Abbott Labs. v. Sandoz, Inc.

No. 07-1300, Fed. Cir. (Newman,* Archer, Gajarsa)

[A preliminary injunction requires a consideration of] the likelihood of success on the merits and equitable factors. [The notion] that if the infringer "raises a substantial question concerning either infringement or validity," it is an abuse of discretion to enjoin infringement pendente lite [is not a proper standard].

On October 21, 2008, the Federal Circuit affirmed the district court's injunction pendente lite that enjoined Sandoz from infringing U.S. Patents No. 6,010,718 and No. 6,551,616, which related to extended release pharmaceutical formulations of an erythromycin capable of reducing gastrointestinal side effects. Abbott markets the patented drug clarithromycin under the brand name Biaxin®XL. The Federal Circuit stated:

> At the stage of the preliminary injunction, before the issues of fact and law have been fully explored and finally resolved, "[t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." . . . Sandoz assigns legal error to the district court's rulings that Abbott is likely to prevail on the issues of validity, infringement, and inequitable conduct, and states that the district court abused its discretion in balancing the equities and granting the injunction. . . . Sandoz states that the factors of irreparable harm, the balance of harms, and the public interest, all weigh in its favor, and outweigh any finding that Abbott is likely to prevail on the issues of validity or enforceability and infringement. . . .
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> Sandoz argued that any harm to Abbott is not irreparable, for damages are available for infringement, if the eventual final judgment is adverse to Sandoz. Sandoz pointed out that the generic producers Teva and Ranbaxy are already in this market, by settlement with Abbott, such that any price erosion due to generic competition is already occurring. The district court considered these relationships, and concluded that they do not negate the market share and revenue loss upon Sandoz' entry while the litigation proceeds. . . . The district court discussed and weighed the hardships argued by both parties, and found that the balance of hardships tipped in favor of Abbott. The court found that preserving the status quo preserves the current market structure, recognizing that Abbott has licensed other generic producers. [T]hat a patentee has licensed others under its patents does not mean that unlicensed infringement must also be permitted while the patents are litigated. [W]hen the patentee is simply interested in obtaining licenses, without itself engaging in commerce, equity may add weight to permitting infringing activity to continue during litigation, on the premise that the patentee is readily made whole if infringement is found. [Here, the district court accepted Abbott 's argument] that it could not be made whole if it prevails in this litigation, for the added erosion of markets, customers, and prices, is rarely reversible. . . . Sandoz argues that the public interest favors the availability of less expensive forms of successful medicines. . . . The district court appreciated that the public interest includes consideration of whether, by shifting market benefits to the infringer while litigation is pending for patents that are

likely to withstand the attack, the incentive for discovery and development of new products is adversely affected. The statutory period of exclusivity reflects the congressional balance of interests, and warrants weight in considering the public interest. [A]s between Abbott and Sandoz the district court objectively weighed the legal probabilities and the equities, and exercised its discretionary judgment as to the entirety of the cause. We have been shown no basis for believing that the district court abused its discretion. . . .

The district court found the likelihood that the patentee would succeed on the merits and that the equities favored the patentee, and exercised its discretion to enjoin infringement during the litigation. The dissent states that the district court applied the incorrect standard, and that if the infringer "raises a substantial question concerning either infringement or validity," it is an abuse of discretion to enjoin infringement pendente lite. The dissent quotes with approval a past panel statement that "In resisting a preliminary injunction, however, one need not make out a case of actual validity. Vulnerability is the issue at the preliminary injunction stages, while validity is the issue at trial.". . . .

The correct standard is not whether a substantial question has been raised, but whether the patentee is likely to succeed on the merits, upon application of the standards of proof that will prevail at trial. The question is not whether the patent is vulnerable; the question is who is likely to prevail in the end, considered with equitable factors that relate to whether the status quo should or should not be preserved while the trial is ongoing. The presentation of sufficient evidence to show the likelihood of prevailing on the merits is quite different from the presentation of substantial evidence to show vulnerability. Thus the evidence that favors the patent must be considered in deciding a motion for a preliminary injunction, as well as the evidence against the patent. The trial court then decides which side is likely ultimately to prevail. . . . Supreme Court precedent, every regional circuit, and controlling Federal Circuit precedent, apply to the preliminary injunction the combination of criteria that includes likelihood of success on the merits and equitable considerations. No other court has held that when the attacker has presented a "substantial question" on its side of the dispute – that is, more than a scintilla but less than a preponderance of evidence in support of its side – no injunction pendente lite is available. Further, equitable factors are of particular significance at the preliminary stage, where the question is whether to change the position of the parties during the litigation.

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