# **United States Court of Appeals for the Federal Circuit**

2009-1085

INNOVATIVE THERAPIES, INC.,

Plaintiff-Appellant,

٧.

KINETIC CONCEPTS, INC., KCI LICENSING, INC., and KCI USA, INC.,

Defendants-Appellees.

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Appealed from: United States District Court for the District of Delaware

Judge Sue L. Robinson

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INNOVATIVE THERAPIES, INC.,

Plaintiff-Appellant,

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KINETIC CONCEPTS, INC., KCI LICENSING, INC., and KCI USA, INC.,

Defendants-Appellees.

Appeal from the United States District Court for the District of Delaware in case no. 07-CV-589, Judge Sue L. Robinson.

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DECIDED: April 1, 2010

Before MICHEL, Chief Judge, NEWMAN and PROST, Circuit Judges.

NEWMAN, Circuit Judge.

Innovative Therapies, Inc. ("ITI") appeals the judgment of the United States District Court for the District of Delaware, dismissing ITI's declaratory judgment action against Kinetic Concepts, Inc. ("KCI") based on absence of an actual controversy within the contemplation of the Declaratory Judgment Act.<sup>1</sup> We affirm the dismissal.

### DISCUSSION

The five patents at issue are United States Patent Nos. 4,969,880; 5,645,081;

<sup>&</sup>lt;sup>1</sup> <u>Innovative Therapies, Inc. v. Kinetic Concepts, Inc.</u>, No. 07-589-SLR/LPS, 2008 WL 4809104 (D. Del. Nov. 5, 2008).

5,636,643; 7,198,046; and 7,216,651, all owned by the defendant KCI or exclusively licensed to KCI from the assignee Wake Forest University. The patents relate to medical devices for negative pressure wound therapy, used in treatment of chronic wounds. Several of the inventors are scientists at Wake Forest University in Winston-Salem, North Carolina.

The declaratory plaintiff ITI was established in 2006 by several former employees of KCI, in conjunction with Dr. Paul Svedman, a surgeon who had worked in the field of negative pressure wound therapy. On September 25, 2007 ITI filed this suit for declaration that the five patents are invalid and/or not infringed by a device that ITI planned to offer for sale "on or about October 1, 2007," called the Svedman Wound Treatment System. KCI moved to dismiss for lack of declaratory jurisdiction, stating that it had not seen the ITI device, had not examined it for possible infringement of any KCI patent, and had not accused ITI of infringement. ITI responded that sufficient adverse interests existed to entitle it to adjudication, citing the liberalized criteria for declaratory actions as established by the Supreme Court in MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007). ITI identified several factors that when considered together, as required by MedImmune's totality of the circumstances test, were stated by ITI to establish declaratory jurisdiction.

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In dismissing the complaint, the district court observed that the mere existence of an adversely held patent does not suffice to establish adverse legal interests, and that the circumstances cited by ITI did not establish declaratory jurisdiction at the time the complaint was filed. On appeal ITI again argues that a confluence of three factors, taken together, established the existence of a controversy of "sufficient immediacy and reality," the words

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of <u>MedImmune</u>, to warrant declaratory jurisdiction. These factors are (1) ITI's representations to the FDA, (2) ITI's phone calls to KCI executives, and (3) KCI's patent enforcement history.

## (1) ITI's representations to the FDA

ITI had obtained expedited pre-marketing approval of the Svedman device based on its representations to the FDA that the Svedman device has the "same technological characteristics" as KCI's previously approved wound therapy device and other FDA-approved devices that KCI has charged with infringement. ITI stated that such expedited approval, obtained pursuant to §510(k) of the Food, Drug and Cosmetic Act, 21 U.S.C. §360(k), demonstrated the reasonableness of ITI's belief that KCI would regard the Svedman device as infringing KCI's patents. ITI stated that it learned through discovery that KCI was aware of ITI's filings with the FDA. ITI thus argued that KCI had sufficient knowledge of ITI's Svedman device, even before its introduction to the market, to suggest that KCI might have been preparing to sue ITI for infringement.

KCI responded in the district court that at the time ITI filed this declaratory action KCI had not seen any device produced or intended to be produced by ITI, that no such device had been sold or offered for sale, and that KCI had not charged ITI with infringement as to any such device. KCI argued that ITI's representations that the Svedman device has the "same technological characteristics" as a patented product did not establish infringement of any KCI patent.

The district court accepted that ITI had requested and received regulatory approval for a product that it intended to place on the market. Although "meaningful preparation" to take infringing action may suffice for declaratory jurisdiction in some circumstances, see

Cat Tech LLC v. Tubemaster, Inc., 528 F.3d 871, 881 (Fed. Cir. 2008), representations to a third person about "technological characteristics" do not establish a justiciable controversy with the patentee. Although the parties disputed the extent of knowledge that KCI had about ITI's filings with the FDA, we agree with the district court that even if KCI knew of ITI's representations to the FDA, this knowledge of itself did not create a controversy within the contemplation of the Declaratory Judgment Act.

