

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

THIRD WAVE TECHNOLOGIES, INC.,

Plaintiff,

v.

DIGENE CORPORATION,

Defendant.

OPINION AND ORDER

05-C-0594-C

Plaintiff Third Wave Technologies filed this suit for declaratory judgment, contending that a justiciable controversy exists between it and defendant Digene Corporation, pertaining to United States Patents Nos. 4,489,332, 4,908,306, 5,643,715 and 5,057,411. Defendant denies that any actual controversy exists and has moved to dismiss the action for lack of subject matter jurisdiction. The case is a close one but on balance, I conclude that plaintiff has shown both that it has a reasonable apprehension that defendant will sue for infringement of one or more of its patents and that it is engaged in activity that could constitute infringement. I conclude, therefore, that an actual controversy exists that gives this court jurisdiction over the suit. I see no reason to exercise my discretion not to hear the case.

From the complaint and the parties' briefs, I find that the parties do not dispute the following matters, which I find as fact solely for the purpose of deciding defendant's motion to dismiss for lack of subject matter jurisdiction.

UNDISPUTED FACTS

Defendant owns United States Patents Nos. 4,489,332 and 4,908,306 and is the exclusive licensee of United States Patents Nos. 5,643,715 and 5,057,411, all of which relate to detection of Human Papillomavirus or HPV, which is a sexually transmitted virus. The potential market for HPV diagnostic testing products is estimated at \$1,000,000,000, because it includes all women over 30 who are or have ever been sexually active.

Defendant is the only company currently offering FDA-approved clinical diagnostic tools for detecting HPV. It purports to own, license or otherwise have rights to patents related to all 13 of the high risk types of HPV that are associated with the development of cervical cancer and are the ones commonly tested. It has spent significant sums to acquire the patents it owns and it has brought suit against Ventana Medical Systems, Inc. and Beckman Coulter, Inc. for alleged infringement of the '332 patent that is one of the patents at issue in this case.

In 2005, plaintiff introduced its HPV analyte specific reagents that may be used to detect the presence of a number of strains of HPV. It has announced publicly that it is

seeking FDA approval to market its own clinical diagnostic test for HPV detection. In addition, it has given public presentations of its HPV technology at industry conferences. Its current analyte specific reagents compete with defendant's products; its clinical diagnostic test will do so if it is approved by the FDA.

In the course of discovery for a suit brought by plaintiff against Stratagene Corporation, involving a wholly different invention, counsel for Stratagene took a deposition of plaintiff's president, John Puisis. He asked Puisis questions about the functionality of plaintiff's HPV products, although technical information about these products had no relevance to the suit against Stratagene, which concerned the probe based detection of target nucleic acid molecules.

Suspicious that the questions by Stratagene's counsel indicated an effort by defendant to learn technical information about plaintiff's HPV products, plaintiff's counsel asked Stratagene's counsel whether his firm represented defendant Digene as well as Stratagene and was told it did. Shortly thereafter, on July 1, 2005, plaintiff's counsel wrote defendant's counsel, saying that plaintiff had learned that defendant's counsel was representing defendant Digene and raising ethical concerns about defendant's counsel and their firm having access to plaintiff's confidential information when they were advising a competitor of plaintiff. Plaintiff's counsel ended the letter by saying, "[t]his letter serves as notice that Third Wave reserves all of its rights and options to address this situation, including all

options with respect to any litigation which later may be brought against it by Digene.”

Stratagene’s counsel responded on July 6, 2005, with a letter that started with two paragraphs objecting to plaintiff’s allegations that it was unethical for counsel to represent both Stratagene and defendant Digene and defending the relevance of the questions asked of John Puisis at his deposition. Counsel went on to say:

I can personally assure you that no information which has been received from Third Wave under the Protective Order of this case has been communicated to Digene, directly or indirectly, in any way, shape or form. As such, the only way Digene will ever learn that fact is if they seek to take action against Third Wave for its publicly noted willful infringement of Digene’s intellectual property. [fn. 1]

1. So there is no question later, Digene’s decision not to take action at this point cannot be construed as the basis for a laches or estoppel defense since Digene is not privy to the information in question.

* * * * *

Finally, with respect to your reservation of “rights and options,” we suspect you will advise your client as you believe necessary under the circumstances. . . . This letter serves as notice that we reserve all of our rights and options to address this situation, including all options with respect to any litigation which later may be brought against [plaintiff] by [defendant].

In a declaration filed in this suit, defendant’s president has averred that defendant did not authorize its counsel to act on its behalf with respect to any patents, that defendant was not informed of the July 2005 correspondence between counsel in the Stratagene case, that at this time, defendant has not studied whether any of plaintiff’s patents infringe any of defendant’s patents and that it has no present intention to sue plaintiff for patent

infringement.

