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In an Issue of First Impression, the Federal Circuit Finds Infringement as a Matter of Law Despite a Sworn Certification Promising No Infringement

BY JOSEPH M. O'MALLEY, JR., ERIC W. DITTMANN, DAVID M. CONCA, & NICHOLAS A. TYMOCZKO

In a September 26th precedential ruling addressing an issue of first impression, the Federal Circuit held that a "so-called certification pledging not to infringe cannot override the conclusion that when a drug manufacturer seeks FDA approval to market a generic compound within the scope of a valid patent, it is an infringement as a matter of law." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 2013-1335, Slip Op. at 15 (Fed. Cir. Sept. 26, 2013). In so holding, the Federal Circuit reversed the district court's entry of summary judgment in favor of Dr. Reddy's Laboratories, the last defendant remaining in the case, and entered a "judgment of infringement as a matter of law under 35 U.S.C. § 271(e)(2)(A)" in favor of firm client Sunovion Pharmaceuticals Inc. *Id.* at 2.

In this large, complex Hatch-Waxman case, Sunovion accused Reddy and nine other groups of generic drug manufacturers of infringing U.S. Patent No. 6,444,673, which is listed in the FDA's "Orange Book" as covering Sunovion's blockbuster sleep aid, Lunesta®. Sunovion's '673 patent covers Lunesta®'s active ingredient, eszopiclone, which consists of the "dextrorotatory" isomer of a prior-art racemic compound known as zopiclone "essentially free" of its "levorotatory" isomer. In approving Lunesta®, the FDA required that each eszopiclone tablet contain no more than 0.3% of zopiclone's levorotatory isomer (*i.e.*, 0-0.3%).

In its eszopiclone ANDA, Reddy initially sought approval to sell tablets containing not less than 0.3% and not more than 1.0% of the levorotatory isomer. Reddy argued that this ANDA product avoided infringement based upon its contention that the '673 patent is limited to eszopiclone products containing "less than 0.25% levorotatory isomer." The FDA, however, repeatedly rejected Reddy's original ANDA specification, and requested that Reddy tighten it to conform to Lunesta®'s not more than 0.3% levorotatory isomer limit. *Id.* at 5. Undeterred, Reddy continued to seek FDA approval for its original ANDA specification, and moved for summary judgment of noninfringement at the district court.

The district court eventually adopted Reddy's proposed construction of the "essentially free" limitation. Shortly thereafter, however, Reddy submitted a revised ANDA specification restricting the amount of the levorotatory isomer to not more than 0.6% (*i.e.*, 0-0.6%). After denying Reddy's initial summary judgment motion without prejudice, the district permitted Reddy to file a renewed motion for

summary judgment of noninfringement directed to its new ANDA product based upon a "so-called 'certification'" that purported to show that it would not manufacture or market a zopiclone product "containing less than 0.3% of the levorotatory isomer" — despite the fact that it was seeking FDA approval for an ANDA specification (*i.e.*, 0-0.6%) that encompassed these purity levels. *Id.* at 5. Relying on Reddy's representations (while forbidding Sunovion from filing any opposition papers), the district court granted summary judgment of noninfringement. *Id.* at 6.

On appeal, the Federal Circuit concluded that Reddy infringed the '673 patent as a matter of law. The court began its analysis by observing that what a generic "ask[s] the FDA to approve as a regulatory matter is the subject matter that determines whether infringement will occur." *Id.* at 12. The Federal Circuit then reasoned that, while it has previously applied this rule to find noninfringement, here it compelled a finding of infringement because Reddy's 0-0.6% ANDA specification encompasses the court's "less than 0.25%" claim construction. *Id.* at 14 (citing *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1250 (Fed. Cir. 2000), and explaining that "if an ANDA specification defines a compound such that it meets the limitations of an asserted claim, then there is almost never a genuine issue of material fact that the claim is infringed").

Because Reddy's ANDA specification controlled the infringement inquiry, the Federal Circuit concluded that Reddy's and the district court's reliance on a certification that Reddy would not make a product with less than 0.3% levorotatory isomer was "misplaced." *Id.* at 13. According to the Federal Circuit:

> [T]he fact that Reddy either tells the court that its manufacturing guidelines will keep it outside the scope of the claims or has even filed a declaration in the court stating that it will stay outside the scope of the claims does not overcome the basic fact that it has asked the FDA to approve, and hopes to receive from the FDA, approval to market a product within the scope of the issued claims. In this case, Reddy's request for approval of levorotatory amounts from 0.0-0.6% is within the scope of the "less than 0.25%" limitation of the '673 patent claims.

Id. at 12. The court also noted that, as a matter of sound policy, "[a]llowing Reddy to avoid infringement based on its unconventional and unenforceable 'guarantee' when it is asking for and may receive FDA approval to market a product within the scope of the innovator's patent, would be incompatible with the basic principles of patent law." *Id.* at 13.

The Federal Circuit's decision is significant not only because it affirms the primacy of the ANDA specification in the infringement inquiry, but also because it prevents generic drug manufacturers from circumventing the patent laws and the Hatch-Waxman regulatory scheme by taking potentially inconsistent positions before the FDA and courts regarding the nature of their proposed products. The decision thus ensures that generic drug manufacturers will not be able to avoid patents through unilateral representations to courts and provides innovators with certainty in defending their most-important products against infringement.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York lawyers:

Joseph M. O'Malley, Jr.
1.212.318.6090
josephomalley@paulhastings.com

Eric W. Dittmann
1.212.318.6689
ericdittmann@paulhastings.com