

<u>IBSA INSTITUT BIOCHIMIQUE</u>, S.A. v. <u>TEVA PHARMACEUTICALS USA</u>, INC., Appeal No. 2019-2400 (Fed. Cir. July 31, 2020). Before <u>Prost</u>, Reyna, and Hughes. Appealed from D. Del. (Judge Andrews).

Background:

IBSA owned a patent that claimed a thyroid medication available as a gel cap. Teva sought FDA approval for a generic version of the medication, and was sued by IBSA for infringement.

The claims at issue recited the term "half-liquid." IBSA proposed that this term should be construed as "semi-liquid." The district court found that IBSA's proposed construction was not supported by the record. IBSA relied on an Italian priority application, which used the term "semiliquido" wherever the U.S. patent used "half-liquid," and its certified translation, which used "semi-liquid" for "semiliquido." IBSA argued that both terms were interchangeable. But the district court found that there were many differences between the priority application and the U.S. patent, including the "Field of Invention" and "Prior Art" sections. Thus, the district court determined that differences between the certified translation and the U.S. patent were intentional.

The district court further noted that the specification disclosed a "half-liquid" as an alternative to a gel or a paste, and reasoned that one skilled in the art would understand from the specification that a "half-liquid" was not a gel or paste, which contradicted IBSA's proposal.

The district court then found that one skilled in the art would not have been able to understand the term "half-liquid" with reasonable certainty. IBSA's expert stated that "semifluid" and "half-liquid" were not necessarily synonymous. Teva's expert testified that the term was not a well-known term in the art. The district court concluded that the claims at issue were indefinite. IBSA appealed.

Issue/Holding:

Did the district court properly find the claim term "half-liquid" indefinite? Yes, affirmed.

Discussion:

Regarding the discrepancies between IBSA's Italian priority application and the U.S. patent, the Federal Circuit viewed the discrepancies as intentional, which implied that the different word choice had a different scope.

Regarding IBSA's patent specification, the Federal Circuit said the specification did not make clear enough what the bounds of a half-liquid would be. The Federal Circuit also said that both "half-liquid" and "semi-liquid" had been included in the patent, and this suggested that the patent owner understood there was a difference.

The Federal Circuit also found that IBSA did not provide any other scientific literature to support its position. In this regard, IBSA did not identify a scientific dictionary with the term "half-liquid" and pointed only to a nonscientific dictionary that defined "semiliquid" as "half liquid; semifluid." Although IBSA had pointed to other patents that use "half-liquid," the Federal Circuit found that the term was disclosed in another context and therefore unhelpful.

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