## (2) ITI's phone calls to KCI executives

ITI placed its strongest reliance on two telephone calls from ITI, arguing that statements made by KCI employees during these phone conversations were sufficient to demonstrate the existence of a justiciable controversy.

On September 12, 2007 ITI's Chief Technology Officer, David Tumey, who had previously been employed at KCI as Director of Research and Development, telephoned his former colleague Michael Girouard, KCI's Director of Marketing. Another ITI employee who also was a former KCI employee, Mark Meents, participated in the call. The parties agree that during the call Tumey described the Svedman device and asked Girouard to predict KCI's response to ITI's planned launch of this product. Tumey and Meents stated that Girouard responded: "KCI will act aggressively. You know that." Tumey and Meents also stated that Girouard qualified his statement by saying that KCI would sue only "if it first determined that the product infringed the KCI patents." Tumey stated that Girouard said that he was aware of one of ITI's two 510(k) filings with the FDA, but Girouard disputed this aspect of the conversation. The district court stated that it accepted ITI's version of this conversation for the purpose of determining whether to accept declaratory jurisdiction.

On September 17, 2007 Tumey telephoned another former colleague, Michael

Burke, Senior Vice President of Manufacturing at KCI. Tumey knew that Burke planned to retire at the end of September. The parties stated that after discussing Burke's imminent retirement, Tumey described the Svedman device and asked Burke how he thought KCI would react when ITI introduced this device. Tumey stated that Burke responded that KCI would "aggressively go after us . . . particularly if it is foam-based." Tumey stated that when he asked Burke if the odds were "100%" that KCI would sue, Burke responded "100% no doubt about it," and stated that any product that "scratches the surface of our patents" would be the subject of a lawsuit. Tumey stated that he asked about the possibility of peacefully coexisting, and that Burke said there was "no way to coexist."

ITI argued that these telephone conversations established that a controversy existed with respect to patent infringement by the devices that ITI intended to market. KCI argued that these phone calls, initiated by ITI in the guise of friendly conversations, did not constitute a threat of legal action by KCI as to products they had not seen and had not reviewed for infringement. KCI stated that neither Girouard nor Burke had authority to decide on his own whether KCI would conduct infringement litigation, although ITI disputed this point.

The district court described these phone calls as a "sub rosa" effort to create jurisdiction "by initiating telephone conversations to employees of the patentee who were not in decision-making positions and who were not informed of the real purpose behind the conversations." The court found that these phone calls, made to former colleagues who had not seen and had not evaluated ITI's device, produced impromptu responses, not an assertion of patent rights.

ITI argues on this appeal that a justiciable controversy was indeed created by KCI's

statements during ITI's telephone calls. ITI states that the district court misunderstood the purpose of the phone calls, and that they were not a subterfuge to establish jurisdiction, but an effort to clear the air as to the product ITI was about to launch. KCI responds that Tumey phoned his ex-colleagues under cover of friendship, without revealing his true purpose and without knowing whether those persons had knowledge of the structure of the ITI device and any basis for threatening an infringement suit. KCI argues that ITI sought to obtain indirect evidence of a controversy without subjecting itself to the possibility of suit. Thus KCI argues that its employees' impromptu responses cannot be deemed to be charges of infringement or other indications of a real and immediate controversy within the cognizance of the Declaratory Judgment Act.

The district court found that these informal conversations did not constitute a threat of suit for patent infringement against a device that had not been seen and evaluated for infringement of any patent. We agree that the indirection reflected in these conversations did not produce a controversy of such "immediacy and reality" as to require the district court to accept declaratory jurisdiction. <u>See SanDisk Corp. v. STMicroelectronics, Inc.</u>, 480 F.3d 1372, 1378 (Fed. Cir. 2007).

## (3) KCI's patent enforcement history

The third aspect on which ITI relied was KCI's history of litigation to enforce its patents. ITI argued that KCI's known enforcement of these patents against others should be given weight in evaluating the telephone statements of the KCI executives. KCI responded that although it indeed enforces its legal rights, it had not seen any ITI device, no ITI device had been sold, and no accusation of infringement or threat of suit had been made, either in these phone conversations or in any other way. KCI stressed that ITI's

assertion to the FDA that similar products had received FDA approval does not equate to a statement that ITI's Svedman device infringes any KCI patent. See CardioVention, Inc. v. Medtronic, Inc., 483 F. Supp. 2d 830, 840 (D. Minn. 2007) ("Courts have repeatedly refused to allow FDA 510(k) notification of substantial equivalence as admission of infringement in patent cases.").

