

# United States Court of Appeals for the Federal Circuit

2009-1094

ASYMMETRX, INC.,

Plaintiff-Appellant,

v.

BIOCARE MEDICAL, LLC,

Defendant-Appellee.

Steven M. Bauer, Proskauer Rose, LLP, of Boston, Massachusetts, argued for plaintiff-appellant. Of counsel was Amy Crafts.

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

Judge Richard G. Stearns

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ASYMMETRX, INC.,

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Appeal from the United States District Court for the District of Massachusetts  
in Case No. 07-CV-11189, Judge Richard G. Stearns.

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DECIDED: September 18, 2009

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Before LOURIE, RADER, Circuit Judges, and CLARK, District Judge.<sup>\*</sup>

LOURIE, Circuit Judge.

AsymmetRx, Inc. (“AsymmetRx”) appeals from the final judgment of the United States District Court for the District of Massachusetts granting summary judgment in favor of Biocare Medical, LLC (“Biocare”). AsymmetRx, Inc. v. Biocare Med. LLC, 578 F. Supp. 2d 333 (D. Mass. 2008). Because we conclude that AsymmetRx does not have statutory standing to pursue this action absent the participation of the President and Fellows of Harvard College (“Harvard”), we vacate and remand.

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<sup>\*</sup> Honorable Ron Clark, District Judge, United States District Court for the Eastern District of Texas, sitting by designation.

## BACKGROUND

The dispute in this case is over the rights to anti-p63 monoclonal antibodies (the “p63 antibodies”), which can be used to detect malignant carcinoma, such as cervical, breast, and prostate cancer. Harvard owns U.S. Patents 6,946,256 (“the ’256 patent”) and 7,030,227 (“the ’227 patent”) by assignment. The patents relate to the p63 antibodies and methods for using them to detect malignant carcinoma.

In May 2002, Biocare approached Harvard seeking to license the p63 antibodies. Later that year, Harvard entered into a Biological Materials License Agreement with Biocare (“the Biocare License”), effective October 15, 2002, to make, use, and sell the p63 antibodies. Section 2.5 of the Biocare License stated, “The license granted by this Agreement does not include a license under any U.S. or foreign patents.” The ’256 and ’227 patents were pending but had not issued prior to the effective date of the Biocare License.<sup>1</sup> The Biocare License also defined a limited field of use, the life science research market, but did not actually limit the license grant to that field.

A few years later, Harvard entered into an agreement with AsymmetRx (the “AsymmetRx License”), effective June 30, 2004, that also concerned the p63 antibodies. Under the AsymmetRx License, AsymmetRx received “an exclusive commercial license” under the ’256 and ’227 patents and “a license” to use the p63 antibodies. The grant under the AsymmetRx License was limited to a field defined as the “[s]ale of clinical and diagnostic products and services based on detecting p63

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<sup>1</sup> U.S. Patent Application 09/538,106 was filed March 29, 2000, and issued as the ’256 patent on September 20, 2005. U.S. Patent Application 09/526,583 was filed April 22, 1999, and issued as the ’227 patent on April 18, 2006.

expression or mutation.”<sup>2</sup> Under § 3.2(b) of the AsymmetRx License, Harvard reserved the right to make and use the p63 antibodies for academic research purposes as well as the right to grant non-exclusive licenses for the p63 antibodies to other non-profit or governmental institutions for academic research purposes. In addition, §§ 3.2(d) and (e) stated that Harvard could render the AsymmetRx License non-exclusive if AsymmetRx did not meet certain benchmarks in terms of commercial use and availability to the public within three years or if AsymmetRx did not meet certain FDA filing milestones. Sections 3.4(f) and (g) indicated that, although AsymmetRx could grant sublicenses, the sublicensees could not further sublicense, and Harvard could suggest who received a sublicense; § 4.4 stated that AsymmetRx was to pay a portion of the sublicense income to Harvard. Section 3.4(h) required AsymmetRx, during the period of exclusivity in the United States, to manufacture any licensed product produced for sale in the United States substantially in the United States unless a waiver was obtained by the U.S. National Institutes of Health.

