), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/121-0028/abbvie-inc-et-al>.

In September 2020, the US Court of Appeals for the Third Circuit, in continuing litigation regarding remaining defendants (including AbbVie) in *FTC v. AbbVie*, 976 F. 3d 327 (3rd Cir. 2020), affirmed the determination of the trial court that AbbVie had engaged in sham patent litigation against Perrigo. It further reversed the district court's dismissal of the FTC's reverse-payment claim, remanding the reverse-payment case back to the trial (federal district) court. In the same decision, the Third Circuit rejected the trial court's order that AbbVie and its co-defendant disgorge US\$448 million in illegally gained revenues on grounds that the relevant statutory provision under which the disgorgement was ordered (i.e. Section 13(b) of the FTC Act) does not encompass monetary remedies. The FTC Act includes provisions for securing monetary remedies, but the FTC's cause of action in the instant case was not initiated under those provisions. The US Supreme Court, in a separate case unrelated to the pharmaceutical sector (*AMG Capital Management v. FTC*, 141 S Ct. 1341 [2021]), affirmed that Section 13(b) of the FTC Act does not encompass monetary remedies. These decisions will affect the administrative and court litigation mechanisms employed by the FTC as it moves forward, pending potential amendment of the FTC Act by the US Congress.

v. Regulatory abuse of generic entry process

Purchasers of injectable insulin products brought a civil antitrust complaint against Sanofi in the US federal court, alleging, *inter alia*, that the originator improperly listed a patent in the US FDA Orange Book and then invoked that patent to block entry of competitive injectables (In re: *Lantus Direct Purchaser Antitrust Litigation*, 950 F.3d 1 [1st Cir. 2020]). In particular, Sanofi listed a patent for a component of an injection device that did not claim any specific relationship to the insulin product to which it asserted infringement, giving it the benefit of a

30-month automatic stay against market entry of generics. Overturning the District Court, the Court of Appeals for the First Circuit said that absence of clarity regarding the precise scope of the patents that can or should be listed in the Orange Book was not a defence to blocking actions by Sanofi based on a patent that was not connected to the product for which it sought to defend against generic entry. The First Circuit remanded the case to the District Court for further proceedings, including allowing Sanofi to offer proof that it had a good faith belief that it was listing the patent to comply with FDA rules, and thereafter invoking it in infringement litigation. This case remains pending in mid-2021.

VI. Monopolization through exclusive distribution agreements

A pharmaceutical producer and distributor may seek to monopolize or maintain a monopoly in a health technology market by entering into exclusive distribution agreements with suppliers that foreclose alternative producers from securing supplies of inputs necessary to compete.

BOX 3.C.17: FTC action on monopolization through exclusive distribution agreements

In April 2015, the FTC filed a stipulated permanent injunction in federal court settling charges that Cardinal Health, Inc. excluded potential entrants and maintained monopoly power in 25 local markets for the sale and distribution of low-energy radiopharmaceuticals, by obtaining *de facto* exclusive rights to distribute an essential input, heart perfusion agents, from the only two manufacturers. Low-energy radiopharmaceuticals are medicines containing radioactive isotopes used by hospitals and clinics for nuclear imaging and other procedures. Radiopharmacies, including Cardinal's, distribute and sell radiopharmaceuticals to hospitals and clinics, which rely on radiopharmacies to compound radiopharmaceuticals and to provide just-in-time delivery on a daily basis for procedures. At the time of the complaint, Cardinal owned the largest chain of radiopharmacies in the United States.

According to the complaint, a radiopharmacy could not profitably operate and compete in a local market without obtaining the right to distribute heart perfusion agents from one of the two manufacturers. Cardinal employed various tactics to induce or coerce the only two manufacturers of heart perfusion agents to refuse to grant distribution rights to potential entrants in the 25 markets in which Cardinal operated the only radiopharmacy. Cardinal's coercive tactics did not enhance efficiency or otherwise serve procompetitive ends, but rather had the purpose and effect of insulating Cardinal's downstream monopolies from competition. The complaint alleged that Cardinal's conduct enabled it to amass substantial ill-gotten gains by charging hospitals and clinics in the 25 geographic markets supra-competitive prices.

Under the terms of the final order and stipulated permanent injunction, Cardinal was required to disgorge its ill-gotten gains by paying US\$26.8 million into a fund for distribution to customers injured by its conduct. The order bars Cardinal from engaging in similar conduct in the future and requires Cardinal to notify the Commission before entering into new exclusive distribution agreements or buying radiopharmacy assets that would not otherwise be subject

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BOX 3.C.17 ...continued

to the notification requirements of the Hart-Scott Rodino Act. The order also contains provisions designed to facilitate entry and restore competition in six of the relevant markets where Cardinal continues to operate as the sole or dominant radiopharmacy.

Source: Distribution: Federal Trade Commission, Federal Trade Commission v. Cardinal Health, Case 15-cv-3031, FTC File No. 1010006 (final order issued 23 April 2015), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/101-0006/cardinal-health-inc>.

b. Excessive pricing doctrine

US federal courts have historically not recognized an antitrust cause of action for 'excessive pricing' as such, even though in principle Section 2 of the Sherman Act (monopolization) could be interpreted to allow such actions. The premise of the refusal is that absent some type of anti-competitive conduct, the market should not permit an enterprise to set prices above competitive prices. That is, without some type of 'artificial constraint', competitors will enter the market and drive the price down towards marginal cost. Therefore, by 'fixing the market'—in the sense of eliminating the artificial constraint—competition authorities seek to ensure that prices that might appear to be excessive will come down.

This may not adequately account for the pharmaceutical sector's special characteristics where patents and regulatory market exclusivity may create legislatively granted 'monopoly' positions. A pharmaceutical originator does not need to enter into an anti-competitive arrangement to set and maintain an 'excessive' price if it is marketing a therapy that is sufficiently unique to be protected from competition by similar therapies. In other words, the market is not broken in the conventional sense of an anti-competitive practice, so there is no artificial constraint to remove—other than the patent or regulatory market exclusivity.

Generic pharmaceutical markets may also be susceptible to dominance by a single enterprise (or small group of enterprises) as a consequence of regulatory barriers, small patient populations or other factors, and this may enable excessive pricing that is not based on an arrangement among suppliers or abusive conduct beyond the excessive price itself.

There are a number of countries where a cause of action for excessive pricing 'as such' is allowed. For example, in the preceding section several cases prosecuted in Europe are detailed.

There is some movement on this front in the United States. In 2019, in response to a question from Congress, the FTC examined whether a cause of action for excessive pricing could be maintained under Section 5 of the FTC Act. Section 5 has language that is broader than the Sherman Act in terms of providing a cause of action for "unfair or deceptive acts or practices"

that include taking unfair advantage of consumers without reference to behaviours *vis-à-vis* competitors. Of note is that the question from Congress related to excessive pricing in the generics markets, and not to patent-protected markets, although such a distinction would not appear to be meaningful from a doctrinal standpoint.

BOX 3.C.18: Statement on the use of Section 5 of the FTC Act to address off-patent pharmaceutical price spikes

“As a practical matter, the Commission can bring, and has brought, enforcement actions when excessive price increases are accompanied by exclusionary conduct or the result of a merger. For example, the FTC can consider whether an acquisition facilitates the exercise of monopoly power or represents an attempt to monopolize. But when the price of vital and sometimes life-saving medication with no therapeutic alternatives suddenly increases, there may be other bases upon which the Commission could challenge an excessive price increase that the Commission could further explore. While excessive pricing enforcement efforts may face significant challenges, such challenges alone should not deter exploration of all powers provided under Section 5.

Unfair or Deceptive Acts or Practices (UDAP): Section 5 also includes a broad prohibition on unfair or deceptive acts or practices. In a situation where the maker of an off-patent drug dramatically raises prices, the facts and circumstances might meet the criteria Congress enumerated for an unfair practice: (1) substantial consumer injury, (2) without offsetting benefits, and (3) one that consumers cannot reasonably avoid. To date, the Commission has not used this unfairness authority to challenge excessive, unjustified drug price increases. However, in situations where (1) a price increase involves off-patent drugs that lack therapeutic alternatives, and where research, production, and regulatory barriers would prevent near-term entry, (2) the price increase bears no reasonable relationship to manufacturing or production cost increases or changes in supply and demand conditions, and (3) the harm to patients is not outweighed by other benefits, the conduct might meet the definition of an unfair practice. In these situations, firm tactics force consumers to pay exorbitant prices or forego potentially life-saving drugs; while applying our unfair practice authority to these fact patterns would be novel, it may well be warranted. If the Commission determined that the pricing practice was unlawful, it could bring an enforcement action to seek redress to patients, disgorgement of ill-gotten gains, and other relief. The FTC Act generally does not provide for civil penalties on the first offence using these procedures.” [footnotes omitted].

Source: Federal Trade Commission, ‘Report on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes: Statement of Commissioners Rohit Chopra and Rebecca Kelly Slaughter’, Washington, DC, 24 June 2019.

The response by the FTC to Congressional requesters did not reject the idea that, in principle, the FTC Act is broad enough to cover a ‘self-standing’ action for excessive pricing, but it did indicate that the FTC majority did not think that it would be appropriate to pursue such claims because of existing judicial resistance to antitrust actions, asserting excessive pricing as such. Basically, the FTC majority said that absent some grounds for concluding that US courts have changed their perspective, it would not be worthwhile to pursue this

type of action. Two of the five FTC Commissioners dissented from this view, arguing that judicial precedent should not stand in the way of the FTC pursuing its legislative authority—judicial doctrine may evolve.

While antitrust prosecution for excessive pricing ‘as such’ remains unrecognized in the United States, it is noteworthy (as per the exchange between Congressional requestors and the Commission in the previous text box) that there has been an opening of discussion on the subject in Congress and at the FTC.

