Competition and Patent Law in the Pharmaceutical Sector

An International Perspective

Edited by

Giovanni Pitruzzella
Gabriella Muscolo

Published by:
Kluwer Law International B.V.
PO Box 316
2400 AH Alphen aan den Rijn
The Netherlands
Website: www.wklawbusiness.com

Sold and distributed in North, Central and South America by:
Wolters Kluwer Legal & Regulatory U.S.
7201 McKinney Circle
Frederick, MD 21704
United States of America
Email: customer.service@wolterskluwer.com

Sold and distributed in all other countries by:
Turpin Distribution Services Ltd
Stratton Business Park
Pegasus Drive, Biggleswade
Bedfordshire SG18 8TQ
United Kingdom
Email: kluwerlaw@turpin-distribution.com

Printed on acid-free paper.

ISBN 978-90-411-5927-4

Printed in the United Kingdom.

Editors

Gabriella Muscolo Commissioner at the Italian Competition Authority, former Judge at the specialized section for IP and Competition Law Litigation of the Court of Rome, former member of the Enlarged Board of Appeal of the European Patent Office, author of several publication in the field of IP Law, Competition Law and Company Law and usual lecturer in several Universities in Italy and abroad.

Giovanni Pitruzzella Chairman of the Italian Competition Authority – full professor of Constitutional Law University of Palermo – former lawyer at the bar of Palermo, author of several publications in the field of European Constitutional Law and Competition Law.

Summary of Contents

BRAZIL

Competition Policy and Life Cycle Management: The Brazilian Experience

Ana Paula Martinez

1 OVERVIEW OF COMPETITION LAW AND PRACTICE IN BRAZIL

At the administrative level,[1] competition law and practice in Brazil are governed by Law No. 12,529/11, which entered into force on 29 May 2012 and replaced Law No. 8,884/94. The Administrative Council for Economic Defense's (hereinafter, 'CADE') structure includes a Tribunal composed of a President and six Commissioners, a Directorate-General for Competition (hereinafter, 'DG') and an Economics Department. The DG, which replaced the former Ministry of Justice's Secretariat of Economic Law (the so-called SDE), is the chief investigative body in matters related to anticompetitive practices. CADE's Tribunal is responsible for adjudicating the cases investigated by the DG – all decisions are subject to judicial review.[2] There are also two independent offices within CADE: CADE's Legal Services, which represents CADE in Court and may render opinions in all cases pending before CADE; and the Federal Public Prosecutor's Office, which may also render legal opinions in connection with all cases pending before CADE.

The basic framework for abuse of dominance in Brazil is set by Article 36 of Law No. 12,529/11. The law prohibits acts '*that have as [their] object or effect*' (1) limitation, restraint or, in any way, harm to open competition or free enterprise; (2) control over

1. Brazil's antitrust system features both administrative and criminal enforcement. The administrative and criminal authorities have independent roles and powers, and may cooperate on a case-by-case basis. Private enforcement actions may also be initiated through the judicial Courts by aggrieved competitors or damaged parties. Although abuse of dominance could also be considered a criminal violation under Art. 4 of Law No. 8,137/90, punishable in the case of individuals, but not corporations, by a criminal fine and imprisonment from 2 to 5 years, no criminal sanction has been imposed to date against individuals for abuse of dominance practices.
2. On average, judicial Courts confirm over 70% of CADE's decisions.

a relevant market of a certain good or service; (3) an increase in profits on a discretionary basis; or (4) engagement in market abuse. Article 36 specifically excludes from potential violations, however, the achievement of market control by means of '*competitive efficiency*'. Under Article 2 of the law, practices that take place outside the territory of Brazil are subject to CADE's jurisdiction, provided that they produce actual or potential effects in Brazil.

Article 36, section 3º, contains a non-exclusive list of acts that may be considered antitrust violations provided they have as their object or effect the above-mentioned acts. The listed practices include various types of horizontal and vertical agreements and unilateral abuses of market power. Enumerated vertical practices (they could be abusive if imposed unilaterally) include RPM and other restrictions affecting sales to third parties, price discrimination and tying. Listed unilateral practices encompass both exploitative and exclusionary practices, including refusals to deal and limitations on access to inputs or distribution channels, and predatory pricing.

