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Federal Circuit Patent Bulletin: *Ferring B.V. v. Watson Labs., Inc.*

August 22, 2014

"The district court is not precluded from considering an amended ANDA when deciding the issue of infringement [under 35 U.S.C. § 271(e)(2)]."

On August 22, 2014, in *Ferring B.V. v. Watson Labs., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Lourie, Dyk,* Reyna) affirmed the district court's dismissal of Ferring's suit alleging that Apotex's Abbreviated New Drug Application (ANDA) for generic Lysteda infringed U.S. Patents No. 7,947,739, No. 8,022,106, and No. 8,273,795, which related to tranexamic acid formulations to treat heavy menstrual bleeding, or menorrhagia, in women. The Federal Circuit stated:

We address whether either of Apotex's filed ANDAs— the original 2010 ANDA or the amended 2014 ANDA— infringed the patents-in-suit. . . . [Here], the ANDA does not "clearly describe[] a product that meets the limitations of the asserted claims." Rather, the 2010 ANDA is silent with respect to the claim limitations of the patents-in-suit, which do not specify dissolved dissolution rate at 60 minutes. When an ANDA is silent with respect to infringement, as is the 2010 ANDA, the . . . "[t]he relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product. What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists." . . . [T]he evidence shows that Apotex is not likely to sell an infringing product and that the district court erred in finding that the 2010 ANDA was infringing.

We must also determine whether the ANDA now in effect infringes the patents-in-suit. Apotex amended that ANDA in 2014 in an effort to preclude infringement. Apotex's 2014 ANDA—the 2010 ANDA with the February 2014 amendment—specified that "each unit dissolved NLT [i.e., not less than] 75% [by weight tranexamic acid] in 45 minutes." We first address whether the 2014 ANDA, stating that not less than 75 percent by weight tranexamic acid would be dissolved at 45 minutes, would likely infringe the patents-in-suit. The district court concluded that the 2014 ANDA would not infringe because the patents-in-suit required that less than about 70 percent by weight tranexamic acid be dissolved at 45 minutes, and therefore, the February 2014 amendment

mooted Ferring's complaint. . . . We affirm the district court's construction of "about" to mean "approximately," as well as its refusal to construe "about" to represent a particular numerical error rate. Under the circumstances it fell to Ferring, the party with the burden of proof on infringement, to produce evidence that the 2014 ANDA infringed by proposing a 75 percent by weight dissolution rate, under the district court's claim construction. Ferring produced no such evidence and made no claim that the ANDA infringed under the district court's claim construction. . . .

Alternatively, Ferring objects to the district court's decision to consider the 2014 ANDA, stating that 35 U.S.C. § 271(e)(4)(A) requires that once a section 271(e)(2)infringement is found based on the ANDA as first submitted, the district court must order a change in the effective date of the ANDA. . . . The district court is not precluded from considering an amended ANDA when deciding the issue of infringement. Both section 355(j), referred to in section 271(e)(2),and the FDA's regulations contemplate that a pending application may be amended for various reasons. For the purposes of section 271(e)(2), "an application" means the ANDA as filed and all amendments to that application that have been allowed by the FDA. There is no support for the proposition that the question of infringement must be addressed solely based on the initial ANDA filing, given that the statute contemplates that the ANDA will be amended as a matter of course. Nor does it appear that Ferring contends otherwise. . . .

A district court may reconsider its own finding of infringement in light of an amended ANDA or other information. Only when the district court has entered a judgment finding that the operative ANDA infringes must it enter a § 271(e)(4) resetting order. We do not suggest that a district court must always consider any ANDA amendment. Allowing an amendment is within the discretion of the district court, guided by principles of fairness and prejudice to the patent-holder. Here, the district court concluded at trial that the 2010 ANDA permitted Apotex to infringe, but agreed not to enter an injunction or resetting order because Apotex agreed to amend its ANDA. We conclude that the district court did not abuse its discretion in reconsidering its judgment of infringement in light of Apotex's amendment.

Ferring also argues that its complaint was not mooted by Apotex's amendment. A case becomes moot when interim relief or events have eradicated the effects of a defendant's act or omission, and there is no reasonable expectation that the alleged violation will recur. In cases where a defendant voluntarily ceases the challenged practice, it is necessary for the court to determine whether "there is no reasonable expectation that the wrong will be repeated." As a result, "'a defendant claiming that its voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur.'"

Ferring makes no argument that Apotex would file an infringing ANDA in the future. Apotex's 2014 amendment meets the governing standard. Apotex cannot sell an infringing product without modifying its ANDA. If Apotex introduced a drug into interstate commerce without complying with the FDA approval process, it would be subject to additional penalties, including criminal sanctions or seizure of the unapproved drug. . . . Apotex has agreed to notify Ferring and the district court if an amendment to the ANDA is filed with the FDA. Therefore, even if the 2010 ANDA were infringing, the 2014 ANDA is properly considered for the purposes of § 271(e)(2) infringement, and any allegedly infringing conduct is unlikely to recur, given the restrictions that Apotex has placed on the amendment and the FDA's own governing statute.