

Pharmaceutical Antitrust 2021

Contributing editors
Mike Cowie, George G Gordon and Mélanie Thill-Tayara



Publisher

Tom Barnes
tom.barnes@lbresearch.com

Subscriptions

Claire Bagnall
claire.bagnall@lbresearch.com

Senior business development manager

Adam Sargent
adam.sargent@gettingthedealthrough.com

Published by

Law Business Research Ltd
Meridian House, 34-35 Farringdon Street
London, EC4A 4HL, UK

The information provided in this publication is general and may not apply in a specific situation. Legal advice should always be sought before taking any legal action based on the information provided. This information is not intended to create, nor does receipt of it constitute, a lawyer-client relationship. The publishers and authors accept no responsibility for any acts or omissions contained herein. The information provided was verified between May and June 2021. Be advised that this is a developing area.

© Law Business Research Ltd 2021
No photocopying without a CLA licence.
First published 2008
Fourteenth edition
ISBN 978-1-83862-696-9

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112



Pharmaceutical Antitrust 2021

Contributing editors

Mike Cowie, George G Gordon and Mélanie Thill-Tayara
Dechert LLP

Lexology Getting The Deal Through is delighted to publish the fourteenth edition of *Pharmaceutical Antitrust*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Mexico.

Lexology Getting The Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.lexology.com/gtdt.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Mike Cowie, George G Gordon and Mélanie Thill-Tayara of Dechert LLP, for their continued assistance with this volume.



London
June 2021

Reproduced with permission from Law Business Research Ltd
This article was first published in July 2021
For further information please contact editorial@gettingthedealthrough.com

Contents

Global overview	3	India	64
Mélanie Thill-Tayara Dechert LLP		Bharat Budholia, Toshit Shandilya, Atish Ghoshal and Kshaema Susan Mathew AZB & Partners	
Brazil	5	Japan	76
Ana Paula Martinez, Alexandre Ditzel Faraco and Mariana Tavares de Araujo Levy & Salomão Advogados		Yusuke Nakano Anderson Mōri & Tomotsune	
Canada	14	Mexico	83
Kevin Ackhurst, Stephen Natrass, Erin Brown and John Greiss Norton Rose Fulbright		Raúl Zepeda Ruiz, César Lechuga Perezanta, Mauricio Gómez Guerrero and Héctor González Martínez CMS Woodhouse Lorente Ludlow	
China	23	Norway	90
Hong (Cathryn) Jin, Mingfang Gong and Yingling Wei JunHe LLP		Eivind J Vesterkjær and Mari Gjefsen Advokatfirmaet Thommessen AS	
European Union	30	Portugal	97
Mélanie Thill-Tayara and Marion Provost Dechert LLP		Joana Gomes dos Santos Caíado Guerreiro	
Finland	39	Romania	104
Hanna Paloheimo and Kiti Karvinen Castrén & Snellman		Lucian Bondoc, Raluca Voinescu and Andreea Lungu Bondoc & Asociatii	
France	46	Spain	112
Christophe Hénin and Julie Vasseur Intuity		Helmut Brokelmann, Mariarosaria Ganino and Beatriz Sánchez-Ortiz MLAB Abogados	
Germany	57	United Kingdom	122
Clemens Graf York von Wartenburg, Marjolein De Backer and Thirith von Döhren Dechert LLP		Alec Burnside, Robert Darwin and Michael I Okkonen Dechert LLP	
		United States	133
		George G Gordon, Mike Cowie, Thomas J Miller and Samuel Stelk Dechert LLP	

Brazil

Ana Paula Martinez, Alexandre Ditzel Faraco and Mariana Tavares de Araujo*

Levy & Salomão Advogados

PHARMACEUTICAL REGULATORY LAW

Regulatory framework

1 | What is the applicable regulatory framework for the authorisation, pricing and marketing of pharmaceutical products, including generic drugs?

The main pieces of legislation that set out the regulatory framework for the pharmaceutical sector in Brazil are:

- Law No. 5,991/1973, which provides for the sanitary control of drugs, medicines, pharmaceutical and related inputs marketing;
- Law No. 6,360/1976, which provides for the sanitary control to which medicines, drugs, pharmaceutical and related inputs are subject;
- Law No. 9,782/1999, which defines the national system of sanitary control and creates the National Health Surveillance Agency (ANVISA);
- Law No. 9,787/1999, which amends Law No. 6,360/1976 by providing for generic drugs;
- Law No. 10,742/2003, which defines rules for the pharmaceutical sector and creates the Chamber of Drug Market Regulation (CMED);
- Decree No. 4,766/2003, which regulates CMED's attributions and operation;
- Decree No. 4,937/2003, which regulates article 4 of Law No. 10,742/2003 to establish the criteria for the adjustment of drugs' prices; and
- Decree No. 8,077/2013, which regulates the conditions for the functioning of companies subject to sanitary licensing, and the registration, control and monitoring of products subject to sanitary control, according to Law No. 6,360/1976.

Moreover, there are several infra-legal rules from ANVISA regarding matters such as drug registration, licences for pharmaceutical laboratories and other agents of the pharmaceutical production chain. Finally, CMED is the interministerial body in charge of price regulation.

Regulatory authorities

2 | Which authorities are entrusted with enforcing these rules?

ANVISA regulates matters regarding drug registration, licences for pharmaceutical laboratories and other agents of the pharmaceutical production chain. CMED regulates prices for original, branded generic and generic drugs, and regularly publishes price lists. Prices of new drugs are defined based on overall reference values and a basket of other countries' market prices.

Pricing

3 | Are drug prices subject to regulatory control?