6. Dominant position and oligopoly

It is possible that several firms may collectively dominate a market. This situation is referred to by economists as an ‘oligopoly’. Article 102 of the EU TFEU refers to “Any abuse by one or more undertakings of a dominant position”.⁷⁶ This textually leaves room for a finding that several firms collectively occupy a dominant position. Section 2 of the US Sherman Act refers to: “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize”. The language of the Sherman Act likewise leaves open the possibility that more than one person combines to dominate a market.⁷⁷

While competition law recognizes the possibility that a dominant position may be occupied by more than a single firm, there yet remains the question of the types of practice that evidence abuse of that dominance. One important question is whether ‘parallel’ behaviours, such as comparable price increases undertaken by more than one firm closely in time, are sufficient evidence to establish the collaborative exercise of market dominant power. This question may be addressed somewhat differently in diverse national jurisdictions.⁷⁸

76 See, generally, Nicolas Petit, ‘The “Oligopoly Problem” in EU Competition Law’, in *Research Handbook in European Competition Law*, I. Liannos and D. Geradin (eds.), Edward Elgar, Cheltenham, UK, 2013. Available at: <http://ssrn.com/abstract=1999829>.

77 The US Supreme Court historically has interpreted the language of the Sherman Act in a way that accommodates the limitations of its late 19th century drafting. The term ‘monopoly’ may be understood in common vernacular to refer to the position of a single (i.e. ‘mono’) enterprise or supplier. The question of multi-firm dominance of a market is the subject of jurisprudential debate within the United States, but there is support among leading commentators for findings of dominance by two or more firms. See William J. Robinson and Ashley M. Koley, ‘Antitrust enforcement against oligopolies’, *Antitrust Law Daily*, October 2019, Wolters Kluwer, citing Areeda and Hovenkamp on ‘shared monopoly’; and Richard A. Posner, ‘Oligopoly and the Antitrust Laws: A Suggested Approach’, *J. Reprints Antitrust L. & Econ.* 1 (1969), p. 1065.

78 See Alan Devlin, ‘A Proposed Solution to the Problem of Parallel Pricing in Oligopolistic Markets’, *Stanford Law Review*, Vol. 59, No. 4 (February 2007), pp. 1111–1151 (including references to US jurisprudence); Jaime Eduardo Castro Maya, ‘The Limitations on the Punishability of Tacit Collusion in EU Competition Law’, *rev. Derecho Competencia*, Vol. 13 No. 13, 195–240, January–December 2017 (including references to EU jurisprudence). See also note of Australian Competition and Consumer Commission regarding price fixing and parallel pricing, available at: <https://www.accc.gov.au/business/anti-competitive-behaviour/cartels/price-fixing>. ‘Parallel pricing’ is sometimes also referred to as ‘shadow pricing’ or as a form of ‘tacit collusion’. Shadow pricing in the US market is described in detail in the Staff Report prepared for Senators Charles E. Grassley and Ron Wyden, Chairman and Ranking Member of the US Senate Finance Committee, respectively (US Senate Finance Committee, ‘Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug’, Staff Report, 14 January 2021, pp. 49–65).

As with other evidentiary issues, providing direct evidence (e.g. such as documents spelling out a plan of collusion) makes it easier to persuade the factfinder. But direct evidence of collusion may be well hidden, and competition authorities may need to rely on indirect or circumstantial evidence such as parallel behaviours.

D. Merger control

One of the principal functions of competition authorities is to exercise supervision over mergers and acquisitions that impermissibly impair or threaten to impair competitive markets and/or cause injury to consumers.⁷⁹ In the pharmaceutical sector, this typically may occur when pharmaceutical companies with health technologies that compete with each other combine and eliminate (or foreclose competition between) one or more of those competing products.⁸⁰ Also, when two or more companies with R&D projects and/or capacity combine, this may lead to a reduction in targets of research, thereby reducing the prospects for the discovery and introduction of new therapies.⁸¹ Merger and acquisition competition concerns in the health sector extend substantially beyond the development and distribution of pharmaceuticals, encompassing physician and hospital services, medical equipment development and supply, health-related insurance services and other areas. Many jurisdictions require that enterprises proposing to merge or combine (in one form or another) notify competition authorities in advance, to secure approval of the combination. Competition authorities may require certain actions by the enterprises as a precondition to approval, such as the divestiture of a product line or lines.⁸² The proposed combining entities typically may choose to reject the conditions and appeal to the courts, though such appeals are more the exception than the rule.

79 See Federal Trade Commission, 'FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers: Agency joins forces with Canadian Competition Bureau, European Commission Directorate General for Competition, United Kingdom's Competition and Markets Authority, U.S. Department of Justice, and Offices of State Attorneys General', Washington, DC, 16 March 2021 ("Given the high volume of pharmaceutical mergers in recent years, amid skyrocketing drug prices and ongoing concerns about anticompetitive conduct in the industry, it is imperative that we rethink our approach toward pharmaceutical merger review,' said FTC Acting Chair Rebecca Kelly Slaughter. 'Working hand in hand with international and domestic enforcement partners, we intend to take an aggressive approach to tackling anticompetitive pharmaceutical mergers.'").

80 Per the European Commission 2019 Enforcement Report: "A key objective of merger control in the pharmaceutical sector is to ensure that the changes in the market structure due to a merger do not result in higher prices. This leads to scrutiny irrespective of whether a merger concerns originator, generic or biosimilar competition" (p. 27).

81 Per the European Commission 2019 Enforcement Report: "mergers may also curb the scale or scope of innovation, and patients and physicians may have a more limited choice of future innovative treatments. For example, this may be the case where one merging company's pipeline product would be in competition with another company's marketed product, and thus be likely to capture significant revenues from the other company's competing product. If this is the case, the merged company may be inclined to discontinue, delay or redirect the competing pipeline project in order to increase the profits of the merged entity. Similarly, merging firms may be working on competing R&D programmes, which would divert profitable future sales from each other in the absence of the merger. By bringing two competing firms under a single ownership, a merger may reduce the incentives to engage in parallel R&D efforts" (p. 29).

82 See European Commission 2019 Enforcement Report, pp. 10–11.

1. Brazil

BOX 3.D.1: CADE prevents merger in capsule market

CADE's Department of Economic Studies (DEE) analysed through Technical Note No. 002/2015/DEE/CADE the merger between Capsugel Brasil Importação e Distribuição de Insumos Farmacêuticos e Alimentos Ltda and Genix Indústria Farmacêutica Ltda. (merger case No. 08700.009711/2014-78). Both of them were big national enterprises responsible for a large part of the manufacture of national hard capsules for medicinal purposes.

The main discussion was about the geographic scope of the relevant market. If the relevant market was defined as the national market for hard capsules, the merger would be responsible for generating a high level of market concentration (almost a monopoly). Therefore, the applicants' main thesis was the existence of significant competition between the use of national rigid capsules and national soft capsules and between national and international capsules.

The analyses that were carried out by the DEE thus covered these arguments. After performing a critical elasticity test, the DEE understood that the relevant market should be defined as national. It also tried to measure the merger's gross upward pricing pressure (GUPP) and upward pricing pressure (UPP) from the merger.

Therefore, the DEE tried to measure the cross-elasticities from both enterprises. To do so, it ran several regressions. In this case, diversion ratios (means) between Capsugel and Genix lie between 0.65 and 0.75. With this number, the DEE performed the UPP test and understood that the merger was problematic from a competitive standpoint. After receiving the DEE's report, the applicants gave up the merger operation.

CADE helped to prevent a concentrated structure in the national capsule market. This is a necessary input for manufacturing and, consequently, CADE helped to implement a policy against undue market power that, otherwise, would allow an increase in medicine prices.

Source: CADE, 'Capsugel Brasil Importação e Distribuição de Insumos Farmacêuticos e Alimentos Ltda and Genix Indústria Farmacêutica Ltda. – 08700.009711/2014-78', Brasília, 2014.

BOX 3.D.2: CADE restrictions imposed on merger to remedy competition concerns

CADE approved with remedies the acquisition of common shares of Diagnósticos da América S/A (Dasa) by Chromosomo Participações II S/A (CP II), owned by the Bueno Group. With the operation, the Bueno Group, which already held 23.59 percent of Dasa's shares, would control more than 70 percent of the company's capital. The transaction was approved by CADE's Tribunal, subject to the signing of a merger control agreement under Law 8.884/1994.

Under the terms of the agreement, among other obligations, the Dasa Group pledged to dispose of assets in the municipality of Rio de Janeiro and not to make acquisitions in the municipalities of São Paulo, Rio de Janeiro or Paraná. CADE's Tribunal held that the restrictions imposed on the merger previously decided are sufficient to remedy the competition concerns detected in the new transaction. Accordingly, the Board approved another merger control agreement presented by the Bueno Group, whereby there was an undertaking to formally adhere to the obligations already provided for in the agreement previously signed with the local authority.

Source: CADE, 'Chromosome Participations II S.A. and Diagnostics of America S.A. – 08700.002372/2014-07', Brasília, 2014.

BOX 3.D.3: CADE approves joint venture between GSK and Novartis, subject to merger control

CADE approved the creation of a joint venture between GlaxoSmithKline PLC companies (GSK) and Novartis AG (Merger Act 08700.008607/2014-66) subject to the signature of a merger control agreement. With the operation, GSK will hold 63.5 percent of the joint venture shares, and Novartis 35.5 percent. The partnership between the companies was global in scope and is being formed for the commercialization of over-the-counter health care products. CADE found that the joint venture could generate a high level of concentration in the anti-smoking medicines market. To mitigate any competition concerns, the companies and CADE have signed an agreement whereby GSK commits to divest an asset package related to the company's main anti-smoking product. The asset package to be disposed of includes assets, tangible or intangible, such as intellectual property rights, licences and contracts. Also, the Applicants have undertaken to take some measures to ensure that there is no undue exchange of information between the joint venture and Novartis.

