Significant Pharmaceutical Backlogs Remain in Brazil

Patent applicants in Brazil experience some of the longest pendency times in the world. While Brazil has made some marginal progress in reducing its backlog – including through hiring new examiners and greater reliance on patent prosecution highways – the reality remains that the estimated average period between submission of a patent application and grant of the patent in Brazil is eight years, and is even longer for more complex technologies such as biopharmaceutical products. To demonstrate the severity of the problem, this paper, based on a search and analysis of the examination timeline for biopharmaceutical patent applications in Brazil conducted by Osha Bergman Watanabe & Burton LLP (Osha)[1], explores the patent examination timelines for biopharmaceutical patents granted between January 1, 2020, to March 23, 2022, as well as the state of play of patents pending. As this data shows, **Brazil continues to experience significant patent examination delays, with average patent examinations for biopharmaceuticals taking longer than 10 years.** Moreover, the data demonstrate that there is little hope for real improvement in these examination timelines in the short to medium term given the significant number of biopharmaceutical patents pending review.

Biopharmaceutical Patent Examination Timelines Remain Excessive in Brazil

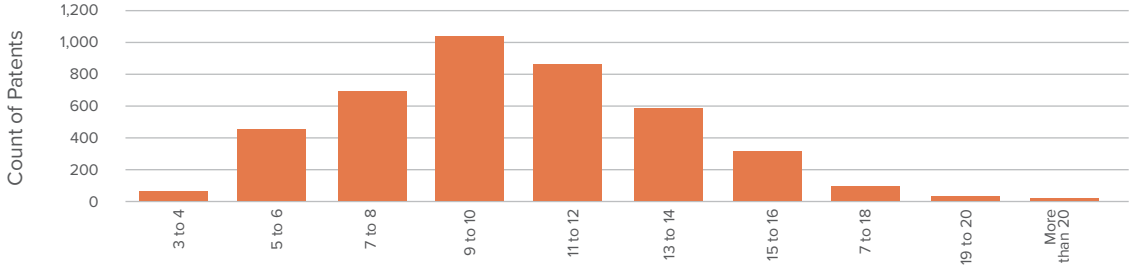
As shown in Table 1 below, the average patent examination timeline in Brazil for biopharmaceutical patents granted from January 1, 2020, through March 23, 2022, was 10.25 years.

Table 1: Biopharmaceutical Patents Granted from January 1, 2020, through to March 23, 2022

Year	Number of Biopharmaceutical Patents Granted	Average Patent Examination Timeline (in years)
2020	2,020	10.45
2021	1,815	10.07
2022 (to date)	241	9.87
Combined	4,076	10.25

As shown in Figure 1 below, more than 98 percent of these applications (4,019 of the 4,076) took more than 5 years to review and almost 60 percent (2,439) exceeded ten years. More than 10 percent (419) of the 4,076 biopharmaceutical patents granted over the study period had been pending for 15 or more years at the time that they were granted.

Figure 1: Number of Biopharmaceutical Patents Granted from January 1, 2020, through to March 23, 2022, Based on Years from Application[2] to Grant



The future does not look much brighter. As of the date of their analysis, Osha determined that there were at least 13,688 biopharmaceutical patents pending. Despite this significant number of pending applications, the pace at which the Brazil Patent Office is reviewing biopharmaceutical patents is slowing. Indeed, as shown in Table 1, the number of patents examined and granted since 2020 has been decreasing each year from 2,020 in 2020 to 1,815 in 2021 to an estimated 1,400 for 2022 (based on the number processed to date). If this trend continues, it offers little hope that Brazil will be able to meaningfully reduce the patent examination review period in the short to medium term.

Within this universe of biopharmaceutical patents pending, 305 applications are marked as being in the "intention to grant" status, suggesting that action may be taken on these applications within the year. The average pendency of those 305 applications is 9.42 years. Similarly, a further 333 applications are marked as "patent application procedure suspended," the review status immediately preceding "intention to grant" status. Those 333 applications have an average pendency of 8.75 years.

This data strongly suggests that there will not be significant improvement in biopharmaceutical patent review timelines in Brazil in 2022-23.

Overall, this data – combined with the Brazilian Supreme Court's 2021 decision revoking a provision in Brazil's Patent Law that guaranteed a minimum patent term of 10 years from the date of grant – highlight the chronic need for a patent term adjustment mechanism in Brazil to restore the patent life lost during these significant patent office delays.

Annex 1: Research Methodology

Osha began its analysis by identifying the relevant patent classification codes that cover **broadly** biopharmaceutical inventions, including **small molecule** and **biologic** medicines.

Generally, Osha found that the relevant classes for biopharmaceutical inventions fall within classification codes A61K or A61P. While some of such inventions are also classified under chapter C, they found that the C classification is a parallel classification that would also bring in a large number of inventions outside of biopharmaceuticals. Thus, they restricted their patent application search to classification codes A61K and A61P. More specifically, they ran the following Boolean search to identify both biopharmaceutical patents granted and patents pending: a61k9* or a61k31* or a61k35* or a61k36* or a61k38* or a61k39* or a61k41* or a61k45* or a61k47* or a61k48* or a61k49* or a61k50* or a61k51* or a61p1* or a61p3* or a61p5* or a61p7* or a61p9* or a61p11* or a61p13* or a61p15* or a61p17* or a61p19* or a61p21* or a61p23* or a61p25* or a61p27* or a61p29* or a61p31* or a61p33* or a61p35* or a61p37* or a61p39* or a61p39* or a61p41* or a61p43*

[1] See Annex I for a summary of Osha's methodology for conducting its patent search and analysis.

[2] For clarity, the application date is either the local filing date or the filing date of an international application under the Patent Cooperation Treaty.