Seção Judiciária do Distrito Federal
5ª Vara Federal da SJDF

DOCKETS # 1004397-46.2016.4.01.3400
CLASS: WRIT OF MANDAMUS (210)
PLAINTIFF: GENENTECH, INC.
DEFENDANT: DIRETOR DE AUTORIZAÇÃO E REGISTRO SANITÁRIO

DECISION

The writ of mandamus was filed by GENENTECH, INC against act of the DIRECTOR OF MARKETING AUTHORIZATION OF THE NATIONAL SANITARY SURVEILLANCE AGENCY - ANVISA, with request fo preliminary injunction to *"... (i) determine to the government authority to publish the granting of the prior approval of the patent application PI9809387-8 in the Official Government Gazette within 48 (forty-eight) hours, due to the absence of public health reasons that prevent its grant (ii) with the subsequent referral of the records of the administrative proceeding to the BRPTO within a period of 48 (forty-eight) hours "*.

Adducing its status as a foreign company, Genentech reports that it has filed patent application PI9809387-8, under articles 8º and 13 of Law # 9,279 of 1996 – Patent Statute (LPI).

Alleging that Provisional Measure # 2006 of 12/14/99, converted into Law # 10,196 of 2001, in its article 229-C conditions the granting of medicines patents to ANVISA's prior approval analysis, since the agency has greater expertise to examine the provisions of article 18, I of LPI, which prohibits the granting of patents for inventions contrary to public health.

Defending that ANVISA, in conducting the prior approval analysis, cannot examine patentability requirements of patent applications, unlike the BRPTO whose legal authorization is provided in Law # 5,68470.

The complainant states that the ANVISA issued the opinion # 486/15/COOPI/SUMED/ANVISA, by which it did not identify any risks to public health resulting from the subject matter of the patent application, however, the agency denied its prior approval under lack of novelty and inventive step, which are patentability requirements.

The complainant sustains that the ANVISA exceeded its statutory authority and stepped into BRPTO´s, violating constitutional principles of legality, specialty and impersonality, aside from others.

Complaint followed by Power of Attorney and documents attached.

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

According to Article 7, item III of Law # 12,016 of 2009, the preliminary injunction in a writ of mandamus presumes juridically plausible and relevant grounds (fumus boni iuris). Another requirement set forth by this Article is the risk of ineffectiveness of the intended decision on the merits (periculum in mora).

In the present case I consider that the requirements for partially granting the preliminary injunction are present.

The core discussion is whether ANVISA may or may not deny its prior approval based on patentability requirements under Article 229-C of Law # 9,279 of 1996.

I observe that ANVISA's rejection in the present case is not related to Public Health (hampering factor according to Article 18, I of the Patent Statute). ANVISA`s technical opinion 012/16/COOP/SEMED/ANVISA (pages 80 to 86) leaves no doubts that the denial was grounded on lack of novelty.

The opinion concluded the following:

"And as appointed before, after comparing the antibodies sequences in the present request and the sequences of variable regions obtained from Drugbank or IGMT, we verify that the antibody F(ab)-12 is 100% equal to the variable portion of bevacizumabe antibody and the antibody Y0317, requested in claim 2 and is 100% equal to the variable portion of ranibizumabe antibody.

In that sense, we verify that the sought scope of protection in the patent application is already in public domain, breaching Article 8, 11 and 13 of the Patent Statute.

Therefore, ANVISA's usual practices according to OS 001/15 are in the sense that patent applications covering inventions already in the public domain are contrary to Public Health and restricts the publics' access to medications, specially under one of SUS's programs."

ANVISA's statutory authority under Law # 9.782/99 is limited to the protection of Public Health. Such protection is carried out by controlling production and distribution of products and services subject to sanitary surveillance.

However, on the issue of pharmaceutical patents, ANVISA shall not reexamine patentability requirements, except the risk of causing harmful reactions on people or when there is doubt about its efficacy. The prior approval set forth in Article 229-C of the Patent Statute should be limited to Public Health aspects as the BRPTO is the sole legitimate to examine patentability requirements.

Therefore, I partially grant the preliminary injunction to determine the authorities to issue a new opinion regarding the patent application within 30 days. This new opinion should only examine Public Health aspects and may not examine patentability requirements.

Notify the authority to comply with the present decision.

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

Thereafter, return the dockets to my chambers so I can issue a final decision on the merits.

Brasilia, June 3rd, 2016.

DIANA MARIA WANDERLEI DA SILVA

Assistant Federal Judge of the 5th Federal District Court