Source: CADE, 'GlaxoSmithKline e Novartis AG – 08700.008607/2014-66', Brasília, 2014.

BOX 3.D.4: CADE approves merger in industrial gases

CADE approved the merger between Praxair industrial and specialty gas multinationals (better known as White Martins) and Linde, after the signing of a merger control agreement. CADE understood that the Brazilian market for industrial and special gases as a whole is highly concentrated, with the applicants (especially Praxair) being the main players. However, Praxair and Linde have proposed a merger control agreement that encompasses the divestment of several businesses and can dispel potential competition concerns caused by the operation, including in the medicinal gases sector. CADE concluded that the agreement eliminates concentrations in the regional markets for bulk and industrial cylinder and specialty gases. Furthermore, it includes all that is necessary for the buyer of the divested business to remain a relevant competitive force in the medium and long term.

Source: CADE, 'Industrial Gases – Praxair and Linde – 08700.007777/2017-76', Brasília, 2017.

BOX 3.D.5: Criteria for review and analysis

CADE approved the acquisition of All Chemistry of Brazil by SM Empreendimentos from Fagron Group after the signing of a merger control agreement. The companies operate in the pharmaceutical supply distribution market for handling pharmacies, in which the Fagron Group is currently the main competitor. After receiving a complaint, CADE found that the group has, over the years, been making a series of acquisitions from smaller competing companies, which has resulted in increased concentration in this market. Based on this assessment, CADE determined that SM Empreendimentos had the obligation to submit for analysis the transaction involving the purchase of All Chemistry, even if it does not meet the mandatory notification criteria provided in Brazilian Antitrust Law 12.529/2011. CADE understood that the operation had competitive concerns.

According to the CADE Tribunal's understanding, although there are other competitors in the segment, the market is significantly concentrated by Fagron Group. Thus, even though acquisitions made in recent years may have generated efficiencies, the group's growth through acquisitions would be close to the acceptable limit from a competitive point of view. At the agreement, SM Empreendimentos undertakes, for the next two years, the obligation not to participate in mergers, incorporations or acquisitions of control or parts of companies that compete in the distribution market. Two years after the end of this period, the company shall also submit similar operations to CADE for its prior appraisal. Further, companies were required for the next four years to submit for prior approval by CADE any corporate transactions in markets that are horizontally or vertically related to the Brazilian pharmaceutical supply distribution market for handling pharmacies.

Source: CADE, 'All Chemistry do Brasil Ltda. e SM Empreendimentos Farmacêuticos Ltda – 08700.005972/2018-42', Brasília, 2018.

BOX 3.D.6: CADE approves GSK and Pfizer merger

After a divestment agreement, CADE approved the joint venture formed by the business combination of the health care divisions of GSK and Pfizer. The resulting company will have a majority stake in GSK, which owns 68 percent, while Pfizer will own 32 percent. With the creation of the joint venture, the companies intend to strengthen their position in the pharmaceuticals market with greater investments in research and development, immune system studies, the use of genetics and digital technology. CADE considers that there is potential for offending competition in the domestic markets for calcium-based products; dermatological topical antifungals; topical antirheumatic and analgesic medicines; non-narcotic analgesics; and over-the-counter antipyretics. However, the post-operation scenario in the domestic market of simple antacids reveals a high level of concentration, a fact that raises competition concerns. To remedy any damage to the competitive environment, the parties proposed a merger control agreement. The agreement established the divestment of the Bisfied Magnesia business held by Pfizer CH, which is the only medicine offered by the company in the market for simple antacids in Brazil. The commitments aligned with the agreement certify that the divestment of the business will occur to safeguard its competitiveness and economic relevance for the company that acquires this asset.

Source: CADE, 'GlaxoSmithKline PLC. e Pfizer Inc. – 08700.001206/2019-90', Brasilia, 2019.

2. China

BOX 3.D.7: Merger control review 2019 (China)

The year 2019 marked the 11th anniversary of the implementation of the Anti-monopoly Law and was also the first full calendar year since the SAMR took over the role as China's single centralized antitrust enforcement agency.

The SAMR maintained a rigorous and prudent attitude towards merger control review in 2019. Overall case handling efficiency improved, given that the total number of cases concluded increased, while the average time for case reviews was reduced. The SAMR concluded 465 cases in 2019. Among them, 460 cases were unconditionally approved, and 5 cases conditionally approved. The SAMR imposed various tailored conditions for the cases that were conditionally approved. No mergers were prohibited in 2019. In addition, the SAMR investigated more non-filing cases and imposed more penalties on non-filers compared with 2018. In particular, a total of 16 penalty decisions against non-filers of merger cases were published in 2019, which was the highest annual figure over the past decade.

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Legislation

On 7 January 2020, the SAMR released a draft of the Interim Provisions for Merger Control Review for public comment. The Interim Provisions incorporated all major regulations for merger control review in one consistent and easy-to-follow comprehensive regulation, although no substantial new changes were proposed.

On 2 January 2020, the SAMR released a revised draft of the Anti-monopoly Law for public comment. Although the revised draft follows the current Anti-monopoly Law's basic framework, it significantly enhances the legal liability of violators. For example, in accordance with Article 55 of the revised draft, the proposed penalty will be up to 10 percent of the non-filer's annual sales in the previous year, instead of the maximum amount of RMB500,000 under the current Anti-monopoly Law, which is clearly insufficient for deterring non-filers. It also clarifies practical issues such as 'controlling rights' for merger filing purposes. At present, there is no clear timetable for the finalization of the revised draft or the promulgation of the new Anti-monopoly Law.

Unconditionally cleared cases

The SAMR unconditionally approved 460 cases in 2019—slightly higher than the previous year (444 cases). As regards simple cases, 341 were concluded in 2019 (73.3 percent of all cases). The proportion of simple cases decreased compared with 2018 (81.5 percent of all cases). On average, simple cases took 15 days to be concluded, which was a slight reduction from the 16-day conclusion rate in 2018. Almost all simple cases were cleared within 30 days of formal acceptance by the SAMR. This demonstrates that simple case procedure plays an active role in enhancing the efficiency of concentration filing, particularly in the sense of reducing reviewing time.

However, in practice, strict rules concerning the material and data required by the SAMR still apply. In particular, during the pre-review stage (i.e. before official case acceptance), notified parties must often submit detailed materials. Therefore, this requirement may also extend the wait time before case filing.

The revised draft introduces a 'stop-the-clock' clause that specifies the following conditions to discontinue the timelines for merger review:

- on application or consent by the notifying parties;
- supplementary submissions of documents and materials at the request of the authority; or
- remedy discussions with the authority.

This proposed 'stop-the-clock' clause would tackle the problem that, in its absence, the notifying parties can only withdraw and refile the case when the statutory review period is running out.

Conditionally cleared cases

In 2019, the SAMR conditionally approved five cases, a similar number to the four cases in 2018.

In 2019, four conditionally cleared cases were approved with behavioural conditions, and the remaining one was approved with both structural and behavioural conditions. All of the

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the five conditionally approved cases in 2019 were withdrawn and resubmitted before the expiry of the first statutory merger review period (i.e. 180 days). This shows that the SAMR is becoming more prudent in reviewing mega mergers that may raise competition concerns. Withdrawal of the filing also provides notifying parties with certain flexibility and more time to communicate with the SAMR. From the first submission of filing materials to a case being conditionally concluded, the review process for the above five cases lasted a minimum of 263 days and a maximum of 562 days.

Penalties on non-filers

In recent years, the antitrust authorities have never relaxed their supervision of non-filing cases. By the end of 2019, the SAMR had released 46 non-filing cases and imposed total fines of RMB16.1 million on 68 undertakings. In 2019, the SAMR significantly strengthened its supervision of and penalties on non-filing parties: 16 cases were published, and 21 undertakings were punished with fines totalling RMB6.25 million. The largest fine issued was RMB400,000, while the smallest was RMB200,000. The SAMR initiates investigations on non-filing cases by means of self-observation, third-party reporting, and voluntary reporting by notifiable parties. Notably, the SAMR has been pursuing non-filers even where their failure of notification occurred many years ago.

Comment

The SAMR has become more stringent and detail oriented with respect to its analysis of relevant markets and the competition impact of mergers. It is expected that its merger control enforcement will maintain its professionalism and stability in 2020.

Further, the large number of non-filing cases and the increased fines indicate that the SAMR is gradually strengthening its enforcement of non-filers. Moreover, the proposed revision of the Anti-monopoly Law is expected to increase the size of penalties for non-filers. Enterprises should acknowledge the thresholds and criteria for merger filing to fulfil their obligations to avoid penalties and any adverse consequences of closing a transaction.

Source: Michael Gu, Sihui Sun and Grace Wu, AnJie Law Firm, 28 May 2020.

The following text box provides examples of Chinese competition authority actions addressing mergers and acquisitions, undertaken by the Ministry of Commerce of the People's Republic of China (MOFCOM), prior to consolidation of the three authorities in SAMR.

BOX 3.D.8: Pre-SAMR integration cases

Merger control

1 Assessment of mergers

In the Novartis/Alcon case, the MOFCOM determined that the parties' combined global market share in ophthalmic anti-inflammatory and anti-infective compounds was over 55 percent, and that their combined share in China was over 60 percent. Novartis reportedly added less than 1 percent to the existing high share held by Alcon, but the MOFCOM still imposed a remedy—albeit behavioural. Similarly, in the Baxter/Gambro case, the MOFCOM determined that the parties' combined global market share in Continuous Renal Replacement Therapies (CRRT) monitors, CRRT bloodlines and CRRT dialyzers was 64 percent, 59 percent and 62 percent, respectively, and that their combined share in China was 57 percent, 84 percent and 79 percent, respectively. The high combined market shares were mainly due to the existing high share held by Gambro, but the MOFCOM still requested Baxter to divest its CRRT business globally.