In terms of patent filing and maintenance, § 7.2 specified that Harvard and AsymmetRx were to cooperate fully in the preparation, filing, prosecution, and maintenance of Harvard’s patents “so as to enable Harvard to apply for, to prosecute and to maintain patent applications in patents in Harvard’s name in any country.” With respect to infringement of the patents, § 8.1 gave AsymmetRx “the right to prosecute in

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<sup>2</sup> A later amendment to the AsymmetRx License expanded the license grant to all other fields of use. The parties dispute whether the amendment is properly on the record before us. Although some numbering changed, the provisions of the AsymmetRx License relating to the commercial diagnostic field relied upon herein were unchanged in substance. Thus, we do not consider the amendment in reaching our decision. All section numbers used in this opinion refer to the non-amended AsymmetRx License.

its own name and at its own expense any infringement” within the commercial diagnostic field, so long as AsymmetRx still had an exclusive license at the time the action was commenced. Before commencing such an action, AsymmetRx was to “give careful consideration to the views of Harvard and to potential effects on the public interest in making its decision whether or not to sue.” If AsymmetRx did commence such an action, § 8.2 stated that Harvard “may, to the extent permitted by law, elect to join as a party in that action.” If Harvard joined such an action, Harvard and AsymmetRx jointly controlled that action. Under § 8.4, no settlement, consent judgment, or other voluntary final disposition of such an infringement suit could be entered into without the prior written consent of Harvard, which was not to be unreasonably withheld. In addition, § 8.6 of the AsymmetRx License provided,

If LICENSEE elects not to exercise its right to prosecute an infringement of the PATENT RIGHTS pursuant to this Article, HARVARD may do so at its own expense, controlling such action and retaining all recoveries therefrom. LICENSEE shall cooperate fully with HARVARD in connection with any such action.

On June 27, 2007, AsymmetRx sued Biocare for patent infringement, alleging that Biocare's sale of the p63 antibodies violated AsymmetRx's exclusive rights in the commercial diagnostic field.<sup>3</sup> Biocare countered that the Biocare License placed no restrictions on the scope of Biocare's sales. The parties made cross-motions for summary judgment. The parties agreed that the issue before the district court involved matters of pure contract interpretation.

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<sup>3</sup> AsymmetRx also sued four other defendants to whom Harvard had previously granted limited, non-exclusive licenses in the research market. AsymmetRx has settled with all defendants except for Biocare.

On September 29, 2008, the district court granted Biocare's motion for summary judgment. First, the court found that the Biocare License was not limited to the life sciences research market. Second, the court found that § 2.5 of the Biocare License excluded only rights to any materials covered by patents already in existence when Biocare received its License. For support, the court pointed to the breadth of the definition of "Know-How," which specified all information disclosed by Harvard, "whether or not patentable"; how the Biocare License remained in effect as long as the licensed products were sold; how the Biocare License did not include the later issuance of a patent as a terminating event or reference any pending patents; and how the issuance of the patents had no effect on the course of dealing between Biocare and Harvard under the Biocare License. In the alternative, the court found that Biocare had an implied license to sell the p63 antibodies in the diagnostic market under the doctrine of equitable estoppel. The court reasoned that Biocare had justifiably relied on what the court deemed to be Harvard's acquiescence in Biocare's understanding of its rights under the Biocare License, notwithstanding the after-acquired patents. Thus, the court denied AsymmetRx's motion for partial summary judgment and granted Biocare's motion for summary judgment.

On September 20, 2008, final judgment was entered in favor of Biocare. On October 29, 2008, AsymmetRx filed a timely appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## DISCUSSION

The parties to this appeal have focused on whether the district court properly interpreted the language of the Biocare License in finding that Biocare did not infringe any patent rights of AsymmetRx. We believe, however, that this appeal must be resolved by addressing an antecedent question: **whether AsymmetRx had the statutory right to bring an action for infringement without joining the patent owner, Harvard.** Because we find that AsymmetRx may pursue its infringement action against Biocare only if Harvard also participates in that action, we conclude that **the district court's decision must be vacated.**

The issue of AsymmetRx's standing to bring suit without Harvard joining as a plaintiff was not raised by either party or by the district court. However, an appellate court must satisfy itself that it has standing and jurisdiction whether or not the parties have raised them. See Mentor H/S, Inc. v. Med. Device Alliance, Inc., 240 F.3d 1016, 1018 (Fed. Cir. 2001). If standing and jurisdiction of a trial court are lacking, an appellate court may vacate a decision that was rendered on the merits at the trial level or, in rare instances, order joinder of a necessary party at the appellate level. See Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1381 (Fed. Cir. 2000) (reversing and vacating a decision on the merits for lack of standing and stating that the exercise of this court's authority to join a party at the appellate level should be used "sparingly"). Here, because neither party asserts that Harvard should be joined in this action at this point in the case, we vacate and remand.

