

1. The Competition Law Context of the Pharmaceutical Industry

Brazilian competition legal framework does not provide a different set of rules for each specific market, nor does it appoint different institutions to enforce competition regulation. Pharmaceutical industry is subject to the same rules applicable to any other industry and in Brazil there are no set of guidelines particularly relevant to pharmaceutical competition law.

Federal Law n° 12.529 of November 30, 2011, which structures the Brazilian Antitrust System, is the basic statute applicable to infractions and merger review, and the Administrative Council for Economic Defense (CADE) is the agency in charge of enforcing such law. The rules set forth by the Law are also, in certain aspects, supplemented by regulation issued by CADE.

CADE is an independent agency. Its decisions are final in an administrative level and can only be challenged in Court. Although the Brazilian Law has provisions applicable to the private enforcement of competition law, so far private enforcement is rare.

Certain antitrust violations (cartel, bid rigging) may also have criminal consequences for the individuals according to Federal Law No. 8,137 of December 27, 1990, and Federal Law No. 8,666, of June 21, 1993. State and Federal Courts have competence to apply criminal antitrust laws.

Infractions to Federal Law No. 12.529/11 are listed in article 36, as follows¹:

Art. 36. The acts under any circumstance, which have as object or may have the following effects shall be considered violations to the economic order, regardless of fault, even if not achieved:

I - to limit, restrain or in any way injure free competition or free initiative;

¹ Translation of the Law obtained at the homepage of the OAB/SP (Brazilian Bar Association, Section of the State of São Paulo)

II - to control the relevant market of goods or services;

III – to arbitrarily increase profits, and

IV - to abusively exercise a dominant position.

§ 1 The conquest of the market resulting from the natural process of the most efficient economic agent in relation to its competitors does not characterize the tort set forth in item II of the caput of this article.

§ 2 A dominance position is assumed when a company or group of companies is able to unilaterally or jointly change market conditions or when it controls 20% (twenty percent) or more of the relevant market, provided that such percentage may be modified by Cade for specific sectors of the economy.

§ 3 The following acts, among others, to the extent in which they configure the hypothesis set forth in the caput of this article and items thereof, shall characterize violation of the economic order:

I – to agree, join, manipulate or adjust with competitors, in any way:

a) the prices of goods or services individually offered;

b) the production or sale of a restricted or limited amount of goods or the provision of a limited or restricted number, volume or frequency of services;

c) the division of parts or segments of a potential or current market of goods or services by means of, among others, the distribution of customers, suppliers, regions or time periods;

d) prices, conditions, privileges or refusal to participate in public bidding;

II - to promote, obtain or influence the adoption of uniform or agreed business practices among competitors;

III - to limit or prevent the access of new companies to the market;

IV – to create difficulties for the establishment, operation or development of a competitor company or supplier, acquirer or financier of goods or services;

V – to prevent the access of competitors to sources of input, raw material, equipment or technology, and distribution channels;

VI - to require or grant exclusivity for the dissemination of advertisement in mass media;

VII – to use deceitful means to cause oscillation of the prices practiced by third parties;

VIII - to regulate markets of goods or services by establishing agreements to limit or control the research and technological development, the production of goods or services, or to impair investments for the production of goods or services or their distribution;

IX - to impose, on the trade of goods or services, to distributors, retailers and representatives, resale prices, discounts, payment terms, minimum or maximum quantities, profit margin or any other market conditions related to their business with third parties;

X - to discriminate against purchasers or suppliers of goods or services by establishing price differentials, or operating conditions of sale or provision of services;

XI – to refuse the sale of goods or provision of services, within regular payment conditions to the business practices and customs;

XII – to hinder or disrupt the continuity or development of business relationships of undetermined term, because the other party refuses to abide by unjustifiable or anticompetitive terms and conditions;

XIII - to destroy, render useless or monopolize the raw materials, intermediate or finished products, as well as to destroy, disable or impair the operation of equipment to produce, distribute or transport them;

XIV - to monopolize or prevent the exploitation of industrial or intellectual property rights or technology;

XV - to sell goods or services unreasonably below the cost price;

XVI – to retain production or consumption goods, except for ensuring recovery of production costs;

XVII - to partially or totally cease the activities of the company without proven just cause;

XVIII - to condition the sale of goods to the acquisition of another or use of a service, or to condition the provision of a service to another or to the acquisition of goods, and

