

Abbott Labs. v. TorPharm, Inc.

No. 07-1019, Federal Circuit (Michel,* Dyk, Otero)

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On October 11, 2007, the Federal Circuit reversed the district court's contempt judgment that Apotex, Inc. violated an injunction barring it from infringing U.S. Patents No. 4,988,731 and No. 5,212,326, which related to the anti-seizure drug divalproex sodium marketed by Abbott as Depakote®, based on Apotex's repetitive filing of an Abbreviated New Drug Application (ANDA) to generic divalproex sodium. The Federal Circuit stated:

[B]efore entering a judgment of contempt of an injunction in a patent infringement case, a district court must address two separate questions. First, the district court must address whether a contempt hearing is an appropriate forum for adjudging whether an allegedly redesigned product is infringing. In doing so, the district court must compare the accused product with the original infringing product. If there is "more than a colorable difference" between the accused product and the adjudged infringing product such that "substantial open issues with respect to infringement to be tried" exist, contempt proceedings are not appropriate. . . . Second, if contempt proceedings are appropriate, the district court must address whether the accused product infringes the claims of the asserted patent. To show infringement, the patentee "must prove by clear and convincing evidence that 'the modified device falls within the admitted or adjudicated scope of the claims.'"

Here, we hold that the district court did not abuse its discretion in holding contempt proceedings. Judge Posner carefully reviewed the evidence presented by the parties and assessed the credibility of the witnesses. Clear and convincing evidence, including Apotex's own evidence, supports his finding that there is no more than a colorable difference, if any, between the Apotex ANDA drug and the Nu-Pharm ANDA drug. Specifically, Apotex's own expert, Dr. Stephens, testified that when he tested and compared the Apotex ANDA drug with the Nu-Pharm ANDA drug, they were identical. Where, as here, a party files a second ANDA to a drug having no more than a colorable difference from the first, the district court is well within its discretion to entertain contempt proceedings. . . .

Judge Posner acted entirely within his discretionary authority to issue an order expanding the original injunction. [T]he original injunction clearly prohibited the FDA from approving the Apotex application and “any other application concerning defendants’ generic divalproex sodium which the Court has found to be infringing.” . . . Because the Nu-Pharm ANDA drug would infringe the claims of the Abbott patents, the district court did not abuse its discretion in extending the injunction to prohibit the FDA from approving the Nu-Pharm ANDA. Therefore, we decline to vacate the revised injunction as Apotex requests. [T]he district court made an error of law in interpreting its original injunction to preclude the conduct of which Abbott complains, namely the filing of the Nu-Pharm ANDA, and thereby abused its discretion in holding Apotex in contempt. . . . While we agree that Apotex could not manufacture generic divalproex sodium in the United States, there is no evidence here that Apotex actually did so. Rather, it is undisputed that Apotex’s actions in attempting to design around the Abbott patent claims occurred outside the United States. Since Apotex did not make, use, sell, offer to sell in the U.S. or import into the U.S. generic divalproex sodium, it did not violate the injunction.

Further, while we agree that Apotex’s filing of the Nu-Pharm ANDA with a paragraph IV certification was an act of infringement under 35 U.S.C. § 271(e) since Apotex’s purpose in doing so was to obtain the FDA’s approval to market generic divalproex sodium in the U.S. before expiration of the Abbott patents, we cannot agree that Apotex’s actions actually violated the original injunction. [W]hile contemplating the filing of new and/or amended ANDAs, the injunction only provided the FDA with the necessary “explicit notice” that it was prohibited from approving the Apotex ANDA or any other ANDA concerning Apotex’s generic divalproex sodium which a court found to be infringing prior to expiration of the Abbott patents. The injunction contains no “explicit notice” to Apotex that the filing of a new ANDA, by itself or a straw party, was forbidden. Therefore, Apotex is foreclosed only from the conduct specifically prohibited, i.e., making, using, selling, offering for sale in the U.S. or importing into the U.S. infringing generic divalproex sodium.

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