

Going Global on Polymorphs

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By: Ted Mathias, Aziz Burgy, Rebecca L. Clegg

We were so pleased to have the opportunity to address InformaMarkets' 13th Annual Pharma IPR Conference in Mumbai on legal challenges to polymorph patents. Patents covering one or more crystalline forms of a drug substance at times have presented steep obstacles to generic drug manufacturers' efforts to enter the market. As we sought to make clear through our presentation, however, polymorph patents are of varying strength and susceptible to both noninfringement and invalidity challenges.

We first addressed a divide in the caselaw on how to construe claims reciting polymorphs with specific x-ray powder diffraction or infrared spectroscopy patterns. A bedrock principle of patent law is that a product or process must meet every limitation of a claim to be deemed infringing. Nevertheless, some courts have held that a claim reciting "characteristic" XRPD peaks at different positions and intensities, for example, can be infringed even if the accused product does not match each of the peaks recited in the claim. For those courts, each peak position and intensity listed in the claim is not treated as a separate claim limitation. See, e.g., *Kowa Co. v. Amneal Pharms., LLC*, Nos. 14-CV-2758 (PAC), 14-CV-7934 (PAC), 2017 WL 10667089 (S.D.N.Y. Sept. 19, 2017). But other courts have stuck more closely to traditional patent law principles and required an exact match to recited peaks, subject to normal experimental error. See, e.g., *In re Sebela Patent Litig.*, No. 14-6414 (CCC) (MF), 2017 WL 3449054 (D.N.J. Aug. 11, 2017). These differing approaches to claim construction can determine the outcome of a noninfringement defense.

We next turned to invalidity. Challenges to polymorph patents based on invalidity frequently turn on inherent anticipation, i.e., whether a prior art compound will necessarily convert to or a prior art process will necessarily produce the claimed polymorph. “Sometimes” is not enough; the prior art compound or process must *always* yield at least some amount of what is claimed in the asserted patent. One notable case demonstrates the link between infringement and inherent anticipation. An originator successfully argued infringement because the accused anhydrate product would inevitably contain trace amounts of the claimed hemihydrate polymorph. But the patent was invalid for inherent anticipation because a process for making the accused anhydrate was described in the prior art, so practicing that prior art would, again, inevitably contain trace amounts of the claimed hemihydrate polymorph. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1344-45 (Fed. Cir. 2005).

Inherent anticipation is frequently a patent challenger’s best invalidity argument because obviousness arguments typically fail. Courts have regularly concluded that polymorphs are “unpredictable” such that an ordinarily skilled artisan could not reasonably expect to make the claimed polymorph based on what was known in the prior art. After all, a variety of factors can influence whether a particular polymorph will form, including the mixing, drying, and storing conditions, and the solvent system used. But we successfully litigated a case, *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, where the district court found that the asserted claims of two polymorph patents were invalid for obviousness. No. CV 20-430-RGA, 2022 WL 3225381, at *7-*8 (D. Del. Aug. 10, 2022). The court ruled that an ordinarily skilled artisan would be motivated to follow prior art teachings for preparing a crystalline form of rifaximin. Further, the artisan would arrive at the claimed form β because it was the most stable crystalline form and served as an intermediate for other crystalline forms of the drug. The decision is now on appeal before the Federal Circuit.

The feedback we received from the audience and throughout the remainder of the conference drove home that polymorph patents are top of mind for Indian drug manufacturers looking to gain a foothold in more profitable (and likely more heavily patented) drug markets. The industry should expect more challenges to polymorph patents in the years to come.

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Aziz Burgy
Ted Mathias
Rebecca L. Clegg

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