A civil action for infringement may be brought by "a patentee." 35 U.S.C. § 281. A "patentee" is defined by statute to include the party to whom the patent was issued

and the successors in title to the patent. 35 U.S.C. § 100(d). Accordingly, a suit for infringement ordinarily must be brought by a party holding legal title to the patent. See Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1130 (Fed. Cir. 1995). Parties not holding title to the patent have been accorded the right to sue, or “standing,” only in certain limited circumstances.

In Waterman v. Mackenzie, 138 U.S. 252 (1891), the Supreme Court addressed the question of standing to sue for infringement. The Court stated that an assignment by the patent owner of the whole of a patent, an undivided part or share of the patent right, or all rights in a specified part of the United States gave an assignee the right to bring an infringement action in his own name. See id. at 255. “Any assignment or transfer, short of one of these, is a mere license, giving the licensee no title in the patent, and no right to sue at law in his own name for an infringement.” Id. In the case of a license only,

the title remains in the owner of the patent; and suit must be brought in his name, and never in the name of the licensee alone, unless that is necessary to prevent an absolute failure of justice, as where the patentee is the infringer, and cannot sue himself. Any rights of the licensee must be enforced through or in the name of the owner of the patent, and perhaps, if necessary to protect the rights of all parties, joining the licensee with him as a plaintiff.

Id. The Court also stated that whether a transfer of a particular right or interest was an assignment or license did not depend on the name applied to it, but on the intention of the parties as revealed by the record. See id.

The reasoning of Waterman was applied in Independent Wireless Telegraph Co. v. Radio Corp. of America, 269 U.S. 459 (1926), when the Court rejected the argument that an exclusive licensee could sue for infringement without joining the patent owner.



The Court held that the participation of the patent owner “as a party is indispensable not only to give jurisdiction under the patent laws, but also in most cases to enable the alleged infringer to respond in one action to all claims of infringement for his act.” Id. at 468. The court noted an exception to this rule: “If the owner of a patent, being within the jurisdiction, refuses or is unable to join an exclusive licensee as co-plaintiff, the licensee may make him a party defendant by process and he will be lined up by the court in the party character which he should assume.” Id. Before this exception to joining the patentee can be applied, the patentee must be given the opportunity to join the infringement action. Id. at 473-74. Thus, as summarized in Abbott,

The right to sue for infringement is ordinarily an incident of legal title to the patent. A licensee may obtain sufficient rights in the patent to be entitled to seek relief from infringement, but to do so, it ordinarily must join the patent owner. And a bare licensee, who has no right to exclude others from making, using, or selling the licensed products, has no legally recognized interest that entitles it to bring or join an infringement action.

47 F.3d at 1131.

Under Waterman and its successors, the critical determination regarding a party’s ability to sue in its own name is whether an agreement transferring patent rights to that party is, in effect, an assignment or a mere license. To determine whether an assignment of patent rights was made, we must “examine whether the agreement transferred all substantial rights” to the patents and “whether the surrounding circumstances indicated an intent to do so.” Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 874 (Fed. Cir. 1991).

We have stated that the exclusive right to sue is “particularly dispositive” in cases where, as here, we are deciding whether a patent owner must be joined as a party. Vaupel, 944 F.2d at 875; see also Abbott, 47 F.3d at 1132 (discussing Vaupel).

