

IP Alert: Inherency and Obviousness: Strange Bedfellows



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The concept of disclosure by inherency exists in tension with the concept of obviousness. Inherency looks back at prior art and analyzes what was disclosed but unappreciated at that time. Obviousness looks at what a person of skill in the art knew at the time of the invention. Inherency uses hindsight, and obviousness shuns it. They seem to be mirror images of each other, and yet they are combined in the analysis of a significant number of cases. One such case, argued at the U.S. Court of Appeals for the Federal Circuit on March 6, 2018, is *Endo Pharmaceuticals Solutions, Inc., Bayer Intellectual Property GmbH, Bayer Pharma AG v. Custopharm Inc.*, Appeal No. 2017-1719.

Custopharm filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration, seeking authorization to produce and market a generic testosterone undecanoate formulation for intramuscular injection.^[1] In response, Endo Pharmaceuticals Solutions, Bayer Intellectual Property GmbH, Bayer Pharma AG (collectively "Endo") brought an infringement action in the U.S. District Court for the District of Delaware. Custopharm asserted the defense of invalidity for obviousness of the patent claims.

The challenged claims contained recitations related to formulation and dosages. With respect to the formulation portion of the claims, Custopharm relied on an inherency theory. Three prior art references were asserted, which disclosed small clinical trials that used but did not describe the formulation recited in the patent claims. Specifically, the articles failed to describe the recited co-solvent of the formulation or the recited proportions of the co-solvent and the solvent. Custopharm showed that the small clinical trials had actually used the recited formulation. Moreover, it asserted that a person of ordinary skill in the art reading the three reference articles would know what formulation was used in the small clinical trials.

Custopharm spent all of its oral argument time on the issue of inherency of the formulation portion of the claims. It pointed to the court's decision in *In re Crish*, 393 F.3d 1253 (Fed. Cir. 2004) as supporting its position. *Crish* relates to a prior art published substance (a gene promoter), which was found to anticipate the same substance when later claimed by its structure (its sequence).

Custopharm urged that the promoter sequence in *Crish* was not known at the time of the prior art publication, but the prior art was nonetheless later held to be anticipating. Similarly, the formulation of the prior art that Custopharm asserted was not known at the time of the prior art publication, but it was later identified as being the recited formulation. Therefore, like the promoter in *Crish*, Custopharm urged that the recited formulation should be held to be inherently disclosed.

Judge Moore told Custopharm that its theory of inherency has a time problem. Rather than determining what a person of ordinary skill in the art would have understood at the time of the publication, Custopharm wanted the court to determine what a person of ordinary skill in the art would have understood today. Judge Moore also criticized Custopharm's theory because it confused an anticipating use with an anticipating disclosure. Judge Moore said that Custopharm's theory would mess up the law of anticipation.

Judge Chen suggested that the defect in the asserted prior art was that it had incompletely disclosed the formulation. This distinguishes the

references from the cited prior art in Crish, which was found to provide the claimed substance to the prior art, albeit without identifying its sequence. Judge Chen noted in questioning Endo that the requirements for public use and on-sale bars are more lenient than the requirements for a prior art publication. The former do not require a full description whereas the latter does. He asked Endo why the law treated these differently. Endo's reply acknowledged the difference in the doctrines, but did not provide a reason why.^[2] Judge Chen's question suggests that Custopharm's theory may have confused the standards for prior public use or on-sale bars with the standards for prior publication. This case may provide a vehicle for the Federal Circuit to clarify the law of inherency and resolve the tension involved in permitting inherent disclosures to contribute to a prima facie case of obviousness. Focus on the public benefit provided by the cited prior art publication as proposed by Professors Burk and Lemley^[3] could provide a helpful analytic framework.

Click [here](#) to listen to the oral arguments in *Endo Pharmaceuticals Solutions, Inc., Bayer Intellectual Property GmbH, Bayer Pharma AG v. Custopharm Inc.*

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^[1] Custopharm only bought the rights to the ANDA product after the district court trial (but before the district court issued its ruling). For simplicity, this alert refers to both the appellant and the litigant as "Custopharm."

^[2] Professors Dan Burk and Mark Lemley may supply the answer in their "public benefit" analysis. See *Inherency*, 47 Wm. & Mary L. Rev. 371, 374 (2005).

^[3] *Id.*

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