

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

ABBOTT LABORATORIES, ABBOTT LABORATORIES, INC., and ABBOTT PHARMACEUTICALS PR LTD,)	
)	
Plaintiffs,)	
)	No. 05 C 5373
v.)	
)	
SANDOZ, INC.,)	JUDGE DAVID H. COAR
)	
Defendant.)	

MEMORANDUM OPINION AND ORDER

Defendant Sandoz, Inc. (“Defendant” or “Sandoz”) moves this Court to dismiss Plaintiffs Abbott Pharmaceuticals PR LTD (“APL”) and Abbott Laboratories, Inc. (“ALI”) for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(h)(3). Sandoz claims that neither APL nor ALI has standing to bring a patent infringement claim. In the alternative, Sandoz moves *in limine* for the exclusion of evidence relating to ALI’s and APL’s alleged lost profits at trial. For the reasons stated below, both of Sandoz’s motions are DENIED.

BACKGROUND

Abbott Laboratories (“Abbott Labs”) filed suit against Sandoz on September 16, 2005, seeking a declaratory judgment that Sandoz’s extended-release clarithromycin formulation would infringe its patents related to Biaxin XL. The complaint sought only declaratory relief because, at the time that it was filed, Sandoz had not yet begun selling its product. Once Sandoz began selling its product in December 2006, Abbott Labs moved to preliminarily enjoin these sales. The Court granted Abbott Labs’s motion on April 16, 2007. *Abbott Labs. v. Sandoz, Inc.*, 500 F.Supp.2d 807 (N.D. Ill. 2007).

Abbott Labs then sought leave to amend its complaint by adding claims for damages related to Sandoz's sale of its product between December 2006 and April 2007. The Court granted Abbott Labs's motion for leave to amend its complaint on June 13, 2007, and on July 25, 2007, the Court also granted Abbott Labs's subsequent motion for leave to amend its complaint to add ALI and APL as co-plaintiffs.

On May 7, 2008, Sandoz filed the instant motion to dismiss ALI and APL for lack of standing, or in the alternative, to exclude evidence of either Plaintiff's alleged lost profits at trial.

LEGAL STANDARD

Under Fed. R. Civ. P. 12(h)(3), "[i]f the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." The question of standing is jurisdictional, *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1551 (Fed. Cir. 1995), and it may be raised by the parties or the court at any stage in the litigation. *Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1367 (Fed. Cir. 2003).

ANALYSIS

Sandoz argues that neither ALI nor APL is an exclusive licensee of the patents at issue, and therefore neither has standing to collect damages for patent infringement. Standing to sue for patent infringement derives from the Patent Act, which provides that the patentee, or his successors in interest, "shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 100(d). Under some circumstances, courts have held that a licensee's interest in a patent is sufficient to confer standing on the licensee to sue for infringement. *Rite-Hite Corp.*, 56 F.3d at 1552. To acquire standing, a licensee usually must be an "exclusive" licensee, meaning that it "received, not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention

within that territory as well.” *Id.* In contrast to “exclusive” licensees, “bare” licensees have no standing to bring patent infringement claims. *Textile Prod., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998). The legal categorization of a licensee as “exclusive” or “bare” depends on “the intent of the parties to the license as manifested by the terms of their agreement and examining the substance of the grant. The use of the word ‘exclusive’ is not controlling; what matters is the substance of the arrangement.” *Id.*

Sandoz contends that neither ALI nor APL has standing to sue because neither is an exclusive licensee of the patents-in-suit. It is undisputed that Abbott Labs is the assignee of the ‘718 and ‘616 patents, which relate to its product, Biaxin XL. The crux of Sandoz’s argument, however, is that Abbott Labs appointed ALI exclusive distributor of Biaxin XL eight years before it conferred the same right to APL, and therefore neither possesses an exclusive license. Sandoz also contends that Abbott Labs entered into another license agreement involving the same patents with Teva Pharmaceuticals U.S.A., Inc. (“Teva”), further demonstrating that ALI’s and APL’s licenses are non-exclusive.