Drug prices are subject to the control of CMED, which defines the criteria for the calculation of the maximum distribution and retail prices of drugs, under the provisions of Law No. 10,742/2003. Retail price limits are calculated based on the manufacturer price, which is adjusted by four factors:

- the official inflation index rate published yearly;
- a productivity coefficient determined by CMED, considering pharmaceutical companies' earnings projections;
- an intra-sector price adjustment coefficient, calculated by companies' market power; and
- an inter-sector price adjustment coefficient, originated by price fluctuation of inputs.

After manufacturer price lists are sent by pharmaceutical companies to CMED, the chamber establishes the applicable coefficients for the factors listed above and then issues an annual resolution, which serves as a guide to calculate the maximum retail price for each drug.

Relevant legislation regarding drug prices control in Brazil is:

- Law No. 10,742/2003;
- Decree No. 4,766/2003;
- Decree No. 4,937/2003;
- Resolution No. 5/2015, which defines the criteria for drug prices adjustment calculation; and
- Resolution No. 1/2017, which has defined the rules for the calculation of maximum distribution and retail prices since 21 March 2017.

Distribution

4 | Is the distribution of pharmaceutical products subject to a specific framework or legislation? Do the rules differ depending on the distribution channel?

ANVISA is responsible for regulating activities related to the distribution of pharmaceutical products in Brazil. Some of the rules issued by the agency on distribution activities are as follows:

- ANVISA's Resolution No. 304/2019, which determines the duties of companies that distribute pharmaceutical products;
- ANVISA's Resolution No. 204/2006, which establishes that all undertakings that perform distribution activities, among other things, must comply with the guidelines provided in the Technical Rules of Good Practices for Distribution and Fractioning of Pharmaceutical Inputs; and
- ANVISA's Resolution No. 39/2013, which provides for the administrative proceedings for granting of the Certificate on Good Distribution Practices.

In general, these rules do not distinguish between the different distribution channels.

Intersection with competition law

5 | Which aspects of the regulatory framework are most directly relevant to the application of competition law to the pharmaceutical sector?

The most relevant aspects of the Brazilian regulatory framework to the application of competition law to the pharmaceutical sector aim to promote competition between originator and generic drugs. These are as follows:

- doctors within the public health system shall prescribe the active ingredient rather than the brand in the prescription;
- the government shall organise bids listing the active ingredient rather than any given brand;
- the entry price of generics must be at least 35 per cent under the price of the originator product (prices are regulated by CMED); and
- originator companies shall supply samples to generic competitors to allow them to produce generic drugs.

COMPETITION LEGISLATION AND REGULATION

Legislation and enforcement authorities

6 | What are the main competition law provisions and which authorities are responsible for enforcing them?

Competition law and practice in Brazil is primarily governed by Law No. 12,529 of 30 November 2011 (Law No. 12,529/2011 or the Competition Law), which entered into force on 29 May 2012. The competition law has consolidated the investigative, prosecutorial and adjudicative competition functions into one independent agency, the Administrative Council for Economic Defence (CADE).

CADE's structure includes a tribunal composed of six commissioners and a president; a Directorate-General for Competition (DG); a General-Attorney's Office; and an economics department. With respect to merger enforcement, the DG is responsible for clearing simple transactions and challenging complex cases before the tribunal, while CADE's tribunal is responsible for adjudicating complex cases challenged by the DG, by the tribunal itself or by third parties. The DG is also the chief investigative body in matters related to anticompetitive practices. CADE's tribunal is responsible for adjudicating the cases investigated by the DG. All of CADE's decisions are subject to judicial review.

Certain anticompetitive conduct (primary cartel conduct) is also a crime in Brazil. Federal and state public prosecutors are responsible for enforcing the Criminal Statute. Also, the police (local or federal) may initiate investigations of anticompetitive conduct and report the results of their investigation to CADE and prosecutors, who may indict the individuals. The administrative and criminal authorities have independent roles and powers and may cooperate on a case-by-case basis.

Public enforcement and remedies

7 | What actions can competition authorities take to tackle anticompetitive conduct or agreements in the pharmaceutical sector and what remedies can they impose?

Brazil's competition law applies to corporations, associations of corporations and individuals. For corporations, fines range between 0.1 and 20 per cent of the company's or group of companies' pre-tax turnover in the economic sector affected by the conduct in the year prior to the beginning of the investigation.

Apart from fines, CADE may also:

- order the publication of the decision in a major newspaper at the wrongdoer's expense;

- prohibit the wrongdoer from participating in public procurement procedures and obtaining funds from public financial institutions for up to five years;
- include the wrongdoer's name in the Brazilian Consumer Protection List;
- recommend that the tax authorities block the wrongdoer from obtaining tax benefits;
- recommend that the IP authorities grant compulsory licences of patents held by the wrongdoer;
- order a corporate spin-off, transfer of control or sale of assets; and
- prohibit an individual from exercising market activities on its behalf or representing companies for five years.

The law also includes a broad provision allowing CADE to impose any 'sanctions necessary to terminate harmful anticompetitive effects'. CADE's wide-ranging enforcement of this provision may prompt judicial appeals.

Regarding anticompetitive conduct in the pharmaceutical sector, CADE's tribunal has traditionally imposed fines of up to 5 per cent of the relevant turnover.

Private enforcement and remedies

8 | Can remedies be sought through private enforcement by a party that claims to have suffered harm from anticompetitive conduct or agreements implemented by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

At the administrative level, private parties can petition CADE to be admitted to the administrative proceedings aimed at investigating the anticompetitive conduct or agreement as an 'interested third party'. Such parties have the ability to file arguments or documents with CADE, but the antitrust authority is responsible for imposing the remedies deemed necessary.