Several of the MOFCOM's decisions in the pharmaceutical sector reflect the increased sophistication of its competitive assessment of mergers. The Pfizer/Wyeth case was the first time that the MOFCOM publicly noted its reliance on the Herfindahl-Hirschman Index (HHI) to assess the impact of a transaction on the relevant market. In the Novartis/Alcon case, the MOFCOM raised possible coordination issues for the first time as a basis for imposing a remedy. Specifically, the MOFCOM raised the issue that the merged entity could coordinate its behaviour with Hydron to restrict competition. The decision noted that the merged Novartis/Alcon entity would be the second largest company in China for contact lens care products. Prior to the transaction, Novartis had already appointed Hydron as its exclusive distributor for one of its subsidiaries. Hydron was the largest producer and distributor in China. The MOFCOM considered the coordination concerns again in the Baxter/Gambro case, and noted that coordination concerns arose where Baxter had an agreement for Nipro to manufacture haemodialysis dialyzers for Baxter. Both Baxter and Gambro produced and sold the product. Nipro also sold the same product. In the Thermo Fisher/Life Technology case, the MOFCOM engaged an independent third-party consultant to conduct an economic analysis on the competition issues and, for the first time, applied the 'estimated price increase test' as a specific tool for the economic analysis.

2. Remedies

The Pfizer/Wyeth case was the first time that the MOFCOM required a substantive structural remedy consisting of the divestment of a product portfolio, including licensing rights to relevant intellectual property and related tangible and intangible rights. In the Baxter/Gambro case, the MOFCOM required the divestment of Baxter's CRRT business globally. In the Thermo Fisher/Life Technologies case, the MOFCOM required the divestment of certain business

continued...

BOX 3.D.8 ...continued

lines as well as a majority stake in a Chinese company. The MOFCOM's stated requirements for suitable purchasers of assets/businesses to be divested are generally in line with the EU and US approaches. In practice, however, the MOFCOM might prefer to approve Chinese buyers due to concerns unrelated to competition policy (e.g. on an industrial policy basis). At the same time, the MOFCOM's practice indicates that it appears more receptive to non-structural remedies than the competition authorities in other jurisdictions. For example, the Novartis/Alcon case demonstrated the MOFCOM's willingness to accept certain behavioural and quasi-structural remedies—in this case, a commitment not to re-enter a particular market for a period of five years and the termination of an existing exclusive distribution agreement in another market. Similarly, in the Baxter/Gambro case, the MOFCOM required Baxter to terminate its Original Equipment Manufacturer (OEM) agreement with Nipro in China by 31 March 2016. In the Thermo Fisher/Life Technologies case, the MOFCOM required Thermo Fisher, for the subsequent 10 years, to commit to certain designated supply arrangements for certain products at the option of the relevant third parties. The MOFCOM also required Thermo Fisher, for the subsequent 10 years, to decrease the list price in China for certain products by 1 percent per year and not to decrease the percentage discount from the list price available to distributors in China.

Remedies imposed in merger cases in China are broadly consistent with international practice, but certain remedies may be unique to China. For example, similar to the European Commission's decision in the same case, the MOFCOM required divestment of certain animal health products in approving the Pfizer/Wyeth case. However, in China, the larger of the relevant overlapping products was required to be divested. In the Novartis/Alcon case, the requirement that Novartis commit not to re-enter a particular market in China for five years also seems unique, especially given the combined market shares involved in the jurisdiction (including the modest post-merger increments in the market share) and Novartis's stated intention to withdraw from the market concerned. In the Thermo Fisher/Life Technologies case, the requirement that Thermo Fisher commit to supply products and to decrease prices by a specific percentage for a period of 10 years in China also seems unique to China. It is also worth noting that the MOFCOM has imposed 'hold-separate' remedies in several cases, requiring the buyer to ring-fence part of the target's operations which conduct business in China. The conditions in these cases are far-reaching and give the MOFCOM discretion to postpone integration further if deemed necessary. Thus far, such unique hold-separate remedies have not been imposed in any case in the pharmaceutical sector. However, the MOFCOM is reviewing the effectiveness of the hold-separate remedies; if they are found to be effective, it may continue to use such remedies. Therefore, it is possible that such hold-separate remedies may be imposed when the MOFCOM reviews cases in the pharmaceutical sector in the future.

Source: Yong Bai and Richard Blewitt, 'The Application of the Anti-Monopoly Law to the Pharmaceutical Sector in China', *China Antitrust Law Journal*, vol. 1, issue 1 (2017).

3. Colombia

In 2019, the Superintendence of Industry and Commerce conditioned the merger between GlaxoSmithKline plc and Pfizer, Inc. In that case, behavioural conditions were imposed tending to prevent discriminatory conditions with respect to suppliers and consumers, and to allow the access of possible competitors to the market.⁸³

4. European Union

BOX 3.D.9: European Commission 2019 Enforcement Report on the Teva/Allergan case

In March 2016, the European Commission found that the Teva/Allergan merger would soften price competition in a number of markets and cleared the acquisition of the generic business of Allergan Generics by Teva Pharmaceutical Industries only after Teva committed to divest relevant parts of the acquired business to independent buyers.

Before the transaction, Teva was already the largest global generics manufacturer, and Allergan was the fourth largest generics manufacturer worldwide. The transaction concerned hundreds of generic medicines marketed and in development, and was unprecedented in the pharmaceutical sector both in its size and the number of markets where the companies' generics competed.

The Commission's market investigation revealed that there was direct competition on prices between all versions of a given off-patent molecule (including generics and the off-patent originator medicines) and that for a number of medicines, competition would have been curbed by the merger. Therefore, the Commission identified potential competition concerns for a large number of medicines all over the EU.

Also, looking at the overall market position of the parties that supply generic medicines at national level, the Commission concluded that in some Member States, the parties were among the largest generics players and each other's closest competitors. Therefore, the Commission assessed the possible impact of the merger on prices not only for specific medicines but also at the level of the parties' whole portfolio of generic medicines.

For example, in the UK, where prices of generics are set freely, Teva and Allergan were the only generics players capable of selling their portfolio of medicines directly (without intermediaries) to pharmacies through loyalty schemes. All the other players had to go through wholesalers. Because of this specific market feature, the Commission concluded that Teva and Allergan exerted a unique pricing competitive pressure on each other in their relationships with pharmacies. This competitive pressure would have been eliminated by the merger, and the elimination of pricing competition would have had a knock-on effect on prices to consumers.

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83 OECD Directorate for Financial and Enterprise Affairs, Competition Committee, 'Annual Report on Competition Policy Developments in Colombia 2019', DAF/COMP/AR(2020)41, Paris, 27 May 2020, at paras. 82–91. Available at: [https://one.oecd.org/document/DAF/COMP/AR\(2020\)41/en/pdf](https://one.oecd.org/document/DAF/COMP/AR(2020)41/en/pdf).

BOX 3.D.9 ...continued

To address the Commission's concerns, including the risk of price increases, the companies offered remedies. Specifically, they committed to selling the bulk of Allergan Generics's generics business in Ireland and the UK, including a manufacturing plant and the full sales organization, to a suitable independent buyer.

Source: European Commission 2019 Enforcement Report.

BOX 3.D.10: Enforcement Report on the Pfizer/Hospira case

In 2015, the Commission cleared Pfizer's acquisition of Hospira, subject to receiving remedies which ensured that price competition between biosimilars was not compromised, as the proposed merger would have brought two competing infliximab biosimilars under Pfizer's ownership (Hospira's Inflectra and Pfizer's pipeline biosimilar) (Commission Decision in case M.7559 *Pfizer/Hospira*).

To prevent such effects and ensure that a sufficient number of biosimilars would enter the market and exert price pressure on the expensive reference biological medicine, the companies proposed that Pfizer's infliximab pipeline development be divested to a suitable buyer. This was accepted by the Commission. In February 2016, Novartis announced that it had acquired the divestment business.

Source: European Commission 2019 Enforcement Report.

5. United States

BOX 3.D.11: Amneal Pharmaceuticals LLC/Impax Laboratories Inc.

The FTC complaint alleged that the proposed acquisition by Amneal of Impax Laboratories would lessen actual or future competition and increase the likelihood of higher prices in 10 US markets for generic medicines.

The order requires Impax to divest its rights and assets for these 10 medicines to 3 other companies.

Source: Federal Trade Commission, C-4650, FTC File No. 1810017 (final order approved 10 July 2018), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/181-0017-c-4650/amneal-holdings-impax-laboratories-matter>.

BOX 3.D.12: Mylan N.V./Meda AB

The FTC complaint alleged that the proposed acquisition by Mylan of Meda would reduce current competition and likely lead to higher prices in the generic markets for 400mg and 600mg felbamate tablets and future competition, including price competition, in the market for 250mg generic carisoprodol tablets.

The order required Mylan to divest all its rights and assets relating to 400mg and 600mg generic felbamate tablets to Alvogen Pharma US, Inc., and return its rights to market generic carisoprodol tablets in the United States to Indicus Pharma LLC.

Source: Federal Trade Commission, C-4590, FTC File No. 1610102 (final order issued 7 September 2016), 'FTC Actions 2019 Overview', Washington, DC, 2019.

Available at: <https://www.ftc.gov/enforcement/cases-proceedings/161-0102/mylan-nv-matter>.

BOX 3.D.13: Teva Pharmaceutical Industries Ltd./Allergan PLC

The FTC complaint alleged that Teva's proposed US\$40.5 billion acquisition of Allergan's generic pharmaceutical business would reduce current and/or future competition and likely lead to higher prices in 79 markets for health technologies, including anaesthetics, antibiotics, weight loss medicines, oral contraceptives, and treatments for a wide variety of diseases and conditions, including Attention Deficit Hyperactivity Disorder (ADHD), allergies, arthritis, cancers, diabetes, high blood pressure, high cholesterol, mental illnesses, opioid dependence, pain, Parkinson's disease, and respiratory, skin and sleep disorders. At the time of the complaint, these markets included individual strengths of medicines where Teva and Allergan offered competing products, as well as 25 medicines where there would likely be future competition absent the merger, because one or both of the parties were developing competing medicines.

