

Superior Court of Justice finds AIDs medication patent granted under pipeline system valid, despite administrative error

In a recent decision issued by the Superior Court of Justice (Superior Court of Justice, Lawsuit No 1753535, 3rd Panel, Minister Nancy Andrighi, 07 June 2019), an AIDS medication patent was deemed to be valid, despite the occurrence of an administrative flaw in its analysis procedure before the National Institute of Industrial Property (INPI).

The case had been debated for years due to the distinctiveness of the patent's characteristics, which – along with a court of appeal decision that reversed the first-instance decision – led to the understanding that the error that occurred in the patent's evaluation had been solved by the time the case reached the Superior Court of Justice.

In this regard, you could ask what made this case special, especially considering the public interest in the nullity of a patent for a medication of such purpose. The answer refers to a specific regime created by the Industrial Property Law (Law No 9,279/96), which established the so-called 'pipeline system'.

The pipeline system

Before 1996, medication formulas could not be protected by patents at the INPI because they were not included in the previous legislation regarding industrial property. With the enactment of Law No 9,279/96, not only did medicines receive protection, but a new regime was created, in order to increase the speed of analysis of these inventions – the pipeline system.

The system, established by Article 230 of the law, determined that patents filed abroad, relating to a series of substances – especially chemical-pharmaceutical products – would be automatically published by the INPI if they were also filed in Brazil. In addition, once the foreign patent was granted, the corresponding Brazilian filing would receive the same effects, without evaluation by the local federal agency.

Therefore, if a patent that was based on a patent granted in another country was filed before the INPI and was not expressly prohibited under Articles 8 and 10 of Law No 9,279/96, it would also be valid in Brazil. This special regime had a one-year term for patent filings based on international patents.

Superior Court of Justice decision

In the Superior Court of Justice decision, the disputed patent was a pipeline-system patent that was almost automatically granted by the INPI in 2000. However, an issue arose that caused a nullity action to be filed in the first instance, as well as in all the appeals that followed.

As determined in the legislation of other countries, the Brazilian National Health Surveillance Agency (ANVISA) is required to report on all filings of pharmaceutical products and methods when granting such patents.

However, this requirement was only introduced by the Industrial Property Law in 2001 – one year after the AIDS medication patent was granted via the pipeline system. Consequently, the plaintiff claimed that the pharmaceutical company's patent should be cancelled, once it was deemed to be valid neither with ANVISA's agreement nor the INPI's evaluation.

The first-instance decision initially ordered the nullity of the medication patent, but this decision was reversed by the court of appeal, which held that the administrative error had been resolved when ANVISA granted a sanitary registration for the same product one year after granting the patent. The court also summoned the Health Surveillance Agency to monitor the patent's proceedings, in another attempt to rectify the past mistake.

Despite the plaintiff's complaints regarding the court of appeal's actions to assure the validity of the patent, the Superior Court of Justice stated that it could not discuss the matter again, since it would be based on facts and not the law itself.

Nevertheless, the Superior Court of Justice appeared to agree with the former court's ruling, by stating that administrative errors in patent nullity actions should be treated individually. In this case, the court affirmed that the expected result – assuring that public health would not be violated by the patent – was achieved; therefore, the administrative error should be validated.

Conclusion

Patents granted under the pipeline system should not represent common objects of judicial discussion, considering that they should have expired, due to their 20-year term commencing from their filing abroad. However, these patents continue to be contested before Brazilian courts, either by institutions seeking their fall into the public domain or by companies attempting to extend their years of profit over these inventions.

The various discussions on this matter have raised so many claims that the Brazilian Supreme Court still faces a pending trial over the statute of limitations of patents granted under the pipeline system.

The surrounding uncertainty allows the maintenance of lawsuits such as the one decided by the Superior Court of Justice, in which a patent that was granted more than 20 years ago is still an object of dispute between companies. In countries such as Brazil, this presents a critical health issue among the population. A patent for an AIDS medication should not be contested in the judiciary to the extreme point that it has not yet achieved a clear status in the public domain. More than a matter of administrative and IP legislation, judicial discussions regarding the pipeline system may create an obstacle to less burdensome health products and procedures.

Despite the Superior Court of Justice's understanding that the error had been validated due to ANVISA's later manifestation, the case should have ended at the moment in which the public prosecutor requested the plaintiff to manifest on its interest to continue the appeal. This could have spared the judiciary of a long prosecution and the public of waiting for two companies to decide on something that had already been settled in the second instance.

Patents granted under the pipeline system have now reached their maximum term. Therefore, it is time to let the public domain regime settle and new inventions in the pharmaceutical industry to be filed according to the standard norms established by the Industrial Property Law.