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Biotechnology/pharma patent litigation in Brazil: an update on preliminary injunctions

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The Brazilian pharmaceutical market is growing fast and is expected to become the fifth largest in the world by the next decade. While the country struggles to recover from economic downturn, the health care sector plays a key role in political speeches and the overall approach by the government. The Brazilian Constitution establishes access to health as a pillar of the democratic state. The Courts interpret that rule as a duty of the state provide free public health care to a population of approximately 210 million.

The broad meaning of public health care system includes providing free drugs and free treatment for the people. The government has committed to pay for the best therapy, even if it is the most expensive one. 70% of the population relies on the public health care system. The government covers 100% of the costs of approximately four billion diagnostic tests and 11 million hospitalizations per year. The government spends approximately 8 billion USD to purchase drugs to distribute to the population.

In view of this scenario, Brazilian courts are consistently considering a correct balance between access to health and protection of IP rights. The Courts agree that allowing companies to recoup R&D investments is of paramount importance to the system. One remarkable case illustrating this balance is how the courts ruled on applications for preliminary injunctions during the enforcement campaign filed by Genentech, seeking to protect the innovation aspects of a biological product.

Genentech case and its positive outcome for the pharma industry

Brazilian food and drug law establish an “obligation to sell” the drug that obtained a marketing approval in 20 months after the approval date.

Thus, when Genentech found out that Amgen Inc had obtained Good Manufacturing Practice (GMP) approval for bevacizumab, the active ingredient in Genentech’s best-selling Avastin® medicine, from the Brazilian FDA [ANVISA] on April 28, 2017 and its Brazilian subsidiary [Amgen Brazil] had filed for a marketing approval on May 19, 2017, it concluded that its patent PI9809387-8 covering Avastin was under imminent threat of infringement, as the patent’s term is November 22, 2026.

Accordingly, Genentech filed a lawsuit against Amgen Brazil, the owner of the MA application, based on threat[1] of infringement. Genentech showed that the timeline between the marketing

approval and obligation to sell the product would certainly occur before patent expiration. Article 42 of the Brazilian Patent Statute (Federal Law #9,279/96) states "*a patent grants its owner the right to impede a third party from producing, using, placing for sale, selling or importing, without consent, a patented product or a process or product obtained directly from a patented process*".

In addition, Genentech filed a lawsuit, against Amgen Inc., based on threat of indirect infringement, as Amgen Inc. would supply its Brazilian subsidiary with the infringing product. A subsection of article 42 of the Brazilian Patent Statute establishes that "*a patent owner is assured the right to prevent third parties from contributing so others may practice the acts referred in this article*".

Genentech was able to secure a preliminary injunction in the lawsuit against Amgen Brazil and a favorable trial court summary judgement against Amgen Inc.

Genentech v. Amgen Brazil[2]

The lawsuit was filed on August 29, 2018 and assigned to the 1st Business Trial Court of the São Paulo State. Genentech enforced Patent PI9809387-9, covering Avastin (bevacizumab), a monoclonal antibody targeting VEGF-A for the treatment of cancer.

Genentech claimed that while Amgen Brazil marketing approval for a biosimilar does not constitute infringement *per se* (bolar exemption), it indicates a threat of infringement.

The preliminary injunction was denied. The trial judge understood that the technical opinions presented by Genentech as evidence of infringement were unilateral and the production of more evidence was necessary. The judge also stated that as the granting of the marketing approval for the biosimilar was still pending, Genentech's request for preliminary injunction would reside on a "*future and uncertain event*" and did not relate to an immediate act of commercialization.

Genentech filed an interlocutory appeal against the denial of the preliminary injunction. The 1st Business Chamber granted Genentech's preliminary injunction on December 17, 2018. The reporting appellate judge, Hon. Lazzarini, voted for the dismissal of the appeal, but the following two judges, Hon. Nishi and Hon. Barbosa sided with Genentech. According to the panel's decision, there was enough evidence that the granting of the marketing approval was imminent, which would grant Amgen Brazil the right to manufacture, distribute and commercialize an infringing product. The urgency rose from the food and drug statutory obligation to commercialize, which would most likely happen during the patent term. The untimeliness of such "preparatory acts" by Amgen Brazil, almost nine years before the end of the patent's term, caught the attention of the panel.

The Trial Court rendered a final judgment dismissing the lawsuit, challenging the regulatory obligation to market, stating that "a norm may not impose a sanction for non-compliance, when compliance infringes another norm", and that it was uncontroversial that Amgen's conduct so far had been compliant with the Bolar Exemption, hence it would be incorrect to infer bad-faith in the future from a good-faith conduct. According to the court, "nothing prevents the defendant from simply enduring the damages from having its MA cancelled [due to non-commercialization] in order to avoid infringing the patent".

Genentech v. Amgen Inc.[3]

The lawsuit was filed in September 2019 and assigned to the 1st Business Court of the Rio de Janeiro State.

Genentech argued that Amgen Inc. obtained a GMP from the Brazilian FDA, which authorized the company to manufacture and export bevacizumab to Brazil. Considering there was at least one party in Brazil with a pending request for a biosimilar (Amgen Brazil), that the granting of the marketing approval was imminent and the regulatory obligation to market, Amgen Inc. would undoubtedly contribute for third parties in Brazil to infringe the patent.

The preliminary injunction was granted by the trial judge, stating that "*the documents attached to the complaint indicate the probability of the plaintiff's right, as they are evidence of ownership of the patent as well possible use by the defendant. There is also urgency, considering the unduly commercialization of the product, infringing the patent*".

Amgen filed an interlocutory appeal seeking to overrule the injunction, which was assigned to the 15th Civil Law Chamber of the Rio de Janeiro State Court of Appeals. The reporting appellate judge Hon. Alves denied Amgen's request for an interim decision staying the injunction, as, according to her, "*the likelihood of the claim and probability of the right sides with the appellee, considering the documents attached to the records, specially, the letter patent*".

As Amgen Inc also did not challenge the scope and validity of the patent, Genentech filed a motion for summary judgement, as no more evidence was needed and the matter under dispute relied solely within the interpretation of the law.

On June 6th, 2019, the court granted Genentech's motion, issuing a final judgment confirming the preliminary injunction. According to the trial judge "*although the GMP can be renewed, it is not logical to infer that the defendant requested the GMP in 2017 only to renew it on 2019, 2021, 2023 and 2025 without exporting the infringing drug to Brazil, as the patent only lapses in 2026. As the plaintiff states, it is not believable that the defendant adopted such actions so many years before the patent lapses without the intention to manufacture and export*".

The court further stated that the defendant's claim that the administrative proceeding for the granting of the marketing approval takes many years became moot after the MA was granted on February 2019. Lastly, the court stated Amgen Inc. was not the owner of the marketing approval and thus, its actions were not covered by the Bolar exemption.

The trial court judgment rendered the interlocutory appeal moot. However, Amgen Inc has already filed an appeal, which is still pending.

Conclusion

The willingness of the courts to understand the commercial landscape surrounding the potential infringement of Genentech's patents and grant preliminary injunctions show a commitment with a strong patent system in Brazil. Despite the fact that public health care plays a relevant role, courts showing a commitment to balance IP rights and allow pharmaceutical companies to continue invest in new drugs to treat complex diseases.

*The authors are representing Genentech in the litigation reported in this article

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[1] Article 5, section XXXV of the Brazilian Constitution: “the law shall not exclude any injury or threat to a right from the consideration of the Judicial Power”.

[2] Lawsuit docket #1089781-80.2018.8.26.0100.

[3] Lawsuit docket #0210345-09.2018.8.19.0001

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