

Teva Gets Fed. Circ. To Affirm Thyroid Patent Is Indefinite

By **Dani Kass**

Law360 (July 31, 2020, 9:02 PM EDT) -- A Delaware federal judge rightly found that claims of a patent covering the thyroid drug Tirosint are invalid as indefinite, the Federal Circuit affirmed Friday in a win for Teva Pharmaceuticals USA Inc.

The patent for IBSA Pharma Inc.'s drug features the term "half-liquid," which the three-judge panel affirmed doesn't have a set meaning in either the patent specification, its priority application or scientific literature. The precedential opinion upholds U.S. District Judge Richard G. Andrews' finding that the claims are indefinite under Section 112 of the Patent Act.

The patent otherwise would have expired in 2024, according to the U.S. Food and Drug Administration's Orange Book.

The drugmaker, its Swiss parent IBSA Institut Biochimique SA and the company they license the patent from had sued Teva for infringement in 2018, after Teva sought FDA approval for its generic version of Tirosint. According to the branded drug's website, it's the only thyroid medication available as a gel cap.

The parties were torn over how to define "half-liquid," which helps describe the inside of the capsule. IBSA said it should be the same as "semi-liquid," meaning "having a thick consistency between solid and liquid." Teva said it was indefinite, or "a non-solid, non-paste, non-gel, non-slurry, non-gas substance."

Judge Andrews agreed that the six claims at issue are indefinite, and that there was no support behind IBSA's proposed construction.

IBSA's appeal pointed to a variety of sources, including sections of the patent specification and the Italian patent application the patent claims priority to, which uses the phrase "semiliquido."

The Federal Circuit said the specification doesn't make clear enough what the bounds of a half-liquid would be, and then said semi-liquid and half-liquid aren't interchangeable. To back up the latter conclusion, the panel said both terms had been included in the patent application, showing the patent owner understood there was a difference.

"Although the claim using 'semi-liquid' was ultimately removed, this is additional evidence that the applicant knew the term 'semi-liquid' yet elected to use 'half-liquid' to mean something different," the opinion said.

The Federal Circuit also shot down IBSA's argument that the Italian application wasn't sufficiently considered because it was in another language.

"Weighing of the evidence does not unfairly subordinate a foreign priority application and does not amount to a refusal to consider a foreign priority document," the panel wrote. "Rather, when discrepancies between a foreign priority document and the U.S. filing exist, it may be proper to view the discrepancies as intentional."

To top it off, the Federal Circuit said IBSA failed to identify a scientific dictionary with the term half-liquid and pointed only to a nonscientific dictionary that defined "semiliquid" as "half liquid; semifluid." While IBSA had pointed to other patents that use the term, it's in another context and therefore unhelpful, the court said. The company's own expert even admitted that it would be difficult for a person skilled in the art to figure out the boundaries of "half liquid," the Federal Circuit said.

"IBSA did not provide any other scientific literature to support its position," the panel said.

Counsel for IBSA and a corporate representative for Teva did not immediately respond to requests for comment Friday.

U.S. Circuit Judges Sharon Prost, Jimmie V. Reyna and Todd M. Hughes sat on the panel for the Federal Circuit.

The patent-in-suit is U.S. Patent No. 7,723,390.

IBSA is represented by Ryan Johnson, Jeffrey J. Oelke, Laura Moran and Erica R. Sutter of Fenwick & West LLP.

Teva is represented by John Christopher Rozendaal, Kristina Caggiano Kelly, Michael E. Joffre and Deirdre M. Wells of Sterne Kessler Goldstein & Fox PLLC.

The case is IBSA Institut Biochimique v. Teva Pharmaceuticals USA, case number 19-2400, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Abbie Sarfo.

All Content © 2003-2020, Portfolio Media, Inc.