XIX - to abusively exercise or exploit intellectual or industrial property rights, technology or trademark

Based on such provision, it is understood that according to the Brazilian antitrust system any acts which have as their object or their possible effect an appreciable restriction of competition or the abuse of a dominant position can be considered unlawful. Historically, most of Brazilian scholars and CADE's decisions applied a rule of reason to the interpretation of the antitrust law, only considering unlawful acts that may have the possible effect of unreasonably restricting competition. Most recently, however, CADE

has ruled that certain conducts, such as horizontal price fixing and bid rigging, shall be regarded as “unlawful by object”, as they, by their nature, would have a high potential to restrict competition. And, as such, it would not be necessary in those cases to prove any actual or likely anti-competitive effects on the market (v.g, Proceeding No. 08012.008507/2004-16). Such approach is even stricter with respect to hardcore cartel cases (Proceeding No. 08012.002127/2002-14).

CADE has also held that in certain circumstances minimum resale price policies could be considered a “quasi” per se infringement, as it would be presumed to be illegal (Proceeding No. 08012.001271/2001-44) and the party under investigation would have the burden to prove that its conduct would not be able to produce anticompetitive effects.

In most of the cases, however, including unilateral conducts such as refusal to supply, excessive or discriminatory prices, a conduct shall be considered unlawful depending on the analysis of its possible consequences in the market. There is no special legislation differentiating such conducts with respect to pharmaceutical cases.

Companies liable for those unlawful conducts may be subject to pecuniary and non-pecuniary penalties, as follows:

Art. 37. The responsible for the violation of the economic order shall be subject to the following penalties:

I - in the case of company, a fine of one tenth percent (0.1%) to twenty percent (20%) over the gross sales of the company, group or conglomerate, in the last fiscal year before the beginning of the administrative proceeding, in the field of the business activity in which the violation occurred, which will never be less than the advantage obtained, when possible the estimation thereof;

II - in the case of natural persons or public or private legal entities, as well as any association of persons or de facto or de jure legal entities, even if temporarily, incorporated or unincorporated, which do not perform business activity, not being possible to use the gross sales criteria, the fine

will be between fifty thousand reais (R\$ 50,000.00) to two billion reais (R\$ 2,000,000,000.00);

III – if the administrator is directly or indirectly responsible for the violation, when negligence or willful misconduct is proven, a fine of one percent (1%) to twenty percent (20%) of that applied to the company, in the case set forth in Item I of the caput of this article, or to legal entities, in the cases set forth in item II of the caput of this article.

§ 1 In case of recurrence, the fines shall be doubled.

§ 2 In the calculation of the value of the fine referred to in item I of the caput of this article, CADE may consider the total turnover of the company or group of companies, when the value of sales in the field of business activity in which the violation occurred is not available, defined by Cade, or when it is incompletely presented and/or not unequivocally and credibly demonstrated.

Art. 38. Without prejudice to the penalties set forth in Article 37 of this Law, when so required according to the seriousness of the facts or public interest, the following penalties may be imposed, whether individually or cumulatively:

I - the publication, in half a page and at the expenses of the perpetrator, in a newspaper stated in the conviction, the extract from final conviction for two (2) consecutive days, of one (1) to three (3) consecutive weeks;

II - ineligibility for official financing and for participation in biddings whose object is acquisitions, divestitures, performance of works and services, provision of public services, in the federal, state, municipal and Federal District public administration, as well as in indirect administration entities, for a term of not less than 5 (five) years;

III - the registration of the wrongdoer with the National Registry for Consumer Protection;

IV - recommendation to the competent public agencies so that: a) a compulsory license over the intellectual property rights held by the wrongdoer be granted, when the violation is related to the use of that right; b) the violator be denied installment payment of federal taxes owed by him or to be canceled, in full or in part, tax incentives or public subsidies;

V - the spinoff of the company, transfer of corporate control, sale of assets or partial interruption of activity;

VI - the prohibition of carrying on trade on its own behalf or as representative of a legal entity for a period of five (5) years, and

VII - any other act or measure required to eliminate the harmful effects to the economic order.

