

Brazil: Sanofi`s Patent covering leflunomide is considered invalid

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The Federal Court of Appeals for the 2nd Circuit reversed the trial court decision to determine the invalidity of Brazilian patent PI 9708108-6, owned by Sanofi-Aventis (case Cristalia Ltda v. Sanofi-Aventis Deutschland GmbH). This patent claimed a combination of leflunomide and teriflunomide. The decision was published on August 24, 2018.

In 2015, the Brazilian generic company Cristalia filed an invalidity lawsuit before the Federal Court of Rio de Janeiro against Sanofi. Cristalia argued the lack of inventive activity of the patent and that leflunomide has been available for decades, so its combination would be obvious for a person having ordinary skills in the art.

Sanofi filed a reply seeking the dismissal of the lawsuit. The defendant provided data showing the increase of the therapeutic action of the drug with the combination of the two pharmaceutical compounds in the quantities claimed (leflunomide at the concentration of 2 to 20 mg and teriflunomide in the proportion of 0.3% to 50% of the second in relation to the first).

The BRPTO, in its answer to the lawsuit, agreed with the plaintiff, supporting the invalidity of the patent. The expert report, produced in the litigation was prepared by Prof. Rodrigo Borges de Oliveira, specialist in Pharmacology. Prof. Oliveira concluded that the patent was obvious since it was not able to find an unexpected technical effect (or synergistic effect) in the combination of leflunomide and teriflunomide.

In the trial decision, Hon. Eduardo Fernandes, of the 25th Federal District Court, considered conclusions of the expert report convincing and agreed with the lack of inventive activity of the patent.

However, considering the Principle of Legal Certainty and the long time elapsed (the administrative process at the BRPTO took 9 years of examination to grant the patent) the judge argued that it would be reckless and harmful to annul a patent two months short of its expiration date (March 07, 2017).

In 2017, Cristalia filed an appeal against the trial decision. Cristalia used the expert report and civil procedure rules to state that it would be illegal to decide a case against the evidence produced.

In its appellee's brief, Sanofi-Aventis argued that the expert report was biased due to how fast it was prepared. Moreover, the pharmaceutical company suggested that the Principle of Legal Certainty should be protected since the patent was already in the public domain, and its invalidity would cause more harm to the public.

The Appellate Court unanimously declared the patent invalid. The reporting Appellate Judge Gustavo Arruda Macedo accepted the conclusions of the expert report. Moreover, in his opinion, Hon. Judge Macedo transcribed an excerpt of the opinion prepared by the Federal Prosecution Office in order to reject the application of the Principle of Legal Certainty:

"Although the judiciary should observe the necessary legal certainty that must guarantee the business activity in the country, it is also certain that the matter concerning the patent of drugs affects the right of the collectivity to the broad access to health treatments and supply of medicines at economically reasonable levels. Such right of exclusivity on the exploitation of the patent, therefore, can only be exercised for a given time and in the face of the fulfillment of various requirements for the granting of exclusivity".

The case creates a relevant precedent: even if the judge is free to evaluate the evidence, it is not possible to decide entirely against the evidence produced in the records.

Sanofi-Aventis filed in August 2019 appeals before the STJ (the Superior Court of Justice) before the STF (the Supreme Court), seeking the annulment of the decision that held its patent invalid.