Accordingly, we found in Abbott that the patent owner had retained too great an interest in the patents to enable the licensee to sue for infringement on its own. Those interests included “a limited right to make, use, and sell products embodying the patented inventions, a right to bring suit if [the licensee] declined to do so, and the right to prevent [the licensee] from assigning its rights under the license to any party other than a successor in business.” Abbott, 47 F.3d at 1132. More specifically, the agreement stated that if the patent owner asked the licensee to bring suit against an alleged infringer and the licensee declined to do so, the patent owner had the right to bring its own infringement action. Thus, although the licensee had the option to initiate a suit for infringement, “it [did] not enjoy the right to indulge infringements, which normally accompanies a complete conveyance of the right to sue.” Id. In addition, even if the licensee did exercise its option to sue for infringement, it was “obligated under the agreement not to ‘prejudice or impair the patent rights in connection with such prosecution or settlement.’” Id.

In contrast, the right to sue was granted in its entirety in Vaupel, subject only to the obligation to inform the patent owner of the existence of the suit. See Vaupel, 944 F.2d at 875. The only rights under the patent that the patent owner retained were a veto right on sublicensing, the right to obtain patents on the invention in other countries, a reversionary right in the patent in the event of bankruptcy, and a right to receive infringement damages. In light of the complete transfer of the right to sue for infringement, we found that the retained rights were not so substantial as to reduce the transfer of patents rights to a mere license, as they did not substantially interfere with the full use of the exclusive rights under the patent and were thus not inconsistent with

an assignment. See id. Similarly, in Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245 (Fed. Cir. 2000), we distinguished Abbott and found that a licensee had standing because “the license grant was not subject to any prior-granted licenses or to any retained rights by the licensor to practice the patent.” Speedplay, 211 F.3d at 1251. Significantly, the license in Speedplay did not grant the original patent owners “the right to participate in an infringement action brought by [the licensee], nor [did] it limit [the licensee’s] management of any action,” in contrast to the agreement in Abbott. Id. (distinguishing Abbott). In addition, and unlike in Abbott, a clause allowing the patent owners to bring their own infringement action if the licensee failed to do so within three months was an “illusory” retention of the right to sue because the licensee could “render that right nugatory by granting the alleged infringer a royalty-free sublicense.” Id. (distinguishing Abbott). Thus, in both Vaupel and Speedplay, the transfer was as if title had passed, at least for the purposes of standing to sue. See Morrow v. Microsoft Corp., 499 F.3d 1332, 1340 (Fed. Cir. 2007) (“[I]f a patentee transfers all substantial rights to the patent, this amounts to an assignment or a transfer of title, which confers constitutional standing on the assignee to sue for infringement in its own name alone.” (internal quotation and footnote omitted)).

This case is more similar to Abbott than to Vaupel or Speedplay in terms of what rights Harvard retained under the patents. Although the AsymmetRx License effected a broad conveyance of rights to AsymmetRx, Harvard retained substantial interests under the '256 and '227 patents, including the right to sue for infringement, and AsymmetRx therefore does not have the right to sue for infringement as a “patentee” under the patent statute.

Under the AsymmetRx License, Harvard also retained the right to make and use the p63 antibodies for its own academic research purposes, as well as the right to provide the p63 antibodies to non-profit or governmental institutions for academic research purposes. In addition, Harvard retained a great deal of control over aspects of the licensed products within the commercial diagnostic field, such as requiring AsymmetRx to meet certain commercial use, availability, and FDA filing benchmarks; specifying that manufacture had to take place in the United States during the period of exclusivity; and maintaining input on sublicensing and receiving a share of those royalties. AsymmetRx was required to grant sublicenses suggested by Harvard, provided they were not contrary to sound and reasonable business practices and materially increased the availability to the public of the licensed products. The agreement also specified that AsymmetRx was to cooperate with Harvard to maintain the patent rights, so as to enable Harvard to apply for, to prosecute, and to maintain patent applications and patents in Harvard's name. Retention of all of those rights is inconsistent with an assignment of the patents. See Abbott, 47 F.3d at 1132 (discussing the patent owner's retention of "the right to make and use, for its own benefit, products embodying the inventions claimed in the patents").

