The Need for Patent Term Adjustment in Brazil

Patents incentivize long term innovation, and support investments in critical research and development activities. For biopharmaceutical innovators, they ultimately help deliver new treatments, vaccines and cures to patients, and facilitate licensing and sharing of technology. Patents also promote competition and greater treatment options. In exchange for the limited period of protection that patents provide, innovators must fully disclose their inventions to the world. That disclosure accelerates innovation and empowers potential competitors to build on those inventions. In the biopharmaceutical sector, competition means more medicines in the same therapeutic class, more options for patients and lower prices.

As noted, patents provide only a limited period of protection, namely a minimum term of 20 years from the date that the patent application is filed. Unreasonable delays in examining and granting patents directly reduce the term and value of granted patents and undermine investment in future research. For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines. They create legal uncertainty for research-based and generic companies alike, and can increase the time and cost associated with bringing a new treatment to market. Long patent examination and approval backlogs harm domestic and overseas inventors in every economic sector.

Patent applicants in Brazil experience some of the longest patent pendency times in the world. Despite the National Institute of Industrial Property's recent efforts to reduce the patent examination backlog, including through the elimination of the dual examination process associated with the Brazilian National Health Surveillance Agency, the average patent examination timeline in the biopharmaceutical sector continues to be more than 10 years.

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Further complicating matters is a 2021 Supreme Court decision finding the sole paragraph of Article 40 of the Patent Law, which ensured a minimum patent term of 10 years from the date of patent grant in Brazil, unconstitutional. The decision immediately nullified at least 30,000 patents in a variety of sectors, and was especially damaging for pharmaceutical and other health-sector innovators because the decision was applied retroactively to their patents. The decision left all patent applicants across all technology sectors with no recourse for unreasonable delays during examination of patent applications. Notably, the decision acknowledged the need to account for unreasonable patent office examination timelines, prompting innovators to file dozens of lawsuits to seek remedies.

Recognizing the deleterious impact of patent office delays on the value of patents and their ability to facilitate access to medicines, a number of countries, including several OECD Members, have implemented mechanisms to safeguard against unreasonable delays during the examination of patent applications

(commonly referred to as Patent Term Adjustment or PTA). In light of the significant patent backlog and the fact that Brazil has access to significantly fewer new medicines than other OECD countries, the time is ripe for Brazil to establish a PTA mechanism to ensure that innovators are not harmed by undue delays in the patent examination process, consistent with OECD best practices and international standards.

GLOBAL PTA MECHANISMS

The PTA mechanisms in **Chile, Korea, and the United States**, and (all of whom are OECD Members) are indicative of the type of mechanism that Brazil should implement.

UNITED STATES

The U.S. Patent and Trademark Office (USPTO) automatically calculates and restores the portion of the patent term lost due to unreasonable delays. The statutory formula for calculating the adjustment is divided into three types of delays: (1) prescribed administrative delays during the patent examination process; (2) failure to issue a patent within three years from the filing date of the application or the date of entry into the U.S. national stage; and (3) when certain procedural matters occur during review of a patent application, such as interferences or derivation proceedings. The formula ensures that there is no double counting of delays incurred across these three categories and deducts for any delays by the applicant. The USPTO provides a PTA calculation with the Issue Notification and is reflected in the patent expiration date indicated for the issued patent. Patent holders may file a petition with the USPTO to challenge the PTA calculation if they believe that it has been calculated erroneously. As such, the U.S. PTA mechanism ensures that no applicant diligently seeking to obtain a patent will receive a term of less than 17 years.

KOREA

In Korea, if a patent holder believes that the patent grant was unduly delayed, it may seek an adjustment of the patent term from the Korean Intellectual Property Office (KIPO). Such requests must be submitted within three months of the grant of the patent. If a patent is granted more than four years after the filing of the patent application and more than three years after a request for examination (whichever is later), the patent is eligible for PTA. As in the United States, the period of the adjustment is reduced by the number of days of delay that are attributable to the applicant rather than KIPO.

CHILE

The PTA mechanism in Chile is similar to that in Korea. The key differences are that: (1) requests for PTA must be submitted within six months of the grant of the patent; and (2) a patent is eligible for PTA if there was an unjustified administrative delay, i.e., the patent was granted more than five years after the patent application was filed or more than three years after a request for examination (whichever is later).

As these examples demonstrate, regardless of the precise methodology used to calculate the PTA term, these mechanisms serve to restore that portion of the patent term that would otherwise be lost unreasonably due to patent office delays, thereby preserving the incentives that patents provide for inventors to innovate. Mechanisms used to compensate for patent office delays **do not extend** the 20-year patent term. Indeed, they only provide a partial restoration of the time and value lost during the patent examination process.