Plaintiff filed this suit on October 7, 2005.

OPINION

Two considerations guide the determination of this motion. The first is the case or controversy requirement for federal jurisdiction. Federal courts are not permitted to give advisory opinions. They may hear only cases that present actual controversies. The Declaratory Judgment Act, 28 U.S.C. § 2201, makes the existence of an actual controversy a condition of the authority it gives to the federal courts to “declare the rights and other legal relations of any interested party seeking such declaration.” To be justiciable, a case must present an “actual controversy,” that is, one in which “the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 278 (1941).

The second consideration is the desirability of preventing patent owners from trying to enforce their patents outside of court with “scare-the-customer-and-run tactics that infect the competitive environment of the business community with uncertainty and insecurity.” Arrowhead Industrial Water, Inc. v. Ecolchem, Inc., 846 F.2d 731, 735 (Fed. Cir. 1988) (citing E. Borchard, Declaratory Judgments 803–04 (2d ed. 1941)). This is the

consideration that led to the enactment of § 2201. The Declaratory Judgment Act gives competitors the option of suing for declaratory judgment of non-infringement or invalidity when they have objective reasons to feel threatened by allegations or innuendos of infringement. Goodyear Tire & Rubber Company v. Releasomers, 824 F.2d 953, 956 (Fed. Cir. 1987) (holding that defendant's innuendos could reasonably have led plaintiff to believe that defendant would bring infringement action). Under § 2201, entities feeling threatened with suit do not have to sit back and wait for the patent owner to bring an infringement suit.

It is not always easy to determine what makes an alleged infringer's apprehension of a possible infringement suit objectively reasonable. Although generalized fear or a nervous state of mind is not enough, a plaintiff "does not have to show that the patentee is 'poised on the courthouse steps.'" Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1255 (Fed. Cir. 2002) (quoting Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1053-54 (Fed. Cir. 1995)).

Courts have identified two questions that help to define the inquiry. First, is there an explicit threat or other action by the patentee that creates a reasonable apprehension on the part of the plaintiff that it will face an infringement suit? Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1332 (Fed. Cir. 2005). Second, is the alleged infringer engaged in activity that could constitute infringement or has it taken concrete steps with the intent to conduct such activity? Id.

The second question is not in dispute. Plaintiff has not started production of the clinical diagnostic test for which it is seeking FDA approval, but it is selling HPV analyte specific reagents that can be used with other components to detect the presence of a number of strains of HPV. These reagents compete directly with defendant's products. Therefore, the only question is the reasonableness of plaintiff's fear that defendant will file an infringement suit against it.

Plaintiff can point to only a few indications of defendant's intent to sue it for infringement. Three are contained in the July 6, 2005 letter from defendant's counsel: the description of plaintiff's "*publicly noted willful infringement* of defendant's intellectual property"; the warning that defendant's decision not to take action *at this time* cannot be construed as a basis for a laches or estoppel defense; and the additional warning that defendant reserves all its rights and options to address the situation, "including all options with respect to any litigation which later may be brought against" plaintiff by defendant. (Emphasis added.) A fourth is the very peculiar questioning of John Puisis at his deposition in the Stratagene suit about plaintiff's work with the HPV virus. It is not surprising that this questioning raised suspicions in plaintiff's counsel's mind. It had nothing to do with any issue raised in the Stratagene case. (Defendant argues that the questions went to damages, apparently because it would have shown that plaintiff's success was not tied solely to the diagnostic process at issue in the Stratagene process, but that makes no sense. Its questions

focused on the exact nature of the way plaintiff was developing its HPV technology, rather than on the size of the market for such technology or estimates of how much money plaintiff expected to earn from the sale of its technology and related products.) The fifth indication of defendant's intent to sue is defendant's ongoing litigation with another company that is alleged to have infringed one of the patents at issue in this case. The litigation demonstrates defendant's willingness to go to court to protect its patents. (Plaintiff has also stated that industry rumors have led it to believe that defendant is planning to bring suit against it. I have disregarded this unsubstantiated allegation.)

Defendant downplays the import of these statements and actions. It points out that its president has averred in a declaration that it did not authorize the statements its counsel made in the July 6, 2005 letter, that it has no present intention to sue plaintiff for patent infringement, that it has not studied whether any of plaintiff's products infringe its patents and that no employee or representative of defendant has been in direct contact with plaintiff regarding the patents. Further, defendant argues that this case lacks a critical component: the existence of ongoing litigation against plaintiff over the same subject matter covered by the patents.