Based on such rules, CADE has already punished some pharmaceutical companies for unlawful conduct. On June 2015, CADE condemned a pharmaceutical producer that held a drug patent for the practice of sham litigation, considering that it would have filed multiple misleading lawsuits in different jurisdictions aiming to obtain the exclusivity for the production of certain substance in order to exclude some potential competitors from the market. CADE applied a fine of approximately US\$ 10 million². On August 2014, a pharmaceutical laboratory was condemned by CADE to pay a fine of approximately US\$ 1.5 million for cartel formation to prevent the sales of generics (Administrative Proceeding no. 08012.005928/2013-12).

² CADE Proceeding No. 08012.011508/2007-91

Besides having a repressive role, CADE is also responsible for pre-merger control review. According to Article 88 of Law No. 12.529/11, concentration acts (as mergers, acquisition of control, significant shareholding or assets, joint ventures, etc.) shall be previously approved by CADE if at least one of the economic groups of the parties involved in the transaction has registered annual gross sales or total turnover in Brazil, in the year preceding the transaction, equal to or exceeding seven hundred and fifty million reais; and at least one other group involved in the transaction has registered gross annual sales or total turnover in Brazil, in the year preceding the transaction, equal to or exceeding seventy five million reais. If the deal is considered harmful to competition, CADE may impose restrictions or additional obligations as a condition for its approval or even determine that the deal cannot go through.

CADE's decisions are usually taken in public sessions held at the entity's head office in Brasilia. However, according to CADE's internal regulations, the parties involved may request the confidentiality of documents related to their business performance whenever such exposure may provide competitive advantage to other players in the market.

As mentioned above, there is no specific antitrust legislation or guidance for the pharmaceutical sector. Pharmaceutical industries are thus subject to the aforementioned provisions and principles like any other industries.

However, certain specific aspects of the pharmaceutical market have been taken into account by CADE in its rulings, such as supply concentration; inelasticity of demand; barriers to entry caused by the high costs related to research and development, compliance with the Brazilian Health Surveillance Agency (ANVISA) regulations and exclusivity rights related to patents; and asymmetry of information that could have negative impacts in the competition in the market.

Market definition in the pharmaceutical sector is not different than market definition in other industries. Brazilian law does not contain a set of rules regarding market definition and CADE, in a case by case basis, may use different methods and a mixture of quantitative and qualitative elements to identify products or groups of products

that may be considered substitutes of the product of a party under investigation in a certain region. The hypothetical monopolist test is frequently applied. Based on such methods, CADE considered, in certain rulings, that the drug's active principle and the drug's therapeutic class should be taken into account in the definition of the relevant market in the pharmaceutical sector. (Administrative Proceedings No. 08012.001288/99-43 and No. 08012.000907/2000-33)

2. Consumer protection and price restrictions

As mentioned before, pharmaceutical competition law issues in Brazil are subject to the same set of rules than any other competition law issues.

According to Federal Law No. 12.529/2011 restrictive agreements and unilateral conducts may be considered unlawful should they have as object or possible effect the restriction of competition in the market; concentration acts are subject to merger review based on certain objective criteria regarding the turnover of the parties. There are no specificities related to pharmaceutical industries in this respect.

Although consumer protection appears as one of the aims of Brazilian antitrust law, there is no direct interaction between consumer protection law (specially Federal Law No. 8,078/90 - Brazilian Consumer Defense Code) and competition law.

ANVISA (*Agência Nacional de Vigilância Sanitária*) is the Brazilian Federal entity responsible for protecting and promoting public health and is in charge of health surveillance over products (including their production process, ingredients and technology) and services. It is not entitled to decide over competition matters, which is, as of today, exclusively attributed to CADE.

However, ANVISA has an important role as it is responsible for controlling prices in the pharmaceutical sector. In fact, according to Federal Law No. 10.742/2003, pharmaceutical companies shall observe, for adjustment and determination of their prices, some rules set out in the law, being prohibited any adjustment in violation of the law. For this purpose, ANVISA's Drug Market Regulatory Chamber (*Câmara de Regulação do Mercado de Medicamentos - CMED*) publishes every year a list of all drugs available in

the market and its respective price limits, that are updated every month. The list contains price restrictions for (i) drug producers, drug importers and drug distributors; and (ii) retailers, such as pharmacies and drugstores. CMED also publishes a second list determining different prices in case of acquisitions by the Brazilian public health system (SUS) by means of a public bidding.

