IP Alert: Obviousness-By-Inherency Argument Nixed

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By Sarah A. Kagan

The U.S. Court of Appeals for the Federal Circuit affirmed on July 13 a Delaware district court's decision that patent challenger Custopharm had failed to prove that Bayer's patents were invalid for obviousness. Endo Pharmaceuticals Solutions, Inc., Bayer Intellectual Property GmbH, Bayer Pharma AG v. Custopharm Inc., Appeal No. 2017-1719. The Federal Circuit found no error in the district court's determination that neither the recited dose, the recited vehicle formulation, nor the injection schedule would have been obvious based on the evidence presented. In doing so, the Court rejected Custopharm's theory of inherent teachings.

Bayer's claims at issue (in U.S. Patents 7,718,640 and 8,338,395) encompass a method of treating testosterone deficiency in a man and a composition for doing so. The composition claims recite a specific concentration of testosterone, a specific concentration range of a specific solvent (castor oil), and a specific co-solvent (benzyl benzoate). The method claims include a specific dosing schedule, a specific range of solvent concentrations, and an unspecified co-solvent. The litigation resulted from Custopharm's filing of an Abbreviated New Drug Application (ANDA) at the U.S. Food and Drug Administration (FDA) to gain permission to market a generic version of Aveed™, a testosterone intramuscular injection.[1] Endo sued Custopharm for infringement. Custopharm stipulated to infringement, but alleged that the patent was invalid.

The most interesting issue in the case relates to the asserted inherency of the recited solvent/co-solvent formulation in the teachings of three prior art references. The references reported using castor oil, but did not disclose using a co-solvent generically, or benzyl benzoate specifically, or 60 percent benzyl benzoate even more specifically. Custopharm

introduced post-critical date articles showing that, in fact, the small clinical studies described in the three prior art references had used a vehicle of 40 percent castor oil and 60 percent benzyl benzoate. The Court's opinion explains in a footnote that Custopharm applied a public policy argument based on a public-use bar to a prior art disclosure-based rejection. The Court determined that Custopharm waived this argument by failing to raise it at the district court.[2]

Custopharm also argued that the pharmacokinetic performance reported in the prior art references would have indicated to a person of skill in the art the identity of the vehicle formulation. The panel found that even if a person of ordinary skill in the art could have determined that the pharmacokinetics were associated with the recited formulation, Custopharm had not shown or asserted that the pharmacokinetics were necessarily associated with the claimed formulation. Custopharm had failed to show that other formulations would not also have led to the disclosed pharmacokinetics. Thus, the Court concluded that Custopharm had not alleged or proven a key determinant of inherency: "the limitation at issue necessarily must be present."[3]

Most helpfully, the court explained at length why the two cases that Custopharm cited to support its theory of inherency, In re Omeprazole Patent Litigation[4] and In re Crish[5], are actually inapposite. The Omeprazole court found that a pharmaceutical composition disclosed in a reference inherently taught an in situ separating layer or subcoating in an omeprazole tablet, even though the reference expressly disavowed it. The record showed that the structure was a natural result (necessarily occurred) of using the ingredients taught in the reference. In contrast, Custopharm had not shown that the pharmacokinetics of the testosterone formulation could only result from claimed solvent/co-solvent formulation.

In the Crish case, a gene promoter for the human involucrin gene was claimed by reciting its sequence. The Crish court found that a prior publication that disclosed the gene, including its promoter, but did not disclose the promoter's sequence, nonetheless anticipated the claimed promoter by inherency. The Court distinguished the Crish facts from the Custopharm facts because Custopharm had failed to show that only the claimed formulation, among the universe of possible formulations, could be responsible for the disclosed pharmacokinetics.

Finally, the Court distinguished Custopharm's prior art from Crish and Omeprazole's based on the quality of the disclosures. The Court found that the latter two involved "known" prior art products. In contrast, the Court found that the Custopharm-asserted prior art did not make the formulations that they used "known." An incomplete description of the formulation in the prior art references "denied skilled artisans from having access to the composition, thereby precluding use of the inherency doctrine to fill in disclosure about the product missing from the" references. Is this reasoning any different from the requirement that a novelty-destroying reference be enabling? Perhaps the Court framed it in this manner because Federal Circuit precedent holds that a non-enabling reference may qualify as prior art for the purpose of determining obviousness under 35 U.S.C. § 103.[6] The Court has limited use of such a non-enabling reference, however, to what is disclosed in it.[7] Perhaps these different framings are consistent in deeming a non-enabling disclosure unavailable for an inherency teaching.

The Court did not discuss Custopharm's use of a reference to inherently anticipate just one

element of a claimed invention. The asserted prior art references that were used for inherency did not disclose either the claimed dose (relevant to both composition and method claims) or the claimed administration regimen (relevant only to the method claim). Are there any limits on using inherency (predicated on having a key unknown property) in an obviousness rejection (predicated on what a person of skill in the art would know)? If such limits exist, the Court did not clarify them here.

Click here to read the decision in Endo Pharmaceuticals Solutions, Inc., Bayer Intellectual Property GmbH, Bayer Pharma AG v. Custopharm Inc.

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[1] Paddock Laboratories actually filed the ANDA, which Custopharm acquired after the district court trial. We refer to the two parties as "Custopharm" for simplicity. Endo holds the approved New Drug Application upon which Custopharm wishes to piggyback.

[2] At oral argument, the Court engaged on this issue with Custopharm, explaining that the law of public use was distinct from the law based on prior art disclosures. One cannot apply the rationale for one to the other without damage to the framework. See our discussion of the oral argument for this case here.

[3] Par Pharmaceutical, Inc. v. TWI Pharmaceutical, Inc., 773 F. 3d 1186, 1196 (Fed. Cir. 2014).

[4] In re Omeprazole Patent Litigation, 483 F.3d 1364 (Fed. Cir. 2007).

[5] In re Crish, 393 F.3d 1253 (Fed. Cir. 2004).

[6] Sumbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569 (Fed. Cir. 1984).

[7] Reading & Bates Const. Co. v. Baker Energy Resources Corp., 748 F.2d 645, 652 (Fed. Cir. 1984).

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