

# Kluwer Patent Blog

## Brazil: Animal Health and Patent Litigation

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With 1.5 billion chickens and 234.3 million cows, Brazil is an important market for the animal health industry. According to the National Syndicate of the Industry of Animal Health Products (SINDAN, in Portuguese), in 2022, 700 million doses of vaccine were manufactured in Brazil for herbivorous animals, and 21 billion for aviary. The Brazilian animal health market generated a net revenue of 10.363 billion *reais* in 2022 (approximately USD 2.11 billion)—a growth of 13% in relation to 2021.

With these strong numbers, it will come as no surprise to readers that Brazil is a key market for investment by companies focusing on R&D in animal health. One such company is Zoetis Inc., an American company that produces medicine and vaccines for pets and livestock.

In August 2022, Zoetis filed two patent infringement lawsuits before the Sao Paulo State Courts against Brazilian companies Farmabase and Ourofino seeking to protect its innovative product Draxxin (swine respiratory disease (SRD) treatment with active ingredient tulathromycin) against generic tulathromycin products. In response, Ourofino filed a patent invalidity lawsuit before the federal court, with a peculiar cause of action: the Brazilian Supreme Court ruling on the unconstitutionality of the 10-year patent term counted from the date of grant. In particular, Ourofino argued that the Supreme Court decision should be applied to animal health patents (not just human health patents).

Recently, trial judgments were rendered in both *Zoetis v. Farmabase* and *Ourofino v. Zoetis*. Whereas the federal court ruled in the invalidity lawsuit that the Supreme Court ruling does not apply to Zoetis' animal health patents, the state court concluded otherwise as basis to deny Zoetis' claim for relief.

### Background: The Brazilian Supreme Court ruling

In 2021, the Brazilian Supreme Court ruled on ADI #5,529, a Constitutional Challenge seeking a declaration of unconstitutionality of the 10-year term of patent protection counting from grant. By majority, the Brazilian Supreme Court declared unconstitutional the sole paragraph of Article 40 of the Brazilian IP Statute (Law #9,279/96) which related to this 10 year term.

The Justices decided that the ruling would apply retroactively only to pharma patents and to those patents whose terms were being challenged in individual lawsuits. These patents would have their terms immediately reduced to 20 years from filing.

## **Infringement lawsuits**

On August 30, 2022, Zoetis filed two separate lawsuits before the Sao Paulo State Courts, based on utility patents PI9810519-1 and PI9915480-3, which cover pharmaceutical compositions comprising isomers A and B (respectively) of the compound tulathromycin. Said compound is sold by Zoetis under the brand name Draxxin™, a single dose swine respiratory disease (SRD) treatment. The two patents were granted with a 10-year term from grant, expiring on February 22, 2022 (PI9810519-1) and December 29, 2025 (PI9915480-3).

One lawsuit was filed against Farmabase, and the other against Ourofino, both Brazilian companies with extensive product portfolios, founded respectively in 1994 and 1987. Farmabase's tulathromycin-based drug is called Treoxin™, while Ourofino's product is sold under brand name Tulaxx™.

In *Zoetis v. Farmabase*, the state court issued a trial judgment last month denying the plaintiff's claim for relief. The reason given for the judgment was the aforementioned Brazilian Supreme Court ruling, since "the sets of claims of patents PI9810519-1 and PI9915480-3 show that the compounds were created and submitted to the Brazilian PTO's analysis with a dual purpose, according to its human or veterinary destination." Consequently, the terms of those patents shouldn't be 10 years from grant, but 20 years from filing, preventing their enforcement against Farmabase.

Since the dockets of *Zoetis v. Ourofino* are under seal, there is not a lot of publicly available information about this dispute, other than the fact that a preliminary injunction was denied. But since this case has been assigned to the same judge of *Zoetis v. Farmabase*, we can expect a similar outcome.

## **Invalidity lawsuits**

The trial judgment rendered by the State Court in *Zoetis v. Farmabase* was surprising, especially considering that two weeks earlier the federal court handling the invalidity lawsuit filed by Ourofino against Zoetis issued a contradictory trial judgment.

The federal court highlighted in its judgment that an important factor in the Supreme Court decision to retroactively apply the terms of its unconstitutionality ruling only to pharma patents was the COVID-19 pandemic.

Since the Supreme Court couldn't regulate "all the hypotheses, especially those wherein the product is pharmaceutical for humans and also veterinary", it was left for the Brazilian PTO to interpret the scope of the ruling in this regard.

On that note, the judge affirms he "agrees with thesis that [the retroactive effects of the Supreme Court ruling] should be as limited as possible," to avoid causing legal uncertainty and violating vested rights. Therefore, the "limitation of the retroactive effects to pharma products, excluding those of veterinary use, defended by the Brazilian PTO and the patent owner, is the best possible interpretation of the Supreme Court ruling, and must be upheld."

## **Next steps**

The trial judgment rendered in *Zoetis v. Farmabase*, as well as the one rendered in *Ourofino v.*

*Zoetis*, are both subject to appeal. The former will be heard by the Sao Paulo State Appellate Courts, the latter by the Brazilian Federal Court of Appeals for the Second Circuit. If the prevailing understanding is that the Brazilian Supreme Court ruling on the unconstitutionality of the 10-year patent term counted from grant should apply retroactively to animal health patents as well, this will have a great impact on the industry.

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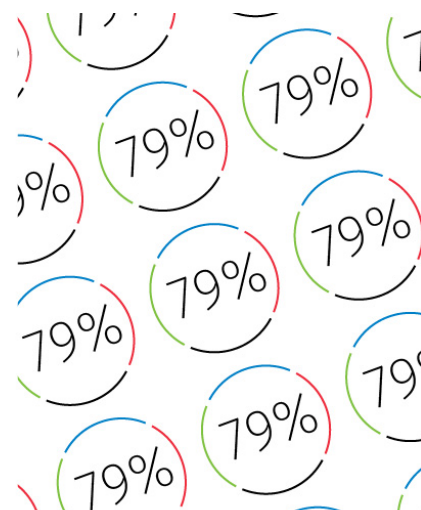
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