CADE Resolution No. 20/99,[3] in its Annex II, provides for the review of unilateral conduct under the rule of reason, as it might have pro-competitive effects. The Brazilian competition agency should, in theory, consider efficiencies alleged by the parties and balance them against the potential harm to consumers. In practice, however, there has been no case in which CADE concluded that harmful conduct was legal in view of the efficiencies derived from the conduct.

Brazil's competition law applies to corporations, associations of corporations and individuals. For corporations, fines range between 0.1% and 20% of the company's or group of companies'[4] pre-tax turnover in the economic sector affected by the conduct in the year prior to the beginning of the investigation.[5]

The law further provides that directors and other executives found liable for anticompetitive behaviour may be sanctioned from 1% to 20% of the fine imposed against the company. Under the law, individual liability for executives is dependent on proof of guilt or negligence, which makes it hard for CADE to find a violation on the part of the company's executives. Historically, while CADE has been investigating the involvement of individuals in cartel cases, it has rarely done so in abuse of dominance

3. CADE is yet to issue regulation under the 2011 law setting formal criteria for the analysis of alleged anticompetitive conduct. The agency has been relying on secondary legislation issued under the previous law.
4. The wording of the new provision lacks clarity and creates legal uncertainty regarding the scope of its application. CADE was expected to issue regulation defining the criteria that would be applied to distinguish when fines would be imposed against the company, the group of companies, or the conglomerate, but has not yet done so. According to Art. 45 of Brazil's antitrust law, the following shall be taken into account by CADE when setting fines: (i) level of seriousness of the infringement; (ii) good faith of the defendant; (iii) gain obtained or aimed by the defendant; (iv) whether the conduct has been consummated or not; (v) level of actual or potential harm to competition, Brazilian economy, consumers or third parties in general; (vi) detrimental economic effects caused by the conduct in the market; (vii) economic situation of the defendant; and (viii) recidivism.
5. CADE's Resolution No. 3/2012 broadly defines 144 '*sectors of activity*', which includes, among others, beverages and agriculture. CADE may resort to the total turnover, whenever information on revenue derived from the relevant '*sector of activity*' is unavailable. Moreover, the fine may be no less than the amount of harm resulting from the conduct. Fines imposed for recurring violations must be doubled.

cases. Other individuals and legal entities that do not directly conduct economic activities are subject to fines ranging from BRL 50,000 to BRL 2 million.

Apart from fines, CADE may also: (i) order the publication of the decision in a major newspaper at the wrongdoer's expense; (ii) prohibit the wrongdoer from participating in public procurement procedures and obtaining funds from public financial institutions for up to five years;[6] (iii) include the wrongdoer's name in the Brazilian Consumer Protection List; (iv) recommend to the tax authorities to block the wrongdoer from obtaining tax benefits; (v) recommend to the IP authorities to grant compulsory licences of patents held by the wrongdoer; (vi) order a corporate spin-off, transfer of control, sale of assets; (vii) prohibit an individual from exercising market activities on its behalf or representing companies for five years.[7] The law also includes a broad provision allowing CADE to impose any '*sanctions necessary to terminate harmful anti-competitive effects*'. CADE's wide-ranging enforcement of such provision may prompt judicial appeals.

CADE is becoming globally known for its aggressive approach in enforcing Brazil's competition law. There are around fifty pending investigations for alleged abuse of dominance, including allegations of sham litigation in the pharmaceuticals market. In practice, CADE has been imposing fines of up to 5% of the company's turnover in connection with abuse of dominance violations.[8]

2 ALLEGED ANTICOMPETITIVE PRACTICES IN THE PHARMACEUTICAL INDUSTRY REVIEWED BY CADE: DRAWING THE LINE FOR LIFE CYCLE MANAGEMENT STRATEGIES

Before discussing the cases that have been reviewed by CADE in connection with alleged anticompetitive practices in the pharmaceutical industry, it is important to note that the Anglo-American concept of binding judicial precedent (i.e., *stare decisis*) is virtually non-existent in Brazil, which means that CADE's Commissioners are under no obligation to follow past decisions in future cases. Under CADE's Internal Regulations, legal certainty is only achieved if CADE rules in the same way at least ten times, after which they codify a given statement via the issuance of a binding statement.[9]

