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Brazil and China in different directions?

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Historically, China promulgated its first patent law in the 1980s, the result of its reopening and affiliation to the WIPO, which led to the country's joining important multilateral agreements, such as the Paris Union Convention for the Protection of Industrial Property (1984) and the TRIPS Agreement (2001).

This patent law entered into force in 1985 and prohibited patent granting for pharmaceutical substances and products. The 1992 amendment, which entered into force in 1993, removed that ban, allowing the patenting of pharmaceuticals and extending the period of protection of patents from 15 to 20 years. In 2001, due to the country's negotiations to enter the World Trade Organization (WTO), China promoted a new change in its national legislation to adapt to the provisions of the Trade Related Intellectual Property Rights Agreement (TRIPs).

In 2020, the 4th Amendment to the Patent Law was promulgated, which promoted significant changes towards a more robust protection of patents. In this sense, new provisions provide for the possibility of adjusting the Patent Protection Agreement of all technologies for an irrational delay in the request of requests, which is internationally called "Patent Term Adjustment" (PTA), as well as the extension of the deadline of patents related to new drugs by the time spent in the analysis and approval procedure of these products for commercialization, called "Patent Term Extension" (PTE).

Finally, the new change in Chinese law implemented a linkage system, which links the marketing authorization for a generic drug to the expiration of a certain patent related to it, as well as stipulated the payment of punitive damage for patent breach.

On the other hand, Brazil, one of the pioneer countries in the protection of inventions worldwide, has already granted exclusivity for fourteen years to inventors through the 1809 permit, with constitutional protection to patents in 1824 and the first patent law was then enacted in 1830, followed by Law No. 3,129 of 1882. It should be noted that it was only in 1945 that national legislation-imposed restrictions on the patenting of pharmaceutical products by Decree-Law No. 7,903, on the grounds of promotion to the national industry.

In 1969, the processes for obtaining pharmaceutical products were also excluded from Decree-Law No. 1,005 and subsequent legislation (Law No. 5.772/71) accompanied the previous two decrees, not allowing the patenting of drugs.

In 1994, Brazil joined TRIPs, whereby minimum standards of protection for the intellectual property were established, which prohibits, in its article 27.1, any legal restriction of technology of the patent protection field. In this step, Brazil promulgated, in 1996, Law No. 9,279, known as the Industrial Property Law (LPI in Portuguese), excluding the “non-privileged” subjects to chemical, pharmaceuticals, and medicines as well as the respective processes.

In addition to extending the period of protection of the invention patents to 20 years from the deposit date (or at least 10 years from the concession), the new legislation, in its articles 230 and 231, established the patents interim “pipeline”, a kind of validation of rights in Brazil from foreign patents for previously prohibited technologies.

With the new law, Brazil assumed a diametrically opposite position and, although as an exception, allowed the granting of patents for pharmaceutical materials that were already in the state of the art and without any examination of merit by the BPTO, which contributed to a rebound effect, fostering discourses on unjust “monopolies”, aggravating existing prejudices, especially with pharmaceutical patents. As a result, the pharmaceutical sector, to the present day, faces significant challenges in the protection of its patents in Brazil.

In 2021, the Federal Supreme Court decided in ADI No. 5529, declaring the unconstitutionality of the sole paragraph of article 40 of the LPI, which provided for a minimum period of protection of the invention patents for 10 years from the concession.

The headline of that article provides that the exclusivity period is 20 years from the date of deposit of the order, but, in view of the long time taken for administrative proceedings in BPTO, most patents had their protection time governed by the sole paragraph since the enactment of the new law. The decision did not retroactively apply to patents already granted with that benefit from the period of the sole paragraph, except for pharmaceutical patents and medical devices that had their protection deadlines immediately adjusted to the smallest or who were declared extinguished when the 20-year term of the deposit date had passed.

Finally, the Federal Senate proposed Bill No. 12/2021, which originated Law No. 14,200/21, including art. 71-A in LPI, to enable, by compulsory license, the production of drugs for export purposes to countries with insufficient or no manufacturing capacity in the pharmaceutical sector to serve their population, aiming, at first sight, COVID treatment and prevention. Such changes promoted were accepted despite statements by authorities of the Butantan Institute and Fiocruz (the main science research institutes in Brazil) refuting the argument that the lack of vaccines would be due to patent issues and that compulsory licensing would be an effective solution.

Between Brazil and China, there are some geographical and public policy approach similarities (aiming at health universality), but there is no denying the difference in the directions of countries in their strategies for protecting intellectual property in the medium and long term. While China seeks to protect its IP, Brazil seeks palliative remedies, which superficially treat symptoms but do not heal the disease. The country completed 2021 in the segment of IP with the strong performance of the legislature and judiciary against the interests of patent holders and, consequently, generating a certain degree of legal insecurity for all those who invest in new technologies, especially those active in the sector pharmaceutical.

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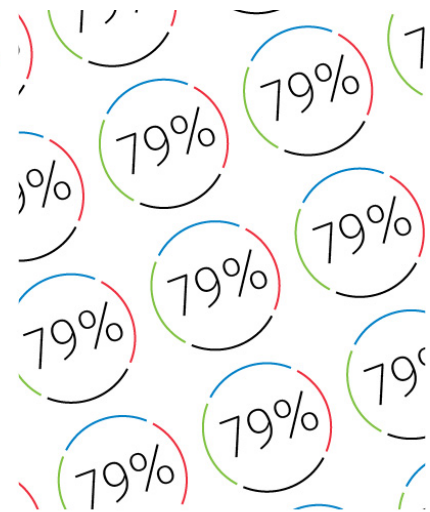
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