Moreover, although AsymmetRx was given the right of first refusal in suing alleged infringers, the AsymmetRx License provides that if AsymmetRx elects not to exercise its right to sue, Harvard has the right to bring its own infringement action. Thus, as in Abbott, although AsymmetRx has the option to initiate suit for infringement, "it does not enjoy the right to indulge infringements, which normally accompanies a complete conveyance of the right to sue." Abbott, 47 F.3d at 1132. In addition, even if

AsymmetRx exercises its option to sue for infringement, it is obligated under the AsymmetRx License to consider Harvard's views and the public interest, and Harvard's approval is necessary for any settlement of suit. Such consideration of Harvard's views is akin to the licensee in Abbott being required "not to 'prejudice or impair the patent rights in connection with such prosecution or settlement.'" Id. Finally, if AsymmetRx does commence an infringement action, Harvard may elect to join as a party in that action and, if Harvard does join such an action, it jointly controls the suit with AsymmetRx. In short, Harvard did not convey the entire right to enforce the patents to AsymmetRx. When viewing the retention of the right to sue in conjunction with all of the other rights retained by Harvard, it is clear that Harvard conveyed less than all substantial rights under the '256 and '227 patents. While any of these restrictions alone might not have been destructive of the transfer of all substantial rights, their totality is sufficient to do so.

The provisions of the AsymmetRx License may all have met the respective needs of the parties; after all, they negotiated and executed the agreement. They may also reflect the perceived needs of a university attempting to balance the public interest with commercializing the results of its professors' research. Be that as it may, in attempting to meet these goals, the contractual result is that Harvard retained substantial control over the patent rights it was exclusively licensing, such that its agreement with AsymmetRx did not convey all substantial rights under the patents and thus did not make the license tantamount to an assignment. AsymmetRx must therefore be considered a licensee, not an assignee. Under Waterman and its successors, AsymmetRx does not have a sufficient interest in the '256 and '227 patents

to sue, on its own, as the “patentee” entitled by 35 U.S.C. § 281 to judicial relief from infringement. Harvard, by retaining the various rights to its patents, must join in any infringement suit its licensee chooses to bring.

Furthermore, the policies underlying Federal Rule of Civil Procedure 19, the federal joinder rule, argue for Harvard's joinder in this case. Rule 19(a) provides that a person who can be joined as a party should be joined if (1) the person's absence would make it impossible to grant complete relief to the parties, or (2) the person claims an interest in the subject matter of the action and is so situated that the disposition of the action in his absence could impede his ability to protect that interest or leave any of the parties subject to a substantial risk of incurring multiple inconsistent obligations. Harvard obviously retains an interest in the patents, and the disposition of AsymmetRx's suit against Biocare could either prejudice Harvard's interests or expose Biocare to the risk of multiple litigations. This is especially true because the Biocare License provides that, upon reasonable notice by Biocare, Harvard is obligated to help Biocare defend against any infringement suit by a third party. Harvard, by granting licenses to two parties involving the same subject matter, has potentially put itself in the conflicting position of having to aid two licensees opposed to each other. Complicating matters is the fact that Harvard is continuing to accept royalty payments from Biocare resulting from sales in the commercial diagnostic market that AsymmetRx asserts are infringing its patent rights. If anything, this added complication indicates that the purpose of Rule 19 to avoid multiple suits or incomplete relief arising from the same subject matter is best served by joinder of Harvard, which would permit the relationships between

AsymmetRx, Biocare, and Harvard to all be resolved at the same time as well as solve the standing problem.

That is not to say that if Harvard declines to participate voluntarily, the action cannot go forward. “A patentee that does not voluntarily join an action prosecuted by its exclusive licensee can be joined as a defendant or, in a proper case, made an involuntary plaintiff if it is not subject to service of process.” Abbott, 47 F.3d at 1133 (citing Fed. R. Civ. P. 19(a); Indep. Wireless Tel. Co., 269 U.S. at 268-74; Phila. Brief Case Co. v. Specialty Leather Prods. Co., 145 F. Supp. 425 (D.N.J. 1956), aff’d, 242 F.2d 511 (3d Cir. 1957)). For the purposes of this case, we need not decide the nature of Harvard’s participation, as it is unclear whether Harvard was ever given the opportunity to join the action at the district court. We thus conclude that Harvard did not convey all substantial rights under the ’256 and ’227 patents to AsymmetRx in the AsymmetRx License, and, as a result, AsymmetRx lacks statutory standing, on its own, to bring an infringement suit against Biocare.

### CONCLUSION

For the foregoing reasons, the grant of summary judgment by the district court is vacated, and the case is remanded to the district court for further proceedings in accordance with this opinion.

VACATED and REMANDED