Moreover, private parties that were victims of anticompetitive conduct or agreement may seek recovery of actual damages and lost earnings, and moral damages by filing a judicial lawsuit. Courts may also order other types of relief, such as court injunctions to cease the illegal conduct. The scope of such orders is broad. Possible examples include ordering a defendant to stop selling a product, or change pricing conditions or any other contractual provisions.

There are already damages claims filed by generic drugs against originator companies pending before judicial courts, and this could represent an additional area of concern when dealing with non-ordinary life-cycle management strategies in Brazil.

Sector inquiries

9 | Can the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

Brazil's antitrust authorities may conduct sector-wide inquiries. According to the Competition Law, CADE's tribunal and DG can retain professionals to conduct analyses, studies and inspections as well as request information from any individual, authority, agency and public or private entities deemed necessary. CADE's economic department can also, by its own initiative or at the request of CADE's tribunal or DG, conduct studies and economic opinions. The Competition Law also provides that the Economic Monitoring Office at the Ministry of Finance is the agency responsible for competition advocacy, and may, among other measures, develop studies examining competition in specific sectors of the national economy.

Similarly to other jurisdictions, there is an increasing number of cases in the pharmaceutical sector being reviewed by CADE, and a sector inquiry was conducted in 2009 and 2010 by the then Secretariat of Economic Law (SDE), following the initiatives of the European Commission and the US Federal Trade Commission. The SDE sent out questionnaires to approximately 40 originator companies questioning practices related to patent extensions. Brazilian Law No. 5,772/1971 explicitly prohibited drug patenting. However, the Agreement on Trade-Related Aspects of Intellectual Property Rights created an obligation for Brazil to protect drug patents, with transitional rules (pipeline patents). The pipeline allowed patent requests to be automatically approved based on the date of the first foreign filing; the maximum period for patent protection is 20 years under Brazilian law.

A number of branded pharmaceutical companies resorted to judicial courts to extend their protection, defending theories such as only the first valid foreign filing should be considered for the purposes of determining the duration of the patent protection (at the time of the sector inquiry, there were over 37 cases pending before the Superior Court of Justice). The issue was settled in April 2010, when the Superior Court of Justice decided that the date of the first foreign filing is the valid one, even if the filing was later withdrawn (see *Viagra* case).

Health authority involvement

10 | To what extent do health authorities or regulatory bodies play a role in the application of competition law to the pharmaceutical sector? How do these authorities interact with the relevant competition authority?

The intersection between the pharmaceutical sector and competition law is widely recognised by the Brazilian authorities. In 2013, National Health Surveillance Agency (ANVISA) and CADE executed a technical cooperation agreement, with the goal of enhancing the relationship between the two agencies through, for example, workshops, technical visits, and joint studies and research. The agreement also provides for the exchange of information, reports, databases and other relevant documents.

In 2019, CADE and ANVISA signed an addendum extending the term of the technical cooperation agreement to January 2023. The addendum points out ANVISA's support in merger cases on topics such as relevant market definition, and analysis of anticompetitive conducts (involving primarily drug patents and information on product that has had its ownership transferred). Also, the agreement raises the need for analysis of abusive practices in the hospital sector, including abusive pricing.

NGO involvement

11 | To what extent do non-government groups play a role in the application of competition law to the pharmaceutical sector?

Any individual or entity, including non-government groups, can file a complaint before CADE's DG in relation to alleged anticompetitive practices. Non-government groups can also be requested to provide information in proceedings related to merger review or anticompetitive conducts. Moreover, non-government groups can also petition CADE to be admitted to different proceedings as an interested third party.

Federal, state and municipal governments, public prosecutors, any governmental consumer protection agency, publicly held entities and private non-profit organisations that have in their bylaws the protection of consumer or antitrust rights and were incorporated at least one year before the filing can stand in class actions related to anticompetitive conducts.

Historically, *Pró Genericos*, the Brazilian association of generic companies, has been playing a very active role before CADE, bringing most of the complaints challenging life-cycle management strategies on the part of originator companies.

REVIEW OF MERGERS

Thresholds and triggers

12 | What are the relevant thresholds for the review of mergers in the pharmaceutical sector?

Law No. 12,529/2011 requires that a transaction be filed in Brazil if the following criteria are met:

- each of at least two parties to the transaction meet the turnover threshold;
- the transaction amounts to 'a concentration act'; and
- the transaction produces effects in Brazil, as defined by article 2 of the Competition Law (the effects test).

Brazil's competition law provides for a minimum-size threshold, expressed in total revenues derived in Brazil by each of at least two parties to the transaction. One party must have Brazilian revenues in the last fiscal year of at least 750 million reais and the other party 75 million reais. Both the acquirers and sellers, including their whole economic group, should be taken into account.

The Competition Law provides that any concentration act must be submitted to Administrative Council for Economic Defence (CADE) for review, provided that the turnover threshold is met. Whereas the law specifically refers to 'concentration acts', it defines those very broadly as when:

- two or more companies merge;
- one company acquires, directly or indirectly, sole or joint control of another, or even a minority shareholding;
- an absorption of other companies takes place; or
- a joint venture, an associative contract or a consortium is formed.

Finally, CADE's DG has been considering the following to assess whether a given transaction fulfils the effects test:

- whether the target has or is expected to have (following the transaction) activities in Brazil or generate revenues in the country (there is no *de minimis* exception);
- whether the parties have horizontal or vertical relationships that could affect Brazil; or
- whether the geographic scope of the relevant market includes a region encompassing Brazil.