The order requires the parties to divest their rights and assets related to pharmaceutical markets for one or more strengths of the 79 medicines to 11 firms. In addition to the product divestitures, to address the anti-competitive effects likely to arise in markets for the 15 medicines where Teva supplies APIs to current or future Allergan competitors, the order requires Teva to offer these existing API customers the option of entering into long-term API supply contracts.

Source: Federal Trade Commission, C-4589, FTC File No. 1510196 (final order issued 7 September 2016), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/151-0196/teva-allergan-matter>.

BOX 3.D.14: Hikma Pharmaceuticals/Boehringer Ingelheim Corporation (Roxane Laboratories, Inc.)

The FTC complaint alleged that the proposed acquisition by Hikma Pharmaceuticals PLC of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. (jointly, Roxane) from Boehringer Ingelheim Corporation would lessen current competition in the markets for 5mg, 10mg and 20mg generic prednisone tablets and generic lithium capsules, and future competition in the market for generic flecainide tablets in the United States.

The order requires Hikma to transfer to Renaissance Pharma, Inc. all of its interests related to 5mg, 10mg and 20mg generic prednisone tablets and all strengths of lithium carbonate capsules. The order also requires Hikma to relinquish to its product development partner, Unimark Remedies Ltd., all marketing rights in generic flecainide tablets, and to divest its ownership interest in Unimark.

Source: Federal Trade Commission, C-4568, FTC File No. 1510198 (final order issued 4 May 2016), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/151-0198/hikma-pharmaceuticals-plc-matter>.

BOX 3.D.15: Lupin Ltd./Gavis Pharmaceuticals LLC and Novel Laboratories, Inc.

The FTC complaint alleged that the proposed acquisition by Lupin of Gavis Pharmaceuticals LLC and Novel Laboratories, Inc. would lessen current competition in the market for generic doxycycline monohydrate capsules and future competition in the market for generic mesalamine extended release capsules in the United States. Gavis and Novel are related companies. Novel researches, develops and manufactures generic medicines, which Gavis markets and sells. The order requires the parties to divest Gavis's rights and assets relating to doxycycline monohydrate capsules and mesalamine extended capsules release to G&W Laboratories.

Source: Federal Trade Commission, C-4566, File No. 1510202 (final order issued 20 April 2015), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/151-0202/lupin-ltd-et-al-matter>.

BOX 3.D.16: Endo International plc/Par Pharmaceutical Holdings, Inc.

The FTC complaint alleged that the proposed acquisition by Endo International plc of Par Pharmaceutical Holdings, Inc. would lessen current competition in the markets for generic glycopyrrolate tablets, used to mitigate the side effects of peptic ulcer medicines, and generic methimazole tablets, used to inhibit the production of excess thyroid hormone. The order requires Endo to divest all of its rights and assets related to generic glycopyrrolate tablets and generic methimazole tablets to Rising Pharmaceuticals.

Source: Federal Trade Commission, C-4539, FTC File No. 1510137 (final order issued 10 November 2015), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/151-0137/endo-international-plc>.

BOX 3.D.17: Pfizer Inc./Hospira, Inc.

The FTC complaint alleged that the proposed acquisition by Pfizer Inc. of Hospira, Inc. would lessen current competition in the markets for generic acetylcysteine inhalation solution and clindamycin phosphate injection, and future competition in the markets for voriconazole injection and melphalan hydrochloride injection in the United States. The order requires Pfizer to divest all its rights to generic acetylcysteine inhalation solution and Hospira to divest all of its rights and assets related to clindamycin phosphate injection, voriconazole injection, and melphalan hydrochloride injection to Alvogen.

Source: Federal Trade Commission, C-4537, FTC File No. 1510074 (final order issued 15 October 2015), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/151-0074/pfizer-inchospira-inc>.

BOX 3.D.18: Novartis AG/GlaxoSmithKline, PLC

The FTC complaint charged that the proposed joint venture to combine the GlaxoSmithKline, PLC (GSK) consumer health care business with most of Novartis AG's consumer health care business would reduce competition and likely lead to increased prices in the market for nicotine replacement therapy transdermal patches (nicotine replacement patches). At the time of the complaint, Novartis and GSK were the only suppliers of branded nicotine replacement patches in the United States. GSK's branded nicotine replacement patches were marketed under the NicoDerm CQ[®] brand, and Novartis's were marketed under the Habitrol[®] brand. GSK and Novartis also were two of only three suppliers of private-label nicotine replacement patches in the United States. The complaint charged that Novartis's ownership of Habitrol, its private-label nicotine patches and a substantial interest in the joint venture that sold GSK's nicotine replacement patches would substantially reduce competition and lead to higher prices for Novartis's Habitrol and its private-label nicotine replacement patches. The order requires Novartis to divest Habitrol, as well as its private-label nicotine replacement patch business, to Dr. Reddy.

Source: Federal Trade Commission, C-4498, FTC File No. 1410141 (final order issued 13 January 2015), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0141-c-4510-c-4498/novartis-ag-matter-glaxosmithkline>.

BOX 3.D.19: Prestige Brands Holdings, Inc./Insight Pharmaceuticals Corporation

The FTC complaint alleged that the proposed acquisition by Prestige Brands Holdings, Inc. of Insight Pharmaceuticals Corporation would eliminate the close competition between Dramamine and Bonine, the only two branded OTC motion-sickness medicines with significant sales, likely leading to higher prices for consumers. The order requires Prestige to divest Bonine to Wellspring Pharmaceuticals.

Source: Federal Trade Commission, C-4487, FTC File No. 1410159 (final order issued 7 October 2014), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0159/prestige-brands-holdings-inc-insight-pharmaceuticals>.

BOX 3.D.20: Actavis PLC/Forest Laboratories, Inc.,

The FTC complaint alleged that the proposed acquisition by Actavis plc of Forest Laboratories, Inc. would delay the introduction of generic competition to Forest's Lamictal ODT, the branded lamotrigine orally disintegrating tablets used to prevent seizures, and insulate the branded medicine from generic competition. The order requires the companies to relinquish their rights to market generic diltiazem hydrochloride to Valeant Pharmaceuticals International, Inc., and sell generic ursodiol and generic lamotrigine ODT to Impax Laboratories, Inc. It also requires Forest to sell its rights to generic propranolol hydrochloride to Catalent Pharma Solutions, Inc.

Source: Federal Trade Commission, C-4474, FTC File No. 1410098 (final order issued 29 August 2014), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0098/actavis-plc-forest-laboratories-matter>.

BOX 3.D.21: Valeant Pharmaceuticals International, Inc./Precision Dermatology, Inc.

The FTC complaint alleged that the proposed acquisition by Valeant Pharmaceuticals International, Inc. of Precision Dermatology, Inc. would reduce competition in the market for branded and generic single-agent topical tretinoins. The order settling the charges requires Valeant to sell Precision's assets related to Tretin-X, its branded single-agent topical tretinoin, to Watson Laboratories, Inc., and Precision's assets related to generic Retin-A to Matawan Pharmaceuticals LLC, a subsidiary of Rouses Point Pharmaceuticals, LLC. In addition, both Watson Laboratories, Inc. and Matawan received partial assignments of the manufacturing contracts for both Tretin-X and generic Retin-A.

Source: Federal Trade Commission, C-4477, FTC File No. 1410101 (final order issued 20 August 2014), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0101/valeant-pharmaceuticals-international-precision-dermatology>.

BOX 3.D.22: Endo Health Solutions, Inc./Boca Pharmacal, LLC

The FTC complaint alleged that Endo Health Solutions, Inc.'s proposed acquisition of Boca Pharmacal, LLC would reduce competition and likely lead to higher prices in seven markets for generic medicines.

The order requires Boca Pharmacal to return to Sonar Products, Inc. all of Boca's rights related to four generic fluoride multivitamin drops. Endo is required to divest to Rhodes Pharmaceuticals, Inc. all of its rights and interests in generic Bromfed-DM and generic Zamicet, as well as all of Boca's rights and interests in generic Vosol HC.

Source: Federal Trade Commission, C-4430, FTC File No. 1310225 (final order issued 19 March 2014), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <http://www.ftc.gov/enforcement/cases-proceedings/131-0225/endo-health-solutions-inc-boca-life-science-holdings-llc-boca>.

BOX 3.D.23: Potential competition mergers

The FTC issued an administrative complaint in July 2017 and issued a final order in August 2017. The complaint alleged that Baxter's proposed acquisition of Claris's injectable business would reduce competition for the antifungal agent fluconazole in saline intravenous bags, which is used to treat fungal and yeast infections. The complaint further alleged that the acquisition would also reduce imminent, future competition in the market for intravenous milrinone, which dilates the blood vessels, lowers blood pressure and allows blood to flow more easily through the cardiovascular system. Used as a short-term treatment for life-threatening heart failure, intravenous milrinone is currently sold in the United States by three companies: Baxter, Hikma and Pfizer. Claris was expected to enter this market shortly, once its pending application at the FDA was approved. The order requires the parties to divest all of Claris's rights to fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags to New Jersey-based pharmaceutical company Renaissance Lakewood LLC.

The order also requires Baxter to supply Renaissance with fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags for up to five years while transferring the manufacturing technology to Renaissance or its contract manufacturing designee. Baxter is also required to assist Renaissance in establishing its manufacturing capabilities and securing the necessary FDA approvals. If the FTC determines that Renaissance is not an acceptable acquirer, or that the divestiture is not carried out in an acceptable way, the parties are required to unwind the sale of rights to Renaissance and divest the products to an FTC-approved acquirer within six months of the date the order becomes final.

