

# United States Court of Appeals for the Federal Circuit

02-1617, -1618

GEN-PROBE INCORPORATED,

Plaintiff-Cross Appellant,

v.

VYSIS, INC.,

Defendant-Appellant.

R. William Bowen, Jr., Gen-Probe Incorporated, of San Diego, California, argued for plaintiff-cross appellant. With him on the brief were Stephen P. Swinton, and

J. Christopher Jaczko, Cooley Godward LLP, of San Diego, California.

Jeffrey I. Weinberger, Munger, Tolles & Olson LLP, of Los Angeles, California argued for defendant-appellant. With him on the brief was Ted G. Dane.

Appealed from: United States District Court for the Southern District of California

Chief Judge Marilyn L. Huff

# United States Court of Appeals for the Federal Circuit

02-1617,-1618

GEN-PROBE INCORPORATED,

Plaintiff-Cross Appellant,

v.

VYSIS, INC.,

Defendant-Appellant.

---

DECIDED: March 5, 2004

---

Before RADER, Circuit Judge, ARCHER, Senior Circuit Judge, and GAJARSA, Circuit Judge.  
RADER, Circuit Judge.

After a jury trial, the United States District Court for the Southern District California entered judgment in favor of the declaratory judgment plaintiff, Gen-Probe. Among other rulings, the district court found that substantial evidence supported the jury's verdicts of noninfringement and invalidity for both obviousness and nonenablement. Gen-Probe, Inc. v. Vysis, Inc., No. 99-CV-2668 H (AJB) (S.D. Cal. Aug. 2, 2002). Vysis has appealed issues relating to subject matter jurisdiction, claim construction, noninfringement, obviousness, and nonenablement. Gen-Probe cross-appeals an issue relating to the priority date of the patent in suit. Because the district court and this court lack jurisdiction to hear the merits of the case, this court vacates the district court's judgment and remands the case to the district

court with instructions to dismiss.

## I.

Since the issuance of U.S. Patent No. 5,750,338 to Collins et al. (the '338 patent), Vysis or its corporate predecessor (collectively, Vysis) has owned the patent. This patent claims methods and kits for use in nucleic acid diagnostic assays. The claimed assays, among other things, test blood for DNA found in the HIV or hepatitis C viruses. The claims generally recite two steps: target capture and amplification. In the target capture step, a nucleic acid binds to a solid support, such as a particle or bead, allowing separation of the nucleic acid from the sample. In the amplification step, the method amplifies the captured nucleic acid to facilitate detection of particular DNA sequences. Although claiming priority on its face as early as October 1986, the '338 patent issued on May 12, 1998.

At the time the '338 patent issued, Vysis and Gen-Probe were involved in litigation regarding other patents. Shortly after the '338 patent issued, a Vysis employee orally informed a Gen-Probe employee that Gen-Probe might be infringing the '338 patent. Eight months later, Vysis's President and Chief Executive sent a letter to his counterpart at Gen-Probe. That letter stated: "Our interest continues to be to obtain resolution of all of the existing intellectual property issues at one time. . . . To that end, I would like to bring to your attention some additional, recently issued patent assets under our control which we believe Gen-Probe should find of interest." One of the identified patents was the '338 patent. After Gen-Probe responded, Vysis wrote back, announcing its awareness of Gen-Probe's "plans to develop blood screening technology to which [the '338 patent] may apply." In light of the overall circumstances, Gen-Probe detected a significant likelihood that it would be sued for infringement of the '338 patent. Accordingly, it decided to take a license to practice the '338 patent as a part of the overall settlement of the unrelated litigation.

On June 22, 1999, Vysis granted Gen-Probe a nonexclusive license to the '338 patent, its foreign counterparts, and any continuations, divisionals, reissues,<sup>[1]</sup> and reexaminations claiming priority to the '338 patent as well as two other related patents (collectively, the Collins Patents). This license, which also extended to Gen-Probe's alliances with third-parties, provided for a one-time,

upfront payment of \$1.5 million as well as a running royalty of 3% on sales of Gen-Probe's assays. Gen-Probe also enjoyed an option, if exercised within six months of the commencement of the license, to extend the license to its third-party allies in the assay market. As a fundamental part of the agreement, the license defined various terms, including "Licensed Method," "Valid Claim," and "Licensed Product." In particular, the license states:

1.2 The term Licensed Method shall mean any method, the use or practice of which would constitute, but for the license granted herein, an infringement of any issued, Valid Claim within the Collins Patents.

