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Reformulated OxyContin Patents Invalid

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Addressing product-by-process limitations and inherent anticipation issues, the US Court of Appeals for the ***Federal Circuit*** affirmed the district court's ruling that the asserted claims of Purdue Pharma's patents covering reformulated OxyContin are invalid. ***Purdue Pharma L.P., et al. v. Epic Pharma, LLC, et al.*****,** Case Nos. 14-1294, -1296, -1306, -1307, -1311, -1312, -1313, -1314 (Fed. Cir., Feb. 1, 2016) (Prost, CJ).

The case concerns four patents related to a version of the pain reliever OxyContin. Three of the patents relate to an improved formulation of oxycodone hydrochloride, which is the active ingredient (API) of OxyContin. The fourth patent covers abuse-resistant formulations of OxyContin.

The first three patents (referred to herein as the low-ABUK patents) describe an oxycodone salt with extremely low levels of a particular impurity (14-hydroxy), which belongs to a class of potentially dangerous compounds known as alpha, beta unsaturated ketones (ABUKs). Purdue scientists discovered that the source of the 14-hydroxy impurity was an oxidation byproduct called 8-alpha, which transformed into 14-hydroxy during the synthesis process. To remove the 14-hydroxy impurity from the API, Purdue included an extra hydrogenation step to convert the 14-hydroxy into oxycodone free base.

The district court found the three low-ABUK patents to be obvious, explaining that using hydrogenation to remove 14-hydroxy was well known, and that the discovery of 8-alpha was not necessary to the claimed invention. According to the district court, "a skilled artisan would recognize that hydrogenation could be used to remove the remaining 14-hydroxy, regardless of the source of the 14-hydroxy." The district court also concluded that because the claims were directed to a product, the process limitation requiring the 14-hydroxy to be derived from 8-alpha was immaterial to the obviousness determination.

Purdue appealed, relying heavily on the seminal 1923 Supreme Court of the United States *Eibel Process* decision for the proposition that "where an inventor discovers a nonobvious source of a problem and then applies a remedy in response, the invention is nonobvious and worthy of a patent—even if the remedy, standing alone, would generally appear to be known in the art." According to Purdue, because the source of the 14-hydroxy was not obvious, the solution must also be nonobvious.

The Federal Circuit found the *Eibel Process* decision inapplicable, explaining that unlike

Eibel, Purdue did not claim the remedy of the problem (performing an extra hydrogenation step), but instead claimed only the end product itself (oxycodone with low ABUK levels). Purdue also argued that without knowing the source of the 14-hydroxy impurity, a person of ordinary skill in the art would not know when or how to perform the hydrogenation step. The Federal Circuit again disagreed, noting that Purdue claimed the end product, not a method for creating that product. As such, the only issue was whether a person of ordinary skill in the art would find it obvious to use hydrogenation to remove the 14-hydroxy—the source of the 14-hydroxy is irrelevant.

Purdue next argued that the district court erred in concluding that the claim language "wherein at least a portion of the 14-hydroxy is derived from 8-alpha . . ." was a process limitation that was immaterial to the obviousness analysis. The Federal Circuit agreed with the district court, noting that the "derived from 8-alpha" limitation does not describe the structure of 14-hydroxy or impart any structural or functional differences in the ultimate end product. According to the Federal Circuit, there was no suggestion in the patents that the hydrogenation process changes depending on the source of the 14-hydroxy impurity. Because the claims at issue were product-by-process claims, the district court properly focused on the product and not the process of making it.

With respect to the fourth patent, the issue was whether the prior art inherently disclosed tablets having the specific breaking strength required by the asserted claims. According to the inventors, a crush-resistant formulation (having a breaking strength of greater than 500N) reduced the potential for abuse, as the original OxyContin tablets were easily crushed into powder, allowing them to be swallowed, snorted or injected.

The district court found the asserted claims of the fourth patent to be anticipated, crediting the experimental work and testimony of defendant's expert Dr. Fernando Muzzio, who recreated a process disclosed in a key prior art reference, McGinity. Using the McGinity process, Dr. Muzzio made thousands of tablets, then tested them for breakage strength. Each and every tablet made according to McGinity had a breaking strength of over 500 nM. The district court thus concluded that the McGinity reference "inherently discloses a breaking strength greater than 500N, because the experimental results indicate unanimously, reliably, clearly and convincingly that any tablet made according to the McGinity Application would exhibit this characteristic."

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