Source: Federal Trade Commission, Baxter International Inc./Claris Lifesciences Limited and Arjun Handa, C-4620, FTC File No. 1710052 (final order issued 28 August 2017), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/171-0052/baxter-international-inc-claris-lifesciences-limited-arjun>.

BOX 3.D.24: Hikma Laboratories, PLC/ C.H. Boehringer Sohn AG & Co. KG (Ben Venue Laboratories, Inc.)

The FTC complaint alleged that the proposed acquisition by Hikma Pharmaceuticals PLC of certain assets of Ben Venue Laboratories Inc., a subsidiary of Boehringer Ingelheim Corporation, which is wholly owned by C.H. Boehringer Sohn AG & Co. KG, would lessen competition by eliminating future competition between Hikma and the Boehringer assets and reducing the number of generic competitors in five generic injectable pharmaceutical markets. Thus, the complaint charged, the proposed acquisition would: (1) increase the likelihood that the combined entity would forego or delay the launch of these medicines; and (2) increase the likelihood that the combined entity would delay, eliminate or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products. The order requires Hikma to divest to Amphastar Pharmaceuticals, Inc. the Ben Venue ANDAs it will acquire from Boehringer related to acyclovir sodium injection, diltiazem hydrochloride injection, famotidine injection, prochlorperazine edisylate injection and valproate sodium injection.

Source: Federal Trade Commission, C-4572, FTC File No. 1510044 (final order issued 28 March 2016), 'FTC Actions 2019 Overview', Washington, DC. Available at: <https://www.ftc.gov/news-events/press-releases/2016/02/ftc-requires-drug-marketer-hikma-pharmaceuticals-plc-divest>.

BOX 3.D.25: Impax Labs. Inc./CorePharma, LLC

The FTC complaint alleged that Impax Laboratories, Inc.'s proposed acquisition of Tower Holdings, Inc., Tower's subsidiary, CorePharma, LLC, and Lineage Therapeutics, Inc. from Roundtable Healthcare Partners II, LP would eliminate future competition between Impax and CorePharma in the market for generic 5mg pilocarpine hydrochloride tablets, used to treat dry mouth, and generic ursodiol tablets, used to treat biliary cirrhosis. At the time of the complaint, the market for generic 5mg pilocarpine hydrochloride tablets was highly concentrated, with only two suppliers. The complaint alleged that CorePharma and Impax each held an approved ANDA and were the only suppliers expected to enter the market in the near future. CorePharma was also among a limited number of firms with an ANDA under review for generic ursodiol tablets and the next likely entrant in the generic ursodiol tablet market. As a result, the complaint charged that the proposed acquisition would significantly reduce future competition, including a likely reduction in the number of future generic ursodiol tablet suppliers from five to four. The order requires the companies to divest CorePharma's rights and assets to generic pilocarpine tablets and generic ursodiol tablets to the Perrigo Company plc.

Source: Federal Trade Commission, C-4511, FTC File No. 1510011 (final order issued 22 April 2015), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/151-0011-c-4511/impax-laboratories-inc-et-al-matter>.

BOX 3.D.26: Novartis AG

The FTC complaint charged that Novartis AG's proposed acquisition of GlaxoSmithKline, PLC's (GSK) marketed oncology medicines, BRAF and MEK inhibitors used to treat cancer would eliminate substantial future competition between GSK and Novartis. The complaint alleged that GSK was one of two companies with a BRAF inhibitor on the market, while Novartis was the only other firm likely to begin competing with a BRAF inhibitor in the near future. The complaint alleged that GSK was the only company with a MEK inhibitor on the market, while Novartis was one of a small number of companies with a MEK inhibitor in late-stage development. Finally, the complaint alleged that GSK was the only company with a BRAF–MEK combination medicine to treat melanoma on the market, while Novartis was one of only two companies likely to compete with a combination medicine in the near future. The order requires Novartis to divest its BRAF and MEK inhibitor medicines to Array BioPharma, Inc.

Source: Federal Trade Commission, C-4510, FTC File No. 1410141 (final order issued 7 April 2015), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0141-c-4510-c-4498/novartis-ag-matter-glaxosmithkline>.

BOX 3.D.27: Sun Pharmaceutical Industries Ltd./Ranbaxy Laboratories Ltd.

The FTC complaint alleged that the proposed acquisition by Sun Pharmaceutical Industries Ltd. of Ranbaxy Laboratories Ltd. would substantially eliminate future competition in the market for various dosages of generic minocycline tablets, used to treat an array of bacterial infections, including pneumonia, acne and urinary tract infections. According to the complaint, Ranbaxy was one of only three US suppliers, while Sun was one of a limited number of firms likely to develop generic minocycline tablets. The complaint charged that the combined entity likely would forego or delay the launch of Sun's medicines, reducing the price competition that would have resulted from Sun's entry. The order requires the parties to divest Ranbaxy's assets and licences in generic minocycline tablets to Torrent Pharmaceuticals Ltd. The order also requires Sun and Ranbaxy to sell Ranbaxy's generic minocycline capsule assets to Torrent to enable Torrent to achieve regulatory approval for its minocycline tablets as quickly as Ranbaxy would have been able to in the absence of the deal.

Source: Federal Trade Commission, C-4506, FTC File No. 1410134 (final order issued 18 March 2015), 'FTC Actions 2019 Overview', Washington, DC, 2019. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0134/sun-pharmaceutical-industries-ltd-et-al-matter>.

BOX 3.D.28: Akorn, Inc./VersaPharm, Inc.

The FTC complaint alleged that the proposed acquisition by Akorn, Inc. of VersaPharm, Inc. and its parent company, VPI Holdings Corp., would reduce future competition for generic injectable rifampin, an antibacterial medication used as a first-line treatment to kill or prevent the growth of tuberculosis. The complaint stated that VersaPharm was one of three generic companies with an approved ANDA for rifampin. At the time of the complaint, Akorn was one of a limited number of firms awaiting FDA approval for a generic rifampin, which was expected in the foreseeable future. As a result, the complaint charged that the proposed acquisition would significantly reduce future competition, including price competition, by increasing the likelihood that the combined entity would forego or delay the launch of Akorn's generic injectable rifampin. The order requires Akorn to divest its ANDA for generic injectable rifampin, pending before the FDA, to Watson Laboratories, Inc.

Source: Federal Trade Commission, C-4479, FTC File No. 1410162 (final order issued 16 September 2014), 'FTC Actions 2019 Overview', Washington, DC. Available at: <https://www.ftc.gov/enforcement/cases-proceedings/141-0162/akorn-inc-matter>.

E. Restricted distribution and risk evaluation and mitigation strategies

To limit abusive practices relating to pharmaceutical distribution that played a role in the proliferation of opioid drugs in the United States, pursuant to legislative authority the FDA mandated that manufacturers implement programmes, such as risk evaluation and mitigation strategies, intended to limit suspicious transactions (e.g. supplying large quantities of prescription medicines to small markets from which trans-shipment might be undertaken). Presumably unforeseen by the legislature in authorizing these risk management programmes, originator and generic pharmaceutical companies have abused them to prevent potential generic competitors from obtaining quantities of products sufficient to allow research towards producing competitive products, which may include testing for bioequivalence.

United States

In early 2020, the FTC and the State of New York filed a complaint against Vyera Pharmaceuticals, its parent company and two individuals, including Martin Shkreli, that includes an allegation that the defendants entered into a series of contractual arrangements that prevented potential competitors from securing quantities of health technologies needed to conduct bioequivalence testing.

BOX 3.E.1: FTC and State of New York action to prevent restricted distribution

The FTC complaint for injunctive and other equitable relief highlighted the following:

1. To establish that the generic product is therapeutically equivalent to the branded product, the ANDA applicant must demonstrate bioequivalence, meaning that there is no significant difference in the rate and extent to which the active ingredient becomes available in the body. To make this showing, the applicant must acquire substantial quantities of the referenced branded medicine and conduct bioequivalence testing to compare its generic version against that branded medicine.
2. The ANDA applicant must conduct both in vivo and in vitro bioequivalence testing. In the in vivo testing, the same small group of human subjects (a minimum of 12, but often 20 to 30 people) sequentially takes the two medicines, and the pharmacokinetic performance of the drug is measured through bloodwork. The in vitro dissolution testing compares the rate and extent to which the branded and generic medicines form a solution from their original dosage form (e.g. tablet or capsule).
3. The ANDA applicant must also reserve enough branded medicine samples to perform each of the required tests five times.
4. Depending on the medicine, a generic manufacturer may need as many as 1,000 to 5,000 doses of the branded medicine to conduct bioequivalence testing, all of which must be from the same manufacturing lot to ensure uniform character and quality.
5. Normally, the ANDA applicant can obtain sufficient samples of the branded medicine by purchasing them through normal distribution channels, such as pharmaceutical wholesalers.
6. An ANDA applicant must also secure an acceptable, steady supply of the medicine's API, which is the ingredient that provides its pharmacological activity. Pharmaceutical companies typically purchase APIs from third-party suppliers. For an API to be used in a health technology, the FDA must approve the API product, the API manufacturing process and the API manufacturer's quality controls, facility and compliance with good manufacturing practices. An ANDA must, therefore, contain extensive information about the API and its manufacturer, including a complete description of the manufacturing process and process controls, the control of materials used in the manufacture of the substance, controls of critical steps and intermediates, process validation, and the manufacturing process development. In addition to reviewing this information in detail, the FDA will typically audit the API manufacturer and its facility.
7. If a generic cannot find an API supplier with an existing process that can meet the FDA's standards, it will typically need to work with a new supplier to develop a manufacturing process for the API, which can take months or years.
8. A supplier that has already developed a process to produce an API can separately submit a drug master file (DMF) to the FDA containing this required information. In that case, an applicant using that supplier can reference the DMF in its ANDA, rather than developing and submitting the information anew. The generic applicant's path to FDA approval is

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BOX 3.E.1 ...continued

easier and faster if the FDA has already inspected the API supplier's facility and approved the manufacturing process. Even if the FDA still needs to inspect the API supplier, the DMF indicates that the manufacturer has an existing, FDA-approvable process to manufacture the API, which can shorten the ANDA development timeline.