The district court found that KCI's history of litigation against others, and general propensity to enforce its legal rights, did not establish an actual controversy between KCI and ITI over a device that KCI had not seen and evaluated. Although MedImmune held that a reasonable apprehension of suit for infringement is not always required to establish declaratory jurisdiction, the particular circumstances must be considered. In MedImmune there was no apprehension of suit for infringement because the challenger was already licensed under the patent and continued to pay royalties, even as the challenger sought to adjudicate the obligation to pay royalties. The Court held that the licensee did not have to terminate or breach the license in order to challenge the licensor's position and that the licensee did not have to risk loss of the license in order to obtain judicial review of its obligations under the license. However, MedImmune did not hold that a patent can always be challenged whenever it appears to pose a risk of infringement. See SanDisk, 480 F.3d at 1380-81 ("In the context of conduct prior to the existence of a license, declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.").

Thus while prior litigation is a circumstance to be considered in assessing the totality of circumstances, the fact that KCI had filed infringement suits against other parties for

other products does not, in the absence of any act directed toward ITI, meet the minimum standard discussed in MedImmune. See Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1341 (Fed. Cir. 2008) (noting that "prior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy," but concluding that no controversy was shown). The holding of Micron Tech., Inc. v. MOSAID Techs., Inc., 518 F.3d 897, 901 (Fed. Cir. 2008), is not otherwise, for in Micron the patentee had not only litigated the patents against others, but also had sent several threatening letters to the declaratory plaintiff. The specific facts of each case must be considered, in deciding whether a declaratory action is warranted.<sup>2</sup>

#### Subsequent events

ITI pointed to events that occurred after its declaratory judgment complaint was filed but before the district court's decision on the motion to dismiss, and argued that the presence of a controversy at the time of filing was confirmed by KCI's later suits against ITI, after KCI had inspected the Svedman device. On December 4, 2007 ITI permitted KCI to inspect the Svedman device and provided KCI with copies of the User Manual and Instructions. On January 2, 2008 KCI filed suit in Texas state court against ITI and three of its employees who had previously been employed by KCI, with counts including breach of confidentiality agreements and misappropriation of trade secrets. On January 10, 2008 KCI and Wake Forest University filed a patent infringement suit in the Middle District of North Carolina, based on acts of alleged infringement that occurred in High Point, North Carolina.

ITI has moved the court to take judicial notice of other litigation involving KCI and third parties. The motion is granted, although these aspects do not affect our affirmance of the district court's judgment.

The district court held that subsequent events could not change the fact that no actual controversy existed at the time the original complaint was filed. The court observed that the existence of justiciable controversy is determined as of the time of the filing of the complaint, citing GAF Building Materials Corp. v. Elk Corp. of Dallas, 90 F.3d 479, 483 (Fed. Cir. 1996) ("[L]ater events may not create jurisdiction where none existed at the time of filing."). See Benitec Austl., Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1344 (Fed. Cir. 2007) ("The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since.").

On January 25, 2008 ITI filed an Amended Complaint, adding counts based on KCl's conduct subsequent to the filing of ITI's original complaint. The Amended Complaint included new counts for false advertising and unfair competition in violation of the Lanham Act, based on KCl's criticism of the Svedman device to potential customers, and requesting a declaration of ITI's unencumbered right to use and sell the Svedman device. KCl then filed another motion to dismiss for lack of declaratory judgment jurisdiction, or in the alternative to transfer the case to the Middle District of North Carolina. The district court observed that ITI's Amended Complaint was actually a "supplemental" complaint, which is the proper pleading when a party seeks to add issues based on events that occurred after the filing of the original complaint. See Fed. R. Civ. P. 15(d) (providing for "supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented"). The district court observed that ITI had not sought leave to file this pleading, as is required by Rule 15, but in the interest of "completeness" the court treated the Amended Complaint as if it were an authorized supplemental pleading.

The district court found that the later acts by KCI, including the filing of an infringement suit, showed that an actual controversy existed as of that later date. See Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 96 (1993) ("If . . . a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to support jurisdiction."). However, we agree with the district court that these acts after the filing of ITI's original complaint did not establish that an actual controversy existed at that earlier time. See Grupo Dataflux v. Atlas Global Group, L.P., 541 U.S. 567, 570-71 (2004) ("It has long been the case that the jurisdiction of the court depends upon the state of things at the time the action was brought.").

ITI argues that the district court erred when it evaluated whether a controversy existed at the time the original complaint was filed. ITI states that the date of the Amended Complaint provided the operative time, citing this court's recent decision in Prasco, 537 F.3d at 1337 ("As the district court accepted Prasco's Amended Complaint, it is the Amended Complaint that is currently under consideration, and it is the facts alleged in this complaint that form the basis of our review."). Prasco indeed focused on the allegations of the complaint as amended, but it did not thereby change the rule that unless there was jurisdiction at the filing of the original complaint, jurisdiction could not be carried back to the date of the original pleading. The district court observed that to hold otherwise "would invite a declaratory judgment plaintiff in a patent case to file suit at the earliest moment it conceives of any potential benefit to doing so, confident that it will either draw an infringement suit in response (thereby retroactively establishing jurisdiction over their first-filed declaratory judgment suit) or will suffer no adverse consequence other than having its suit dismissed." Innovative Therapies, No. 07-589-SLR/LPS, 2008 WL 2746960, at \*10 (D.

