2021 highlights in Brazil: PATENTS

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This article is part of a series reviewing the IP landscape in 2021.(1)

This article looks particularly at developments that took place in the field of patents.

Brazilian Supreme Court Decision on Patent Term Validity

On May 6, 2021, the Brazilian Supreme Court has decided that the sole paragraph of Section 40 of the Brazilian IP Law is unconstitutional. This legal provision allowed a minimum validity term of 10 years for patents of invention and 7 years for utility models, counted from the granting date. After this decision, all patents granted will be valid for 20 years counted from the filing date, regardless of the time spent by the Brazilian PTO to examine the applications. In addition, the decision applies retroactively to already granted patents related to pharmaceutical products and processes, as well as equipment and materials for use in healthcare. This *ex tunc* effect of the decision also covers patents that were subject to lawsuits challenging the 10-year rule filed by April 07, 2021, irrespective of the technological field.

Since the Supreme Court decision did not provide any information on how to determine whether a patent relates or not to the group of cases defined as “pharmaceutical products and processes, medical equipment and materials for use in healthcare”, this classification was made by the Brazilian PTO based on the following criteria:

(a). Patents that were sent to Anvisa for prior consent;

(b). Patents having the following IPC classifications: A61B, A61C, A61D, A61F, A61G, A61H, A61J, A61L, A61M, A61N; H05G (technologies associated with medicine according to WIPO);

(c). Patents having the following IPC classifications: A61K/6, C12Q/1, G01N/33, G16H;

(d). Patents having a published lawsuit decision; and

(e). Granted Certificates of Addition.

The granted patents affected by the retroactive effect were reissued with the validity term adjusted in the BPTO Official Bulletin. In case of patents for which the 20-year term counted from the filing date has already elapsed, the extinction of the patent is being subsequently published.

However, in cases wherein the patentee did not agree with the adjusted term, the Brazilian PTO provided a 60-day term counted from the publication of the validity term adjustment in the BPTO Official Bulletin to submit arguments evidencing that the patent should not be affected by the Brazilian Supreme Court decision. If the arguments are accepted by the Brazilian PTO, the original term of the patent (10-year rule) will be maintained. If the arguments are not considered to be valid, the patentee will be notified of the rejection of the petition along with the reasons for this rejection. Then, it will be possible to lodge an appeal to challenge the rejection as a final attempt to revert the validity term adjustment of the patent in the administrative instance.

Extinction of ANVISA's prior consent for patent applications related to pharmaceutical products and processes

Another relevant decision that directly impacted the life sciences field in Brazil, more specifically the patent applications related to pharmaceutical products and processes, was the extinction of the mandatory prior consent provided by the Brazilian Health Agency (ANVISA).

Law no. 14,195 was sanctioned on August 27, 2021 and it eliminates the requirement of prior consent from ANVISA for patent applications related to pharmaceutical products and processes before the technical examination performed by the Brazilian PTO. This requirement was established in Article 229-C of the Brazilian Industrial Property Law.

The measure (Article 57, XXVI of the above-mentioned Law) modified the current rule for patent applications belonging to the pharmaceutical field that was in force in Brazil since 2001. In practical terms, it allows the pharmaceutical industry to prosecute its patent applications without the need for prior consent from ANVISA, which means that the whole prosecution will only take place within the scope of the Brazilian PTO, providing more agility to the procedure.

Only pharmaceutical patent applications were first sent to a regulatory agency to be approved in Brazil. However, ANVISA's role is to approve the commercialization of drugs and not examining patent applications. There is no similar procedure in other countries. Finally, after 20 years, Brazil no longer has this bureaucratic stage in the examination of patent applications in the pharmaceutical field.

New Bill on Compulsory Licenses

After several months of discussion, Bill no. 12/2021 was sanctioned on September 02, 2021, which modifies the rules for compulsory licenses set forth by the Brazilian IP Law in cases of national or international emergency, as well as in case of public interest or public calamity.

Although the originally proposed amendments had many controversial aspects, such as the requirement of mandatory technology transfer and provision of all relevant information, data, biologic material, etc. to the third parties involved in the compulsory exploitation of the patent, these aspects were vetoed and, in the end of the day, the amendments do not substantially change the original provisions of the Brazilian IP Law.

The main differences from what has already been provided by the current IP Law are that (i) patent applications are also subject of compulsory license; (ii) the government will publish a list of patents and patent applications which are potential cases for compulsory licenses; (iii) the royalties are fixed as 1,5% of the net selling price of the product associated with the patent until its value is effectively established; and (iv) for humanitarian reasons, the compulsory license of a patent related to a pharmaceutical product may be declared in Brazil with the objective of exporting said product to countries that have insufficient or no capacity of manufacturing it.

