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How Fed. Circ.'s Commil Ruling Could Affect Drug Patents

Law360, New York (December 06, 2013, 1:51 PM ET) -- Over the past several years the U.S. Supreme Court and the Federal Circuit have issued a series of decisions that have made it more and more difficult for patentees to prove induced infringement. Most recently, in Commil USA LLC v. Cisco Sys. Inc., the Federal Circuit followed the Supreme Court's lead from its seminal Global-Tech v. SEB decision in 2011, in holding that a finding of inducement requires both knowledge of existence of the patent and "knowledge that the induced acts constitute patent infringement."

Breaking new ground, the court also held that evidence of a good-faith belief of invalidity can be relied on as rebuttal evidence to defeat the intent element of inducement. The technology at issue in Commil was not life sciences — the disputed patent claimed an improved method of mobile device handoffs; however, the implications of the decision (and the trend in the law it reflects) likely will be significant for life sciences companies that often rely on method of treatment, mechanism of action and method of manufacturing patents as key value drivers. Such patents may be materially weakened by the higher burden of proving actual knowledge of infringement as a component of the threshold infringement determination.

Method-of-treatment patents traditionally have been central to enforcement strategies, particularly in the context of Hatch-Waxman litigation. Such patents are commonly listed in the Orange Book and often have later expiration dates than composition of matter patents. Because the act of treatment always is carried out by doctor and patient (not drug marketer), proving infringement necessarily requires a finding of inducement.

Under the traditional, "knew or should have known" paradigm, not much was required of a patentee to establish inducement beyond pointing to a product label that directed use of the infringing method of treatment. Now, post-Global-Tech and Commil, patentees must show actual knowledge of infringement; a standard that can only be satisfied by evidence of actual knowledge or willful blindness. To defeat inducement, accused infringers also have a new weapon in their arsenal; evidence of good-faith belief of invalidity — such as a reasonable invalidity opinion from counsel — may be enough to avoid inducement liability.

The Pre-Commil Landscape

The patent statute provides that whoever "actively induces infringement of a patent shall be liable as an infringer." In the context of a method of use patent asserted in Hatch-Waxman litigation, statements in a proposed abbreviated new drug application label that promote infringing use of a drug product alone have been found sufficient to establish intent to encourage direct infringement.

The Federal Circuit's 2010 decision in AstraZeneca v. Apotex, 633 F.3d 1042 (2010) is representative. At issue were claims providing a new method of treating respiratory diseases that involved administering a budesonide composition once daily. Apotex submitted an ANDA seeking U.S. Food and Drug Administration approval to manufacture and sell a generic version of budesonide for twice-daily use, which was not claimed in AstraZeneca's patent. However, even though "once-daily" language was not used in the proposed label, the label was essentially identical to AstraZeneca's product label, including a warning that patients should "titrate down" to the lowest effective dose of the medication to avoid any adverse effects from excessive use of the medication.

The district court had held that the downward titration language would lead many users to directly infringe the asserted claims because titrating down from the recommended doses would necessarily lead to once-daily usage. The Federal Circuit agreed. The court stated that it was irrelevant that some users may choose to ignore the warnings in the proposed label, and that the "pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of Apotex's intent to induce infringement."

The Federal Circuit clarified that the specific intent finding was not based solely on the proposed label, but also on Apotex's decision to proceed with its plan to distribute the drug despite being aware that the label presented infringement problems, as highlighted by a previous FDA letter that opined that the downward titration language did not "teach" once-daily dosing.

In a more recent — but still pre-Commil — Hatch-Waxman case, the District of Delaware found that a brand company's method claim had been infringed by inducement. In Bone Care Int'l v. Roxane Labs., No. 09-cv-285, the claim at issue involved Hectorol (doxercalciferol), Genzyme's drug for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease. Citing AstraZeneca, the district court began its analysis with the proposition that in ANDA cases, the pertinent question is "whether the proposed label instructs the user to perform the patented method and promotes or encourages others to practice that method."

Quoting other Federal Circuit precedent, the court stated that to prove inducement, the patentee must prove that the defendant "knew or should have known" that its actions would induce actual infringement. Applying this standard, the court found that the defendants' proposed label would infringe by instructing users to perform each element of the asserted claim.

Furthermore, the court concluded that, based on clinical trials and literature available, the defendants "knew or should have known" that doxercalciferol "has been shown to lower and maintain lowered PTH levels with a lower incidence of hypercalcemia that would result from using calcitriol or alfacalcidol at the same level of PTH suppression," which was a limitation in the asserted claim as construed after a Markman hearing. This level of intent was sufficient for inducement purposes.