13 | Is the acquisition of one or more patents or licences subject to merger notification? If so, when would that be the case?

The acquisition of licences of patents would be subject to mandatory filing assuming the relevant criteria are met.

Market definition

14 | How are the product and geographic markets typically defined in the pharmaceutical sector?

The product market is generally defined by CADE as including all the products and services considered substitutable by consumers because of their features, prices and usage. A relevant market of the product could encompass a certain number of products and services that present physical, technical or business characteristics that recommend the grouping.

CADE has consistently taken as a starting point for market definition purposes the anatomical therapeutic chemical (ATC) classification system devised by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and IMS Health.

In most of the cases, CADE has adopted the fourth ATC level (ATC4) as the criterion to define the relevant product market. However, CADE

has also stated that it may be necessary to analyse pharmaceutical products at a higher, lower or mixed level of ATC classification and based on the effective substitutability of the products in order to define the relevant market. In most of those exercises, CADE took into account ATC3 and the drug's therapeutic use. Further, in a recent CADE decision (June 2019) referring to the acquisition by GSK of Pfizer's healthcare products division (Pfizer CH), in which overlaps in five ATC codes were identified, a segmentation between the drug's therapeutic use and over-the-counter medicines was also conservatively adopted by CADE to assess one overlap (Merger Case No. 08700.001206/2019-90).

Also, CADE has considered in the past that originator drugs and their generic copies belong to the same relevant product market, as generics can effectively substitute originator drugs after patent expiry, especially if the regulatory system encourages switching, as is the case in Brazil.

Furthermore, in its decisional practice, CADE has defined separate product markets for out-licensing, supply of active pharmaceutical ingredients and contract manufacturing.

From a geographic perspective, CADE has traditionally defined the market to be national in scope, given the limited weight of imports, the high level of regulation, the obligation for laboratories and medicines to be registered before National Health Surveillance Agency (ANVISA) and the fact that pharmaceutical companies generally offer their medicines throughout the country with uniform price policies.

Sector-specific considerations

15 | Are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

While analysing mergers concerning the pharmaceutical industry, CADE usually considers sector-specific features only in complex cases.

Some of these features are listed in the Procedural Guideline for setting and performing the antitrust analysis of the relevant drug markets, issued by the former SDE. According to this document, the relevant market definition for cases involving the pharmaceutical industry should take into account the following features:

- medicines are subject to different and specific legislation regarding their production, distribution and advertising;
- prescription-bound and over-the-counter (OTC) medicines may follow different competition patterns;
- the strong information asymmetry leads to high advertising costs, especially for OTC products, which may sometimes cause product differentiation and market segmentation;
- there are relevant barriers to entry, including patent protection; and
- the strength of generic drugs and strategic brand-positioning for some medicines should also be taken into account.

Addressing competition concerns

16 | Can merging parties put forward arguments based on the strengthening of the local or regional research and development activities or efficiency-based arguments to address antitrust concerns?

CADE traditionally follows a five-step review process provided for in the Horizontal Merger Guidelines, consisting of:

- 1 definition of relevant market;
- 2 determination of the parties' market share;
- 3 assessment of the probability of the parties exercising market power following the transaction;
- 4 examination of the efficiencies; and
- 5 evaluation of the net effect on welfare.

Based on this review process, the authorities will consider whether perceptible efficiencies resulting from the merger are likely to reduce or reverse adverse effects arising from the transaction. It is incumbent upon the merging firms to substantiate efficiency claims so that CADE can verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved, how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific.

CADE's case law shows that efficiencies arguments have limited weight in the agency's decision-making process. Historically, whenever CADE has reached item (4), the transaction was either blocked or cleared subject to substantial remedies.

Non-competition issues, such as industrial policy or public interest, are not traditionally factored into the review process.

Horizontal mergers

17 | Under which circumstances will a horizontal merger of companies currently active in the same product and geographical markets be considered problematic?

The Competition Law presumes market power to exist if the parties jointly hold a share of at least 20 per cent of the market. CADE's recently published Guidelines on Horizontal Mergers describe threshold levels of market concentration that raise concerns about the possible exercise of market power in a few ways: by a single firm unilaterally, when that firm has a market share of at least 20 per cent; or through coordination of firms (collective dominance) in a market in which the four-firm concentration ratio is at least 75 per cent and the resulting firm has a market share of at least 10 per cent. If the market concentration exceeds either of those levels, CADE proceeds to step three (market power exercise). Following the US or the European Commission standards, CADE's guidelines also consider the Herfindahl-Hirschman Index (HHI) as a measure of concentration.

Forexample, when reviewing Merger Case No. 08700.009834/2014-09 (*Anovis/União Química*), CADE considered that no competition concerns would arise if the combined market share was under 20 per cent. For the two ACT4 category classes for which the resulting concentration was over 20 per cent, CADE resorted to the HHI index, which indicated the high market share was prior to the transaction, with little increment following the transaction. As concentrations were over 50 per cent, CADE took a conservative approach and proceeded with the analysis of the possibility of exercise of market power, which would not be significantly affected by the merger, and thus cleared the case. More recently, in Merger Case No. 08700.005093/2016-59 (*Sanofi/Boehringer Ingelheim*), despite finding concentration above 20 per cent in the market segments involved in the transaction and an HHI variation above 200 points, CADE unconditionally cleared the case owing to the fact that (i) the parties' products included in the same market segment were not close substitutes; and (ii) there is a great number of companies with high market share in the segments affected. A similar approach was taken by CADE while reviewing Merger Case No. 08700.006159/2016-28 (*Pfizer/AstraZeneca*). Even though the transaction resulted in a high market share in some of the affected markets – and in some cases the HHI variation was also relevant – CADE cleared the transaction without restrictions because, among other things:

- Pfizer's high market share was only identified considering the scenario in terms of value (as opposed to volume), which could be related to drugs over which the company previously had patents;
- the market share of the parties in terms of units was very low;
- new drugs entered the market and there is projection of new products; and
- the presence of important competitors in the affected markets.