1.3 The term Valid Claim shall mean an issued claim of a Collins Patent which has not been ruled invalid by a court or an administrative agency of competent jurisdiction from which all appeals have been exhausted.

1.4 The term Licensed Product shall mean any of the following:

- (a) Any product specifically intended for use in practicing a Licensed Method;
- (b) Any product which lacks substantial use other than in practicing a Licensed Method; and
- (c) Any product, the making, using, selling, offering for sale or importing of which, would constitute, but for the license granted herein, an infringement of any issued, Valid Claim within the Collins Patents.

On December 22, 1999, Gen-Probe filed this declaratory judgment lawsuit, alleging that its tests did not infringe any claims of the '338 patent and that the '338 patent is invalid. Later Gen-Probe amended its complaint to include claims relating to unfair competition, unenforceability of the '338 patent, and a declaration of its rights and obligations under the license. Gen-Probe, however, continued paying the royalties due under the license agreement, albeit under protest.

In a letter to Vysis dated December 21, 1999, Gen-Probe not only exercised certain options relating to third-party alliances but also clearly set forth in the letter its intent to maintain the status quo by continuing to pay royalties throughout the litigation. Explaining its decision to hedge its bet, Gen-Probe wrote:

This letter concerns the June 22, 1999 agreement between Vysis and Gen-Probe concerning the Collins Patents. Since the date of that agreement, we have analyzed the Collins Patents. Based upon that analysis, we have concluded that the claims of the Collins Patents are invalid. Furthermore, we don't believe that any product made, used or sold by Gen-Probe, either individually or in conjunction with

others, infringes any claims [sic] of the patents that might ultimately be determined to be valid.

Based on our prior dealings and conversations, we understand that Vysis disputes those positions. Therefore, concurrently with the delivery to you of this letter, Gen-Probe is filing an action in the United States District Court seeking relief concerning the Collins Patents.

In order to preserve the status quo pending resolution of the litigation, Gen-Probe and Chiron Corp. have exercised the options [sic] . . . to extend the license to Gen-Probe and Chiron Corp. for purposes of their blood screening business. For the same reason, Gen-Probe and Bayer Corp. have exercised the option . . . to extend the license to Gen-Probe and Bayer Corp. for purposes of their infectious disease testing business.

Gen-Probe has participated in the exercise of the foregoing options not because we believe the patents are valid, but solely in order to preserve the status quo pending resolution of the litigation. Based on present circumstances, Gen-Probe and its allied parties expect to fulfill their obligations under the licenses during the pendency of the litigation.

Gen-Probe indeed fulfilled its obligations and continued paying royalties at all times relevant to this appeal.

In February 2002, Vysis filed a motion to dismiss the action for lack of subject matter jurisdiction. In support of this motion, Vysis argued in part that, as a licensee in good standing, Gen-Probe could not have had a reasonable apprehension of suit when it initiated this action. The district court disagreed, denying Vysis's motion and, thus, paving the way for a two-week jury trial in May 2002.

## II.

This court reviews a denial of a motion to dismiss for lack of subject matter jurisdiction without deference. Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 554 (Fed. Cir. 1990). Nevertheless, this court may not disturb factual findings, including those on a reasonable apprehension of suit, unless they are clearly erroneous. Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002). Any party or this court sua sponte may raise the question of subject matter jurisdiction. See Am. Fire & Cas. Co. v. Finn, 341 U.S. 6, 16-18 (1951).

Vysis argues that this case presents an unprecedented situation: a patent licensee in good standing has filed and fully litigated a declaratory judgment action that challenged the validity and scope of the licensed patent. Gen-Probe counters that this case is not truly groundbreaking because the

Declaratory Judgment Act authorizes a suit where the parties dispute the rights and obligations under the license and pay royalties only under protest.

The Declaratory Judgment Act only supports jurisdiction in the event of an “actual controversy.” 28 U.S.C. § 2201(a). This requirement effectuates Article III of the Constitution, which only authorizes the federal judiciary to hear justiciable cases and controversies. See EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996). “In general, the presence of an ‘actual controversy’ within the meaning of the statute depends on ‘whether the facts alleged, under all the circumstances, show . . . a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.’” Id. (quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)). Thus, “[t]he long established rule of law is that a declaratory judgment plaintiff must establish an actual controversy on the ‘totality of the circumstances.’” Spectronics Corp. v. H.B. Fuller Co., 940 F.2d 631, 634 (Fed. Cir. 1991). Indeed, the Supreme Court has noted the inherently fact-specific nature of the question of jurisdiction: “The difference between an abstract question and a ‘controversy’ contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy.” Md. Cas., 312 U.S. at 273. Through its cases, this court has developed a pragmatic inquiry that focuses on not only the conduct of the patentee but also the conduct of the putative infringer: “There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.” BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993). This court, therefore, must evaluate the totality of the circumstances in light of precedent to discern the presence or absence of an actual, and thus justiciable, controversy within the meaning of the Declaratory Judgment Act.

