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Federal Circuit Patent Bulletin: *Alcon Res. Ltd. v. Barr Labs, Inc.*

March 18, 2014

"Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry."

On March 18, 2014, in *Alcon Res. Ltd. v. Barr Labs, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Newman, Lourie,* Bryson) affirmed-in-part and reversed-in-part the district court's judgment that Barr did not infringe U.S. Patents No. 5,631,287 and No. 6,011,062, which related to methods for enhancing the stability of prostaglandin compositions containing the synthetic prostaglandin fluprostenol isopropyl ester travoprost marketed by Alcon as Travatan Z® for treating glaucoma and ocular hypertension, and that the '062 patent was invalid for lack of enablement and adequate written description under 35 U.S.C. § 112, ¶1, as well as the district court's denial of Barr's post-judgment Fed. R. Civ. P. 59(e) motion for judgment as a matter of law that Barr did not infringe U.S. Patents No. 5,510,383 and No. 5,889,052. The Federal Circuit stated:

Unlike a classic patent infringement case in which infringement exists if at least one claim of an asserted patent reads on a product or process that the accused infringer has introduced into the U.S. marketplace, an infringement inquiry provoked by an ANDA filing under the Hatch-Waxman system pursuant to 35 U.S.C. § 271(e)(2)(A) is focused on a comparison of the asserted patent against "the product that is likely to be sold following ANDA approval." That determination is based on consideration of all of the relevant

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evidence and, "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry. "

In its attempt to prove that the addition of PECO in Barr's proposed generic product would chemically stabilize the prostaglandin travoprost and thus infringe the asserted claims of the '287 and '062 patents, Alcon relied solely on a theory that the data reported in Table 7 of a stability study that Alcon conducted during its development work could be extrapolated to infer that the addition of PECO would chemically stabilize travoprost in Barr's ANDA composition. [T]he district court found, and the parties do not dispute on appeal, that the composition of the generic product proposed in Barr's ANDA is significantly different from the compositions tested in Alcon's study. [T]he generic product proposed in Barr's ANDA is maintained at a different pH, is composed of 0.004% weight by volume of travoprost and a buffered preservative system comprising propylene glycol, sorbitol, and zinc chloride, but does not contain benzalkonium chloride or a tromethamine/boric acid/mannitol buffer solution. Alcon itself admitted that variation in parameters including pH, preservatives, and buffers can have a substantial impact on the chemical stability of a prostaglandin in an ophthalmic formulation. The data in Table 7 therefore were not evidence that Barr's product, if and when approved, would infringe the asserted claims. We thus conclude that the district court did not clear- ly err in finding that the data in Alcon's Table 7 had no bearing on whether Barr's proposed generic product infringed Alcon's patents. The formulations tested in Alcon's stability study were meaningfully different from the product described in Barr's ANDA and thus provided no basis from which to draw any reliable inferences regarding whether the PECO in Barr's composition would chemically stabilize the prostaglandin.

[T]he patents disclose exemplary compositions within the scope of the claims, detail how those example compositions are prepared from commercially-available ingredients, and provide step-by-step procedures for adding PECO to a prostaglandin composition in a way that embodies the claimed invention. The patents also identify the various prostaglandins and PECOs that can be used and a range of suitable concentrations for both components, including narrow preferred embodiments. In light of those disclosures, the district court's non-enablement ruling was premised on testimony that many "variables" including the number of prostaglandins and the range of PECOs encompassed by the claims, as well as "[v]arious parameters including pH, buffer, buffer concentration, preservatives, chelating agents, and other excipients *may* affect the chemical stability of prostaglandins in ophthalmic formulations." Indeed, Barr's expert observed that "when 'you have a lot of variables on top of one another, the experimentation gets out of control quickly.'" But such an unsubstantiated conclusory statement is not sufficient. Barr adduced no evidence at trial that changing any of the "variables" or "[v]arious parameters" identified by the district court would render Alcon's claimed invention inoperable, nor was there any evidence that experimenting with those variables was required for an ordinarily skilled artisan to be capable of increasing the chemical stability of a prostaglandin by adding

PECO. Adjusting variables may be relevant to *optimizing* the stability of a given prostaglandin composition, but Barr proffered no evidence that any experimentation, let alone undue experimentation, with those variables would be necessary in order to *practice* the claimed invention. Without that evidence, there is no foundation for the district court's nonenablement ruling. . . .

Barr argues that it is entitled to an affirmative judgment that Alcon's '383 and '052 patents are not infringed because Alcon neither put forward evidence of infringement nor formally obtained a dismissal of the claims involving those patents from its complaint prior to trial. Alcon responds that the district court correctly denied Barr's motion because Barr never filed a counterclaim seeking a declaratory judgment of noninfringement, which could have preserved its ability to seek an adjudication of the '383 and '052 patents after they were removed from the case. . . . Had Barr invoked that right during the pendency of the action below, the district court might have exercised its discretion differently. If an accused infringer has filed a counterclaim, then the patentee has notice that, even if it drops its infringement claims, the issue of infringement remains to be litigated. On the other hand, if the accused infringer does not file a counterclaim, then it is up to the patentee to decide what claims are to be litigated and decided at trial.