

## Vulnerability Or Validity: Which Standard Is Correct?

Law360, New York (January 15, 2009) -- Everyone agrees that the court grants or denies a preliminary injunction based on four factors: (1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest.[1]

The patentee must demonstrate that the injunction it seeks should issue.[2] Generally, Federal Circuit precedent has held that an accused infringer may successfully challenge a motion for preliminary injunction by raising a "substantial question" concerning validity, enforceability or infringement.[3]

But a recent Federal Circuit opinion, *Abbott Labs. v. Sandoz Inc.*, 544 F.3d 1341 (Fed. Circ. 2008) ("Sandoz"), calls that standard into question and heightens the defendant's burden for successfully challenging the likelihood of success on the merits factor.

### *Judge Newman Sets Forth The "Clear and Convincing" Standard In The Dissent In Erico*

In *Erico Int'l Corp. v. Vutec Corp.*, decided earlier this year, the Federal Circuit, with Judges Rader and Dyk as the majority and Judge Newman dissenting, vacated the district court's grant of a preliminary injunction in favor of Erico.[4]

Erico is the assignee of U.S. Patent No. 5,740,994 ("the '994 patent"). Claim 17, the only asserted claim, claims a method for supporting a bundle of communication cable using J-hooks (the subject matter of the '994 Patent apparatus claims).

Interestingly, claim 17 survived a 2000 re-examination, which resulted in the PTO canceling several of the apparatus claims based on obviousness. The district court granted the preliminary injunction finding that defendant's obviousness defense would likely fail in light of the PTO's decision to uphold the validity of claim 17 during reexamination.

The Federal Circuit majority found "substantial questions" as to the validity of the patent at issue and reversed the grant of the preliminary injunction. The Court emphasized that validity challenges that may not succeed at trial may suffice to stave off a preliminary injunction.

"Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." [5]

That is, at the preliminary injunction stage, a defendant need not prove actual invalidity, but must put forth a "substantial question" of invalidity to show that the claims at issue are vulnerable.

"Thus, a showing of a substantial question of invalidity requires less proof than the clear and convincing standard to show actual invalidity." [6]

Judge Newman's dissent criticized the panel majority for not clearly indicating what it viewed was an abuse of discretion, for giving no consideration to the public policy of maintaining the "status quo," and for not considering the equitable factors supporting the district court's decision to grant the preliminary injunction. Although the majority cited to the district court's analysis of such factors, [7] Judge Newman argued that the majority needed to do more.

More critically, Judge Newman believed the majority improperly applied the likelihood of success on the merits factor. Judge Newman argued that the trial burden of proof should apply at the preliminary injunction stage.

"The correct criterion is not whether there is a 'substantial question'; it is whether the defendants have shown that they are likely to succeed on the merits, on the standards and burdens of proof as would prevail at trial." [8]

As such, to defeat a preliminary injunction motion, Judge Newman requires defendants prove by clear and convincing evidence the likelihood of success on the merits of their defense; raising a "substantial question" of validity, enforceability or infringement does not equate to such a likelihood.

This is not Judge Newman's first time dissenting on this issue. In 2006 in *Abbott Labs. v. Andrx* ("Andrx"), Judge Newman criticized the panel majority for "hold[ing] that if the attacker raises no more than a 'substantial question' of invalidity, that suffices to establish the likelihood that the attacker will succeed on the merits. That is incorrect in law and in procedure." [9]

*Writing For The Majority, Judge Newman Sets Forth The "Clear And Convincing" Standard In Sandoz*

The difference is that in October of this year, Judge Newman authored the majority opinion in *Sandoz*, affirming a preliminary injunction in favor of Abbott. The claims at issue pertained to extended release compositions of the antibiotic drug clarithromycin and methods for its administration.

In part VI of the opinion, which Judge Archer did not join, Judge Newman went out of her way to address what she deemed "the issue of conflicting precedent" surrounding the proper burden to be placed on a

defendant when challenging the patentee's likelihood of success on the merits.

That is, can a defendant defeat a preliminary injunction by raising a "substantial question" as to infringement or validity and thus attack the "vulnerability" of the patent, or must the defendant prove by clear and convincing evidence that the patentee likely will not succeed on the merits.

Echoing her dissent in *Erico*, Judge Newman wrote, "[t]he 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." [10]

The proper test, according to Judge Newman, involves weighing the evidence in favor of the patent versus the evidence against the patent, both in view of the same burdens that apply at trial. [11]

Judge Newman notes that a substantial question concerning validity can prevent a summary judgment, but is "not the same as showing likelihood of eventual success on the merits." [12]

In dissenting, Judge Gajarsa emphasized Federal Circuit precedent stating that the test for the likelihood of success factor is whether the alleged infringer raises a "substantial question" as to validity. [13]

"Indeed, this court has consistently held that an alleged infringer can negate the patentee's likelihood of success on the merits — and thus defeat a preliminary injunction — by raising a substantial question as to validity." [14]

#### *Can Defendants Meet The Clear And Convincing Standard At The Pretrial Stage?*

Judge Newman's analysis fails to address a substantial hurdle a defendant will face if it is held to the clear and convincing standard at the preliminary injunction stage.

Indeed, a defendant will be challenged to prove the likelihood of succeeding on its invalidity defense by clear and convincing evidence at the outset of a case, before complete discovery has occurred.