Product overlap

18 | When is an overlap with respect to products that are being developed likely to be problematic? How is potential competition assessed?

An overlap concerning products that are being developed may be problematic in some scenarios, such as if the patent rights related to the active principles of the developing product may increase current and potential costs of third parties, strengthening the merging parties' dominant position and increasing barriers to entry; or if there is a risk that the merged entity will terminate or reduce the development of the product to avoid competition with products currently being marketed by the other party to the transaction. In more recent years, CADE has reviewed a number of joint ventures between pharmaceutical companies aimed at developing new products in Brazil. In such cases, competition concerns arose when the partnership resulted in potential elimination of future competition between the parties, preventing them from entering the market alone.

When Pfizer and Orygen filed the formation of a joint venture aimed at producing and selling up to five biosimilar products in Brazil (Merger Case No. 08700.005601/2014-37), CADE assessed the estimated market shares and potential horizontal overlaps with regard to each relevant ATC4 class. Since there were no relevant horizontal overlaps, CADE identified no risk of potential competition elimination, leading to the approval of the transaction with no conditions.

Remedies

19 | Which remedies will typically be required to resolve any issues that have been identified?

The Competition Law allows CADE to take whatever measures deemed necessary to ensure the merger would not impact competition, and there is a preference for adopting structural rather than behavioural remedies. If CADE finds a transaction to be harmful to competition, it may block it or accept remedies, particularly divestitures of production facilities, stores, distribution networks or brands. Under the Competition Law, parties can negotiate undertakings with CADE to remedy perceived competition issues. Parties can offer undertakings from the day of filing up to 30 days following the challenge of the transaction before the tribunal by the DG.

For example, in *Sanofi/Medley* (Merger Case No. 08012.003189/200910), CADE cleared the transaction in 2010 on the condition that the merged entity would sell three drugs – Lopigrel (Plavix), Digedrat and Peridal – to market players with less than 15 per cent market share to improve competition. The merger entity would otherwise have over 50 per cent of the problematic relevant markets, considered to have high entry barriers. The transaction was also viewed as creating portfolio effects. The case also involved the adoption of an interim measure in 2009 aimed at ensuring that the parties would preserve the reversibility of the transaction in case CADE ultimately decided to block it or impose remedies (at that time, CADE did not have a pre-merger review and parties were allowed to close the transaction pending CADE's decision).

More recently, in March 2019, CADE cleared the acquisition of All Chemistry do Brasil by SM Empreendimentos Farmacêuticos (Merger Case No. 08700.005972/2018-42) on the condition that SM does not make any acquisitions of rivals in the next two years and that it will notify CADE of all transactions in the next two years. The transaction was not originally submitted to CADE for review because it did not meet the thresholds, but the authority determined the notification of the deal after receiving a complaint.

ANTICOMPETITIVE AGREEMENTS

Assessment framework

20 | What is the general framework for assessing whether an agreement or concerted practice can be considered anticompetitive?

The basic framework for the assessment of anticompetitive agreements or conducts in Brazil is set by article 36 of Law No. 12,529/2011. Article 36 deals with all types of anticompetitive conduct other than mergers. The Competition Law prohibits acts 'that have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

Article 36(3) contains a lengthy but not exhaustive list of acts that may be considered antitrust violations provided they have the object or effect of distorting competition. Potentially anticompetitive practices include resale price maintenance, price discrimination, tying sales, exclusive dealing and refusal to deal.

Administrative Council for Economic Defence (CADE) Resolution No. 20/1999 specifically provides that exclusivity agreements, refusal to deal, price discrimination and other vertical restraints are not per se infringements in Brazil and shall be assessed under the rule-of-reason test. Annex II of CADE Resolution No. 20/99 outlines 'basic criteria for the analysis of restrictive trade practices', including:

- definition of relevant market;
- determination of the defendants' market share;
- assessment of the market structure, including barriers to entry and other factors that may affect rivalry; and
- assessment of possible efficiencies generated by the practice and balance them against potential or actual anticompetitive effects.

In practice, no case has yet been decided on the basis that harmful conduct was justified by pro-competitive efficiencies.

Technology licensing agreements

21 | To what extent are technology licensing agreements considered anticompetitive?

Article 36 of Brazil's Competition Law includes as examples of anticompetitive practices conduct performed through the abuse of intellectual property rights, and CADE has been consistently stating that the grant of intellectual property rights may lead to anticompetitive effects (when, for example, a party licenses intellectual property rights to one party and refuses to do the same to its rivals). Restraints involving intellectual property rights are assessed under the rule of reason; therefore, it is likely that the assessment would take into account the specific characteristics of each case, and balance potentially competitive against anticompetitive effects.

In 2013, for example, CADE cleared with conditions four transactions involving licensing agreements between Monsanto and four other companies (Don Mario Sementes, Nidera Sementes, Syngenta and Coodetec – Cooperativa Central de Pesquisa Agrícola) in relation to the development, production and marketing of soybean seed with Monsanto's Intacta RR2 PRO technology. The conditions refer to changes in clauses of the agreement that granted Monsanto the possibility of influencing strategic decisions of the licensee companies (eg, the agreement established a compensation mechanism for licensee companies that was based on the sales of the Intacta product and on the sales of certified seeds of Monsanto's competitors).