6. In 2012, CADE has, for the first time, imposed this sanction in connection with an abuse of dominance case (see Case No. 08012.001099/1999-71; Defendants: Comepla Indústria e Comércio et al.; Reporting Commissioner: Carlos Ragazzo; adjudication date: 23 May 2012).
7. The idea behind this provision was to deal with situations in which CADE prohibited the wrongdoer from participating in public procurement procedures and obtaining funds from public financial institutions for up to five years. To avoid this penalty, the parties simply set up a new company and resumed activities in the same sector without being subject to the restrictions imposed by CADE's decision.
8. In absolute terms, the record fine for a unilateral practice was BRL 352 million (2009), later reduced through a judicial settlement to BRL 229 million (2015).
9. To date, CADE has issued nine binding statements, all related to merger review but one (Binding Statement No. 7), which provides that it is an antitrust infringement for a physicians' cooperative holding a dominant position to prevent its affiliated physicians from being affiliated with other physicians' cooperatives and health plans.

Regarding alleged anticompetitive practices in the pharmaceutical industry, the vast majority of cases relate to unilateral practices as opposed to horizontal agreements.[10] Below is presented an overview of key cases that should be taken into account by pharmaceutical companies when devising their life cycle[11] management strategies for drugs marketed in Brazil. Similarly to other jurisdictions, there is an increasing number of cases being reviewed by CADE and even an attempt to conduct a sector inquiry (2009/2010[12]), following the initiatives of the European Commission and the US Federal Trade Commission (the latter focusing more on the pay-for-delay agreements[13]).

2.1 Boycott against Generic Drugs

In 1999, Brazilian Congress passed the so-called Law on Generic Drugs. The new law contained several provisions aimed to promote competition, such as (i) doctors with the public health system shall include in the prescription the active ingredient rather than the originator product; (ii) government shall organize bids listing the active ingredient rather than the originator product; (iii) pharmacists may automatically substitute prescriptions for a brand to a generic; (iv) entry price for generics has to be at least 35% under the price of the originator product (prices are regulated by the Government); and (v) originator companies shall supply samples to generic competitors to allow them to produce generics.

According to CADE, nineteen branded companies allegedly met in July 1999 and agreed to boycott distributors that would distribute generics and engaged into a public campaign against the use of generics. In 2005, CADE sanctioned branded pharmaceutical companies to pay 1%-2% of their turnover in the year before the initiation of the investigation.[14] In 2011, a federal judge reversed CADE's decision based on the lack of

10. There are some cases involving bid-rigging practices. See Cases No. 08012.002222/2011-09, 08700.001640/2013-84, 08012.008821/2008-22.
11. Life cycle could be defined as the period from the product's first launch into the market until its withdrawal.
12. The investigative agency under the previous law, SDE, sent out questionnaires to approximately forty originator companies questioning on practices related to patent extensions.
13. Different institutional frameworks result in different types of practices considered by the originator companies to extend the life cycle of a given drug. For example, the fact that in Brazil there is no exclusivity period for the first generic drug to enter the market make it less likely to have pay-for-delay agreements. The same is true for delisting practices, under investigation by the UK competition agencies.
14. Case No. 08012.009088/1999-48. Defendants: Abbott Laboratórios do Brasil Ltda., Eli Lilly do Brasil Ltda., Indústria Química e Farmacêutica Schering Plough S.A., Produtos Roche Química e Farmacêutica S.A., Pharmacia Brasil Ltda. (sucessora de Searle do Brasil Ltda. e, posteriormente, Monsanto do Brasil Ltda.), Laboratório Biosintética-Ltda., Bristol Myers Squibb Brasil S.A., Aventis Pharma Ltda., Bayer S.A., Eurofarma Laboratórios Ltda., Akzo Nobel Ltda., Glaxo Wellcome S.A., Merck Sharp & Dohme Farmacêutica e Veterinária Ltda., AstraZeneca do Brasil Ltda., Boehringher Ingelheim do Brasil Química e Farmacêutica Ltda., Aventis Behring Ltda. (sucessora de Centeon Farmacêutica Ltda.), Sanofi-Synthelabo Ltda. (sucessora de Sanofi Winthrop Farmacêutica Ltda.), Laboratórios Wyeth-Whitehall Ltda., Janssen Cilag Farmacêutica Ltda. e Byk Química Farmacêutica Ltda. Adjudication date: 18 Oct. 2005.

evidence of anticompetitive conduct,[15] which was confirmed by the second instance court in March 2015. CADE has appealed this decision to the superior Courts and a final decision is pending. An interesting aspect of the case was the sanctioning of Merck only in August 2014, after lengthy discussions, for having taken part in the same meeting back in 1999 and not having voiced out its disagreement, which, according to CADE, amounted to tacit collusion.

