

New Hope for Nipping Infringement in the Bud

Court Lowers Hurdle for Patentee Seeking Preliminary Injunction

By Lee Carl Bromberg

The Federal Circuit recently upheld the grant of a preliminary injunction to Abbott Laboratories, even though defendant Sandoz, Inc. had challenged Abbott's patents as invalid and unenforceable. The October 21, 2008 ruling provides new hope to patentees that enforcement of their patent rights may be available early in a case, without having to slog through years of litigation and trial proceedings before rightfully excluding a competitor from the market.

At stake in *Abbott Laboratories v. Sandoz* were valuable patent rights to the extended-release formulation of the antibiotic drug clarithromycin, sold by Abbott under the brand name Biaxin®XL. Sandoz sought to introduce its own version of the antibiotic, and Abbott sued, quickly obtaining a preliminary injunction barring the Sandoz product.

In a split decision written for the majority by Circuit Judge Newman, the court upheld the preliminary injunction, emphasizing rulings by the Supreme Court and the Federal Circuit itself that the traditional four-part test for a preliminary injunction applies in a patent case just as it would in any other case.

On the crucial factor – a reasonable likelihood of success on the merits – the patentee must carry the day. But Judge Newman rejected the notion that an injunction must be denied if the accused infringer raises a substantial question of validity (or enforceability), or so much as shows that the patent is “vulnerable.” The test, she insisted, is whether the patentee can sufficiently prove a likelihood of prevailing on the merits at trial.

Judge Gajarsa in dissent stated that the injunction should be vacated because Sandoz raised serious questions – even though they were rejected by the lower court after hearing – as to whether the Abbott patents were valid or enforceable. Relying upon the Federal Circuit's 2001 formulation – when it vacated the preliminary injunction

obtained by Amazon.com, Inc. against Barnesandnoble.com, Inc. in the notorious “one-click” patent case – Judge Gajarsa stressed that “vulnerability” of the patent is a key consideration at the preliminary injunction stage. Once the defendant raises a substantial validity (or infringement, or enforceability) defense, the patentee must prove that the defense “lacks substantial merit;” otherwise the preliminary injunction should be denied.

How had Federal Circuit precedent gotten twisted to require the patentee, who enjoys a statutory presumption of validity, to prove a negative, namely, that the defense “lacks substantial merit”? This “special rule” for patent cases must have sneaked in to certain Federal Circuit decisions out of an exaggerated concern that the patentee could too easily show a likelihood of prevailing on the merits by coasting on the statutory presumption.

The result of this “special rule,” however, is to contradict the clear Supreme Court requirement that patent cases be treated like any other. In addition, it turns on its head the advantage that the statutory presumption of validity confers upon the patentee, instead requiring the patentee to prove a negative whenever the defendant raises a plausible challenge to the patent. Contrary to Supreme Court mandate, this puts the patentee seeking a preliminary injunction in a worse position than a plaintiff in a non-patent case seeking the same thing.

Judge Newman's opinion gives new hope that a patentee can obtain a preliminary injunction and halt infringement in the early stages of a litigation, instead of having to endure years of proceedings before its patent rights are upheld. An early ruling by the trial court may also prod the parties to find a basis for settlement short of full-scale litigation. The lowering of the hurdle to injunctive relief is thus a welcome development in efforts to lessen the adverse impact of the delay inherent in litigation. ✧