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Brazilian Supreme Court grants preliminary injunction that puts pharmaceutical patents at risk

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The judgment of the lawsuit that challenges the constitutionality of the sole paragraph of Article 40 of the Brazilian Patent Law (ADI no. 5,529) scheduled for April 07, 2021 was removed from the Supreme Court agenda in view of the urgent need to analyze a pandemic-related court action. However, the Reporting-Minister granted a preliminary injunction that suspends this legal provision only for patents related to pharmaceutical products and processes until the trial occurs. Article 40 establishes that the term of protection of patents for invention in Brazil is 20 years counted from the filing date. The sole paragraph of the same article, reason for the establishment of ADI no. 5,529, guarantees that a patent must be valid for at least 10 years. Therefore, this provision allows the extension of the term of validity of Brazilian patents as a compensation for patentees if there is an excessive delay of the Brazilian Patent and Trademark Office (BPTO) to grant the patent. In other words, if the BPTO takes a long time to analyze and grant a patent, such patent will be valid for 10 years counted from the granting date. Therefore, the sole paragraph of Article 40 should be used as an exception to guarantee a reasonable minimum period for the exploitation of the rights conferred to the patent holder. However, due to the accumulation of pending patent applications at the BPTO, known as the “patent backlog”, an expressive number of patents was granted with a validity of 10 years counted from the granting date. According to data provided by the BPTO, almost half of the patents currently in force in Brazil were granted based on this legal provision, that is, approximately 31,000 patents. In such cases, the original term of the patents, which should be 20 years, can reach 30 years or even more.

The delay in granting patents is not a recent problem in Brazil. The BPTO has been accumulating patent applications for decades due to several factors, notably the lack of technological infrastructure and the reduced number of examiners to analyze the patent applications. This situation gets worse because the BPTO does not have financial autonomy over its revenue, which makes it impossible to solve these problems quickly and in a sufficient manner. However, even facing various obstacles, the BPTO launched a plan to combat the patent backlog in 2019, which has proved to be efficient in reducing the backlog of 150,000 pending applications. According to data made available by the BPTO, the backlog was reduced in 51.2% by December 2020. The final goal is to reduce in 80% the number of pending applications by August 2021, in addition to reducing the average examination time to around two years. The current average time for granting a patent in Brazil is around 8 years, which may vary according to the technological area.

It is undeniable that all technological sectors will be affected if the sole paragraph of Article 40 of the Brazilian Patent Law is deemed unconstitutional. However, the two areas that are known to have the greatest impact are telecommunications/electronics and pharmaceuticals. Companies in the telecommunications/electronics sector, the most affected by the delay in granting patents in Brazil, would lose almost 90% of their patents currently in force. At a time when Brazil is discussing relevant issues related to this area, such as the 5G technology, it would be extremely harmful to the country that companies which developed these technologies have their rights adversely affected after decades of investment and expectation for the grant of patents in Brazil.

The pharmaceutical industry is ranked in the second position in the group of patents that are granted with a delay of more than 10 years, with more than 70% of the patents in force benefiting from the legal provision under discussion. Specifically in the pharmaceutical sector, there is an additional complicating factor. All patent applications related to pharmaceutical processes and products must be submitted to ANVISA (the Brazilian Regulatory Agency, similar to the FDA in the United States) to obtain its prior consent. In short, the Agency checks whether the object of the patent application includes substances that are prohibited for use in the country and, if so, requests that the applicant remove these substances from the scope of the claimed invention. In addition, ANVISA can also issue opinions on the patentability of inventions related to substances of interest to SUS (Brazilian Unified Health System). However, these opinions are sent to the BPTO as third-party observations to the technical examination that will be carried out by the Patent Office. Therefore, they cannot prevent the grant of patents. As much as the procedure for prior consent has already been simplified, it is undeniable that this procedure creates even more delay in the BPTO's prosecution, which can only start its technical examination after receiving the prior consent from ANVISA.

The preliminary injunction granted by the Reporting-Minister accepting the request of the Attorney General's Office and suspending the effects of the sole paragraph of article 40 of the Brazilian Patent Law affects precisely the pharmaceutical patents that, in addition to the usual delay caused by the BPTO, still need to overcome the prior consent stage at ANVISA. It is important to mention that the patents currently in force are not affected by this preliminary injunction, since it does not establish a retroactive effect. In practical terms, the patents that will not benefit from the minimum 10-year term established by the Brazilian Patent Law are those granted from now on and until the trial happens, probably next week (April 14th).

There are several possible decisions for this important judgment, whether for or against the patent system currently established by the Brazilian Patent Law. The first would be to maintain the decision issued in the preliminary injunction, but covering all technological sectors. A second possibility would be to maintain Article 40 in its entirety. This decision would keep the current scenario, but it is important to mention that due to the positive results of the BPTO's plan to eliminate the patent backlog, the trend in the medium term would be to use the sole paragraph as an exception. Another possible decision, but which does not seem likely to happen given the scope of the recent preliminary injunction would be the extinction of this legal provision retroactively. In this case, approximately 31,000 patents currently in force would be extinct or would have their term reduced.

Anyone who thinks that the patent system only benefits multinational companies is wrong. By declaring the sole paragraph of Article 40 of the Brazilian Patent Law unconstitutional, Brazilian universities and research centers, such as UNICAMP, UFRJ, USP, Embrapa and FAPESP, would lose various patents currently in force and their content would be available to be freely exploited in Brazil.

Although it is undeniable that the legal provision judged by ADI 5,529 should be used as an exception, this is not what actually happen considering the current scenario. On the other hand, by deciding for the unconstitutionality of this provision, the Supreme Court would be imparting the burden of the State's inefficiency to the patentee itself and, therefore, to the developer of the technologies that allow the economic development. This attitude discourages innovation and slows the economy down, running against robust patent systems, such as those in the USA, Europe, Japan and China. Therefore, a careful analysis of the facts surrounding this controversial judgment leads to the understanding that the entire society loses when arbitrary decisions are taken without considering all players in the Brazilian innovation ecosystem.

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