Sandoz is incorrect, both legally and factually. As an initial matter, Sandoz glosses over the nuances in the relationship between Abbott Labs, ALI, and APL, and it therefore misconstrues each entity’s rights to the patents-in-suit for the purposes of standing. In its motion, Sandoz focuses entirely on two agreements: (1) the 1998 Distribution Agreement between Abbott Labs and ALI (Def. Mem., Ex. F) and (2) the 2004 License and Sublicense Agreement between Abbott Labs and APL (Def. Mem., Ex. I). Sandoz argues that the 1998 agreement gave ALI the exclusive right to sell Biaxin XL under the ‘718 and ‘616 patents in the United States, and the 2004 agreement purported to give the same “exclusive” right to APL. According to Sandoz, the 2004 agreement could not have provided APL with an exclusive

license to sell Biaxin XL in the United States since Abbott Labs had already granted that same right to ALI.

In fact, three agreements govern the relationship between Abbott Labs, ALI, and APL. Contrary to Sandoz's assertion, the 1998 agreement between Abbott Labs and ALI did not explicitly provide ALI with exclusive distribution rights for Biaxin XL. Nor did the agreement expressly license any patent rights at all. Through this agreement, Abbott Labs appointed ALI, its wholly-owned subsidiary, as its exclusive United States distributor for certain "products," which are defined broadly as "such quantities of products requested by [Abbott Labs]" for sale to ALI. (Def. Mem., Ex. F at ABBOTT295677.) When Abbott Labs and ALI executed this agreement in January 1998, Biaxin XL was not yet available for sale, and neither of the patents-in-suit had issued. According to Plaintiffs, Abbott Labs began distributing Biaxin XL in the United States through ALI in 2000.

When APL was formed in 2004, Abbott Labs and APL entered into two contemporaneous agreements. In its motion, Sandoz addresses only one of these agreements: the "License and Sublicense Agreement," which was executed by Abbott Labs and APL on December 1, 2004. (Def. Mem., Ex. I.) Through this agreement, Abbott Labs granted APL an "exclusive license under the Abbott Patents to make, have made, use and sell the Products" in the United States. (*Id.* ¶ 2.01(a) at ABBOTT341612.) The license defines the "Abbott Patents" to include the patents-in-suit and "Products" to include Biaxin XL. (*Id.* at ABBOTT341620.) Significantly, the license expressly states that it is exclusive even as to Abbott Labs and its affiliates. (*Id.* ¶ 2.01(a) at ABBOTT341612.)

Simultaneously with this agreement, Abbott Labs and APL formed another agreement, which Sandoz fails to acknowledge in its motion. Under this agreement, entitled "Distribution

Agreement,” APL granted back to Abbott Labs “an exclusive right during the Terms of this Agreement to purchase the Products for resale” in the United States. (Pl. Br., Ex. 1 ¶ 2.01 at ABBOTT238405.) “Products” are defined to include Biaxin XL. (*Id.* at ABBOTT238418.) Plaintiffs construe this arrangement as an exclusive sub-license from APL to Abbott Labs for the right to sell Biaxin XL in the United States. According to Plaintiffs, since the express purpose of Abbott Labs’s exclusive right to purchase Biaxin XL was for resale in the United States, implicit in this arrangement was an exclusive sub-license from APL to Abbott Labs of the right to sell the product in the United States.

Functionally, as a result of these three agreements, APL has served as the exclusive manufacturer of Biaxin XL, and ALI has served as the exclusive distributor of Biaxin XL in the United States. APL has not sold Biaxin XL in the United States to any third parties, and Abbott Labs has obtained all of its supply of the product from APL since 2004. (Pl. Br., Ex. 2, Novak Dep. 66:8-10, 84:14-22.) Abbott Labs, in turn, distributes Biaxin XL in the United States exclusively through ALI; no entity other than ALI sells Biaxin XL in the United States.

