

Establishing The Weight Of Evidence After Sciele

Law360, New York (August 13, 2012, 1:18 PM ET) -- Patents are presumptively valid under 35 U.S.C. § 282 and can be proven invalid only by clear and convincing evidence. Thus, accused infringers hoping to prove a patent invalid must do so by satisfying a heavy burden. This is partly based on “the basic proposition that a government agency such as the then Patent Office [is] presumed to do its job.” [1] But critics complain that such great deference to the Patent Office makes little sense when measuring a patent against prior art that the Patent Office didn’t know about — or, as in *Sciele Pharma Inc. v. Lupin Ltd.*, when the Patent Office issued a patent with errors.

In *Sciele*, the Federal Circuit confirmed that the burden of proof does not depend on whether the Patent Office considered the prior art being offered against the patent during litigation — or even on whether the Patent Office made an obvious mistake when it granted the patent in suit. According to the court, facts like those go to the weight of the evidence at hand, not to the total weight of evidence required to invalidate a patent. In the *Sciele* court’s words:

The burden does not suddenly change to something higher — “extremely clear and convincing evidence” or “crystal clear and convincing evidence” — simply because the prior art references were considered by the [Patent Office].

This means that a prior-art reference that the Patent Office didn’t consider during patent examination can be a stronger threat to patent validity during litigation than a prior-art reference that the Patent Office did consider. But the weight of evidence needed to invalidate a patent — clear and convincing evidence — remains the same no matter what.

Likewise, if the Patent Office issued a patent by mistake, that fact can be heavy evidence of invalidity, but a defendant must still overcome the presumption of validity, which applies to all patents. Thus, juries evaluating a patent’s validity can, and should, be instructed to weigh all such facts accordingly, a topic addressed at the end of this article.

One Standard — But Varying Weights of Evidence — To Prove Invalidity

Last year, the Supreme Court, in *Microsoft Corp. v. i4i Ltd.*, [2] reaffirmed that clear and convincing evidence is the standard for proving invalidity, regardless of what happened during patent prosecution. There, the Supreme Court credited a passing statement made in a 2007 Supreme Court decision, *KSR Int'l Co. v. Teleflex Inc.*, [3] which noted that the rationale underlying the presumption of validity is less convincing when applied against prior art that the Patent Office didn't see.

Accordingly, said the Supreme Court, "if the [Patent Office] did not have all material facts before it, its considered judgment may lose significant force. And, concomitantly, the challenger's burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain." [4] The court further noted that jury instructions should instruct jurors to adjust the weight of evidence in this manner as needed.

Sciele Reiterates the Standard

Sciele involved a pharmaceutical patent relating to extended-release medication. [5] During prosecution, the applicant cancelled several claims that the examiner found obvious in light of prior art. But then, mistakenly and without explanation, the examiner issued a Notice of Allowance that included the cancelled claims. The honest applicant, however, brought this mistake to the Patent Office's attention, and the dutiful examiner issued a corrected Notice of Allowance. Unexpectedly, and again without explanation, the Patent Office included the cancelled claims in the issued patent.

Anybody who has been given too much change at a cash register can relate to how the patentee must have felt. Indeed, just as some would walk away with the incorrect change, Sciele, now with patent in hand, asserted some of the incorrectly allowed patent claims against Lupin, to attack Lupin's Abbreviated New Drug Agreement (ANDA) submission for a generic version of the diabetes drug Fortamet. The District Court for the District of Delaware granted Sciele a preliminary injunction, based in part on its finding that the patent would probably not be found invalid, because here, unlike in *KSR*, the Patent Office had already considered the prior art. [6]

At oral argument on appeal, the patentee in Sciele relied on this reasoning. [7] The unconvinced Federal Circuit nonetheless vacated the injunction, finding the district court's analogy to the facts of *KSR* — which didn't directly relate to Patent Office error — misplaced. The burden of proof, the court emphasized, neither depends on what references the Patent Office had before it nor changes for erroneously issued patents.

Patent Jury Instructions and the Burden of Proof

Sciele reinforces the practice of carefully drafting jury instructions to correctly differentiate between the burden of proof and the proper weight of various facts. Particularly, patent jury instructions should set forth the clear-and-convincing standard, but should also explain that the patent's file history can affect the weight of other evidence.

Two districts where this is especially important are the Northern District of California and the Eastern District of Texas, both being favorite forums for patent litigants. Model patent jury instructions in each district state that the alleged infringer must prove that invalidity is highly probable. But only the Northern District of California's model instructions were issued after *i4i*. They correctly instruct jurors that "[p]rior art differing from the prior art considered by the [Patent Office] may carry more weight than the prior art that was considered and may make the ... burden ... easier to sustain." Litigants may want to modify these model instructions based on *Sciele*, to account for other important facts in the patent's file history.

On the other hand, the Eastern District of Texas provides model instructions, issued in 2009 by the National Jury Instruction Project, that direct the jury to base its "decision on all the evidence," without commenting on how to jurors might weigh the evidence. These instructions don't guide jurors on how to weigh evidence based on, for example, whether the Patent Office considered the pertinent prior art or issued a patent by mistake. Litigants in the Eastern District of Texas, therefore, can look to the Northern District of California's model instructions for proposed improvements.

As another example, the Federal Circuit Bar Association's Model Patent Jury Instructions, last edited in February, state that:

When a party attacking the validity of a patent relies on prior art which was specifically considered by the examiner during the prosecution of the application leading to the issuance of the patent, that party bears the burden of overcoming the deference due a qualified government agency official presumed to have performed his or her job. [8]

This instruction can be read to imply that when a defendant relies on prior art that was not specifically considered by the examiner, that party can invalidate the patent on less than clear and convincing evidence. This reading directly contradicts the law of *Sciele* and *i4i*.

Similarly, the American Intellectual Property Law Association's (AIPLA) Model Patent Jury Instructions, which are over five years old, appear to slant in the wrong direction when they provide that: "One example of a way in which the presumption may be overcome is if the [Patent Office] has not considered, for whatever reason, invalidating prior art that is presented to you." [9] While not technically wrong, that statement too might give the wrong impression to jurors, since another way to overcome the presumption of validity is to rely on a reference that the Patent Office did consider.

In sum, when a patent's file history is important to the outcome of a case, litigants should prepare the jury to fairly weigh the evidence by giving it clear, accurate and updated jury instructions on patent invalidity. Courts, or their advisers, should therefore assist this cause by moving quickly to refresh model patent jury instructions based on the law of *Sciele* and *i4i*. This will help maintain the delicate balance between deferring to the Patent Office's unique expertise and recognizing its fallibility.

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[1] *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 59 (Fed. Cir. 1984).

[2] 131 S. Ct. 2238 (2011).

[3] 127 S. Ct. 1727 (2007).

[4] *i4i*, 131 S. Ct. at 2251.

[5] No. 2012-1228, slip op. at 2 (Fed. Cir. July 2, 2012).

[6] No. 09 Civ. 0037, slip op. at 5–6 (D. Del. Feb. 14, 2012).

[7] Sciele, Oral Argument before the Federal Circuit, at 26:00.

[8] Federal Circuit Bar Association, Model Patent Jury Instructions, p. 48.

[9] AIPLA Model Patent Jury Instructions, p. 5.

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