Concerning defendants' anti-competitive agreements to maintain Vyera's Daraprim monopoly

Vyera knew that the dramatic price increase on its own would not secure long-term revenues because, with no patent or regulatory protection, Daraprim would be vulnerable to generic entry. Thus, to protect its Daraprim revenues, Vyera launched an elaborate scheme to prevent generic competition: it entered agreements prohibiting distributors from reselling Daraprim to potential generic competitors or their agents, and entered data-blocking agreements to prevent distributors from selling their Daraprim sales data, thus masking the true size of the Daraprim market to deter generic competitors. Defendants Shkreli and Mulleady implemented, oversaw and participated in this scheme.

Concerning defendants' agreements restricting resale and limiting purchases to block generic entry

Before 2015, Daraprim was distributed openly for more than 60 years without any restrictions. Generic companies were able to purchase Daraprim from a local pharmacy without entering into any written contract or obtaining any type of approval.

One of Vyera's co-founders testified that "closed distribution can increase a product life cycle by preventing generics from potentially getting your referenced product", which they need for FDA-required bioequivalence testing. Vyera's former general counsel further testified that the use of a closed distribution system was "considered an integral part of the company's desire to block a generic entrant for at least three years".

Source: FTC and State of New York v. Vyera Pharmaceuticals, et al. 20 CV 00706, S.D.N.Y. filed 27 January 2020. Complaint for Injunctive and Other Equitable Relief, FTC and State of New York v. Vyera Pharmaceuticals, et al., US Federal District Court, SDNY, 20 CV 00706, 27 January 2020.

To receive approval from the FDA, generic firms are required to conduct bioequivalence testing to demonstrate that a generic formulation is therapeutically equivalent to the brand medicine. This testing process requires a limited amount of the brand product. Certain brand medicines are subject to distribution restrictions that can be used to prevent generic firms from obtaining samples of the brand product for testing purposes. In many instances, these restricted distribution programmes are implemented as part of FDA-mandated risk management programmes known as risk evaluation and mitigation strategies. When Congress authorized the FDA to require such programmes, it directed that the FDA was not to use such programmes to block or delay approval of generic medicines.

BOX 3.E.2: FTC actions to prevent restricted distribution

The Mylan versus Celgene 2014 case involves allegations that Celgene prevented Mylan from offering competing generic versions of Celgene's brand medicine, Thalomid and Revlimid, by precluding it from obtaining samples of those medicines to perform necessary testing, even though the FDA had determined that Mylan's testing protocols for the proposed generics were sufficient. Both medicines are used to treat several forms of cancer, as well as other serious conditions. Mylan in this private antitrust action alleged that Celgene stalled Mylan's efforts to obtain samples of the products by imposing voluminous and unnecessary requests for information, requests that were a pretext to allow Celgene to delay providing samples with an intention of foreclosing potential competition. Defendant Celgene sought dismissal of the case. Celgene argued that, as a matter of law, a private firm is ordinarily free to choose with whom to do business, and vertical agreements, such as those between a manufacturer and its distributors, rarely raise antitrust concerns.

Without taking a position on the factual merits of the case, the FTC's brief explained that Mylan's antitrust claims were not barred as a matter of law. It described how Mylan's allegations in this case fit within established Supreme Court precedent holding that a monopolist's refusal to sell to its potential competitors may, under certain circumstances, violate Section 2 of the Sherman Act. It also explained that a distribution agreement between a brand medicine manufacturer and its distributors may violate Section 1 of the Sherman Act, and that under established law a brand-name pharmaceutical manufacturer's patents do not reach activities undertaken in connection with bioequivalence testing.

The Actelion v. Apotex 2013 case involves allegations that Actelion Pharmaceuticals Ltd. prevented Actavis, Apotex and Roxane from offering competing generic versions of Actelion's brand medicines by precluding them from obtaining samples of those medicines to perform necessary testing. Actelion's Tracleer is used to treat pulmonary arterial hypertension, and Zavesca is used to treat type 1 Gaucher disease. Plaintiffs in this private antitrust action alleged that Actelion imposed distribution restrictions that prevented them from buying samples of Actelion's Tracleer and Zavesca through customary distribution channels, and that Actelion refused to sell the medicines directly, thereby precluding them from meeting the FDA requirements for developing generic versions of these products.

continued...

BOX 3.E.2 ...continued

Defendant Actelion argued that it was under “no duty or obligation” to sell its medicines to potential competitors, whether or not those products fell under the FDA’s risk evaluation and mitigation strategies requirements. In its 11 March 2013 amicus brief, the FTC explained that the Hatch-Waxman Act, the regulatory framework designed to encourage the introduction of low-cost generics while preserving incentives for innovation, could not function as Congress intended if generics were unable to access samples of brand medicines. Without taking a position on the factual merits of the case, the Commission explained that the generic firms’ claims were not barred as a matter of law. It described how the allegations in this case fit within established Supreme Court precedent holding that a monopolist’s refusal to sell to its potential competitors may, under certain circumstances, violate the antitrust laws. The brief also clarified that a distribution agreement between a brand-name pharmaceutical manufacturer and its distributors may also violate the antitrust laws, even when a patented health technology is involved.

Source: Mylan Pharmaceuticals, Inc. v. Celgene Corporation, Federal Trade Commission’s Brief as Amicus Curia, Case No. 2:14-CV-2094-ES-MAH (D. N.J. 17 June 2014); and Actelion Pharmaceuticals Ltd. v. Apotex Inc., Federal Trade Commission’s Brief as Amicus Curiae, Case No. 1:12-cv-05743-NLH-AMD (D. N.J. 11 March 2013). Federal Trade Commission Briefs available at: https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf; and https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

Market definition

Chapter 4 of the 2014 UNDP Guidebook explained the importance of market definition in the prosecution of competition cases. Competition law is designed to address foreclosure of or barriers to market entry and participation. Generally speaking, to determine whether there is a barrier, it is necessary to define the ‘relevant market’. To illustrate, a health technology patent owner is often referred to colloquially as holding a monopoly by virtue of the exclusive right to make and sell the technology. But the scope and effect of the patent owner’s exclusivity grant is dependent on various factors, perhaps most importantly whether there are substitute health technologies that accomplish the same purpose, and whether those substitutes are readily available. On the one hand, the patented health technology may be uniquely capable of treating a disease or medical condition, with no reasonably effective substitutes. In such a case, the ‘relevant market’ may be that single medicine. On the other hand, a newly patented health technology may be entering a market where there are already many effective substitutes (i.e. a crowded field). In that case, the patent may not confer meaningful market power. A patent owner in a crowded field generally should not be able to extract a higher than competitive market price.

Defining the relevant market in pharmaceutical competition cases can be quite complicated because it may involve addressing questions such as the comparative efficacy of using different medicines to treat a particular disease, and that is something that medical experts may not always agree on.

To hold a dominant position on the relevant market, a medicine or other health technology does not need to be patented or covered by a regulatory-based exclusive marketing right. In a number of important recent cases, including the *NCA v. Aspen (Italy)* case in Box 3.C.6 and the *CMA v. Pfizer/Flynn (UK)* case in Box 3.C.8 (both discussed earlier), off-patent/generic medicines were found to hold dominant positions on their relevant markets due to the particular characteristics of the relevant products and markets.

Following are other illustrative cases where the issue of market definition was important.

A. Brazil

BOX 4.1: Example of market definition in Brazil

In the medicines market, the analyst needs to simultaneously examine several scenarios. Besides that, there is no single definition of a relevant market that can address the diversity of competitive issues that may be affected by a merger.

The relevant market definition methodology traditionally used by CADE in the product dimension for medicines follows the definition criteria based on the therapeutic indication of each medicine, commonly the Anatomical Therapeutic Chemical (ATC) system, most often following ATC level 4 (see merger cases 08012.000168/2009-34, 08012.009680/2005-12, 08012.001095/2004-93, 08012.000569/2008-11 and 08012.005306/2002-03, among others.)

The ATC classifies medicines according to the anatomical class/subclass of the medicine. The ATC system has five distinct levels. The higher the level, the greater the degree of disaggregation: (i) anatomical group: ATC1; (ii) therapeutic group: ATC2; (iii) pharmacological group: ATC3; (iv) chemical group: ATC4; and (v) active ingredient: ATC5. The main advantage of the ATC system is the possibility of quick access to market statistics, as the system is maintained by Intercontinental Marketing Services (IMS) for commercial use.

However, CADE has sometimes recognized the weakness of the ATC4 use for relevant market definition (as in AC 08012.009680/2005-12 Aché-Biosintética and AC 08012.004436/2010-21, between Laboratório Pfizer Ltda. and Eurofarma Laboratories Ltda.). To use the ATC4, first, the authority would need to know the weaknesses of this classification to make a broad counter-check exercise, then it would be able to be sure about the merger's competitive impact.

In the case of companies that use the ATC4 to classify their products, the problem is the extremely broad categories that exist in this classification. For this reason, with the ATC4 classification, CADE may not even be alerted whether or not there is a competitive problem. It should be also be highlighted that there are several such overly broad ATC-4 classifications.

