

Michael Tobin: 'Consisting Essentially of' Claims Nixed at Federal Circuit

February 26, 2020 Michael Tobin

PRACTICES Intellectual Property, Patent Litigation

In *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, the U.S. Court of Appeals for the Federal Circuit affirmed the district court's holding that the transitional phrase "consisting essentially of" was indefinite as used in several claims of patents owned by HZNP Medicines LLC and Horizon Pharma USA, Inc. ("Horizon").

Background

Horizon's patents cover its PENNSAID 2% product, which is a non-steroidal anti-inflammatory drug ("NSAID") and the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of pain of osteoarthritis of the knees. Claim 49 of U.S. Patent No. 8,252,838 (the "'838 patent") is illustrative of Horizon's formulation patents and recites:

A topical formulation consisting essentially of:

- 1–2% w/w diclofenac sodium;
- 40–50% w/w DMSO;
- 23–29% w/w ethanol;
- 10–12% w/w propylene glycol;
- hydroxypropyl cellulose; and
- water to make 100% w/w, wherein the topical formulation has a viscosity of 500–5000 centipoise.

Prior to the appeal to the Federal Circuit, the district court found that the phrase "consisting essentially of" in claim 49 of the '838 patent was indefinite. The district court noted that, under *PPG Indus. v. Guardian Indus. Corp.*, "consisting essentially of" limits a claim to the recited ingredients and any unlisted ingredients that would not materially affect the basic and novel properties of the invention.

Excerpted from *Intellectual Property & Technology Law Journal*. To read the full article, click on the PDF below.

[Consisting-Essentially-Of-Claims-Nixed-at-Federal-Circuit.PDF](#)