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CLIENT ALERT

Chief Scientific Officer's Contradictory Statements to the FDA and the Patent Office Rendered the Patent Covering Epinephrine Formulations Unenforceable

OCTOBER 18, 2021

Belcher Pharmaceuticals, LLC v. Hospira, Inc., No. 2020-1799 (Fed. Cir. Sept. 1, 2021)

The patentee appealed the district court's decision finding the patent-in-suit unenforceable because of inequitable conduct by the patentee's chief science officer ("CSO"). The Federal Circuit panel affirmed.

The CSO worked on obtaining regulatory approval for the patentee's products and on drafting and prosecuting patent applications. In November 2012, the patentee submitted a New Drug Application ("NDA") to the FDA for an injectable epinephrine formulation. The NDA described the 2.8–3.3 pH range of the reference product as "old" and sought approval for a "new" 2.4–2.6 pH range. After the FDA requested more data related to the "new" pH range, and to expedite approval, the patentee updated its NDA to an application for a product with the "old" pH range. The FDA approved the NDA in July 2015.

The patentee filed the application leading to the patent in suit in August 2014. The application covered injectable epinephrine formulations with a 2.8–3.3 pH range. The specification described a need for stable epinephrine formulations and claimed to provide an answer to this need—an answer that "seemed impossible" and "had never been accomplished before." The specification stated that the idea of raising the pH above the 2.2–2.6 range "was contradictory to one skilled in the art" before the claimed invention. The CSO helped draft the application and respond to the examiner's office action. The patent in suit issued in March 2016.

The Federal Circuit panel found that the CSO had withheld material information from the patent office during the prosecution of the patent in suit. The CSO was admittedly aware of the prior-art product with the "old" pH range but did not disclose it to the patent office. The prior-art product was material because the court found that the patent office would not have allowed the claims had it been aware of the prior-art product. The panel rejected the patentee's argument that the prior-art product was cumulative over a product label that was before the patent office and disclosed a 2.2–5.0 pH range. The patentee's "cumulative" argument contradicted what it had told the patent office—that the narrower claimed pH range was a critical improvement over the prior art.

The panel also found that the CSO had the requisite intent to deceive the patent office. He was an active participant in obtaining the FDA approval and the patent prosecution. The panel rejected the patentee's post hoc explanation that the CSO had withheld the prior art, as he believed it was irrelevant because it differed from the asserted claims in certain respects.

Read the full decision here.

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