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Annotation of patents: a threat to second medical use patents in Brazil?

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A recent decision issued by the federal district court could impact medical use patents in Brazil. In an invalidity lawsuit filed by the Brazilian affiliate of *Sun Pharma* against *Boehringer Ingelheim*, Federal Judge Carvalho, sitting at the 9th Federal District Court in Rio de Janeiro, has granted a preliminary injunction ordering the Brazilian Patent and Trademark Office (BRPTO) to annotate that a second medical use patent (covering Ofev) doesn't prevent the manufacturing and/or selling of generic or brand-generic nintedanib-based drugs for other uses.

The Brazilian Patent Statute (Law #9,279/96) provides that "[t]he BRPTO will make the following annotations: […] II – of any limitation or burden that falls on the application of patent." Other generic companies have tried in the past, without success, to use this legal provision to seek a judicial remedy for the BRPTO to add limitations related to the scope of a granted patent. In 2020, for instance, Brazilian generic company *Cristália* filed a lawsuit requesting a preliminary injunction to annotate that a second medical use patent covering Gleevec does not prevent the manufacturing and selling of imatinib-based drugs for uses other than gastrointestinal stromal tumors (GIST). The preliminary injunction was denied by both the federal trial judge and by Appellate Judge Simone Schreiber, from the Brazilian Court of Appeals for the 2nd Circuit, in an interlocutory appeal filed by *Cristália*.

In *Sun Pharma v. Boehringer*, the latter has filed an interlocutory appeal against the trial court decision. The appeal was assigned to Hon. Schreiber, who denied Boehringer's request to stay the decision on the annotation of the patent. In the aforementioned *Cristália v. Novartis*, Hon. Schreiber had stated that the annotation sought by *Cristalia* was a "partial declaration of invalidity" of the patent which could frustrate the expectations of the patent owner, and that even if *Novartis* tried to enforce the patent beyond its scope, *Cristalia* would have the opportunity to address this issue before state courts, where infringement is litigated. In *Boehringer*'s recent appeal, however, Hon. Schreiber concluded that "the annotation determined by the trial court only reinforces the scope of patent protection and does not constitute a partial declaration of invalidity of the patent by other means."

In a few months, *Boehringer*'s appeal will be heard by a Panel of three appellate judges. Considering the lack of case law, this case should be of paramount importance for patent owners in Brazil.

Additional Background of *Sun Pharma v. Boehringer* dispute

The dispute between *Sun Pharma* and *Boehringer* over the Brazilian market for nintedanib-based drugs began in 2021, with the filing of a noninfringement declaratory judgment lawsuit by *Sun Pharma* against *Boehringer*'s patents PI0312811-3 (polymorph) and PI0913434-4 (formulation). The lawsuit was filed before Sao Paulo state courts, and the dockets are under seal.

On June 13, 2023, *Sun Pharma* filed both an invalidity lawsuit before the federal district courts in Rio de Janeiro, and a noninfringement declaratory judgment lawsuit before Sao Paulo state courts, related to *Boehringer*'s patent PI0519370-2 (second medical use). On that same day, *Boehringer* filed an infringement lawsuit based on the same patent before Rio de Janeiro state courts.

An interesting sequence of decisions followed. On June 16, 2023, the state court in Rio de Janeiro granted a preliminary injunction in *Boehringer*'s favor, ordering *Sun Pharma* to cease manufacturing, selling, and importing generic and brand-generic drugs containing nintedanib esylate, "which can be used in the treatment of idiopathic pulmonary fibrosis." On June 26, 2023, Hon. Laura Carvalho, from the 9th Federal District Court in Rio de Janeiro, issued the abovementioned decision in the invalidity lawsuit ordering the annotation of the limitation pertaining to unpatented uses of the nintedanib. On June 28, 2023, the state court in Sao Paulo granted a PI in *Sun Pharma*'s favor, ordering *Boehringer* to abstain from seeking measures to prevent the selling of *Sun Pharma*'s generic and brand-generic drugs, "as long as the goal is [to sell] for uses other than prevention and treatment of idiopathic pulmonary fibrosis."

The Sao Paulo state judge also affirmed his jurisdiction over all cases related to the enforcement of *Boehringer*'s patent portfolio for nintedanib against *Sun Pharma* and requested that the infringement lawsuit in Rio de Janeiro be sent to Sao Paulo. This conflict of jurisdiction will have to be adjudicated by the Brazilian Superior Court of Justice (STJ).