The Takeda/Multilab case (08700.004123/2012-86)—involving Takeda Pharmaceuticals of Brazil Ltda. and Multilab Industry and Commerce of Pharmaceuticals Ltda.—involved several relevant markets. In one of them, it was found that the applicants alleged that class ATC4-A01A0 would be a separate relevant market, although the products, under ATC4-A01A0, had several non-substitute medicines. Some examples are mouthwash products, toothpaste, cold sore remedies, constipation remedies and local first dentition dental anaesthetics for babies, which were obviously heterogeneous products and not substitutes for each other (from the medical/pharmaceutical point of view). CADE did not accept ATC4-A01A0 as a relevant market but narrowed the market only to encompass first dentition dental anaesthetics for babies.

In the same case, the applicants maintained that all medicines listed in ATC4-D08A0 would be substitutes, such as intimate soaps, antiseptic gels, foot deodorants, contact lens solution, acne remedies, and topical antiseptics used for general wound care such as Merthiolate, dye and iodine. In the Takeda/Multilab case, CADE did not accept ATC4-D08A0 as a relevant market but narrowed the market to encompass only topical antiseptics used for general wound care.

Source: CADE.

B. China

BOX 4.2: Example of market definition in China

The practice of the NDRC and the State Administration for Industry and Commerce (SAIC) indicates that the relevant product market for the health technology can be defined even more narrowly—for instance, at the level of a specific product. For example, in the Allopurinol API case, the Chongqing Administration for Industry and Commerce (AIC) conducted a detailed analysis into the pharmacology and prices of allopurinol tablets. The Chongqing AIC noted that allopurinol tablets are used to treat gout, a type of arthritis disease. There are several other medicines used in the treatment of gout, but the Chongqing AIC found them to not be sufficiently substitutable with allopurinol tablets due to the difference in the mode of action, the price and the reimbursement policy. Allopurinol API is an indispensable ingredient for the production of allopurinol tablets. As a result, the Chongqing AIC concluded that the allopurinol API market was the relevant market.

In the Phenol APIs case, the Chongqing AIC followed the same approach as that in the Allopurinol API case, but further clarified that prescription and OTC pharmaceuticals should be defined as different relevant product markets. The Chongqing AIC noted that salicylic acid and phenol plasters are the only available OTC pharmaceuticals to treat clavus, and phenol API is an indispensable ingredient for the production of salicylic acid and phenol plasters. As a result, it concluded that the phenol API market was the relevant market. In the Allopurinol tablets cartel case, the NDRC did not conduct a detailed analysis on the definition of the relevant market, but focused its investigation and analysis on allopurinol tablets. More recently, in the estazolam cartel case, the NDRC expressly defined the relevant product markets as the markets for estazolam API and estazolam tablets.

Source: Administrative Penalty Decision of Chongqing Administration for Industry and Commerce No. 15, 28 October 2015, summarized in Yong Bai and Richard Blewitt, 'The Application of the Anti-Monopoly Law to the Pharmaceutical Sector in China', *China Antitrust Law Journal*, Vol 1, Issue 1 (2017).

E. United States

BOX 4.3: Staley v. Gilead Sciences

In the Amicus Brief submitted in 2019, the FTC highlighted that courts have recognized the possibility of co-existing broad and narrow relevant markets for pharmaceuticals. For example, the relevant market might consist of an entire therapeutic class of medicines when the anti-competitive effects are likely to manifest among that entire class, such as in a merger between two branded manufacturers. See, for example, *In re Novartis AG & GlaxoSmithKline*, Dkt. No. C-4510 (FTC, 8 April 2015) (Novartis’s proposed acquisition of GlaxoSmithKline’s cancer portfolio required divestiture of Novartis’s development-stage BRAF and MEK inhibitor medicines); *In re Prestige Brand Holdings, Inc. & Insight Pharm. Corp.*, Dkt. No. 4487 (FTC, 14 October 2014) (proposed merger required the maker of Dramamine to divest Bonine to preserve competition in OTC motion-sickness medicines); and *In re Sanofi-Synthelabo & Aventis*, Dkt. No. C-4112 (FTC, 24 September 2014) (proposed merger required divestiture of Arixtra because consolidation with Lovenox would have reduced competition in the relevant market of Factor Xa inhibitors).

In other circumstances, the relevant market might be limited to only a subset of a therapeutic class. In *Safeway Inc. v. Abbott Laboratories*, plaintiffs alleged monopolization of the market for “boosted protease inhibitors (PIs) used to treat HIV” (761 F. Supp. 2d 874, 884–885 [N.D. Cal. 2011]). Defendants argued that this market definition was overly narrow, because another class of HIV therapies—non-nucleoside reverse transcriptase inhibitors (NNRTIs)—are functionally comparable to boosted PIs (*ibid.* at 888). The court held that “this similarity does not preclude Plaintiffs’ definition of the boosted market for antitrust purposes”, noting that the availability of “several HIV therapies, including NNRTIs and boosted PIs ... is not inconsistent with Plaintiffs’ definition of a boosted PI submarket that exists within a broader HIV therapy market” (*ibid.*). Similarly, in *SmithKline Corp. v. Eli Lilly & Co.*, the Third Circuit acknowledged “a certain degree of interchangeability among all antibiotics”, but limited the relevant market to cephalosporin antibiotics because they were sufficiently differentiated from other antibiotics such that Lilly’s conduct to maintain dominance over them could have anti-competitive effects (575 F.2d 1056, 1064–1065 [3d Cir. 1978]).

Where anti-competitive effects are alleged to result from conduct excluding lower-cost generic versions of a given medicine, the relevant market is frequently even more limited, consisting of only the brand and generic versions of that product. See, for example, *Lidoderm*, 296 F. Supp. 3d. at 1176 (defining a market for 5 percent lidocaine patches—i.e. Lidoderm and its generic equivalents); *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 668, 668 (D. Conn. 2016) (“The existence of a broader market that imposed some price constraints on Aggrenox—but without approximating the more competitive market that developed after generic entry—has no bearing on any issue in this case.”); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (concluding that the relevant market consisted of the brand and generic alone); and *In re Impax Labs.*, Dkt. No. 9373 (FTC, 7 June 2019) at 26 (defining the relevant antitrust product market as branded and generic oxymorphone ER, noting “in most cases arising in the [pharmaceutical reverse-payment] context, a brand and its generics will constitute the relevant market”).

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BOX 4.3 ...continued

Even a product market limited to generic versions of a particular branded medicine may be a relevant market in which to analyse alleged anti-competitive effects. In *Geneva Pharm. Tech. Corp. v. Barr Labs.*, a manufacturer of a generic warfarin sodium alleged that Barr, the manufacturer of another warfarin sodium generic, had locked up a critical source of supply and thereby excluded it from the market (386 F.3d at 485). The Second Circuit found that “once Barr entered the market, the market became segmented so that Coumadin [the brand-name warfarin sodium] and Barr each had smaller, distinct customer groups”, and that Barr could charge higher prices for its generic if it excluded its generic competitor (*ibid.* at 500). Thus, the relevant market was appropriately limited to generic warfarin sodium, excluding the branded version of the same product (*ibid.*). See also *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 82 (D.D.C. 2006) (relevant antitrust market was generic Lorazepam and Clorazepate tablets).

The FTC claimed that, as these cases demonstrate, the relevant product market may vary considerably, depending on the alleged anti-competitive effects at issue. And if there are multiple theories of harm in the same case, as here, the case may implicate multiple relevant markets. In such cases, the FTC said the court’s task is to assess each alleged market on its merits. The two cases *Gilead* relies on in its motion to dismiss are not to the contrary. Neither *Hicks v. PGA Tour, Inc.*, 897 F.3d 1109 (9th Cir. 2018), nor *Siegler v. Sorrento Therapeutics, Inc.*, No. 3:18-cv-01681-GPC-NLS, 2019 WL 3532294 (S.D. Cal. 2 August 2019), dismissed antitrust claims merely because plaintiffs alleged multiple product markets. Rather, in both instances, the court found that plaintiffs failed to plead sufficient facts to support any of their alleged relevant markets. Antitrust plaintiffs frequently plead broad relevant markets and narrower relevant markets within, and courts assess each alleged relevant market individually to analyse the corresponding alleged anti-competitive effects. Such pleading is not inherently contradictory. The linchpin for market definition is properly defining a market in which alleged anti-competitive effects can be assessed. *Gilead* cites no case that holds as a matter of law that there can never be more than one well-pleaded product market relevant to assessing all the alleged anti-competitive harm.

The FTC takes no position on whether the complaint contains sufficient facts supporting the alleged product markets in this case to satisfy the plausibility standard applicable at the motion to dismiss stage. But an argument that alleging multiple relevant markets is impermissible as a matter of law is, the FTC submits, contrary to both the underlying purpose of market definition and the weight of case law.

Source: Case No. 3:19-cv-02573-EMC, N.D. Cal. Amicus Curiae Brief of the Federal Trade Commission, filed 25 October 2019.

This Supplement elucidates trends in competition law enforcement since the publication of the UNDP Guidebook in 2014. During the past seven years, competition authorities have stepped up investigations and enforcement in the pharmaceutical and health technology sectors. While competition enforcement remains active in the European and United States markets, increased enforcement activity among higher-middle-income countries is illustrated by the number of cases in this Supplement reported from authorities in Brazil, Chile and China, among others.

There has also been participation by patient and consumer advocacy groups through initiation of civil competition actions in a number of countries, including Brazil and the Netherlands.

From a doctrinal standpoint, a notable development is the increased attention to investigations and prosecutions aimed at excessive pricing of health technologies, which is a course of action typically based on abuse of dominant market position or monopoly. Such prosecutions have so far addressed unjustifiable increases in the prices of off-patent or generic pharmaceuticals, though there is attention to addressing excessive pricing of patented pharmaceuticals in the academic literature.

Competition law enforcement can be resource-intensive. As a consequence, investigations and prosecutions remain concentrated in high-income countries and regions, and in middle-income countries. One potential avenue for enhancing the participation of developing-country competition authorities is greater collaboration and cooperation among competition authorities, particularly at the regional level and across regions.



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