The Commil Decision

In Commil USA LLC v. Cisco Sys. Inc., No. 2012-1042, the Federal Circuit purported to follow the Supreme Court's lead in raising the required level of intent on the part of a defendant in order to establish induced infringement. Specifically, in reaffirming that proof of specific intent to induce infringement was necessary to establish a finding of inducement, the court: (1) overruled the sufficiency of plaintiffs proving that defendants "knew or should have known" that their actions would induce infringement, and (2) held that a fact finder should consider whether an accused inducer had a good-faith belief of invalidity in determining whether the defendant had the requisite intent.

The patent at issue in Commil claimed an improved method of handoffs of mobile devices between base stations in a network area. Cisco objected to a jury instruction by the district court telling the jury that it could find inducement if Cisco "knew or should have known that its actions would induce actual infringement." The Federal Circuit determined that, in light of the Supreme Court decision in Global-Tech v. SEB, 131 S. Ct. 2060 (2011), the "knew or should have known" standard was no longer good law. Rather, Global-Tech required both knowledge of an existing patent and actual knowledge that the induced acts constitute patent infringement.

Actual knowledge, the court continued, could only be satisfied by a showing of at least willful blindness — a departure from the quasi-negligence standard applied in both AstraZeneca and Bone Care Int'l. Because the jury was permitted to find induced infringement based on mere negligence where knowledge was required, the court vacated Commil's favorable verdict and remanded for a new trial.

The Federal Circuit did not stop there. The court found that the district court erred in preventing Cisco from presenting evidence on its good-faith belief of invalidity to rebut Commil's inducement allegations. The court reasoned that it had previously held that a good-faith belief of noninfringement is relevant evidence that an accused inducer lacked the intent required to be held liable for inducement; the court saw "no principled distinction" between a good-faith belief in invalidity and one in noninfringement for the purpose of whether a defendant possessed the requisite intent to induce.

Notably, there appears to be a significant schism within the Federal Circuit on the issue of whether the Commil court should have permitted evidence of a good faith belief in invalidity to be considered to counter an inducement charge. On Oct. 25, 2013, the court denied a request for en banc review on the issue. However, Judge Jimmie Reyna authored a scathing dissent in which he was joined by Chief Judge Randall Rader and Judges Pauline Newman, Alan Lourie and Evan Wallach.

Judge Reyna observed that Global Tech "did not alter the fundamental meaning of infringement," including in particular "that infringement is resolved solely with reference to the limitations of a patent claim." Rejecting the notion that opinions of invalidity should be considered, he observed that "infringement and invalidity are separate issues under the patent code and our precedent ... there is no reasonable basis to impute questions of invalidity or liability into 271(b) through the term 'infringement.'" Of course, notwithstanding Judge Reyna's spirited objection, the court did not undertake en banc review, thereby putting the issue to rest for the time being.

Implications

Fortunately for patent holders, the new Commil standard is unlikely to materially impact the availability of prospective injunctive relief, for example in the context of method of treatment claims asserted in Hatch-Waxman litigation. In the Hatch-Waxman situation, the NDA holder has the statutory right to bring suit against a generic applicant who files an ANDA (or 505(b)(2) application) seeking approval "for a drug ... the use of which is claimed in a patent." 35 U.S.C. § 271(b)(2).

Assuming the NDA holder then prevails on the merits before the ANDA filer is able to launch, with respect to prospective conduct (that would be covered by an injunction), the ANDA filer could no longer rely on any prior invalidity/non-infringement opinion (such as in a Paragraph IV certification letter) as evidence of a good faith belief that using the method of use directed on the label would not infringe. That said, Commil's impact may be quite significant in cases where a party seeks damages for past conduct on an inducement theory, such as in the situation where an ANDA filer launches at risk during

pending Hatch-Waxman litigation.

For example, if after expiration of a statutory 30-month stay of ANDA approval, but before resolution on the merits in the district court, an ANDA filer is able to overcome a motion for entry of a preliminary injunction and launch at risk, then the heightened intent standard may present a significant barrier to the NDA holder's ability to recover damages for the at-risk period even if, in the end, the NDA holder prevails on the merits.

More precisely, in circumstances where the 30-month stay has expired, and the ANDA filer then defeats a motion for preliminary injunction by raising a "substantial question" of validity or noninfringement, then the NDA holder will face a very high bar to establish the intent prong of induced infringement during the launch of risk period. To defeat a finding of infringement the ANDA filer could simply point to both its prior opinion of counsel (i.e., its Paragraph IV certification) and, more significantly, the court decision denying the preliminary injunction on grounds that the NDA holder is not likely to succeed on the merits.

That evidence is highly likely to be enough to defeat inducement. That means that, during the launch at-risk period, there would be no infringement and, therefore, no damages. An injunction may yet issue if the NDA holder ultimately prevails on the merits (thereby rendering the prior opinion and preliminary injunction decision moot as a defense to inducement of the prospective conduct), but the damages claim for the at risk period likely would still not be recoverable.

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