Typically, defenses such as invalidity are fleshed out and further refined during the discovery process and with the aid of expert reports and testimony.

#### *Another True Split Among The Federal Circuit Judges Or Simply Fodder For Patentees Seeking A Preliminary Injunction?*

It will be interesting to observe whether Judge Newman's clear and convincing standard will create a split among district courts with regard to the proper standard to apply or whether Judge Newman's analysis regarding the proper burden to place on a defendant challenging a preliminary injunction will be an

anomaly. No doubt, patentees will liberally cite to Judge Newman's majority opinion in *Sandoz*.

*Can Judge Newman's Ruling Temper The Impact Of KSR?*

A more stringent clear and convincing standard for likelihood of success on the merits may temper the application of *KSR Int'l Co. v. Teleflex Inc.*, to obviousness challenges at the preliminary injunction stage. [15]

In the clear majority of cases citing KSR in the obviousness analyses, the district courts have denied the patentee's request for preliminary injunction. [16]

Perhaps Judge Newman's position regarding the clear and convincing standard is, in part, a reaction to the uphill battle faced by patentees in seeking a preliminary injunction post KSR.

Interestingly, although seemingly coincidentally, in four cases where KSR was relied upon and which were decided after Judge Newman wrote her dissent in *Erico*, the district courts have granted preliminary injunctions. [17]

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[1] See e.g. *PHG Techs., LLC v. St. John Cos., Inc.*, 469 F.3d 1361, 1365 (Fed. Cir. 2006).

[2] *Abbott Labs. v. Andrx Pharms. Inc.*, 452 F.3d 1331, 1334 (Fed. Cir. 2006).

[3] See e.g. *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350 (Fed. Cir. 2008) reh'g and reh'g en banc denied (April 10, 2008).

[4] *Id.* at 1355-56.

[5] *Id.* at 1355-56 (quoting *Amazon.com Inc. v. BarnesandNoble.com Inc.*, 239 F.3d 1343, 1358 (Fed. Circ. 2001)).

[6] *Id.* at 1356.

[7] *Id.* at 1355.

[8] *Id.* at 1359 (relying on *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429 (2006)).

[9] *Abbott Labs. v. Andrx*, 452 F.3d at 1350.

[10] Abbott Labs. v. Sandoz, 544 F.3d at 1364.

[11] Id. at 1364 (citing Gonzales, 546 U.S. at 429).

[12] Id.

[13] See, e.g., E.I. du Pont de Nemours & Co. v. MacDermid Printing Solutions LLC, 525 F.3d 1353, 1358 (Fed. Cir. 2008) ("[I]f the accused infringer raises a substantial question regarding validity, the district court should find that the patentee has not shown a likelihood of success on the merits.") (citing Entegris Inc. v. Pall Corp., 490 F.3d 1340, 1351 (Fed. Cir. 2007)).

[14] Abbott Labs. v. Sandoz, 544 F.3d at 1372 (citing Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997)).

[15] 127 S. Ct. 1727 (2007).

[16] See e.g. Novartis Pharm. Corp. v. Teva Pharm. USA Inc., No. 05-1887, 2007 WL 2669338, \*6-9 (Sept. 6, 2007) (Judge Cavanaugh denied the patentee's motion for preliminary injunction, ruling that his preliminary finding of obviousness defeated the patentee's likelihood of success on the merits); Altana Pharma AG v. Teva Pharm.USA Inc., No. 04-2355, 2007 WL 2688917 (D.N.J. Sept. 6, 2007) (Judge Linares denied the patentee's motion for preliminary injunction, ruling that the existence of serious questions regarding obviousness prevented a finding in favor of the patentee's likelihood of success on the merits).

See also Torspo Hockey Int'l Inc. v. Kor Hockey Ltd., 491 F. Supp. 2d 871 (D. Minn. 2007); Andersen Mfg. Inc. v. Diversi-Tech Corp., No. 05-923, 2007 WL 1892509 (D. Utah July 2, 2007); Pass & Seymour Inc. v. Hubbell Inc., 532 F. Supp. 2d 418 (N.D.N.Y. 2007); MMJK Inc. v. Ultimate Blackjack Tour LLC, 513 F.Supp.2d 1150 (N.D. Cal. 2007); Titan Tire v. Case New Holland Inc., 2007 U.S. Dist. LEXIS 74173 (S.D. Iowa Oct. 3, 2007); Printguard Inc. v. Anti-marking Sys. Inc., 535 F. Supp.2d 189 (D. Mass. 2008).

[17] See NuClimate Air Quality Sys. Inc. v. M&I Heat Transfer Prod. Ltd., No. 5:08-CV-0137 2008 WL 2917589 (N.D.N.Y. July 24, 2008); Everett Lab. Inc. v Breckenridge Pharm. Inc., 573 F. Supp. 2d 855 (D.N.J. 2008); Elantech Devices Corp. v. Synaptics Inc., No. C 06-01839 CRB, 2008 WL 1734748 (N.D. Cal. April 14, 2008); Warrior Sports Inc. v. STX LLC, No. 07-14597 2008 WL 783768 (E.D. Mich. March 19, 2008). But see MacDermid Printing Solutions LLC v. E.I. du Pont de Nemours & Co., No. 07-4325, 2008 WL 4126255 (D.N.J. Sept. 4, 2008) (denying preliminary injunction).

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