Co-promotion and co-marketing agreements

22 | To what extent are co-promotion and co-marketing agreements considered anticompetitive?

The Competition Law provides no clear-cut guidance on the subject. However, since these agreements are reviewed under the rule of reason, it is likely that the assessment would take into account the specific characteristics of each case, and balance potentially pro-competitive and anticompetitive effects.

Other agreements

23 | What other forms of agreement with a competitor are likely to be an issue? How can these issues be resolved?

Under article 36 of Law No. 12,529/2011, agreements with competitors would be an issue if they 'have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

Therefore, there is no specific form of agreement that is forbidden a priori by the legislation. Besides their object and effect, CADE will take into consideration the market power held by the involved parties to assess the likeliness of antitrust risks. For those agreements that may concern the exchange of commercially sensitive information among competitors, confidentiality provisions will be useful tools to help reduce this exchange and thus avoid further antitrust liability.

Cartel cases, however, are an exception to the assessment under the rule of reason, as CADE historically defined it as a per se conduct. CADE also includes in the cartel definition the exchange of commercially sensitive information that may lead to the change of market conditions, even if an agreement is not reached by the parties.

Issues with vertical agreements

24 | Which aspects of vertical agreements are most likely to raise antitrust concerns?

Vertical agreements raise antitrust concerns when they 'have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

Article 36(3) contains a lengthy but not exhaustive list of acts that may be considered antitrust violations provided they have the object or effect of distorting competition. Potentially anticompetitive practices include resale price maintenance, price discrimination, tying sales, exclusive dealing and refusal to deal.

Patent dispute settlements

25 | To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

CADE has recently considered pay-for-delay conduct to be a potential violation of the Competition Law and liability may apply if a pharmaceutical company settles a patent dispute with the sole purpose of delaying the entry of a competitor into the market. We are not aware of a case targeting this conduct being reviewed by CADE.

Joint communications and lobbying

26 | To what extent can joint communications or lobbying actions be anticompetitive?

Joint communications or lobbying actions, by themselves, are not presumed to be harmful to competition. However, when communications result in the exchange of commercially sensitive information such as prices, discount policies, costs, clients and suppliers, among others, the practice may amount to an antitrust infringement and companies and individuals may be subject to sanctions imposed by CADE.

Regarding lobbying actions, the regular exercise of the right to complain before the public sector with the purpose of defending the sector's best interests and ensure the defence of rights do not arouse competition concerns. This only happens when the exercise of such right is considered abusive, which can also amount to a sham litigation.

Although there have been no recent relevant cases involving pharma companies, recently, in an investigation concerning petrol stations located in Natal that allegedly acted to prevent the enactment of a law that would increase rivalry in their market, CADE considered three cumulative conditions to assert the abusive exercise of the right to complain:

- the complaints' success probability;
- the argument's plausibility; and
- the adequacy of the forms and instruments used (Administrative Proceeding No. 08700.000625/2014-08).

CADE's tribunal concluded that the companies aimed only to maintain the legislation already in force, which was more beneficial to them, and that they did this through adequate means, not abusing its rights.

Public communications

27 | To what extent may public communications constitute an infringement?

Public communications are potentially anticompetitive when they involve the exchange of commercially sensitive information that can be used to facilitate or induce collusive practices. Such statements can also constitute a competition violation if they result in one of the effects established in article 36 of the Competition Law.

In 2009, ABICAB (the Trade Association of Chocolate and Candy Producers), its president and vice-president disclosed in a press conference its expectations for price increases and volume of production adjustments before Easter. CADE found that such signalling had the potential to promote uniform commercial conditions among competitors. The case was settled in 2013, after the payment of a fine of 96,000 reais and the commitment to stop signalling future commercial policies.

Similarly, in 2020, CADE opened a preparatory procedure to investigate statements made by the executives of two Brazilian companies active in the food market (JBS and BRF). During a conference held by a global investment bank, the executives stated that their products' prices would increase since the price of corn had increased. Ultimately, the case was dismissed by CADE's General-Superintendence, owing to the lack of evidence of antitrust violations.

Exchange of information

28 | Are anticompetitive exchanges of information more likely to occur in the pharmaceutical sector given the increased transparency imposed by measures such as disclosure of relationships with HCPs, clinical trials, etc?

The Brazilian Research-Based Pharmaceutical Manufacturers Association Code of Conduct sets forth transparency clauses with regard to relationships (section 1.1.5), contracts (section 3) and

donations (section 12) in the pharmaceutical sector. Clinical trials are also experiencing growth in Brazil and are contributing to the development of scientific research in Latin America.

The increased transparency granted by these measures does make it more likely for anticompetitive exchanges of information to occur. We are not aware of a case targeting a similar conduct being reviewed by CADE.

ANTICOMPETITIVE UNILATERAL CONDUCT

Abuse of dominance

29 | In what circumstances is conduct considered to be anticompetitive if carried out by a firm with monopoly or market power?

Conducts carried out by a firm with monopoly or market power will be considered anticompetitive if they 'have as [their] object or effect':

- the limitation, restraint or, in any way, harm to open competition or free enterprise;
- control over a relevant market for a certain good or service;
- an increase in profits on a discretionary basis; or
- engagement in market abuse.

De minimis thresholds

30 | Is there any de minimis threshold for a conduct to be found abusive?

No, there is no de minimis threshold for a conduct to be found abusive.

