

Results of the Plan to Reduce Brazilian PTO's Patent Backlog

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The plan implemented by the Brazilian Patent and Trademark Office (BPTO) to tackle the patent backlog reduced in 51.2% pending patent applications in 2020, according to data provided by the Office. The final goal is to reduce the number of applications pending decision by 80% by August 2021, in addition to reducing the average grant term to approximately two years.

The strategy used by the BPTO to achieve the proposed goal is relatively simple: use the results of the analysis of patent applications in other countries and regions, such as e.g., the examination performed by the USPTO (United States Patent and Trademark Office) and the EPO (European Patent Office). In doing so, the Brazilian examiners, who are responsible for evaluating the inventions proposed in patent applications pending at the BPTO, can benefit from high-quality technical work while saving valuable time. In addition, it is important to mention that, even starting from a technical examination already carried out abroad, the BPTO's examiner has the right to perform his own analysis based on the Brazilian legislation in force and even disagree on the merits of an invention that has obtained a patent in other countries. Consequently, the procedure for evaluating Brazilian patent applications has become quicker, while respecting the decision-making independence by BPTO examiners.

However, for a patent application to no longer be considered part of the backlog, it is necessary that its prosecution be finished, that is, there must be a decision to grant or reject the application. At this stage, one of the main challenges of the BPTO arises: the examiners must not only issue preliminary Office Actions for applicants to submit amendments and technical arguments that make the Brazilian patent application similar in scope to a patent granted in another country for the same technology, but they also need to analyze the contents submitted to the BPTO and issue a final decision. According to the BPTO, the technical examination of approximately 52,000 patent applications has already started, but they still need to be analyzed in order to have a final decision. This number corresponds to approximately 84% of the current backlog. The high percentage creates concern for the users of the patent system, as it may lead to the creation of a “backlog of the backlog”, that is, a new bottleneck of applications pending analysis in the short term.

The backlog issue can also be analyzed from the perspective of technological areas. Currently, the areas most affected by the delay in granting patents in Brazil are chemistry, mechanical engineering and electrical engineering. The chemistry area alone, which includes patent applications of the pharmaceutical sector, among others, is responsible for almost 40% of the current backlog.

Specifically in the pharmaceutical area, there is an additional complicating factor. All patent applications related to pharmaceutical processes and products must be submitted to ANVISA (Brazilian Health Surveillance Agency) to obtain its prior consent. Generally speaking, the Agency analyses whether the object of the patent application includes substances of prohibited use in the country and, if so, requests that the applicant remove these substances from the scope of the claimed invention. Moreover, 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 then be performed by the Patent Office. Therefore, they cannot prevent the granting of patents. As much as the procedure for prior consent has already been simplified, it is undeniable that it creates even more delay in the analysis of the BPTO analysis, which can only start its technical examination after receiving the prior consent from ANVISA.

In Brazil, the term of protection of for patents of invention is 20 years counted from the filing date or 10 years counted from the granting date, based on Article 40 of the Brazilian Industrial Property Law (LPI). Currently, with the high backlog, an expressive number of patents in Brazil has been granted within the 10-year term from the granting date. This issue has recently gained more attention due to the judgment of the Direct Action of

Unconstitutionality (ADI) No. 5,529 in the Brazilian Supreme Court (STF), which challenges the constitutionality of the sole paragraph of article 40 of the LPI, namely, the legal provision that extends the term of validity of Brazilian patents as a compensation for the BPTO delay in granting patents.

In this scenario, it is necessary to evaluate at least two situations. On the one hand, there are innovative pharmaceutical companies that benefit from the provisions of the sole paragraph of Article 40 due to the backlog in the BPTO's examination, but that should not be harmed by the delay exclusively caused by the BPTO, if this legal provision is to be extinguished at the LPI. On the other hand, there are companies that manufacture generic drugs, which obtain the registration of commercialization for drugs identical to the brand-name ones, but they need to wait for the patent to expire. An example of this situation is Sprycel® (Dasatinib). The patent covering this compound was due to expire in 2020, but based on the exception of the LPI, it will expire only in 2028. The brand-name medicament has high price, being used for the treatment of cancer, more specifically leukemia.

As can be seen from the above discussion, the long prosecution of patent applications creates several legal uncertainties in the country, which can lead to a reduction in investments and causes strong economic impact. Therefore, it is essential that the BPTO plan to tackle the patent backlog be maintained and even improved, as this new scenario creates a more favorable environment for innovation in Brazil for both national and international companies.

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