Although the provision of a list of potential cases for compulsory licenses seems to be a negative outcome of Bill no. 12/2021, according to the new Article 71 (paragraph 7), patents or patent applications that have not yet been subject to a compulsory license may be excluded from the list in cases wherein the government considers that the patentees have assumed objective commitments capable of ensuring compliance with the domestic demand under conditions of volume, price and term compatible with the needs of national or international emergency, public interest or state of public calamity nationwide through one or more of the following alternatives:

I – direct exploitation of the patent or patent application in the country;

II – voluntary licensing of the patent or patent application; or

III – transparent product sale contracts associated with the patent or patent application.

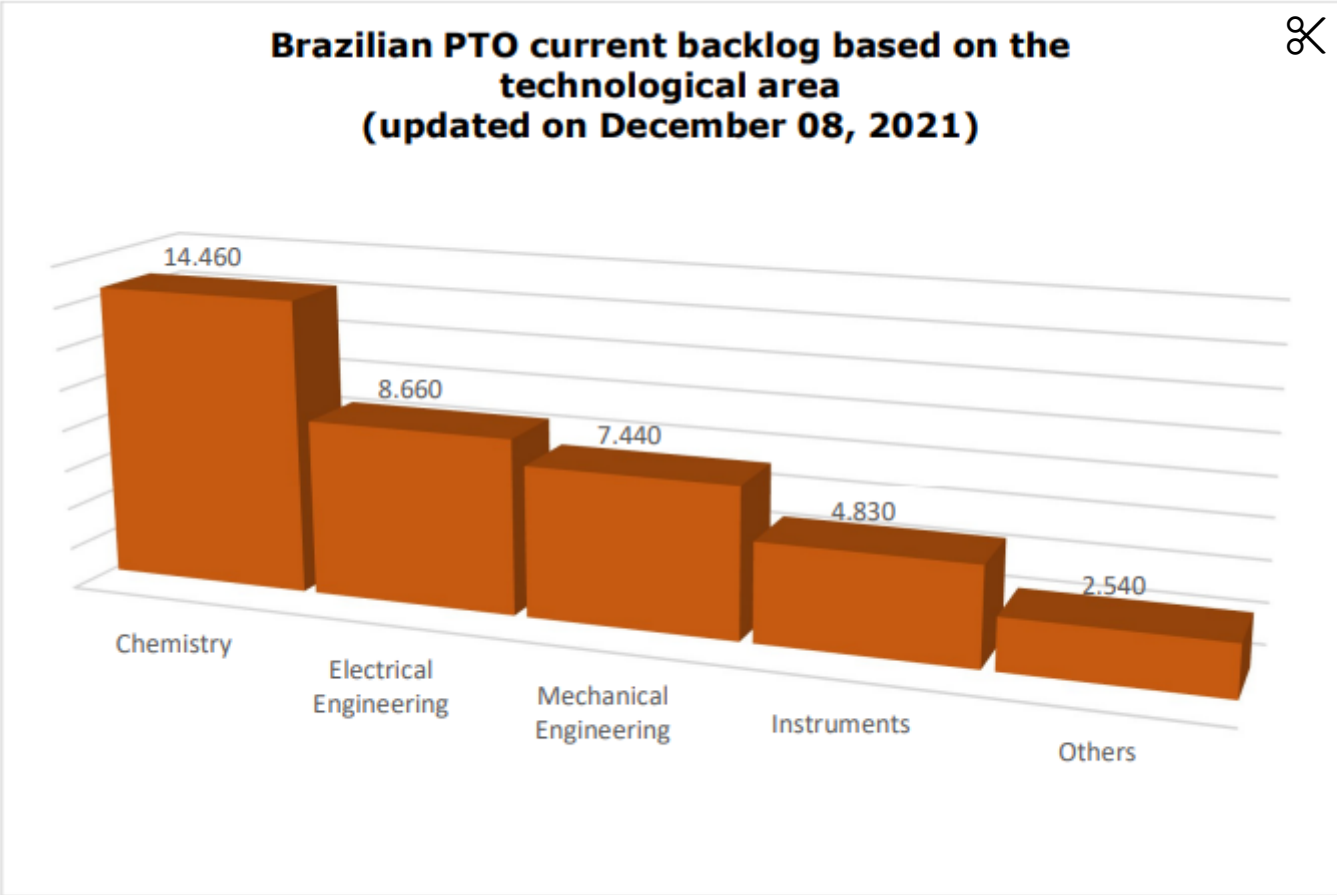
Even with the current pandemic scenario, it is unlikely to have a considerable amount of compulsory licenses being granted after the amendments provided to the current IP Law, since the local institutions that could actually manufacture pharmaceutical products covered by patents are quite a few in the country.