Market definition

31 | Do antitrust authorities approach market definition in the context of unilateral conduct in the same way as in mergers? If not, what are the main differences and what justifies them?

In theory, yes, but in practice the agency tends to be less restrictive when defining a relevant market in behavioural cases.

Establishing dominance

32 | When is a party likely to be considered dominant or jointly dominant? Can a patent owner be dominant simply on account of the patent that it owns?

The Competition Law provides that a dominant position is presumed when 'a company or group of companies' controls 20 per cent of a relevant market. Article 36 further provides that Administrative Council for Economic Defence (CADE) may change the 20 per cent threshold 'for specific sectors of the economy', but the agency has not formally done so to date. Such an assumption provides some guidance to private parties as it would be unlikely for CADE to find a violation in the absence of market power.

IP rights

33 | To what extent can an application for the grant or enforcement of a patent or any other IP right (SPC, etc) expose the patent owner to liability for an antitrust violation?

The application for the grant or enforcement of a patent will not, by itself, expose the patent owner to antitrust liability. However, a patent owner may be found liable if it uses its patent right in an abusive manner, resulting in at least one of the effects listed in article 36 of the Competition Law.

In 2007, Pró Genéricos filed a complaint against Eli Lilly do Brasil and Eli Lilly and Company for allegedly abusing their rights regarding

Gemzar, a drug to treat cancer, to prevent generics entry. Among other alleged practices, Eli Lilly filed six different claims before the judicial courts to enforce its rights and required one additional five-year period of exclusive marketing rights given the discovery of a new use for the drug. An injunction ensured an additional protection for eight months, and for three months the pharmaceutical company Sandoz was not allowed to offer the competing drug Gemcit in the market.

In June 2015, CADE's tribunal found that Eli Lilly abused its rights by presenting misleading information to courts, with 'serious harm to public health and economy'. According to the agency, the drug maker did not clearly explain before the courts that the request for a patent was never granted, an omission that was considered to be strategic and malicious, enabling the company to exclude competitors from the market. According to the Reporting Commissioner, 'the company behaved in an anticompetitive manner by presenting multiple claims before several courts, omitting information to obtain artificially the monopoly in the sale of the medicine, besides unduly obtaining an exclusive right to sell the drug'.

CADE imposed a fine of 36.6 million reais. When calculating the fine, CADE doubled the expected fine in view of recidivism considering Eli Lilly's sanction in the alleged cartel against generic drugs (Administrative Process No. 08012.011508/2007-91).

34 | When would life-cycle management strategies expose a patent owner to antitrust liability?

Life-cycle management will not, by itself, expose the patent owner to antitrust liability. However, a patent owner may be found liable if this management comprises the use of the patent right in an abusive manner, resulting in at least one of the effects established in article 36 of the Competition Law.

In 2008, Pró Genéricos, a local generic manufacturers' association, filed a complaint against Abbott for allegedly abusing its power through patent violation claims against Cristália Produtos Químicos e Farmacêuticos regarding anaesthetics and the launch of a new antiviral drug that was not considered to be an improvement over the original drug (Administrative Inquiry No. 08012.011615/2008-08). In January 2019, the investigation was dismissed owing to lack of evidence.

Furthermore, in 2011, Pró Genéricos filed a complaint against AstraZeneca for allegedly abusing its rights as a consequence of patent violation claims against Germed/Brazil's FDA regarding a number of blockbuster drugs, namely Crestor (cholesterol drug), Nexium (acid reflux relief drug) and Seroquel (drug for schizophrenia, bipolar disorder and major depressive disorder). AstraZeneca was accused of engaging in ring-fencing practices regarding its IP holdings to deter generic entry, as well as sham litigation practices before courts (Administrative Inquiry No. 08012.001693/2011-91). The investigation is pending.

Communications

35 | Can communications or recommendations aimed at the public, HCPs or health authorities trigger antitrust liability?

Statements with the intent to influence costumers or healthcare professionals are not per se antitrust infringements. Those actions will only be found anticompetitive if they result in one of the effects listed under article 36 of the Competition Law.

We are not aware of any cases related to this conduct being adjudicated by CADE. However, we understand, for example, that recommendations made by pharmaceutical companies that harm the credibility of an entrant competitor and its products, without having grounds on solid arguments, may constitute the creation of a barrier to entry and amount to an antitrust infringement.

Authorised generics

- 36 | Can a patent owner market or license its drug as an authorised generic, or allow a third party to do so, before the expiry of the patent protection on the drug concerned, to gain a head start on the competition?

No. Generic drugs may only be registered with National Health Surveillance Agency (ANVISA) when the patent expires or is totally withdrawn by the patent holders. Individual licensing agreements or a decision by the owner of the patent to manufacture a generic drug are not sufficient to obtain the regulatory approval.

Restrictions on off-label use

- 37 | Can actions taken by a patent owner to limit off-label use trigger antitrust liability?

Yes. CADE has already adjudicated actions of patent holder companies to prevent off-label drugs entry, through strategic use of intellectual property in several judicial and administrative claims.

In 2015, CADE's tribunal found that Eli Lilly do Brasil and Eli Lilly and Company abused its rights to prevent generics entry by presenting misleading information to courts in six different claims, with 'serious harm to public health and economy'. According to the Reporting Commissioner of the case at CADE, 'the company behaved in an anti-competitive manner by presenting multiple claims before several courts, omitting information to artificially obtain the monopoly in the sale of the medicine, besides unduly obtaining an exclusive right to sell the drug'. CADE imposed a fine of 36.6 million reais.