2.2 Extension of Pipeline Patent Protection

Brazilian Law 5,772/1971 explicitly prohibited drug patenting. On the contrary, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 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; and the maximum period for patent protection is twenty years under Brazilian law.

A number of branded pharmaceutical companies resorted to judicial Courts to extend their protection, defending theories like only the first valid foreign filing should be considered for the purposes of determining the duration of the patent protection. The issue was settled in April 2010, when the Superior Court of Justice decided that the date of the first foreign filing is the one valid, even if the filing was later withdrawn (Viagra case).[16]

In this context, the Brazilian association of generic drugs (called Pró-genericos[17]) filed a complaint before the competition authorities in 2007 against Sanofi-Aventis claiming that it has abused its market power by presenting a request to extend a 'pipeline' patent related to Plavix, a drug directed to prevent blood clots after a heart attack/stroke.[18] CADE dismissed the case in 2012, concluding that the IP Law provisions allow two possible interpretations and the one argued by Sanofi-Aventis was also reasonable even though it ultimately failed in Courts. In this case, CADE has indicated that a company with a dominant position is entitled to take reasonable steps to protect its intellectual property rights.

2.3 Refusal to Deal

Under the current regulatory framework, originator companies are required to supply samples to generic competitors to allow them to produce generics.

In 2011, Pró-genericos filed a complaint against Janssen Cilag claiming that it has directed its distributors not to supply samples of the blood-cancer drug Velcalde to generic companies (Eurofarma).[19] Although recognizing that taking measures not to supply the originator drugs to competitors would amount to an antitrust violation,

15. Case No. 2007.34.00.043980-0. Federal Judge Itagiba Catta Preta Neto.
16. REsp 731.101. Reporting Justice João Otávio de Noronha.
17. http://www.progenericos.org.br/.
18. Case No. 08012.013624/2007-44. Defendant: Sanofi-Aventis Farmacêutica Ltda.
19. Case No. 08012.000841/2011-51. Defendant; Janssen Cilag Farmaceutica Ltda.

CADE dismissed the case in 2013 stating that no evidence of illegal conduct was found in connection with that particular case. To support this conclusion, CADE highlighted that Eurofarma acquired 211 samples of the originator drug in 2011.

2.4 Extension of EMR Due to New Use

In 2007, Pró-genericos 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.[20] 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. According to CADE, during this period, the price offered by Eli Lilly in public bids was BRL 540.00 more than double of the price offered by the same Eli Lilly following the reversal of the injunction (BRL 189.00).

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 BRL 36.6 million – 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.

In its decision, CADE stated that '*measuring market share is irrelevant in sham litigation cases, where the success of a judicial claim may be sufficient to exclude competitors from the market*'.[21] This position might be stricter than the one adopted by foreign competition agencies.

Eli Lilly has filed an appeal and a final decision is pending.

There is another case worth mentioning with a different outcome. In 2005, Eurofarma filed a complaint before Brazil's competition agencies claiming that Aventis Pharma abused its rights when trying to secure exclusive marketing rights over

20. Case No. 08012.011508/2007-91. Defendants: Eli Lilly do Brasil Ltda., and Eli Lilly and Company. Reporting Commissioner: Ana Frazão.
21. Brazil's 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. The 20% threshold is relatively low compared with practices in other jurisdictions, especially the US and the EU.

docetaxel trihidratado, a drug used to treat breast cancer.[22] In 2013, CADE dismissed the case stating that the evidence presented was not enough for the authority to find a violation, and that the request regarding the exclusive marketing rights followed the IP agency procedures.

2.5 Abuse of Data Protection Rights

In 2010, Pró-genericos filed a complaint against Lundbeck claiming that it has allegedly abused its data protection rights regarding the antidepressant Lexapro to prevent generic entry.[23] In December 2011, the investigative arm of CADE opened a formal investigation against Lundbeck. According to Pró-genericos, Lundbeck, through frivolous judicial claims, aimed to prevent Brazil's FDA from using data related to Lexapro's files (Lexapro data package) to issue authorization for generic drugs, increasing the entry costs for generic drugs. The investigation is still pending.

