

Dockets # 1009743-75.2016.4.01.3400

DECISION

The writ of mandamus was filed against the Brazilian Food and Drug Administration (ANVISA) with a preliminary injunction request to compel the defendant to grant prior approval to patent application PI0409250-3 within 48 hours.

Those are the facts, and the Court decision is as follows.

Indeed, I consider that the requirements for partially granting the preliminary injunction, regarding the request to stipulate a deadline for ANVISA to examine the referred application, are present.

The likelihood of what was alleged by the plaintiff, regarding the request to stipulate a deadline for ANVISA to examine the referred application, relies on the fact that the party shall not be harmed by the stagnant practices of the Public Administration.

Accordingly, the plaintiff shall not be harmed by ANVISA's inaction. The lack of an examination of the application may harm the plaintiff's activities, since the referred invention could be claimed by a competitor.

Moreover, according to the case law, ANVISA's examination should stick to its statutory authority concerning Public Health, while the BRPTO shall assess the patentability requirements.

Nevertheless, this Court shall not grant the Agency's prior approval directly, under penalty of substituting the Public Administration on its practices. That is why I find prudent to stipulate a deadline for ANVISA to finish the proceeding.

Therefore, I partially grant the preliminary injunction to order ANVISA to analyze the prior approval of patent application PI0409250-3 within 15 days. Patentability requirements shall not be examined.

Notify the authority to comply with the present decision.

After that, send the dockets to the Federal Prosecutor's Office.

(electronically signed)

IOLETE MARIA FIALHO DE OLIVEIRA
Federal Judge of the 22nd Federal District Court