Inducing Patent Infringement – Developments that Pharmaceutical Companies Need to Know

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Claims for inducing patent infringement have particular significance in the pharmaceutical industry. Pharmaceutical patents often consist of method claims for treating or administering a drug. Direct infringers of these types of patent claims are patients or prescribing physicians. As a result, patent owners often turn to a theory of inducing infringement in order to assert these types of claims against competitors.

This article reports recent developments on the proof required to establish a claim for inducing infringement. Two recent developments stand out: (1) the debate over the state of mind requirement for inducement now before the Supreme Court in Global-Tech Appliances Inc. v. SEB S.A.; and (2) the Federal Circuit’s recent decision affirming a lower court’s determination that a proposed label for a generic drug constituted proof of intent to induce infringement.

Supreme Court to Tackle Inducing Infringement Standard for Intent

The Supreme Court has agreed to hear a case that presents the question of the proper standard for establishing intent in claims of inducing infringement. Unlike direct infringement which imposes strict liability, a claim for inducing infringement requires a form of intent. But just what standard governs the intent requirement for "inducing" patent infringement?

"Inducing" is often referred to as "encouraging" infringement. One who induces infringement has liability as an infringer. The governing statute provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." The question presented to the Supreme Court asks whether the proper state of mind standard is either:

- "deliberate indifference of a known risk", as the Federal Circuit held in the case under review; or
- "purposeful, culpable expression and conduct" to encourage an infringement, as the Supreme Court held in the copyright case MGM Studios, Inc. v. Grokster.

Arrival of the "Deliberate Indifference" Test Spawns Supreme Court Review

In the typical claim of inducement, proof exists that the accused infringer knew of the asserted patent and the dispute centers on the defendant's specific intent and action to induce infringement. In DSU Medical Corp. v. JMS Co., Ltd et al., the Federal Circuit stated that inducement requires proof of culpable conduct directed to encouraging another's direct infringement. The court in DSU Medical cited to the Supreme Court's decision in the Grokster copyright case for the intent requirement for inducement. The DSU Medical decision further stated that the knowledge requirement—that the
alleged infringer knew or should have known that its actions would induce actual infringement—necessarily includes the requirement that the accused infringer knew of the asserted patent.

The intent requirement for inducing infringement found its way to the Supreme Court as a result of a case that presented a twist on the typical fact pattern. In SEB S.A. v. Montgomery Ward, the case presented facts where the accused infringer did not know of the patent-in-suit. Proof indicated, however, that lack of knowledge of the patent should not insulate the defendant from liability as an inducer. In SEB, evidence showed that the accused infringer purchased an SEB deep fryer in Hong Kong and copied the patented features in developing its allegedly infringing deep fryer. The accused infringer obtained a "right-to-use study" from a New York lawyer but withheld from counsel that it had copied the SEB deep fryer. That attorney analyzed 26 patents without the benefit of learning that SEB’s patent warranted review and analysis.

The Federal Circuit’s opinion in SEB held that claims of inducement do not always require proof that the accused infringer knew of the patent-in-suit. Rather, proof that the accused infringer "deliberately disregarded a known risk" that the plaintiff had a patent could give rise to an inducement claim. The court in SEB further wrote that "failure to inform one's counsel of copying would be highly suggestive of deliberate indifference in most circumstances." The Federal Circuit determined that the accused infringer deliberately ignored the risk that SEB had a patent covering its deep fryer and affirmed the lower court’s finding of inducement.

Reconciling SEB with Grokster

Just what does a "deliberate indifference" standard mean for induction claims? In SEB, the court stated that a "deliberate indifference" standard is a form of actual knowledge that requires a subjective determination. Critics of the SEB decision argue that it lowers the bar for proving inducement to a negligence standard. That need not be the case.