This brief description of the three agreements governing the relationship between Abbott Labs, ALI, and APL reveals two key flaws in Sandoz’s understanding of the parties’ rights with respect to the patents at issue. First, Sandoz fails to recognize that APL unquestionably holds an exclusive right to manufacture Biaxin XL. Second, ALI’s right to sell Biaxin XL in the United States flows from APL, not merely from Abbott Labs. Once Abbott Labs granted APL a license to make, use, and sell Biaxin XL, APL granted the right to sell Biaxin XL back to Abbott Labs, which in turn, sub-licensed that right to ALI through the two parties’ longstanding distribution agreement.

These two points bear significantly on the analysis of whether ALI and APL are exclusive licensees for the purposes of obtaining standing to participate in the instant patent infringement suit. To meet the definition of an “exclusive” licensee, a licensee must be “a beneficial owner of some identifiable part of the patentee’s bundle of rights to exclude others.” *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1032 (Fed. Cir. 1995). The licensee must hold *some*, but not necessarily *all* of the proprietary sticks in the bundle, and similarly, it need “only be able to exclude ‘others,’ not *all* others.” *Ropak Corp. v. Plastikan, Inc.*, No. 04-C-5422, 2005 WL 2420384, at *2-3 (N.D. Ill. Sept. 30, 2005) (citing *Ortho Pharm.*, 52 F.2d at 1032) (emphasis in original); *Hill Phoenix Inc. v. Systematic Refrigeration, Inc.*, 117 F.Supp.2d 508, 512 (E.D. Va. 2000) (“The Federal Circuit has never stated that the licensee must have the right to exclude *all* others.”). With respect to the proprietary rights necessary to acquire standing, “[a] licensee can be deemed exclusive where the license pertains to less than all . . . of the rights granted under the patent, such as where the licensee has obtained only the exclusive right to *sell* the patented invention.” *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 808 F.Supp. 894, 900 (D. Mass. 1992). A licensee with only the exclusive right to *manufacture* has standing as well. *Seiko Epson Corp. v. Print-Rite Holdings, Ltd.*, No. CV 01-500-BR, 2005 WL 1231240, at *3 (D. Or. May 23, 2005) (applying *Amgen*, 808 F.Supp. 894).

Following from these principles, an exclusive licensee may sub-license its rights without destroying the exclusive character of the license for standing purposes. *See Invacare Corp. v. Ortho-Kinetics, Inc.*, 155 F.3d 573 (Fed. Cir. 1998) (affirming district court’s award of lost profits damages to exclusive licensee even though licensee and patentee jointly granted sub-licenses); *see also Honeywell Int’l, Inc. v. Avionics Sys. Corp.*, 347 F.Supp.2d 124 (D. Del. 2004) (denying motion *in limine* to exclude exclusive licensee’s evidence of lost profits because joint

grant of sub-license by exclusive licensee and assignee did not destroy exclusivity of license). After such a transfer of rights, both the exclusive licensee and the sub-licensee retain standing to sue for patent infringement. *See Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, No. IP-96-1718-C-H/G, 2001 WL 388874 (S.D. Ind. Mar. 12, 2001) (exclusive licensee's grant of sub-license to named plaintiff did not destroy licensee's standing to participate in infringement suit); *Howes v. Zircon Corp.*, 922 F.Supp. 957, 964 (N.D. Ill. 1998) (holding, without detailed analysis, that exclusive licensee and sub-licensee both had standing to join patentee in infringement suit).

Plaintiffs characterize APL as an exclusive licensee of the patents-in-suit and ALI as an exclusive sub-licensee. However, as stated above, merely labeling a license "exclusive" is not dispositive. *Textile Prod., Inc.*, 134 F.3d at 1484; *Ortho Pharm. Corp.*, 52 F.3d at 1032. Rather, the court must examine the terms of the parties' agreement to determine whether they intended to create an exclusive license. *Textile Prod., Inc.*, 134 F.3d at 1484. To obtain standing as an exclusive licensee, "a licensee must hold some of the proprietary sticks from the bundle of patent rights, albeit a lesser share of rights in the patent than for an assignment and standing to sue alone." *Ortho Pharm. Corp.*, 52 F.3d at 1031. When acquiring proprietary rights, the licensee must "have received, not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory as well." *Rite-Hite Corp.*, 56 F.3d at 1552. With these principles in mind, further analysis of the parties' agreements supports Plaintiffs' characterization of APL as an exclusive licensee and ALI as sub-licensee of the patents-in-suit.

