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The Federal Circuit Affirms the New Jersey District Court's Preliminary Injunction to Bar Generic Drug Pulmicort

In a recent decision, *AstraZeneca LP v. Apotex, Inc.*, No. 2009-1381 (Fed. Cir. Nov. 1, 2010), the Court of Appeals for the Federal Circuit affirmed the U.S. District Court for the District of New Jersey's grant of a preliminary injunction barring defendant Apotex from distributing the generic version of AstraZeneca's Pulmicort®.

Apotex filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to manufacture and sell a generic version of Pulmicort, a budesonide inhalation suspension developed and patented by AstraZeneca for treating asthma. AstraZeneca then filed a declaratory judgment action and moved to enjoin Apotex from distributing the generic drug. The district court granted AstraZeneca's request for a preliminary injunction, finding that Apotex would not likely prevail at trial in proving the AstraZeneca claims were invalid and that AstraZeneca would likely prevail in proving Apotex's infringement by inducement.

A party is entitled to a preliminary injunction if it can satisfy a four-part test: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in the requesting party's favor; and (4) the injunction's favorable impact on the public interest. Generally, a patentee can establish a "likelihood of success on the merits" by demonstrating both (1) the likelihood of proving infringement of at least one of the disputed claims, and (2) the likelihood of at least one of the disputed claims withstanding validity challenges. Defendant Apotex opposed patentee AstraZeneca's motion for a preliminary injunction regarding the likelihood of success on the merits, i.e., the validity and infringement of the disputed claims.

Regarding Apotex's likelihood of success on proving invalidity, the Federal Circuit affirmed the district court's determination "that at trial Apotex will likely not be able to demonstrate by clear and convincing evidence" that AstraZeneca's asserted patented method claims are invalid. Apotex contended that a prior art patent claiming the administration of budesonide within liposomes anticipated AstraZeneca's method claims. However, the district court construed the term "budesonide composition" in AstraZeneca's asserted method claims as involving solutions or suspensions, but not liposomes, and therefore the reference involving liposomes did not anticipate the asserted method claims. The Federal Circuit affirmed the district court's claim construction, and, accordingly, found that the district court was correct in concluding that "the asserted method claims are likely to withstand the [Apotex] validity challenge posed by the [prior art] '528 Patent."

Likewise, the Federal Circuit agreed with the district court's finding that Apotex would not likely prevail in proving at trial that an advertisement by AstraZeneca anticipated its asserted claims. AstraZeneca's asserted method claims limit the claimed treatment to dosages "at a frequency of not more than once per day." The advertisement in question stated that the initial recommended dosage frequency was twice per day and that the maintenance dosage "should be the lowest dose which keeps the patient symptom-free." While this might seem to indicate the possibility of decreasing administration of the drug to a once-daily frequency, an AstraZeneca expert testified that at the time of the advertisement, it was believed that a twice per day dosage frequency was adequate. Accordingly, the Federal Circuit agreed with the district court's finding that the alleged prior art advertisement was not referring to a once-daily dosage because a person having ordinary skill in the art would have understood it to mean twice per day as stated in the advertisement.

Regarding infringement, the Federal Circuit agreed with the district court that AstraZeneca would likely succeed in showing induced infringement under Section 271(b) of the U.S. Patent Law. The Federal Circuit emphasized that inducement requires that the alleged infringer knowingly induces infringement and possesses specific intent to encourage another's infringement. The district court found that Apotex's proposed label would induce consumers to infringe the method claims because the label implicitly instructed users to administer the generic drug once daily by starting with more frequent administration and "titrating down" to a minimum necessary dosage. Thus, based on the evidence presented at the hearing, the district court found that Apotex "was aware of and certainly concerned about the potential infringement problem posed by its label," but nevertheless decided to proceed with the label.

The Federal Circuit agreed with the district court's finding on specific intent. First, the Federal Circuit noted that Apotex was correct in arguing "where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the [alleged inducer] has actual knowledge that some users of its product may be infringing the patent." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). However, in this case, the evidence was not clear that there were substantial noninfirnging uses.

Regarding intent, the district court found that Apotex had the requisite specific intent to induce infringement because Apotex included instructions in its proposed label that would cause at least some users to infringe the asserted method claims. The district court also found that, despite being aware of the infringement problem presented by the proposed label, Apotex nonetheless proceeded with its plans to distribute its generic drug product. Thus, the Federal Circuit noted "[i]n the context of specific intent, it is irrelevant that some users may ignore the warnings in the proposed label. The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of Apotex's affirmative intent to induce infringement."

Furthermore, the district court noted that Apotex could have sought approval for smaller dosages of budesonide that patients could administer more often than once daily, but that Apotex did not do so. Noting that the district court's specific-intent finding was not based solely on the proposed label, "but also on Apotex's decision to proceed with its plan to distribute the drug despite being aware that the label presented infringement problems," the Federal Circuit concluded that the district court did not err in finding that AstraZeneca was likely to succeed on infringement because Apotex apparently knew of the potential to induce infringement and had other options that it did not pursue to avoid infringement.

A copy of the opinion may be found at http://www.cafc.uscourts.gov/images/stories/opinions-orders/09-1381-1424.pdf.

