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First Impacts of The Judgment of ADI 5,529 in The Brazilian Patent Scenario from The Perspective of Pharmaceutical Patents

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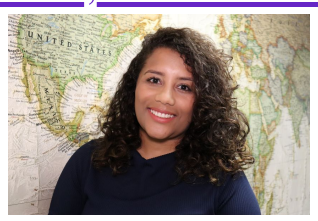

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Almost one year ago, the Brazilian Supreme Court has finally judged the lawsuit that challenged the constitutionality of the sole paragraph of article 40 of the Brazilian IP Law (ADI 5,529). ADI 5,529 was filed on 2016 but its judgment was being postponed over and over until April 2021, when the subject got a lot of attention in view of the possible impacts thereof in the fight against the COVID-19 pandemic in Brazil. Then, last May, the lawsuit has been finally decided and now, one year later, it might be interesting to analyze what has happened due to this decision so far. However, in order to understand the current situation, it is necessary to, at first, understand the provision of the Brazilian IP Law that was challenged by the lawsuit as well as the situation of the patent examination in Brazil by then.

According to the *caput* of Article 40 of the Brazilian IP Law, a patent is valid for 20 years and a utility model for 15 years, counted from its filing date. In addition, the sole paragraph of this article established a minimum validity term of 10 years for patents and 7 years for utility models, counted from the grant date, for cases granted more than 10 years after their filing dates. This provision was a compensation to the patentees for the excessive delay of the Brazilian Patent Office (BRPTO) in examining and granting patents.

However, this paragraph, which should be exceptionally used, has become the rule in the last years, due to the delay in the technical examination of patents and, therefore, the patent expiration date in Brazil was mostly subject to its granting date. In most technical fields, including the pharmaceutical one, the patent examination could take more than 10 years, in 2016, when the lawsuit was filed.

Although the number of years to have a pharmaceutical patent granted was already being reduced due to the BRPTO successful Backlog Elimination Plan, in 2021, almost 70% of the patents covering medicaments, in force at that moment, benefited from the sole paragraph of Article 40 of the Brazilian IP Law. According to those who were against this law provision, this provision unduly extended the patents' validity and also generated legal insecurity, as they argue it was not possible to foresee the precise patent expiration date of patents in Brazil. Specifically in the pharmaceutical field, this could jeopardize the entrance of generic drugs in the market.

Considering this scenario, in May 2021, the Brazilian Supreme Court decided on the unconstitutionality of the sole paragraph of Article 40 of the Brazilian IP Law. Consequently, all patents granted from that date on are valid for a 20-year term, counted from their filing date, in accordance with the provisions of the *caput* of this

article.

This decision affected almost 9,000 patent applications of all technological fields, which were waiting for a final decision in the first instance for more than 10 years. Among them, around 200 applications could be granted already expired. Additionally, a specific group of valid patents which had their validity term established based on the 10-year rule was retroactively affected.

Driven by the pandemic emergency, the Brazilian Supreme Court decided for the retroactive (*ex tunc*) application of the unconstitutionality of the sole paragraph of Article 40 for patents related to pharmaceutical products and processes, and equipment and/or materials for use in healthcare. However, it was up to the BRPTO to select which patents already granted should have the validity adjusted.

For such selection, the BRPTO used some criteria, such as the prior consent of the National Health Surveillance Agency (ANVISA) and certain IPC classifications. In the first Official Bulletin after the Supreme Court's decision, a first list with 3,341 patents that had their validity changed was published and in total, around 7,000 patents were affected. In other words, practically overnight, thousands of patents have lost years of validity, and some technologies have even become part of the public domain. Companies holding the technologies faced an unexpected scenario of loss of market exclusivity and uncertainty. On the other hand, it is a mistake to believe that this scenario brought surprise and uncertainty only to patentees.

As soon as the patents were republished with their validity changed, the patentees began to file lawsuits requiring adjustments to the expiration dates (PTA's – Patent Term Adjustments), based on an excerpt from the vote of the Rapporteur Minister Dias Toffoli, which mentions the use of PTA's in certain cases of delayed examination. In general, said lawsuits require the settlement of an adjusted validity, adding some years to the current term based on the disproportionate and unjustified delay of the BRPTO to analyze and grant patents. Until now, more than 30 PTA's lawsuits have already been filed before the Federal Courts.

It is important to mention this is the first time Patent Term Adjustments are required in Brazil. These Court Actions are very recent in the country and there is still no case law on the subject. So far, it is only possible to know that patentees are requesting validity extensions, some of them exceeding the original period of 10 years counted from the patent granting date. Furthermore, since each case took a different time to be examined, the number of years to be added to the validity varies on a case-by-case basis. As an immediate consequence, until the end of such Court Actions, it is not possible to predict, for instance, how it is going to be the situation for generics aiming at entering the Brazilian market.

Meanwhile, it is not possible to state that the retroactive effect of the decision on the sole paragraph of article 40 for pharmaceutical patents provided any benefit for the COVID-19 pandemic. As it is widely known, the success in the fight against the virus is the result of the massive vaccination campaigns and the patents or patent applications related to the vaccines used in said campaigns were not affected by said decision. As a matter of fact, before the judgment itself, BRPTO provided to the Courts information about how the change in the legislation could actually affect the patent applications related to COVID-19. According to the Institute, among the 90 patent applications that contained indication of possible use in the fight against COVID-19 that were pending decision, only 4 could possibly be granted based on the sole paragraph of Article 40.

In a nutshell, the *ex tunc* application of the decision did not result in any beneficial effect so far. In fact, it seems to create a scenario of legal uncertainty not only for patentees but also for generic drug companies. It is not possible to guarantee when the court actions directed to PTAs will be judged, nor the outcome of these judgments.

Ironically, the fight against the alleged legal uncertainty caused by the lack of definition in the validity of patents, which was exactly one of the major arguments used to defend the unconstitutionality of the sole paragraph, might have led to a much more indetermined scenario. Has it backfired?

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