Pricing

- 38 | When does pricing conduct raise antitrust risks? Can high prices be abusive?

Conducts such as coordination of prices between competitors, abusive increase of prices compared with the increase of costs, price of sale intentionally below of cost price and resale price-fixing may be considered anticompetitive if they result in one of the effects established in article 36 of the Competition Law.

There is no record of a fine imposed by CADE to a pharmaceutical company owing to high prices practices. Even though CADE can theoretically rule on this matter, our understanding is that this control is done by the regulatory body, since Law No. 10,742/2003 establishes the sanctions for companies that disrespect the Chamber of Drug Market Regulation's price regulation.

Despite the above, more recently, in March 2020, CADE opened a preparatory administrative inquiry to investigate the healthcare sector, in view of increases amid the covid-19 outbreak. The purpose of the investigation is to verify whether such price increases were abusive. CADE issued several RFIs to collect information and a final decision is still pending.

Sector-specific issues

- 39 | To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

CADE has historically not been open to extra-economic reasons as an acceptable justification for anticompetitive practices.

LEVY & SALOMÃO ADVOGADOS

Ana Paula Martinez

amartinez@levysalomao.com.br

Alexandre Ditzel Faraco

afaraco@levysalomao.com.br

Mariana Tavares de Araujo

mtavares@levysalomao.com.br

Av Brigadeiro Faria Lima 2601
São Paulo
SP 01452-924
Brazil
Tel +55 11 3555 5050
www.levysalomao.com.br

UPDATES AND TRENDS

Recent developments

- 40 | Are there in your jurisdiction any emerging trends or hot topics regarding antitrust regulation and enforcement in the pharmaceutical sector?

The Brazilian government has recently increased its investment in state-owned laboratories. Another trend is CADE's increased attention to conducts that have the potential to create entry barriers to off-label drugs. Regarding pharmaceutical sector regulation, companies willing to register similar drugs are now required to carry out bioequivalence and bioavailability studies taking into consideration the reference drug. Finally, another important aspect is the expiration of all pipeline patents registered in Brazil since Law No. 9,279/1996 established a maximum validity term of 20 years for them. Therefore, only patents registered within the new terms and requirements established under Law No. 9,279/1996 are now in force in the pharmaceutical sector.

In March 2019, the DG issued a decision in Merger Case No. 08700.00831/2019-14 (*GlaxoSmithKline/Ares Trading*) that could prove important for other pharmaceutical companies. The two companies entered into an agreement by which they would develop and commercialise a product to treat biliary tract cancer and non-small cell lung cancer, which is still at the early development stage. The DG decided that the agreement did not require antitrust clearance because the product that will result from this agreement is not marketable yet and, since the drug does not even have an ATC classification, the authority would not have the means to conduct the antitrust assessment. This view could potentially reduce the number of merger filings involving pharmaceutical companies in Brazil.

Coronavirus

- 41 | What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

No updates at this time.

* *The information in this chapter was verified between May and June 2020.*

Other titles available in this series

Acquisition Finance	Distribution & Agency	Investment Treaty Arbitration	Public M&A
Advertising & Marketing	Domains & Domain Names	Islamic Finance & Markets	Public Procurement
Agribusiness	Dominance	Joint Ventures	Public-Private Partnerships
Air Transport	Drone Regulation	Labour & Employment	Rail Transport
Anti-Corruption Regulation	e-Commerce	Legal Privilege & Professional Secrecy	Real Estate
Anti-Money Laundering	Electricity Regulation	Licensing	Real Estate M&A
Appeals	Energy Disputes	Life Sciences	Renewable Energy
Arbitration	Enforcement of Foreign Judgments	Litigation Funding	Restructuring & Insolvency
Art Law	Environment & Climate Regulation	Loans & Secured Financing	Right of Publicity
Asset Recovery	Equity Derivatives	Luxury & Fashion	Risk & Compliance Management
Automotive	Executive Compensation & Employee Benefits	M&A Litigation	Securities Finance
Aviation Finance & Leasing	Financial Services Compliance	Mediation	Securities Litigation
Aviation Liability	Financial Services Litigation	Merger Control	Shareholder Activism & Engagement
Banking Regulation	Fintech	Mining	Ship Finance
Business & Human Rights	Foreign Investment Review	Oil Regulation	Shipbuilding
Cartel Regulation	Franchise	Partnerships	Shipping
Class Actions	Fund Management	Patents	Sovereign Immunity
Cloud Computing	Gaming	Pensions & Retirement Plans	Sports Law
Commercial Contracts	Gas Regulation	Pharma & Medical Device Regulation	State Aid
Competition Compliance	Government Investigations	Pharmaceutical Antitrust	Structured Finance & Securitisation
Complex Commercial Litigation	Government Relations	Ports & Terminals	Tax Controversy
Construction	Healthcare Enforcement & Litigation	Private Antitrust Litigation	Tax on Inbound Investment
Copyright	Healthcare M&A	Private Banking & Wealth Management	Technology M&A
Corporate Governance	High-Yield Debt	Private Client	Telecoms & Media
Corporate Immigration	Initial Public Offerings	Private Equity	Trade & Customs
Corporate Reorganisations	Insurance & Reinsurance	Private M&A	Trademarks
Cybersecurity	Insurance Litigation	Product Liability	Transfer Pricing
Data Protection & Privacy	Intellectual Property & Antitrust	Product Recall	Vertical Agreements
Debt Capital Markets		Project Finance	
Defence & Security			
Procurement			
Dispute Resolution			

Also available digitally

[lexology.com/gtdt](https://www.lexology.com/gtdt)