On July 14, 2023, STJ Justice Og Fernandes issued a decision ordering the stay of the lawsuits before state courts, revoking the injunction granted in *Boehringer*'s infringement lawsuit (at least for the time being), and appointing the 9th Federal Court in Rio de Janeiro as temporarily in charge of urgent measures related to the protection awarded by PI0519370-2.

Lack of skinny labeling in Brazil

In countries where skinny labeling exists, generic companies have the option of seeking marketing approval only for unpatented uses of a compound, thus circumventing infringement of second medical use patents. This isn't an option in Brazil.

ANVISA (Brazilian equivalent to the US FDA) currently has a Rule establishing that the labels of generic drugs must follow the structure and content of the reference-listed drug (Article 14 of ANVISA's Board of Directors' Rule #47 of 2009). There is no exemption for patented therapeutic indications.

In December 2022, ANVISA's Board of Directors opened a public consultation (until March 2023) on a proposed amendment of Rule #47 of 2009 that would allow generic and brand-generic drugs to exclude patented used from their labels. For the moment, though, generic and brand-generic drugs must still possess the same therapeutic indications (including any patented uses) as the reference-listed drug.

The decision in *Sun Pharma v. Boehringer* validity case

As a premise for ordering the annotation of *Boehringer*'s second medical use patent, Federal Judge Carvalho (9th Federal District Court in Rio de Janeiro) highlighted that under "the terms of marketing approval of the reference-listed drug, it is impossible for generics/brand-generics to exclude the patent-related therapeutic indication." Hon. Carvalho further acknowledged that "ANVISA's regulatory requirement from Rule #47/2009 obstructs the selling of a drug excluding the therapeutic indication for which there is an exclusive right. Due to the need of providing on the label the therapeutic indication related to the second medical use patent, one can argue that the manufacturing of the generic or brand-generic drug represents a patent infringement." According to Hon. Carvalho, this regulatory system generates "an extension of the scope of the patent granted by the BRPTO, and a potential abuse of patent right."

The decision to order the annotation of the patent was thus justified on the grounds of the "gravity of the damages caused to public health and to free competition by the concrete effects of patent PI0519370-2."

At its core, this decision doesn't really change the *status quo*. After all, it only determined that the BRPTO annotates an undisputable fact about patent PI0519370-2: it can only be enforced against the manufacturing and selling of generic and brand-generic nintedanib-based drugs for the patented use. But these drugs will continue to have the same label as the reference-listed drug—which includes the patented use.

The 9th Federal District Court decision, which was cited by the state court as grounds for the granting of the preliminary injunction in *Sun Pharma*'s non-infringement lawsuit, may give rise, however, to difficulties in the enforcement of *Boehringer*'s patent. The public bids for the purchase of drugs not always disclose the therapeutic indication for which the product is being purchased. In the private sector, there is even less transparency. How can the state courts handling infringement (and noninfringement) be sure that the generic/brand-generic manufacturer is respecting the patented use? For one, attorneys representing patent owners will have to be more creative and diligent in monitoring these manufacturers' activities.

There is another important consequence that may derive from the 9th Federal District Court decision, affecting patent litigation even beyond pharma cases. As mentioned in the beginning of this article, this is the first case in which a judge determined the annotation of the claim interpretation of a patent—and based on a statutory provision the applicability of which is questionable at best. Article 59, item II, of the Patent Statute, isn't meant as a tool for the BRPTO to clarify or define claim construction. To this date, as it should be, the Court of Appeals for the Second Circuit has only determined the annotation of a patent to amend claims of a granted patent, but never to affirm a claim interpretation.

In *Sun Pharma v. Boehringer*, putting aside the potential issues in terms of enforcement, there is no controversy in relation to the scope of the patent. It is undisputed that the patent only covers a specific use of the compound: for the treatment of idiopathic pulmonary fibrosis. There are plenty of cases, however, in which there is room for discussion regarding claim construction. The 9th Federal District Court decision thus creates a reasonable risk that alleged infringers may seek before federal courts an order for the BRPTO to annotate a limitation that is not as clear—and certainly not undisputed—about the scope of the patent. In such a case, we would be facing not

only a discussion pertaining to the legal grounds of this determination, but also a potential conflict of jurisdiction, with federal judges binding state judges to their claim constructions.

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