Pharma Innovators and Generics in Brazil. The legal and case law environment

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Within the industrial property discussion environment, more specifically with regard to innovation and technology protection through patents, companies that manufacture generics and similar drugs for many years were considered rivals to pharmaceutical laboratories holding patents. They were often nicknamed the “copy industry”, despite the fact that generic manufacturing is a legal and regulated activity.

Today, in Brazil, 25 years after the approval of Law No. 9,787/99, which regulates the entry of generic medicines in Brazil and created the conditions for their implementation in the market, in line with standards adopted by the WHO (World Health Organization), there is a much more mature commercial and legal scenario, in which both patent holders and laboratories specializing in generics even have converging profiles.

The truth is that, currently, many patent-holding laboratories also have a generic/similar division or have acquired generic companies to develop this business. According to information provided by the organization *Progenéricos* (https://progenericos.org.br/genericos/mercado/), among the 10 largest pharmaceutical companies installed in Brazil, all of them have a manufacturing line for generic medicines. In other words, companies that developed and are responsible for marketing internationally known brand products also began to focus on manufacturing generics, recognizing their commercial relevance.

Likewise, laboratories that initially focused on generic drug manufacturing hold a large and growing patent portfolio and have increasingly invested in research, development, and innovation. This fact can be proven by consulting the main patent office databases, or even after a visit to the campuses of these laboratories.

This reality, today, is also reflected in the Brazilian judicial landscape, which gains more solid contours through a more mature scenario of legal theses and jurisprudence.

Among the new developments in jurisprudence over the last two years, legislative changes and emerging trends, special emphasis is placed on the legal actions brought by patent holders in the pharmaceutical area to discuss the extension of the patent validity period (called PTAs), patent validation actions, in the Federal Court, brought in response to post-grant opposition proceedings at the BRPTO, inhibitory measures and injunctive relief requests to prevent the launch of any generic product in the market, litigated in the State Court, among others.

The decision issued by the Supreme Court in May of 2021 (lawsuit ADI No. 5529 / DF), declaring the unconstitutionality of the sole paragraph of Article 40 of the Industrial Property Act, and consequently abolishing the 10-year minimum validity term for patents of invention has opened a channel for discussion in life sciences, as Patentees have been filing lawsuits requesting patent term adjustments based on the unjustified delay of the BRPTO in the analysis of the patent application(s), in a case-by-case analysis inspired in the US model of patent term adjustment.

Nowadays, there are around 50 lawsuits claiming Patent Term Adjustments before the Brasília Federal Court, and most of them rely on the same arguments: seeking patent term adjustment, based on a potential excerpt from Hon. Judge Dias Toffoli, who quoted the PTA (patent term adjustment) expression as an institute of other countries, which, in theory, allows for the extension of the patent validity term depending on the fulfillment of some requirements that are legally defined in the legislation of these countries.

Most of the decisions already issued regarding preliminary injunctions decisions do not aim to effectively extend the patent term definitively, but rather suspend the patent expiry date until a decision is made on the merits of the matter (all of them still pending)[1].

Another judicial trend spotted within the last two years is the filing of lawsuits in Brasília Federal Courts seeking confirmation of the validity of an already granted patent, once there is a post-grant opposition filed or any risk for the patentee to have its IPR challenged by any means.

The Brazilian Federal Court of Appeals of the 1st region, in Brasília, is being assigned to analyze most of such cases, which are intended to anticipate a judicial discussion on the patentability criteria, by which the patentee requests for an unbiased technical opinion. The Expert will be appointed by the trial court, and will examine the documents that

were filed by a third party either as a matter of defense in infringement lawsuits or in post-grant oppositions.

When it comes to state courts discussions, the Bolar exemption has been in the spotlight, sparking debates in courts that normally occur shortly after the patentee targets the regulatory approval granted by ANVISA for a generic or similar drug.

According to the Brazilian IP Act, the patentee has the right to prevent third parties, without his consent, from producing, using, offering for sale, selling, importing for these purposes, or contributing to such practices, a patented product, process or product obtained directly by a patented process.

Article 43, VII of the Brazilian Act expressly provides exceptions to patent protection - among them, acts carried out by unauthorized third parties, related to the invention protected by a patent, which aim to obtain marketing approval in Brazil, or another country, for the exploitation and marketing of the product that is the subject of the patent, after the expiry of the patent term. The usefulness of the Bolar exemption is justified by the significant and excessive bureaucracy of regulatory agencies, including the Brazilian agency (ANVISA), for approving the commercialization of pharmaceutical products in Brazil, a procedure that can take years to be concluded.

So, generics are allowed to request the Marketing Authorization before ANVISA and to perform any experimental activities aimed at obtaining the data required for the Marketing Authorization Request, what corresponds to the Bolar exemption *ratio legis.*

Although marketing authorization applications or grants are typically viewed as pre-launch permitted activities, applications for reimbursement, pricing or listing, submissions or awards of tender, and offers to supply before patent term expiry, are subject to infringement lawsuit. That is why generic companies must be very careful whenever they intend to prepare for the launch of a new product in Brazil. For instance, the importation of samples of a patented medicine must be carefully observed, since depending on the imported amount, it can lead to an accusation of stockpiling, which is not allowed under the Bolar exemption.

Another relevant information about the Brazilian market when it comes to generics is that there is no obligation to “clear the way”, meaning that there is no formal obligation to prove non-infringement of a certain patent. However, it is highly advisable to perform a clearance analysis before entering the market to avoid unnecessary loss of time and financial resources.

Last but not least, in December 2023, ANVISA issued a resolution that allows a patented indication to be carved from a generic label in Brazil, the practice commonly known as skinny label.

Such new legal provision was enacted as a response to the generics that now are able to have a “skinnier” label excluding indications protected by patents in force or pending applications. Prior to this

resolution, a generic company would be at potential risk of being accused of patent infringement because the general rule stated that the generic label must be identical to the reference drug. Therefore, in order to be on the safe side, some generic companies delayed the launch of generic products to avoid patent litigation.

After the issuance of ANVISA's resolution allowing a skinny label, new medical use patents will not impair the market entry of the generics, contributing to a more balanced scenario in the pharmaceutical industry.

Of course, much discussion will arise from this new resolution, thus, for the future we can expect the challenging of the skinny label provision and further legislative discussion in setting the limits and boundaries between patentees and generics, both aiming for market growth in Brazil.

[1] the First Panel of the Supreme Court has already had the opportunity to analyse two constitutional complaints (no. 56.378 and nº 53.181) related to PTA lawsuits filed in Brasilia and decided that the request for patent term adjustment conflicts with what was decided in the ADI5529.