PURDUE PHARMA L.P. v. EPIC PHARMA, LLC, Appeal Nos. 2014-1294, etc. (Fed. Cir. Feb. 1, 2016). Before Prost, Reyna and Stark (D. Del., by designation). Appealed from S.D.N.Y. (Judge Stein).

Background:

Purdue sued a number of generic pharmaceutical companies based upon the generics' filing of ANDA applications relating to reformulated versions of OxyContin. Purdue alleged infringement of a group of patents collectively known as the "Low-ABUK Patents," and also of the "383 Patent" directed to an abuse-resistant tablet reformulation of oxycodone.

The Low-ABUK Patents were based upon a discovery of a particular isomer known as "8α" that was found to transform into potentially toxic 14-hydroxy, and the asserted Low-ABUK patents recite products containing low amounts of 14-hydroxy, at least a portion of which is derived from 8α. The 383 Patent is directed to an abuse-resistant formulation composed of a tablet that is formed by heat and pressure and can withstand breaking despite 500 N of force.

The district court held that the asserted claims would have been infringed in view of the ANDA filings, but that both the Low-ABUK Patents and the 383 Patent were invalid as anticipated or obvious over prior art.

Issue/Holding:

Did the district court err in finding the Low-ABUK Patents and 383 Patent invalid as anticipated or obvious? No, affirmed.

Discussion:

Regarding the Low-ABUK Patents, the Federal Circuit stated that the discovery of 8α and its recitation in the claims did not distinguish over the prior art. Purdue had argued based upon *Eibel*, which indicated that when a non-obvious source of a problem is found, and a remedy is applied in response, the invention is nonobvious even if the remedy, standing alone, would generally appear to be known in the art. The Federal Circuit distinguished this case from *Eibel*, asserting that this case involved determining a source of 14-hydroxy (being 8α), but the problem did not need to be solved to arrive at the claimed invention. The Federal Circuit repeatedly pointed out that Purdue claimed the end product, not the remedy of the problem (which was characterized as performing a second hydrogenation step to eliminate 14-hydroxy). The Federal Circuit also agreed with the district court's giving no weight to the phrase that "at least a portion of the 14-hydroxy is derived from 8α," considering it a process limitation and insufficient to structurally distinguish. The Federal Circuit also indicated that Purdue's arguments for commercial success were insufficient because it relied on sales of a corporate affiliate that sold the active ingredient only to Purdue.

Regarding the 383 Patent, the district court found that the claims were anticipated or invalid over a single prior art reference. The prior art reference described analgesics, and the Federal Circuit found that a reasonable reading of the reference would have led one skilled in the art to have applied the technology to opioids. Further, the Federal Circuit found that the district court did not err in relying upon expert testimony as demonstrating that the claimed breaking strength was inherent in the prior art. The Federal Circuit also reasoned that though multiple sections of the reference were used in the analysis, they were all directly related and sufficient to show anticipation.


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