Plaintiffs have persuaded the Court that the substance of the license agreement between Abbott Labs and APL confirms the license's "exclusive" label. When granting APL "an

exclusive license . . . to make, have made, use and sell” Biaxin XL under the patents-in-suit, Abbott Labs also made explicit that “‘exclusive’ means to the exclusion of all other parties including [Abbott Labs] and its Affiliates.” (Def. Mem., Ex. I ¶ 2.01(a) at ABBOTT341612.) As Plaintiffs point out, the license agreement also conferred upon APL the right to “grant one or more sublicenses” (*id.* ¶ 2.03 at ABBOTT341612) and provided that Abbott Labs and APL “will jointly participate in any action to suppress any infringement” (*id.* ¶¶ 7.03-.04 at ABBOTT341614-15). With respect to the specific proprietary rights granted to APL, Sandoz’s motion ignores that Abbott Labs unquestionably granted APL the exclusive proprietary right to manufacture Biaxin XL. That right, alone, is sufficient to endow APL with standing to participate in the instant patent infringement suit. *See Seiko Epson Corp.*, 2005 WL 1231240, at *3; *Amgen, Inc.*, 808 F.Supp. at 900.

The analysis of APL’s exclusive right to sell Biaxin XL under the patents-in-suit, which it sub-licensed to ALI, is somewhat more complex. As fleshed out in more detail below, the important point for standing purposes is that ALI’s right to sell Biaxin XL is not co-extensive with APL’s proprietary rights; rather, it *derives from* APL’s rights. Before 2004, ALI sold Biaxin XL in the United States under its exclusive distributorship agreement with Abbott Labs, which was executed before the patents related to Biaxin XL were issued and did not explicitly mention Biaxin XL. (*See* Def. Mem., Ex. F.) Any implied license that resulted from this exclusive distributorship agreement was terminable at will since the agreement was for an indefinite duration. *See id.* ¶ 13 at ABBOTT295682; *see, e.g., Jespersen v. Minnesota Mining and Mfg. Co.*, 700 N.E.2d 1014, 1016 (Ill. 1998) (applying the rule that “contracts of an infinite duration are terminable at the will of either party” to exclusive distributorship agreement). As Plaintiffs argue, by the 2004 agreement granting APL the exclusive right to sell Biaxin XL, even

to the exclusion of Abbott Labs and its affiliates, Abbott Labs terminated any implied license to sell that it previously had granted to ALI. (Def. Mem., Ex. I ¶ 2.01(a) at ABBOTT341612.) APL simultaneously sub-licensed its right to sell Biaxin XL back to Abbott Labs, and that right flowed to ALI through the parties' general exclusive distributorship agreement. (See Def. Mem., Ex. F.) As a result of these agreements, ALI continues to operate as the only entity selling Biaxin XL in the United States. As sole distributor of Biaxin XL in the United States, ALI holds an exclusive license for the sale of Biaxin XL. See *Weinar v. Rollform, Inc.*, 744 F.2d 797, 806-808 (Fed. Cir. 1984) (holding that sole distributor was exclusive licensee).

Importantly, as discussed above, APL's sub-license of its rights to ALI did not destroy the exclusive character of its license for standing purposes. See *Invacare Corp.*, 155 F.3d 573; see also *Honeywell Int'l, Inc.*, 347 F.Supp.2d 124. Both APL, as exclusive licensee, and ALI, as exclusive sub-licensee, possess standing to sue for patent infringement. See *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 2001 WL 388874; *Howes v. Zircon Corp.*, 922 F.Supp. at 964. Moreover, ALI has standing as an exclusive sub-licensee even though its sub-license was granted from APL through Abbott Labs. See *Hill Phoenix, Inc.*, 117 F.Supp.2d at 514 ("The fact that a sub-licensee derives its interest through an intermediary does not affect the exclusive sub-licensee's critical status as one with the proprietary right to exclude.").

