

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 exceeds seven years,¹ 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),² explores the patent examination timelines for biopharmaceutical patents granted between January 1, 2020, to September 26, 2023, 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 9.5 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

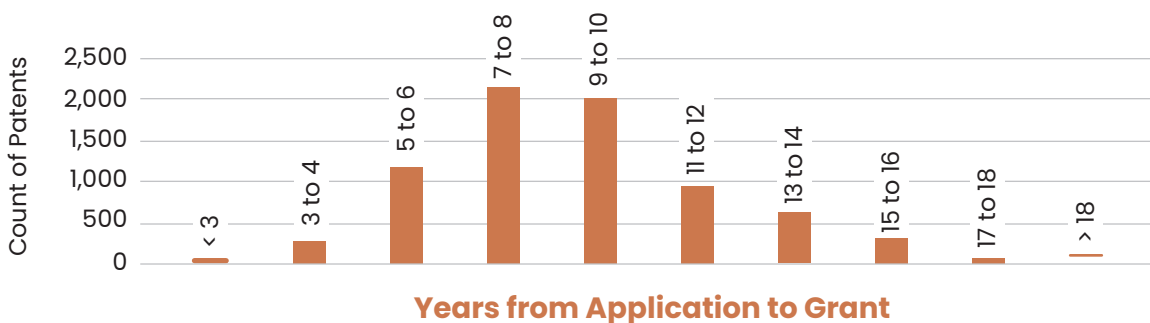
As shown in Table 1 below, the average patent examination timeline in Brazil for biopharmaceutical patents granted from January 1, 2020, through September 26, 2023, was 9.52 years.

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	1,860	10.07
2022	2,374	9.03
2023 (to date)	1,440	8.25
Combined	7,694	9.52

As shown in Figure 1 below, almost 96 percent of these applications (7,383 of the 7,694) took five or more years to review and almost 42 percent (3,230) took 10 or more years. More than five percent (448) of the 7,694 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 September 26, 2023, Based on Years from Application³ to Grant



The future does not look much brighter. As of the date of their analysis, Osha determined that the number of pending biopharmaceutical patents increased in 2023 (i.e., there were at least 15,114 biopharmaceutical patents pending in September 2023 compared to 13,688 in March 2022), and the pace at which the Brazil Patent Office is reviewing biopharmaceutical patents has not significantly increased. Indeed, as shown in Table 1, the number of patents examined and granted since 2020, decreased in 2021 (from 2,020 in 2020 to 1,860 in 2021), ticked up in 2022 (to 2,374), but is on track to return, in 2023, to levels below those in 2020 (approximately 1,920, assuming that the Brazil Patent Office reviews at the same rate over the remainder of 2023 as during the first nine months). 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 the universe of biopharmaceutical patents pending, 217 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 217 applications is 8.19 years.



This data also strongly suggests that there will not be significant improvement in biopharmaceutical patent review timelines in Brazil for the remainder of 2023 and into 2024.

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 <https://www.mondaq.com/brazil/patent/1341542/insights-from-the-brptos-2022-annual-report-patent-activity-and-backlog-in-brazil#:~:text=Therefore%2C%20the%20backlog%20in%202022,currentl%20of%206.42%20and%20decreasing.&text=This%20graph%20shows%20two%20interesting,along%20the%20past%205%20years.>

2 See Annex I for a summary of Osha’s methodology for conducting its patent search and analysis.

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