Ambiguity arises when one compares the Federal Circuit decision in SEB with the "question presented" in the case at the Supreme Court. Does a "deliberate indifference" standard apply to the entire question of inducement or only to the limited issue of knowledge of the patent? The former would affect pharmaceutical litigation while the latter would not—because in pharmaceutical litigation the patents are known to all through the U.S. Food and Drug Administration’s Orange Book.

One can harmonize the holdings of Grokster and SEB by finding that inducement requires both:

- "purposeful, culpable expression and conduct" to encourage an infringement; and
- proof that the accused infringer knew of the patent-in-suit or deliberately disregarded a known risk that the patent-in-suit existed.

These need not be mutually exclusive standards if the "deliberate indifference" test speaks to the issue of knowledge of the patent-in-suit (and not to the broader inducement question as a whole).

As a practical matter, parties should have concern over exposure to claims of inducing infringement whether or not they have actual knowledge of a patent. Lack of actual knowledge of a patent is unlikely to defeat a claim of inducing infringement if the patentee can show that the accused infringer did not know of a patent because it buried its head in the sand. In the meantime, we can expect a decision from the Supreme Court on the standard for intent to induce by June 2011.

The Federal Circuit’s Decision that Proposed Labeling Showed Intent to Induce Infringement

In a recent decision, the Federal Circuit ruled that a generic pharmaceutical company's proposed labeling, combined with its distribution plans, constituted proof of intent to induce infringement. Ironically, the generic company had specifically
aimed to defeat any claim of intent to induce through the content of its label.

In Astrazeneca LP v. Apotex, Inc., the Federal Circuit affirmed a lower court's granting of a preliminary injunction barring a generic pharmaceutical company from launching a generic version of a drug. The Federal Circuit held that the patentee demonstrated specific intent to induce infringement through evidence of (1) the generic entity's proposed label; and (2) the generic company's decision to proceed with distribution of the drug despite being aware that the label presented infringement problems.

The patents-in-suit claimed methods for treating respiratory diseases through administration of a composition once per day. The generic entity sought FDA approval to manufacture and sell a twice-daily generic version—a use not claimed by the patents-in-suit. The generic's proposed label did not have any mention of once-daily administration, but the proposed label retained the FDA-mandated downward-titration language found in the patentee's label (patients should titrate down to the lowest effective dose). This downward-titration language proved problematic for the generic entity as it would lead some users to once-daily dosing.

The generic company defended against accusations of intent to induce with arguments including that it had removed all explicit references to once-daily dosing from its label, and that the FDA had instructed it to delete the phrase "by administration twice-daily" from the label. The generic entity's concession to the FDA's position would later backfire in court.

The Federal Circuit first reiterated that intent to induce cannot be inferred in the case of a product with substantial noninfringing uses. The appellate court then stated that inducement may be found where evidence shows statements or actions directed to promoting infringement. The proposed labeling demonstrated that proof. In short, the Federal Circuit held that the proposed label would cause at least some users to infringe the asserted method claims. The Federal Circuit also cited as proof of the requisite intent that evidence in the record showed that the generic company knew of the infringement problem presented by the proposed label but proceeded with its plans to distribute the generic drug.

While the generic company believed that its compliance with the FDA's instructions would insulate it from an inducement claim, the result turned out otherwise. The Federal Circuit rejected the defense from the generic company that the FDA required that the label read as it did. The decision in Astrazeneca v. Apotex reaffirms the importance of a proposed label as proof in support of a claim for inducing infringement.

**Looking Forward**

The Supreme Court's upcoming ruling on the necessary intent for inducing patent infringement will clarify the ambiguity in the existing court decisions. Whichever standard the Supreme Court adopts, product labels undoubtedly will remain important proof in assessing intent to induce infringement.

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3 471 F.3d 1293 (Fed. Cir. 2006).
4 594 F.3d 1360 (Fed. Cir. 2010).
5 Id. at 1377.
6 Id.
7 97 U.S.P.Q.2d 1029 (Fed. Cir. 2010).