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Del. July 14, 2008).

Federal Rule of Civil Procedure 15(c) does not treat events that post-date the original pleading as if they had occurred at an earlier time. The district court so recognized when it treated the Amended Complaint as a supplemental, rather than amended, pleading. We discern no error in the district court's conclusion that ITI's supplemental complaint did not establish an actual controversy at the time of the original pleading, and that jurisdiction based on subsequent events did not relate back to the filing date of the initial complaint. KCI points out that its suits in the Middle District of North Carolina and in state court in Texas were filed before the supplemental complaint. See, e.g., Electronics for Imaging, Inc. v. Coyle, 394 F.3d 1341, 1347 (Fed. Cir. 2005) ("We apply the general rule favoring the forum of the first-filed case, unless considerations of judicial and litigant economy, and the just and effective disposition of disputes, requires otherwise."); Genentech, Inc. v. Eli Lilly & Co., 998 F.2d 931, 937 (Fed. Cir. 1993) ("The general rule favors the forum of the first-filed action, whether or not it is a declaratory action.").

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The district court also held that the case should be dismissed in the exercise of the court's discretion. See Wilton v. Seven Falls Co., 515 U.S. 277, 282 (1995) ("[D]istrict courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites."). The district court explained that ITI had used a ploy to attempt to generate jurisdiction through informal phone calls to past colleagues, and that this strategy did not comport with the purposes of the Declaratory Judgment Act. The district court did not abuse its discretion in observing that "where (as here) a declaratory

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judgment plaintiff was not willing to make its concerns of record pre-suit, I am not convinced that the objectives of the Declaratory Judgment Act are being served by allowing such a plaintiff to plead uncertainty and delay." The district court also observed that all of the issues raised by ITI were subject to resolution in the cases pending in Texas and North Carolina.

ITI argues that the district court abused its discretion. However, the discretion afforded to district courts to administer the declaratory judgment practice is broad. See id. at 287 (noting the "unique breadth" of district courts' declaratory discretion); Sony Elecs., Inc. v. Guardian Media Techs., Ltd., 497 F.3d 1271, 1288 (Fed. Cir. 2007) ("If a district court's decision is consistent with the purposes of the Declaratory Judgment Act and considerations of wise judicial administration, it may exercise its discretion to dismiss (or stay) the case."); EMC Corp. v. Norand Corp., 89 F.3d 807, 813-14 (Fed. Cir. 1996) (same). We discern no abuse of discretion in the district court's discretionary decision on the facts and circumstances of this case.

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ITI also argues that the district court committed legal error because it failed to apply the "convenience factors" of choice of forum, discussed in Micron as relevant to the exercise of declaratory jurisdiction. In Micron an infringement suit was filed the day after a declaratory judgment action was filed in a different forum, and this court ruled that the reasons whereby the district court dismissed the earlier-filed declaratory suit were insufficient. This court stated that "in cases such as this with competing forum interests, the trial court needs to consider the 'convenience factors' found in a transfer analysis under 28 U.S.C. §1404." 518 F.3d at 902-03.

Although Micron did not hold that forum convenience is the dominant consideration relevant to the court's exercise of discretion in every case, the convenience factors of this case do not weigh against the district court's dismissal. ITI is incorporated in Delaware, but its principal place of business is in Maryland. KCI is incorporated in Texas and has its principal place of business in Texas, the situs of the asserted state law violations. Codefendants KCI Licensing and KCI USA are incorporated in Delaware, but have their principal places of business in Texas. The Middle District of North Carolina is the home of Wake Forest University and the inventors of four of the five patents in suit, and is the forum in which the sole act of infringement is stated to have occurred. ITI's unfair competition count in its supplemental complaint is based on conduct that is asserted to have occurred in the Middle District of North Carolina. ITI has not stated that any party has any significant business operations in Delaware, nor that any witness resides in Delaware, nor that any conduct relevant to any aspect of the parties' dispute occurred there. We hence reject ITI's argument that the convenience of the forum requires retaining the action in Delaware, for the undisputed facts are incompatible with such a conclusion.

#### CONCLUSION

The district court did not clearly err in its findings concerning the factors on which ITI relied to support declaratory jurisdiction, and did not abuse its discretion in its decision to dismiss the declaratory action including the supplemental complaint. The dismissal is affirmed.

#### **AFFIRMED**