Pharmaceutical Antitrust

Contributing editors
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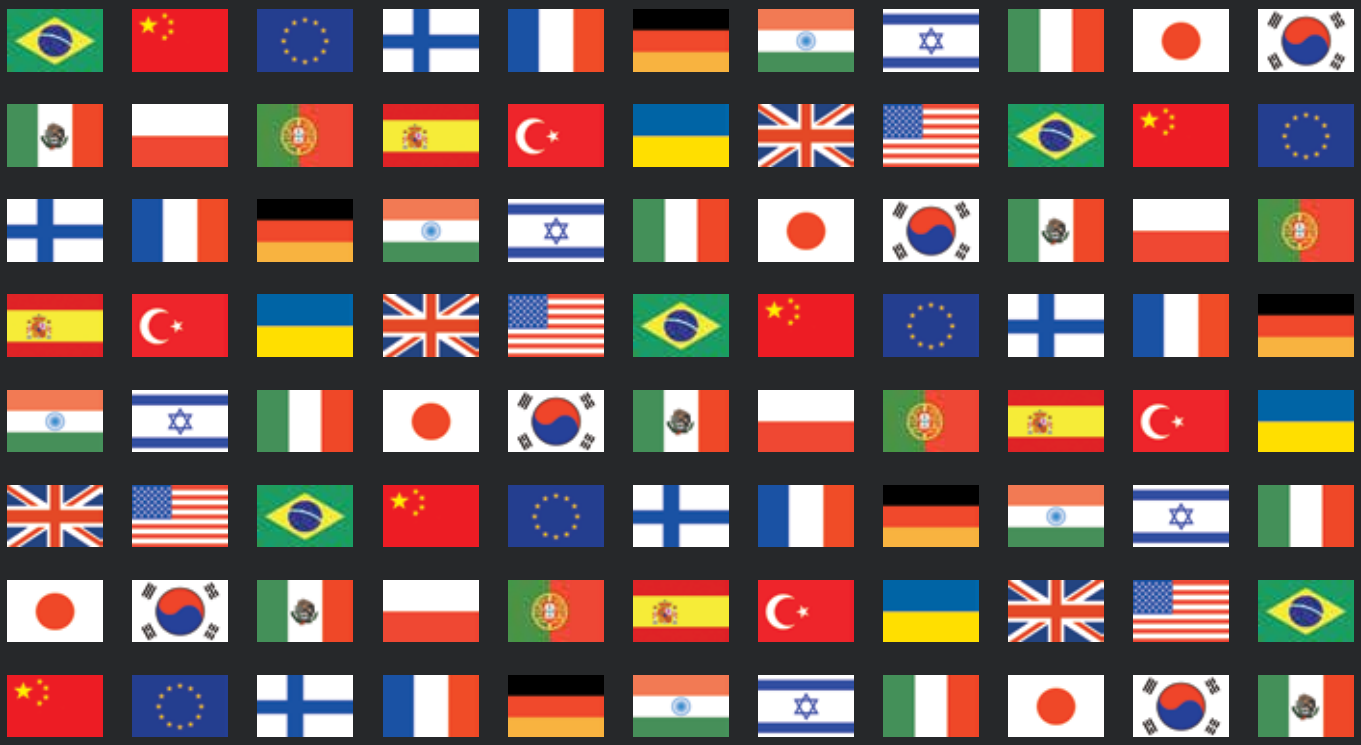

2017

GETTING THE DEAL THROUGH

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Pharmaceutical Antitrust 2017

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Law Business Research

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 3708 4199
Fax: +44 20 7229 6910

First published 2008
Tenth edition
ISSN 1757-6288

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

CONTENTS

Brazil

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs? Which bodies are entrusted with enforcing these rules?

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;
- Decree No. 3,675/2000, which provides for special measures related to the registration of 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 regulatory acts from ANVISA regarding matters such as drug registration, licences for pharmaceutical laboratories and other agents of the pharmaceutical production chain, and price regulation, the latter made by CMED.

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.

2 Is there specific legislation on the distribution of pharmaceutical products?

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:

- ANVISA's Resolution No. 320/2002, which determines 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.

3 Which aspects of this legislation 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:

- doctors within the public health system shall consider the active ingredient rather than the brand in the prescription;
- the government shall organise bids listing the active ingredient rather than the brand;
- the entry price of generics has to 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 generics.

The intersection between the pharmaceutical sector and competition law is widely recognised by the Brazilian authorities. In 2013, ANVISA and the Council for Economic Defence (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.

Competition legislation and regulation

4 Which legislation sets out competition law?

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, CADE.

5 Which authorities investigate and decide on pharmaceutical mergers and the anticompetitive nature of conduct or agreements in the pharmaceutical sector?

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.

6 What remedies can competition authorities impose for anticompetitive conduct or agreements by pharmaceutical companies?

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.

7 Can private parties obtain competition-related remedies if they suffer harm from anticompetitive conduct or agreements 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, to 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.

