



Polymorph Patent Not Invalid as Obvious

The Federal Circuit upholds the validity of a patent covering a polymorphic form of a chemical compound.

The United States Court of Appeals for the Federal Circuit recently held in *Grünenthal GmbH v. Alkem Labs. Ltd.* that patented polymorphic forms of the chemical compound at issue were not invalid as obvious.

Assertio Therapeutics, Inc., the exclusive licensee of patents held by Grünenthal GmbH covering the compound tapentadol hydrochloride, markets NUCYNTA® ER for management of "pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Alkem Laboratories Limited and others filed abbreviated new drug applications for generic versions of NUCYNTA® ER, and Grünenthal sued under the Hatch-Waxman Act.

The District of New Jersey found that U.S. Pat. No. 7,994,364 ("364 patent"), directed to Form A of tapentadol hydrochloride, was not invalid as obvious. On appeal, Alkem argued that in light of a patent disclosing Form B of tapentadol hydrochloride, a person of skill in the art ("POSA") using the teachings of a 1995 article ("Byrn") would have had a reasonable expectation of success in arriving at Form A.

The Federal Circuit disagreed and affirmed the district court's finding of no invalidity. It found that Byrn did not disclose which specific variables should be altered, or to what extent they should be altered, to obtain a polymorph. ("Indeed, a POSA could alter any number of variables and still fail to find a polymorph of a particular compound.") *Grünenthal GmbH v. Alkem Labs. Ltd.*, No. 2017-1153, at *15 (Fed. Cir. Mar. 28, 2019).

The Federal Circuit also held that it would not have been obvious to try to create Form A because Byrn did not provide a "detailed enabling methodology." *Id.* at *19. The Federal Circuit thus held that Alkem failed to establish: (i) that a POSA would have had a reasonable expectation of success in arriving at Form A; or (ii) that it would have been obvious for a POSA to try to produce a different polymorphic form (i.e., Form A) of tapentadol hydrochloride.

We will continue to monitor what effect this ruling has on other obviousness arguments for patents claiming polymorphs.



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