Additionally, despite Sandoz's argument to the contrary, the retroactive license Abbott granted Teva in 2006 did not affect APL's status as an exclusive licensee of the patents-in-suit either. The 2006 Settlement Agreement between Abbott and Teva provides: "Abbott hereby grants to Teva USA a retroactive exclusive (except as to Abbott) limited license under the Patents in Suit for any manufacture, importation, marketing, offers for sale, sales or uses of Teva USA's Product prior to June 27, 2006." (Def. M., Ex. J at 5.) Sandoz argues that this agreement

destroyed APL's status as an exclusive licensee, pointing out that "if a patentee-licensor is free to grant licenses to others, licenses under that patent are not exclusive." *Textile Prods.*, 134 F.3d at 1484. However, this argument ignores the fact that the 2006 Teva Settlement Agreement defines "Abbott" to include Abbott Labs, its subsidiaries, and Affiliates. (*Id.* at 2.) Contrary to Sandoz's understanding that Abbott Labs unilaterally granted a license to Teva, under the terms of the parties' agreement, Abbott Labs, APL, and ALI jointly granted Teva rights to the patents-in-suit. Such a grant is perfectly consistent with APL's and ALI's rights to exclude and has no effect on either entity's status as an exclusive licensee. *See Invacare Corp.*, 155 F.3d 573 (joint grant by patentee and exclusive licensee of sub-license to a third party did not destroy licensee's exclusivity).

Because neither APL's sub-license to ALI nor the Abbott entities' joint license to Teva destroyed the exclusivity of APL's proprietary rights to the patents-in-suit, APL has standing to participate in this lawsuit. Moreover, as exclusive sub-licensee of the right to sell Biaxin XL in the United States, ALI has standing as well.

Neither *Poly-America v. GSE Lining Tech.*, 383 F.3d 1303 (Fed. Cir. 2004), nor *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359 (Fed. Cir. 2008), the primary cases upon which Sandoz relies, conflict with the Court's conclusion. In *Poly-America*, a subsidiary's lost profits were not recoverable by the parent corporation because the subsidiary was clearly identified in the license agreement as a non-exclusive licensee, and as such, it received only a "bare license" insufficient to confer standing. *Poly-America*, 282 F.3d at 1311. Similarly, in *Mars, Inc.*, the court denied standing to a licensee where both the licensee and its sister corporation had the same rights to practice the patents-in-suit in the United States. Unlike the entities in *PolyAmerica* and *Mars, Inc.*, APL and ALI have non-overlapping, exclusive proprietary rights to

the patents-in-suit; APL holds an exclusive right to manufacture Biaxin XL, and ALI holds an exclusive right to sell Biaxin XL in the United States. Moreover, rather than possessing these proprietary rights co-extensively, ALI's rights derive from APL's exclusive license, flowing vertically from APL to ALI through an exclusive sub-license. As a result of this arrangement, and their distinct proprietary rights, both ALI and APL hold exclusive licenses, and both have standing to participate in this lawsuit. Sandoz's motion to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(h)(3) is therefore DENIED.

Alternatively, Sandoz moves *in limine* to exclude evidence of ALI's and APL's purported lost profits. Sandoz argues that, because neither ALI nor APL has standing, evidence of their lost profits should be excluded as irrelevant and unfairly prejudicial under Federal Rules of Evidence 402 and 403. Because the Court has determined that ALI and APL do have standing in this case, Sandoz's argument must fail. Therefore, Sandoz's motion *in limine* is DENIED.

CONCLUSION

For the reasons stated above, Sandoz's motion to dismiss ALI and APL for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(h)(3) [Dkt. 493] is DENIED, and Sandoz's alternative motion *in limine* to exclude evidence relating to ALI's and APL's alleged lost profits at trial [Dkt. 493] is also DENIED.

Enter:
/s/ David H. Coar

David H. Coar
United States District Judge

Dated: May 12, 2010