BELCHER PHARMACEUTICALS, LLC v. HOSPIRA, INC., Appeal No. 2020-1799 (Fed. Cir. September 1, 2021). Before Reyna, Taranto, and Stoll. Appealed from D. Del. (Judge Stark).

Background:

Belcher owned a patent directed to an epinephrine pharmaceutical formulation having a pH between 2.8 and 3.3. Belcher sued Hospira for infringement under the Hatch-Waxman Act, and Hospira counterclaimed that the patent is unenforceable. The district court agreed with Hospira, finding the patent unenforceable for inequitable conduct on the ground that Belcher's Chief Science Officer, Darren Rubin, knowingly withheld three pieces of information from the PTO. The information included: (i) Sintetica's epinephrine formulation, which Mr. Rubin had named as a reference product in Belcher's New Drug Application (NDA) to the FDA, (ii) a journal article by Stepensky et al. that Mr. Rubin had disclosed to the FDA, and (iii) an epinephrine formulation sold by a company named JHP, which Mr. Rubin had tested and found to have a pH within the claimed range.

The district court found that each of these pieces of information were but-for material because they disclosed an epinephrine formulation having a pH within the claimed range. The district court also found that Mr. Rubin acted with the requisite intent to deceive the PTO because, in the course of seeking FDA approval, Mr. Rubin argued that the pH range of 2.8 to 3.3 was "old" and had cited to Stepensky and submitted data on Sintetica's and JHP's formulations to support his position. In fact, during the FDA process, Belcher had switched from a lower pH range of 2.4 to 2.6 to the claimed pH range between 2.8 and 3.3 to expedite FDA approval because that range matched the pH range of Sintetica's formulations. On the other hand, when dealing with the PTO, Mr. Rubin not only withheld this information, but he argued that the recited pH range was unexpectedly found to be critical for avoiding degradation of epinephrine.

Issue/Holding:

Did the district court err in finding the patent unenforceable for inequitable conduct? No, affirmed.

Discussion:

The Federal Circuit agreed with the district court that the information was but-for material and that Mr. Rubin knew of the information, knew that it was material, and made a deliberate decision to withhold it. As to materiality, the Federal Circuit agreed that the information was material because it showed that Belcher's alleged critical improvement was already known. The Federal Circuit also noted that Belcher did not challenge the district court's finding of obviousness over the JHP product, making the JHP product necessarily material.

As to intent, although there was no direct evidence of deceptive intent, the Federal Circuit agreed with the district court that the single most reasonable inference is that Mr. Rubin specifically intended to deceive the PTO when withholding this information. Belcher argued that Mr. Rubin genuinely believed the references to be irrelevant because of their high overages. But the Federal Circuit found this to be implausible because the references directly undercut his criticality argument, which had resulted in allowance of the application.