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Biotechs Face Higher Bar For Induced Infringement

Law360, New York (June 03, 2010) -- Patent claims covering methods of treatment; methods of performing certain diagnostic tests; and, increasingly, personalized medicine are common and important parts of patent portfolios developed by biotech and pharmaceutical companies. Patent owners, however, face a difficult hurdle in enforcing this type of claim against potential infringers.

These claims often are not infringed directly until individual physicians, laboratory technicians or even patients carry out the claimed method. For example, a method of treating a particular disease or condition by taking a drug or combination of drugs is not directly infringed until the patient actually takes the medicine.

Consider this exemplary claim found from a USPTO search:

A method of treating disease X caused by the proinflammatory effects of human IL-X, comprising administering to a subject a monoclonal antibody or antigen binding portion thereof which binds to human IL-X, in an amount effective to treat disease X, wherein the heavy chain variable region of the antibody comprises the amino acid sequence set forth in SEQ ID NO:2.

Such claims have become a mainstay of biopharma patents, especially since the human genome project and related efforts basically put all known open reading frames in the public domain.

The patent owner cannot assert a claim for direct infringement against a traditional defendant (i.e., the marketer of the infringing product). Since it is impractical, if not impossible, to sue the direct infringers (individual patients, doctors, etc.), the patent owner is left with no choice but to assert claims for inducement to infringe against the company selling products for use in the infringing method.

However, recent developments in the law have made proving inducement much more difficult than proving direct infringement and, therefore, made these categories of patents potentially less valuable.

The high legal hurdle comes from a 2006 decision by the Federal Circuit en banc that established a more stringent standard for proving induced infringement than the standard required to prove direct infringement. See DSU Medical Corp. v. JMS Co., 471 F.3d 1293 (Fed. Cir. 2006) (en banc in relevant part).

Unlike direct infringement, which requires no knowledge of the patent or of the infringement, the Court found that induced infringement under 35 U.S.C. § 271(b) requires a showing of specific intent. The patent owner must show that the defendant knew of the patent and actively and knowingly aided and abetted another's direct infringement.

It is not enough merely to demonstrate active encouragement to commit the acts which would constitute infringement. Thus, advertising and/ or labeling that describes methods which would infringe are not enough standing alone.

Notably, the Federal Circuit has indicated that a defendant may avoid a finding of inducement by presenting evidence that it did not believe its products infringed, including evidence that it reasonably relied on an opinion of counsel.

In DSU Medical, the defendant submitted evidence that it had obtained opinions of counsel that stated that the use of its medical needle guards did not infringe the patent-in-suit. The defendant also presented testimony that it had no intent to infringe.

Following this precedent, the Federal Circuit found that the jury was "well within the law" to conclude that the defendant did not purposefully and culpably encourage infringement. Because the record contained evidence that the defendant did not believe that its product infringed, the court found that the defendant did not have the requisite intent.

Based on this reasoning, it appears that reasonable noninfringement, and even invalidity, opinions of counsel may shield defendants from inducement liability, thereby preventing patent owners from recovering damages for infringement of their key method patents.

In this respect, the standard for inducement has been elevated to a point where it is effectively (although not literally) co-extensive with the heightened standard for proving willful infringement. See Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 699-700 (Fed. Cir. 2008) (discussing the standards for willful infringement and induced infringement).

Like in the case of willful infringement, in some circumstances patent owners may still prevail despite the defendants' reliance on an opinion of counsel. Since DSU Medical, both the Federal Circuit and district courts have recognized that opinions of counsel are not dispositive regarding intent.

For example, in SEB S.A. v. Montgomery Ward & Co., the Federal Circuit upheld a jury verdict of inducement despite the fact that there was no evidence that the defendant had actual knowledge of the patent-in-suit and the defendant had also hired an attorney to conduct a right-to-use study regarding 26 other patents.

Because there was evidence that the defendant had copied its product from the patent owner's product, and then failed to inform its counsel of the copying, the Federal Circuit found that the defendant was deliberately indifferent to the risk that the plaintiff owned a patent that covered its product. See SEB S.A. v. Montgomery Ward & Co., 594 F.3d 1360, 1375-78 (Fed. Cir. 2010).

Some district courts have denied defendants' motions for summary judgment of no inducement even where the defendant could show that it obtained noninfringement opinions of counsel immediately after being notified of the patent-in-suit.

Because "intent is a factual determination particularly within the province of the trier of fact and may be inferred from all of the circumstances," it appears that courts are not willing to grant defendants summary judgment of noninfringement merely because they obtained opinions of counsel. See Semiconductor Energy Lab. Co. v. Chi Mei Optoelecs. Corp., 531 F. Supp. 2d 1084, 1113 (N.D. Cal. 2007); Medtronic Xomed Inc. v. Gyrus Ent LLC, 440 F. Supp. 2d 1300, 1313-14 (M.D. Fla. 2006).

Likewise, an exculpatory opinion of counsel appears to be sufficient to defeat a patent owner's motion for summary judgment of induced infringement. See VNUS Medical Techs. Inc. v. Diomed Holdings Inc., No. C-05-2972-MMC, 2007 WL 2900532 (N.D. Cal. Oct. 2, 2007).

Because many pharmaceutical and biotech patent owners often have to rely on the doctrine of induced infringement to assert their method patents, their ability to assert their intellectual property has been disproportionately impacted by the high standard of proof imposed by the Federal Circuit in DSU Medical.

While it remains possible to prove induced infringement despite an exculpatory opinion of counsel, it is clear that infringers of claims requiring proof of inducement may more easily escape liability than the infringers of claims requiring only proof of direct infringement. Thus, DSU Medical has potentially disproportionate implications for the life sciences industry, where method claims that can be infringed only by individual patients and doctors often are an important part of the patent portfolios.

From a policy standpoint, this result makes little sense. The patent statute draws a clear distinction between proof of willful infringement, which carries with it the possibility of enhanced damages in order to penalize intentional conduct, and proof of underlying infringement, which requires no proof of specific intent.

Yet, in the context of certain method patents where inducement to infringe is the only practical avenue for patent owners to seek relief, a finding of intentional conduct is required in all circumstances. In view of the Federal Circuit's definitive statement on this issue, the only avenue for redress is the Supreme Court (which, at least in the context of copyright infringement, appears to side with the Federal Circuit — see Metro-Goldwyn-Mayer Studios Inc. v. Grokster Ltd., 545 U.S. 913, 934-40 (2005)) or the legislature.

The DSU Medical decision, coupled with the recent and much publicized Association for Molecular Pathology and ACLU v. USPTO and Myriad Genetics (S.D.N.Y. Mar. 29, 2010) decision finding that patents claiming "isolated DNA" do not qualify as patentable subject matter under 35 U.S.C. 101 (if it holds up on Appeal), will present a powerful challenge to the biopharma industry.

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