The value adjustment by active principle is calculated taking into account: (i) Brazil's Amplified Consumer Price Index (*Índice Nacional de Preços ao Consumidor Amplo* - IPCA); (ii) manufacturers' efficiency gain estimates; (iii) degree and level of market concentration based on, respectively, the Anatomical Classification level 4 (AC4) from the European Pharmaceutical Market Research Association (EPHMRA) and the Herfindahl–Hirschman Index - HHI; and (iv) cost variation of non recoverable inputs in all economic sectors.³

3. Generics and Intellectual Property

Federal Law No. 9,787/99 (the Generic Drugs Act) allows the trade of certain drugs that had their patents expired. The law does not contain any specific provision concerning competition law since, as stated before, competition matters are governed by Federal Law No. 12,529/2011. However, it is worth mentioning that Article 3rd of the Generic Drugs Act states that generics will have preference over other drugs in acquisitions made by the Brazilian public health system.

Another interesting detail concerns generics packages and marketing, that must not be similar to the original product. Some generic producers started to adopt layouts and marketing campaigns similar to the ones practiced by the original drugs' manufacturers, which has been greatly criticized by Brazilian courts⁴, as it constitutes a clear case of unfair competition.

³ CMED Resolution No. 01/2015 and CMED Resolution No. 04/ 2015.

⁴ Appeal No. 0027367-83.2005.8.26.0564 (São Paulo Court of Chancery); Appeal No. 2009.002.59430 (Rio de Janeiro Court of Chancery); and Appeal No. 0390020-44.2009.8.19.0001. (Rio de Janeiro Court of Chancery)

The interplay between antitrust and intellectual property regulations concerning generics deserves a deeper analysis, since, at first sight, these two may seem conflicting, as antitrust law focus on free competition and intellectual property law focus on exclusivity. However, in Brazil, this conflict has been overcome. Federal Law No. 9,279/96 (Industrial Property Law) is guided by principles derived from competition law, for the exclusivity it protects aims to promote investments in research and development and to stimulate competition in the market. The system adopted in Brazil intends to conciliate innovation incentives and benefits for consumers.

In the pharmaceutical industry, and especially in relation to generics, two aspects of such interplay are noteworthy: (i) accusation of practice of cartel and/or sham litigation by pharmaceutical industries in order to extend their exclusivity rights and block the production of their respective generics; and (ii) the execution of patent settlements in order to solve patent-related conflicts that, in certain conditions is not illegal *per se*. When analyzing such patent settlements, CADE makes use of the rule of reason in order to decide whether the executed patent settlement produces negative economic and competitive effects in the market or not. Only if such damages are recognized such a settlement could theoretically be considered unlawful.

Another mechanism aiming to avoid the practice of abuses is the granting of a compulsory license, as prescribed in Article 68 of Federal Law No. 9,279/96⁵:

Art. 68. The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision.

§1 The following also occasion a compulsory license:

I - non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or

⁵ Translation of the Law obtained at the homepage of the World Intellectual Property Organization

also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted; or

II - commercialization that does not satisfy the needs of the market.

§2 A license may be requested only by a person having a legitimate interest and having technical and economic capacity to effectively exploit the object of the patent, that shall be destined predominantly for the domestic market, in which case the exception contained in Item I of the previous Paragraph shall be extinguished.

§3 In the case that a compulsory license is granted on the grounds of abuse of economic power, the licensee who proposes local manufacture shall be assured a period, limited to the provisions of Article 74, to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent.

§4 In the case of importation to exploit a patent and in the case of importation as provided for in the preceding Paragraph, third parties shall also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent.

§5 The compulsory license that is the subject of Paragraph 1 shall only be required when 3 (three) years have elapsed since the patent was granted.

According to such provision, patent holders shall be subject to having its patent licensed on a compulsory basis whenever it exercises its exclusivity rights in an abusive manner or engages in abuse of economic power. Such abuse must be submitted and recognized by CADE or by a Brazilian Court, which once more attests to the interplay between antitrust and intellectual property regulations in Brazil.

4. Conclusions

Players in the pharmaceutical industry must abide by the Brazilian antitrust system, constituted by Federal Law No. 12,529/11 and the Brazilian antitrust authority, in what concerns competition matters, and by ANVISA's supervision and regulation, regarding technical aspects related to health and safety to consumers in the drug production process and distribution. It is understood in Brazil that CADE and ANVISA do not have conflicting competences, but rather, complementary competences. The same applies to the interplay between Brazil's antitrust and intellectual property regulations.

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