8 May 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 analysis, 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 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 5,772/1971 explicitly prohibited drug patenting. On the other hand, 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 (*Viagra* case).

9 To what extent do non-government groups play a role in the application of competition rules 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', as mentioned in question 7.

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 Genericós, 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

10 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 the more 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.

11 How are 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.

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 products 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 ANVISA and the fact that pharmaceutical companies generally offer their medicines throughout the country with uniform price policies.

12 Is it possible to invoke before the authorities 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:

(i) definition of relevant market;
(ii) determination of the parties' market share;
(iii) assessment of the probability of the parties exercising market power following the transaction;
(iv) examining the efficiencies; and
(v) evaluating 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 (iv), 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.

13 Under which circumstances will a horizontal merger of companies currently active in the same product and geographical market 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 EC standards, CADE's guidelines also consider the Herfindahl-Hirschman Index (HHI) as a measure of concentration.

For example, when reviewing Merger Case No. 08700.009834/2014-09 (*Anovis and 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 in fact prior to the transaction and was little affected by it. 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 and Boehringer Ingelheim*), despite finding concentration above 20 per cent in the market segments involved in the transaction and a HHI variation above 200 points, CADE cleared the case without restrictions due to: (i) the fact that the parties' products included in the same market segment were not close substitutes; and (ii) that 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 and 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: (i) Pfizer's high market share was only identified considering the scenario in terms of value, which could be related to drugs over which the company previously had patent; (ii) the market share of the parties in terms of units was very low; (iii) new drugs entered the market and there is projection of new products; and (iv) the presence of important competitors in the affected markets.

14 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, and strengthening the merging parties' dominant position, 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.

15 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 08012.003189/2009-10), CADE cleared the transaction in 2010 on the condition that the merged entity would sell three drugs 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 to ensure 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).

16 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

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 (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 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, the effects test is met whenever a given transaction is wholly or partially performed within Brazil or, if performed abroad, it is capable of producing effects within Brazil. This will be the case if the target to the transaction has a direct or indirect presence within the country or the market is global in scope. Direct presence is achieved through, among other things, a local subsidiary, distributor or sales representative. Although indirect presence is most commonly established through export sales into the country, the possibility that CADE considers third-party sales (eg, via a licensing agreement) as evidence of indirect presence in Brazil cannot be ruled out. Intention to enter the Brazilian market in the near future may also be considered by CADE when assessing the potential effects in the country.

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

Anticompetitive agreements

17 What is the general framework for assessing whether an agreement or 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.

CADE Resolution 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 (Annex II) 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.

18 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 Mosanto's Intacta RR2 PRO technology. The conditions refer to changes in clauses of the agreement that granted Monsanto the possibility to influence 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).

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

The Antitrust 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.

20 What other forms of agreement with a competitor are likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

Under article 36 of Law 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 in order 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.

21 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.

22 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 in case 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.

23 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

24 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.

25 When is a party likely to be considered dominant or jointly dominant?

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 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.

26 Can a patent holder be dominant simply on account of the patent that it holds?

Yes. This would be the case of a valid patent that is related to a product that has no or few substitutes in the market.

27 To what extent can an application for the grant or enforcement of a patent 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 (see question 17).

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 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).

28 Can certain life-cycle management strategies also expose the 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 (see question 17).

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). The investigation is pending.

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. The investigation is pending.

Update and trends

CADE's case law in the pharmaceutical sector is not straightforward; cases have a complex set of facts that make it difficult to extract a safe-harbour rule. The pending cases provide a unique opportunity for CADE to shed light on when business practices in the pharmaceutical sector can amount to an antitrust violation.

Market players need to take into account three aspects when devising their life cycle management strategies regarding products offered in Brazil. The first is that the association of generic drug makers is very active in Brazil and has been bringing a significant number of complaints before CADE since 2007. The second aspect is that CADE is understaffed and investigations generally last for over five years. This means that even when there is no violation, an investigation could be before the agency for numerous years, with all the associated uncertainty and costs; for example, the case against Aventis Pharma, which took eight years to be finally dismissed by CADE in 2013. The final aspect is that CADE has been extremely aggressive when sanctioning anticompetitive conduct, not limiting the sanctions to severe fines but also prohibiting sanctioned parties from benefiting from tax incentives, for example. The combination of those three aspects requires market players in Brazil to be extra-cautious.

Apart from targeting sham litigation and life-cycle strategies more generally, CADE has been devoting resources to the fight against bid rigging in the pharmaceutical sector, and we can expect the agency to bring new investigations in the near future.

29 May a patent holder 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 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 is not sufficient to obtain the regulatory approval.

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

For conducts examined under the rule of reason, for which CADE undertakes detailed market analysis, including assessment of market shares, market structures and other economic factors, specific features of the pharmaceutical sector could provide an objective justification for the conduct.

31 Has national enforcement activity in relation to life cycle management and settlement agreements with generics increased following the EU Sector Inquiry?

Not applicable.

* *The authors would like to thank Marcos Drummond Malvar and Júlia Gierkens Ribeiro for conducting the research needed for this chapter.*

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