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Inconsistent Positions at FDA and USPTO Render Patent Unenforceable

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Unenforceability of a patent for a drug formulation was affirmed by the US Court of Appeals for the Federal Circuit earlier this month in *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, Appeal No. 2020-1799 (Fed. Circ. Sept. 1, 2021). The decision highlights the potential impact of contradictory positions taken before the Food and Drug Administration (FDA) and the US Patent and Trademark Office (USPTO).

The decision quickly drew the attention of Congress, with Senate Judiciary Subcommittee on Intellectual Property Chair Patrick Leahy (D-Vermont) and Ranking Member Thom Tillis (R-North Carolina) writing a letter to the USPTO to request the agency "take steps to reduce patent applicants' making inappropriate conflicting statements in submissions to the [USPTO] and other federal agencies."

The Federal Circuit's precedential opinion in the case upheld the decision of the federal district court for Delaware that the asserted patent was unenforceable because the patent owner had **withheld material information from the USPTO with deceptive intent**.

While this case arose under the Hatch-Waxman Act governing generic drug approval, contradictory FDA and USPTO positions could have similar impacts on other patents directed to FDA-approved products, including biologics and medical devices.

Inequitable conduct – a trap for the unwary

A duty of disclosure, candor and good faith applies to all dealings with the USPTO, per 37 CFR 1.56(a). Practically speaking, an applicant for a patent must disclose to the USPTO any information material to patentability (37 CFR 1.97). This includes not only journal articles and patent literature from before the effective filing date of the patent application ("prior art"), but also *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent. Moreover, the duty of candor is not expressly limited to public information, as the USPTO has a procedure for submission of confidential information (MPEP 724.02).

In *Belcher Pharmaceuticals*, the material information included a journal article, as well as knowledge of two other companies' prior, similar formulations of the same drug, epinephrine. Evidence was admitted at trial showing that the patent owner had told the FDA that racemization of the drug – a consideration in formulation – was a "well-known process," citing the journal article withheld from the USPTO. The patent owner had also characterized an in-process pH change as a "very minor change" compared to the manufacturing process for one of the two formulations not disclosed to the USPTO.

Agreeing with the district court, on appeal, the Federal Circuit found this withheld information to be material to patentability, because it "would have blocked the issuance of a patent." And the appeals court found that the patent owner's chief scientific officer acted with deceptive intent, because he "was an active participant in the FDA approval process," where the company represented that a key feature of the claimed drug formulation was "old," but also in dealing with the USPTO, wherein the same feature was described as a "critical" innovation. Together, these findings supported holding the patent unenforceable.

Regulatory and IP considerations

The FDA and the USPTO do not coordinate their respective drug approval and patent examination processes. As noted in the senators' letter, no regular channel of information from other federal agencies to the USPTO exists. Without due caution, innovator companies can undermine their own patents. To avoid such a scenario, such companies should consider the following:

- If the regulatory process causes company employees to identify any information material to patentability, the company's patent counsel should be promptly informed, so any appropriate disclosure to the USPTO can be arranged.
- The company's scientific, product development, regulatory and legal teams should coordinate to avoid inconsistency in arguments made before the FDA and the USPTO.

If you have questions or would like more information on how to ensure consistency, please contact a member of Cooley's patent counseling, healthcare regulatory or IP litigation groups.

Key Contacts

Jonathan Davies Washington, DC	jdavies@cooley.com +1 202 776 2049
Dr. Carol Laherty Seattle	claherty@cooley.com +1 206 452 8777