The Federal Circuit Clarifies the Domestic Invention Requirement in Section 102(g)(2)

In an October 13, 2010 decision, the Court of Appeals for the Federal Circuit held that reproduction of an invention that was conceived and reduced to practice abroad does not qualify as an invention under 35 U.S.C. § 102(g)(2) of the U.S. Patent Laws. The case is *Solvay S.A. v. Honeywell International, Inc.*, No. 2009-1161 (Fed. Cir. Oct. 13, 2010).

Under Section 102(g)(2), a person is not entitled to a patent if "before the applicant's invention thereof the invention was made in this country by another inventor who had not abandoned, suppressed or concealed it."

Solvay brought suit against Honeywell alleging infringement of U.S. Patent 6,730,817 (the '817 patent), which is directed to a chemical process for making HFC-245fa that Honeywell used at its plant in Geismar, Louisiana. Honeywell moved for summary judgment of invalidity of claims 1, 5, 7, 10, and 11 of the '817 patent on the ground that Honeywell was a prior inventor of the claimed invention under Section102(g)(2).

In early 1994, Honeywell entered into a research contract with the Russian Scientific Center for Applied Chemistry (RSCAC). It was undisputed that the process that the RSCAC engineers conceived of, performed, and reported to Honeywell in July 1994 corresponded to the invention claimed in Solvay's '817 patent, and that RSCAC engineers had conceived of the invention and reduced it to practice in Russia. It was also undisputed that Honeywell had used this process in the United States prior to Solvay's priority date of October 23, 1995. Honeywell's Geismar plant was in successful operation by February 1996. Shortly thereafter, Honeywell began drafting a patent application on an improvement process for making HFC-245fa in March 1996. The application was filed on July 3, 1996 and eventually issued as U.S. Patent No. 5,763,706 (the '706 patent).

The district court granted Honeywell's motion for summary judgment of invalidity of claims 1, 5, 7, 10, and 11 of the '817 patent and denied Solvay's motion for summary judgment of no invalidity. The district court ruled that Honeywell had previously made the invention of the '817 patent in the United States in August 1995, prior to the '817 patent's priority date, and that the asserted claims thus were invalid based on Honeywell being a prior inventor under Section 102(g)(2).

The district court rejected Solvay's contention that Honeywell was not an "inventor" under Section 102(g)(2). Solvay argued that the invention at issue was "conceived" abroad by RSCAC's engineers and that Honeywell's "mere reproduction" of a foreign invention in the United States did not make Honeywell an inventor. The district court found "no authority" that barred Honeywell from being an "inventor" for purposes of Section 102(g)(2) merely because it derived the invention from RSCAC as "the original inventor." The district court concluded that Honeywell conceived of the invention at issue in the United States upon receipt of RSCAC's instructions because it was at this point that Honeywell's possessed a definite and permanent idea of the complete and operative invention.

Therefore, the district court determined that Honeywell was the first inventor of the subject matter claimed in the '817 patent, and that the '817 patent should be invalidated under Section 102(g)(2) unless Honeywell abandoned, suppressed, or concealed its invention. The district court found that Honeywell was moving toward public disclosure, and that Solvay had failed to show that Honeywell withheld its invention from the public. Accordingly, the district court concluded that Honeywell had not intentionally abandoned, suppressed, or concealed the invention described in the '706 patent.

On appeal, Solvay again argued that Honeywell was not a prior inventor of the claimed subject. In particular, Solvay argued that Honeywell could not be "another inventor" under Section 102(g)(2) because it is undisputed that it did not invent the claimed process for preparing HFC-245fa, but rather derived it from RSCAC, whose engineers invented it in Russia. In response, Honeywell argued that it is "another inventor" under Section 102(g)(2) because it reduced the claimed invention to practice in the United States before the October 1995 priority date of Solvay's '817 patent.

The Federal Circuit reversed the district court and held that Honeywell did not invent in the United States the process claimed in the '817 patent, as required by Section 102(g)(2). According to the statute, a person is not entitled to a patent if "before the applicant's invention thereof the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2). The Federal Circuit determined that the statutory language, "the invention was made in this country," refers to the act of inventing in the United States. Invention requires conception and reduction to practice. Thus, the question before the Federal Circuit became whether Honeywell conceived of the invention at issue and reduced it to practice in the United States, such that Honeywell is "another inventor" of the process claimed in the '817 patent under Section 102(g)(2).

The Federal Circuit noted that "[c]onception is 'the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice'" (quoting *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994)). The Federal Circuit held that Honeywell is not "another inventor" under Section 102(g)(2) because it merely reproduced an invention previously conceived of and reduced to practice by RSCAC in Russia. "In this case, Honeywell did not have, or formulate, a definite and permanent 'idea' of its own capable of being reduced to practice. Rather, it reproduced the invention previously conceived and reduced to practice by RSCAC in Russia." The Federal Circuit clarified that such "reproduction" cannot be considered "conception" because, if it were, "the result would be that one who simply followed another inventor's instructions to reproduce that person's prior conceived invention would, by so doing, also become an 'inventor.'" Thus, because Honeywell did not qualify as "another inventor" under Section 102(g)(2), the Federal Circuit found that the district court erred in ruling claims 1, 5, 7, 10, and 11 of Solvay's '817 patent invalid by reason of prior inventorship.

A copy of the opinion may be found at http://www.cafc.uscourts.gov/images/stories/opinions-orders/09-1161.pdf.

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