In this respect, the case that most closely approximates the present circumstances is C.R. Bard, Inc. v. Schwartz, 716 F.2d 874 (Fed. Cir. 1983). In Bard, this court noted: “[A] patent license need not be terminated before a patent licensee may bring a declaratory judgment action.” Id. at 875. Indeed,

this court evaluated the law of various circuits and rejected “the blanket approach . . . that there can never be an apprehension of a federal infringement suit and thus no controversy when a license is still in effect.” Id. at 880.

This court in Bard reached that judgment because the totality of circumstances showed an actual controversy between the declaratory judgment plaintiff and its licensor. In particular, the court identified two critical circumstances. In the first place, “Bard, the licensee, had ceased payment of royalties under the agreement to the licensor and patentee Schwartz.” Id. at 880-81. The cessation of royalties “was a material breach of the agreement that, under the very terms of the agreement, enabled Schwartz to terminate the agreement.” Id. at 881. Notably, that material breach granted Schwartz the power to file an infringement lawsuit against Bard at any time. That material breach, furthermore, precluded Bard from avoiding the lawsuit. In addition, “after Bard ceased payment of royalties, Schwartz filed suit in state court for recovery of the royalties.” Id. This court found that significant because “[i]nvolvement in that litigation shows a willingness by Schwartz to enforce his patent rights,” which “is a factor to be considered in determining whether there is a threat of an infringement suit.” Id.

These significant facts distinguish Bard from this case. Gen-Probe did not cease paying royalties and materially breach its license agreement with Vysis; Vysis did not file a breach of contract action. In fact, Gen-Probe was a licensee in good standing that continued paying royalties throughout the declaratory judgment lawsuit. In fact, Gen-Probe expressly acknowledged its desire to maintain the status quo and remain a faithful licensee. Moreover, Gen-Probe exercised options to extend the duration of the license for its alliances with Chiron and Bayer contemporaneously with its filing of the declaratory judgment lawsuit. Far from breaching its license agreement, Gen-Probe affirmatively confirmed its desire to remain in good standing.

These jurisdictional facts differ significantly from the jurisdictional facts in Bard. Accordingly, this court declines to extend Bard to the present situation. This court, therefore, must determine whether these different circumstances evince an actual controversy or call for an improper advisory opinion.

In finding an actual controversy, the district court relied on the oral notification, the letters regarding possible infringement of the '338 patent, and the history of litigation between these parties. Each of those facts, however, occurred before the consummation of the license agreement. Upon entering into the agreement, Vysis promised not to sue Gen-Probe. See Ortho Pharm. Corp. v. Genetics Inst., Inc., 52 F.3d 1026, 1031-32 (Fed. Cir. 1995); Spindelfabrik Suessen-Schurr Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft, 829 F.2d 1075, 1081 (Fed. Cir. 1987). In other words, the license insulated Gen-Probe from an infringement suit instituted by Vysis. Gart v. Logitech, Inc., 254 F.3d 1334, 1346 (Fed. Cir. 2001). This license, unless materially breached, obliterated any reasonable apprehension of a lawsuit based on the prior circumstances cited by the district court for jurisdiction. Fina Research, S.A. v. Baroid Ltd., 141 F.3d 1479, 1483-84 (Fed. Cir. 1998); Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058 (Fed. Cir. 1995). Accordingly, once Gen-Probe and Vysis formed the license, an enforceable covenant not to sue, the events that led to the formation became irrelevant. Since the formation of the license, Gen-Probe and Vysis have each fulfilled their obligations without material breach. The record discloses no facts that have arisen since the license to give Gen-Probe a reasonable apprehension of a lawsuit. Thus, no record evidence supports the district court's finding that Gen-Probe suffered under a reasonable apprehension of a lawsuit.

