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Inconsistent Statements to USPTO and FDA May Render Patents Unenforceable

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In the course of obtaining regulatory approval for a drug product in the United States, a pharmaceutical company will make numerous representations about its product in submissions to the Food and Drug Administration ("FDA"). If these representations contradict arguments made during prosecution of a patent at the United States Patent and Trademark Office ("USPTO"), they may serve as the basis for an inequitable conduct finding. In *Belcher Pharms., LLC v. Hospira, Inc.*,[1] the Federal Circuit held Belcher's patent unenforceable due to inequitable conduct based on representations made during prosecution that were inconsistent with statements made to the FDA.

Background

Belcher owned a patent on the formulation for its FDA-approved epinephrine product. The patent purportedly was directed to the innovation that increasing the pH of the formulation prevented degradation of epinephrine.[2] It claimed formulations of epinephrine with a pH range of 2.8 to 3.3.[3] During prosecution, Belcher argued that the pH range was a critical part of the invention.[4]

However, these remarks were inconsistent with statements Belcher made to the FDA in connection with its New Drug Application ("NDA"). In its NDA, Belcher described the pH range of 2.8 to 3.3 as "old."[5] Belcher also named a Sintetica product as a reference product, submitted data that showed the Sintetica product maintained a pH of 3.1 to 3.3, and ultimately changed its own product to match the Sintetica product pH to expedite FDA approval.[6]

The Federal Circuit's Inequitable Conduct Analysis

Establishing inequitable conduct requires showing that (1) the material withheld from the USPTO was "material" to patentability, and (2) the patentee intended to deceive the patent office.[7] On appeal, Belcher did not challenge that the withheld prior art rendered the claims obvious. Because that was the case, the art was "necessarily material to patentability."[8]

The Federal Circuit also found the intent prong satisfied, and that deceptive intent was "the single most reasonable inference able to be drawn from the evidence."[9] The court noted that Mr. Rubin, Belcher's Chief Science Officer, was "an active participant" in both the prosecution of the patent

and in overseeing regulatory approval of the NDA.[10] As Mr. Rubin knew of the prior art products and made arguments about the "criticality" of the pH range, it was reasonable for the district court to conclude that Mr. Rubin had the specific intent to deceive the patent office.[11] As a result, the Federal Circuit affirmed that Belcher's patent was unenforceable for inequitable conduct.

Consequences of *Belcher*

Shortly after the *Belcher* decision, in a joint letter to the USPTO, U.S. Senators Patrick Leahy and Thom Tillis requested that the USPTO take action to ensure that patent applicant disclosures at the USPTO are consistent with disclosures to other federal agencies.[12] The letter argues that these situations must be prevented to improve the quality of the patents issuing from the USPTO, and it specifically highlights potentially conflicting statements made to the FDA during the drug approval process.

It is unclear what, if any, effect this letter will have on the USPTO's practices. Senators Leahy and Tillis only request that the USPTO "take steps" to require applicants to disclose statements made to other government agencies. While patent applicants already have a duty to disclose all relevant information in their possession, the USPTO may release more specific guidance regarding disclosures to government agencies, which may result in increased scrutiny of FDA disclosures.

In any event, *Belcher* makes clear that pharmaceutical companies need to coordinate submissions to the USPTO and FDA to ensure no inconsistent statements are made.

References[+]

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