Brazilian PTO Plan to Reduce the Backlog in Technical Examination

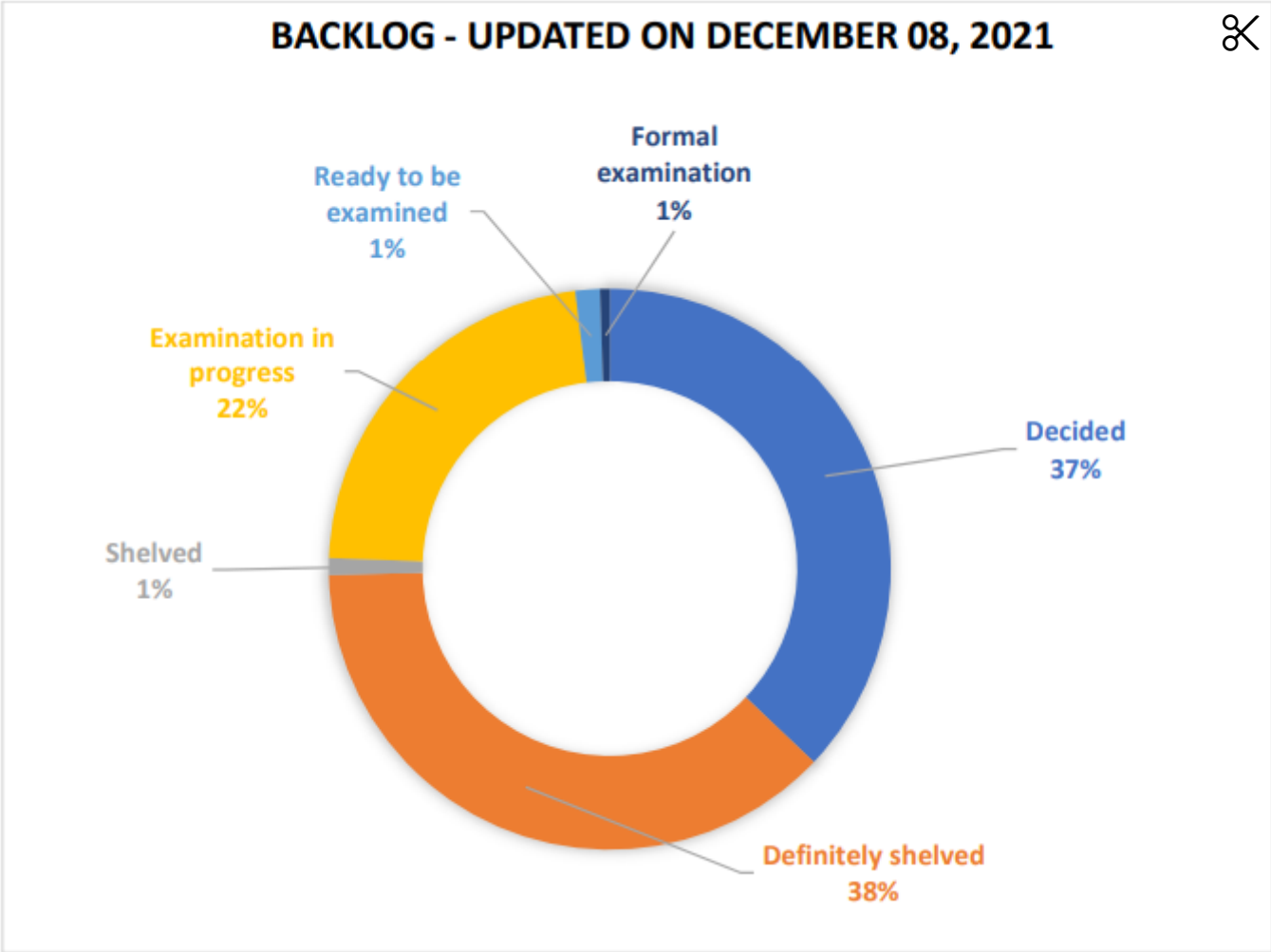
The plan implemented by the Brazilian PTO to tackle the patent backlog reduced in 67.8% pending patent applications in two years. The final goal is to reduce the number of applications pending decision by 80%, in addition to reducing the average grant term to approximately two years.

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 and EPO.

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 and biotechnology fields, is responsible for almost 40% of the current backlog (please see the chart below).



According to the Brazilian PTO, 113,334 applications were examined in approximately 28 months out of 149,912 applications pending examination, thus reducing the backlog in about 76%. Additionally, according to a recent update provided by the Brazilian PTO, among the pending patent applications, 22% are already under examination (please see the chart below). This means that by keeping this pace, the Brazilian PTO will probably be able to solve the backlog issue in the short term.



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