The district court also relied on Lear, Inc. v. Adkins, 395 U.S. 653 (1969), wherein the Supreme Court explained that a license does not alone bar the licensee from challenging the validity of a patent. See, e.g., Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368 (Fed. Cir. 2001). The Lear doctrine, however, does not grant every licensee in every circumstance the right to challenge the validity of the licensed patent. In several instances, this court has declined to apply the Lear doctrine. Id. at 1368-70; Studiengesellschaft Kohle m.b.H. v. Shell Oil Co., 112 F.3d 1561, 1567-68 (Fed. Cir. 1997); Foster v. Hallco Mfg. Co., 947 F.2d 469, 476-77 (Fed. Cir. 1991); Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 991-93 (Fed. Cir. 1989), overruled on other grounds by A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992); Hemstreet v. Spiegel, Inc., 851 F.2d 348, 350-51 (Fed. Cir. 1988); Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220, 1224-25 (Fed. Cir. 1988).

Among these clarifications of the Lear principle, Shell Oil is particularly relevant, though not factually identical, to this case. In Shell Oil, this court decided that a licensee is liable for unpaid royalties that accrued under the terms of the license before invalidation of the subject patent's claims. While that case did not discuss jurisdiction under the Declaratory Judgment Act, this court stated: "[A] licensee . . . cannot invoke the protection of the Lear doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid." Shell Oil, 112 F.3d at 1568. This language posits that a licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent.

Gen-Probe asserts that the absence of material breach is irrelevant. Instead it argues that its payment of royalties under protest was sufficient to create an actual controversy. In support of this contention, Gen-Probe cites Altwater v. Freeman, 319 U.S. 359 (1943). Altwater, however, does not stand for the general proposition that any licensee may challenge the patent subject to the license in a declaratory judgment so long as it pays royalties under protest. The royalty payments in Altwater were paid not under the terms of a license agreement; rather, they were paid "under the compulsion of an injunction decree." Id. at 365. Indeed, Altwater expressly refused to decide whether "a licensee is estopped to challenge the validity of a patent." Id. at 364. Lear, of course, later decided that question. Thus, Altwater simply does not inform this court's search for a reasonable apprehension of suit in the face of a valid and operable covenant not to sue. In sum, Gen-Probe has shown no actual controversy in this case and thus no facts supporting jurisdiction.

Gen-Probe further argues that the Declaratory Judgment Act facilitates a determination of rights and obligations before either party breaches the agreement. In support, Gen-Probe cites the following language in Aetna Life Insurance Co. v. Haworth, 300 U.S. 227, 242 (1937): "Such a [contractual] dispute is manifestly susceptible of judicial determination. It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts." While this language suggests that a litigant may sue to determine contract rights before a breach, this 1937 Supreme Court case did not involve a declaratory judgment action instituted by a patent licensee in

good standing. Rather, an actual controversy arose between an insured and his insurance company over the refusal to pay disability benefits. Because the insured believed that his beneficiary was entitled to the disability benefits, he ceased paying the premiums. As a result, the insurer sought to nullify the policies for nonpayment of the premiums. Thus, the insurer identified an actual controversy “as to existence of the total and permanent disability of the insured and as to the continuance of the obligations asserted despite the nonpayment of premiums.” *Id.* at 239. The Supreme Court agreed and held that the controversy was indeed justiciable. *Id.* at 244. Gen-Probe does not cite any declaratory judgment contract case in which the totality of circumstances is even remotely similar or analogous to those in this case. In fact, this court has considered Gen-Probe’s other arguments but finds none persuasive.

Moreover, permitting Gen-Probe to pursue a lawsuit without materially breaching its license agreement yields undesirable results. Vysis voluntarily relinquished its statutory right to exclude by granting Gen-Probe a nonexclusive license. In so doing, Vysis chose to avoid litigation as an avenue of enforcing its rights. Allowing this action to proceed would effectively defeat those contractual covenants and discourage patentees from granting licenses. In other words, in this situation, the licensor would bear all the risk, while licensee would benefit from the license’s effective cap on damages or royalties in the event its challenge to the patent’s scope or validity fails.

Under these circumstances, there is not a reasonable apprehension of suit. Therefore, this court holds that no actual controversy supports jurisdiction under the Declaratory Judgment Act for Gen-Probe’s suit against Vysis over the ’338 patent. Accordingly, this court vacates the district court’s judgment and remands with instructions to dismiss.

#### COSTS

Each party shall bear its own costs.

VACATED and REMANDED

---

[1] Two months after the district court entered final judgment, the United States Patent and Trademark Office reissued the '338 patent as United States Reissue Patent No. RE 37,891. Although superseding the '338 patent, the reissue patent is irrelevant to the disposition of this case.