There is a similar case pending against Genzyme initiated by Germed in 2009.[24] According to Germed, Genzyme alleged abused its data protection rights regarding Renagel, a drug used to reduce levels of phosphorus in people with kidney disease who are on dialysis. After six years acting alone in the market, Genzyme started to face competition from EMS and Germed, following the registration of their drugs at Brazil's FDA. Subsequently, Genzyme filed judicial claims raising rivals' costs according to Germed. In December 2011, the investigative arm of CADE opened a formal investigation against Genzyme. According to public available information, in 2013 Genzyme tried to settle the judicial claim with EMS/Germed, which was subject to the approval of Brazil's FDA.[25] The investigation is still pending.

2.6 Ring-Fencing Practices

In 2011, Pró-genericos filed a complaint against AstraZeneca for allegedly abusing its rights due to 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[26] (drug for schizophrenia, bipolar disorder and major depressive disorder). AstraZeneca was accused of engaging into ring-fencing practices regarding its IP holdings to deter generic entry, as well as sham litigation practices before courts. The investigation is still pending.

22. Case No. 08012.004393/2005-16. Defendants: Aventhis Pharma S.A., and Aventhis Pharma Ltda. Adjudication date: 20 Feb. 2013.
23. Case No. 08012.006377/2010-25. Defendants: Lundbeck A/S, and Lundbeck Brasil Ltda.
24. Case No. 08012.007147/2009-40. Defendants: Genzyme do Brasil Ltda., and Genzyme Corporation.
25. See Case No. 2009.34.00.018712-0/DF. http://portal.anvisa.gov.br/wps/wcm/connect/9be0ef0042e1d0ceb595bf348b3626d1/REUNI%C3%95ES+EXTERNAS+-+2013+-+Victor+Valen%C3%A7a.docx?MOD=AJPERES.
26. Case No. 08012.001693/2011-91. Defendants: AstraZeneca AB, and AstraZeneca do Brasil Ltda.

2.7 Launch of Second Generation Drugs

In 2008, Pró-genericos filed a complaint against Abbott for allegedly abusing its rights due to (i) patent violation claims against Cristália Produtos Químicos e Farmacêuticos regarding anesthetics and (ii) the launch of a new antiviral drug (Meltrex, which replaced Kaletra), not considered to be an improvement over the original drug.[27] The allegation regarding the latter practice concerns shifting consumers from an old version of a drug to a new version, preventing or creating barriers to generic drugs to compete. The investigation is still pending.

3 EXPECTED FUTURE DEVELOPMENTS

CADE's case law in the pharmaceutical sector is not straightforward; cases have a complex set of facts which makes it difficult to extract a safe-harbour rule. Some cases seem to point to an enhanced scepticism or outright disregard for the role economic analysis in connection with unilateral practices. The reason this trend is counter-intuitive and somewhat paradoxical in light of the larger role currently played by economics in antitrust analysis is obvious: standard economic analysis would recommend caution against 'over-enforcement' regarding unilateral conduct, especially considering an area so dependent on research and development.

Still, it seems CADE has not been (and will continue not to be) shy about intervening, even though there is a fair amount of cases involving life cycle management strategies that have also been dismissed by the agency. The pending cases provide a unique opportunity for CADE to shed light on when life cycle management strategies 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 one 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 other 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 pend before the agency for numerous years, with all the associated uncertainty and costs – take for example the case against Aventis Pharma, which took eight years to be dismissed by CADE. 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 examples. The combination of those three aspects requires market players in Brazil to be extra-cautious.

Furthermore, private antitrust enforcement in Brazil has been on the rise over the past five years.[28] This may be due to reasons such as the global trend of antitrust

27. Case No. 08012.011615/2008-08. Defendants: Abbott Laboratórios do Brasil Ltda., and Abbott Laboratórios Inc.
28. Pursuant to Art. 47 of Brazil's Competition Law, victims of anticompetitive conduct may recover the losses they sustained as a result of a violation, apart from an order to cease the illegal conduct. A general provision in the Brazilian Civil Code also establishes that any party that

authorities encouraging damage litigation by potential injured parties; the growing number of infringement decisions issued by CADE; as well as the increasing general awareness of competition law in Brazil. There are already damage 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.

causes losses to third parties shall indemnify those that suffer injuries (Art. 927). Plaintiffs may seek compensation in the form of pecuniary damages (for actual damage and lost earnings) and moral damages. Under recent case law, companies are also entitled to compensation for moral damage, usually derived from losses related to their reputation in the market.