As to the lack of authorization of defendant's counsel's statements, the test with respect to any statement is not whether the person making the statements speaking was authorized to do so, or whether the person had a legitimate ground for making the statement

or even whether the statement is true, but whether the statements would have produced an objectively reasonable apprehension of suit in the listener. Capo, Inc. v. Dioptics Medical Products, 387 F.3d 1352, 1356 (Fed. Cir. 2004) (rejecting defendant’s argument that it should not find that plaintiff had reasonable apprehension of suit because defendant had not studied the accused product and therefore could not have meant its threats; declaratory judgment plaintiff “is not required to verify the extent to which the accuser has studied the accused product before acting to declare its commercial rights”). If the question is whether the speaker is authorized to say what he does, it is the speaker’s apparent authority that will determine the effect of his words upon the person hearing them.

As in Capo, plaintiff is not required to verify the basis for the patent holder’s statements, which in this case would be counsel’s authority to speak on its client’s behalf. In any event, the speaker in this case was defendant’s counsel. Who would have more *apparent* authority than a party’s legal counsel? In that respect, this case is unlike West Interactive Corp. v. First Data Resources, 972 F.2d 1295 (Fed. Cir. 1992), in which a third party told the plaintiff about statements about infringement made by a representative of joint venture between AT&T and defendant’s wholly owned subsidiary during a business negotiation. The court of appeals agreed with the defendant that these statements would not have created a reasonable apprehension in the plaintiff that the defendant parent company would sue it for patent infringement. Id. at 1297. The speaker “was not an owner,

officer, agent, or even an employee” of defendant or “even an officer of the joint venture of [defendant’s] subsidiary, but merely one of its employees” (albeit an inventor of the patented devices). Id. He was not the defendant’s counsel.

Defendant’s counsel’s statement in the July 6 letter that defendant was not going to bring suit *at this time* would have done little or nothing to allay plaintiff’s apprehensions. As the Federal Circuit has noted, the mere fact that a defendant has not authorized infringement suit against plaintiff at the present time is not dispositive of its intentions for future; “a patentee’s intentions ‘may change over time.’” Goodyear Tire, 824 F.2d at 956 (quoting C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 881 (Fed. Cir. 1983)).

Plaintiff argues that the July 6, 2005 letter stated that defendant had considered but had decided against suing plaintiff at this time. This is not an unreasonable inference to be drawn from the letter but it is not something the letter states explicitly. Nevertheless, the letter does suggest that litigation is a possibility for the future. Were it otherwise, defendant’s counsel could have said something to the effect that defendant had never considered bringing suit against plaintiff. Instead, he referred to “the publicly noted willful infringement of defendant’s intellectual property,” suggesting strongly that defendant believes that plaintiff has infringed its patents relating to HPV testing.

Defendant suggests that ongoing litigation between the parties is necessary to a court’s finding that a plaintiff has a reasonable apprehension of suit. It is true that ongoing

litigation between the parties is a factor in a number of cases in which the Court of Appeals for the Federal Circuit has reversed the lower court's dismissal of declaratory judgment actions. However, it does not appear to be critical to jurisdiction. What does seem to be important is an actual indication that the patentee has demonstrated that it will resort to litigation to protect its patent rights. In Arrowhead Industrial Water, Inc. v. Ecolochem, Inc., 846 F.2d 731 (Fed. Cir. 1988), as in this case, the defendant had commenced suit against a third party. In addition, Ecolochem had demanded that Arrowhead cease any practice of Ecolochem's patented process immediately and had warned Arrowhead that Ecolochem had not hesitated to protect its patent rights in the past. Id. at 733. In light of these indications of an intent to sue, the court of appeals took strong issue with the district court for dismissing the case for lack of an actual case or controversy. See also C.R. Bard, Inc., 716 F.2d at 881 n.6 (lawsuits against other manufacturers of similar products can be factor giving rise to reasonable apprehension of infringement suit).

In this case, defendant has filed suit against Ventana Medical Systems, Inc. and Beckman Coulter, Inc. for alleged infringement of defendant's '332 patent, one of the four patents at issue in this suit. Clearly, defendant is prepared to sue to protect its patent rights from infringing competitors.

In sum, I am persuaded that plaintiff has an objectively reasonable fear that it will be subject to an infringement suit by defendant, preventing it from developing and selling its

own clinical diagnostic test for HPV detection and selling its analyte specific reagents. It should not have to sit back while defendant “engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword.” Arrowhead Industrial Water, 846 F.2d at 735.

ORDER

IT IS ORDERED that defendant Digene Corporation’s motion to dismiss plaintiff Third Wave Technologies’ suit for declaratory judgment is DENIED.

Entered this 10th day of January, 2006.

BY THE COURT:
/s/
BARBARA B. CRABB
District Judge