IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P.; NAPP PHARMACEUTICAL GROUP LTD.; and ORTHO-MCNEIL, INC.,	)	
Plaintiffs/Counterclaim-defendants,	)	Civil Action No. 07-255-KAJ (CONSOLIDATED)
v.	)	
PAR PHARMACEUTICAL, INC.; and PAR PHARMACEUTICAL COMPANIES, INC.,	)	REDACTED
Defendants/Counterclaim-plaintiffs.	)	

MEMORANDUM OPINION

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JORDAN, *Circuit Judge.*[1]

Plaintiffs Purdue Pharma Products L.P. ("Purdue"); Napp Pharmaceutical Group LTD. ("Napp"); and Ortho-McNeil, Inc. ("OMI") filed this patent infringement action against Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. under the Hatch-Waxman Act, 35 U.S.C. § 271(e). Biovail Laboratories International, SRL ("Biovail") was also at one time a plaintiff but has since been dismissed by consent. (DI 275.) I asked the remaining parties to address OMI's basis for standing, and the issue has been fully briefed by OMI and Defendants. (D.I. 277, 281 and 286.) I have considered the parties' submissions and, for the reasons set forth below, dismiss OMI from this suit.

I. Factual and Procedural Background

Purdue and Napp are owners by assignment of U.S. Patent Nos. 6,254,887 (the "'887 patent") and 7,074,430 (the "'430 patent"). (D.I. 78 at 1-2.) The '887 and '430 patents teach formulations for controlled release tramadol. On August 12, 2005, Purdue granted Labopharm Europe Ltd ("Labopharm") a "sole license" to the '887 patent and other intellectual property (the "Labopharm Agreement"). (D.I. 277 Ex. 2 at 12.) The license granted Labopharm the right to manufacture, market and sell[2] its tramadol

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[1]Sitting by designation (Docket Item ["D.I."] 241).

[2]In its submission, OMI contends that Labopharm did not receive the right to sell its tramadol product. (D.I. 281.) That contention, however, is inconsistent with the terms of the Labopharm Agreement. In the Agreement, Purdue grants Labopharm the right "to make, have made, package, import, export, use, Distribute and have Distributed the Licensed Product in the Territory in accordance with the terms of this agreement." (D.I.

formulation—a "once daily ... solid oral dosage formulation"—in the United States. (*Id.* Ex. 2 at 8, 11 and 12.) Under the Labopharm Agreement, Purdue retained the right to grant additional licenses [redacted] (*Id.* Ex. 2 at 39.)

On September 8, 2005, the United States Food and Drug Administration approved Biovail's New Drug Application ("NDA") for a "single entity extended release tramadol product." (*Id.* Ex. 1 at 4.) Biovail's NDA listed the '887 patent, though the record at this point does not show whether Biovail had a license to the '887 patent prior to submitting the NDA.

Soon thereafter, on October 31, 2005, Purdue and Labopharm amended their agreement to "address the uncertainty caused by Biovail Corporation's" NDA (the "Labopharm Amendment"). (*Id.* Ex. 3 at 1.) Under the amendment, Purdue was allowed to grant one or more additional licenses of its intellectual property for the Biovail product to be manufactured, marketed and sold in the United States. (*Id.*)

On November 3, 2005 Purdue exercised the rights it negotiated under the Labopharm Amendment and entered a licensing agreement with OMI (the "OMI Agreement"). (*Id.* Ex. 1.) In that agreement, Purdue granted OMI a "semi-exclusive license" under the '887 patent, among others, to manufacture, market and sell the Biovail product in the United States.[3] (*Id.* Ex. 1 at 6-7, Appx A.) OMI also received the right to

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277 Ex. 2 at 12.) The Agreement states that the term "'Distribute(s)' ... will mean market, advertise, promote, *offer to sell and sell*." (*Id.* Ex. 2 at 7 (emphasis added).)

[3]It is undisputed that the OMI Agreement does not include the '430 patent. (*Id.* at 1, 2 n.2; D.I. 281 at 1, 5.)

grant sublicenses for the Biovail product, through which it granted Biovail a royalty-free sublicense to Purdue's patents. (*Id.* Ex. 1 at 6, Ex. 4 at 65:8-66:17.) The OMI Agreement states explicitly that it does not interfere with Purdue's license with Labopharm or Purdue's right to grant an additional license [redacted] (*Id.* Ex. 1 at 3.) Effective the same day as the OMI Agreement, Purdue, Labopharm, OMI, and Biovail entered into a covenant not to sue one another. (*Id.* Ex. 5.)

II. Analysis

In a patent infringement suit, the party bringing the suit has the burden of establishing that it has standing. *See Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed Cir. 2006). "Only a patent owner or an exclusive licensee can have constitutional standing to bring an infringement suit; a non-exclusive licensee does not." *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. June 2, 2008) (citing *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005) ("A nonexclusive license confers no constitutional standing on the licensee to bring suit or even to join a suit with the patentee because a nonexclusive licensee suffers no legal injury from infringement." (internal citations omitted)). "To be an exclusive licensee for standing purposes, a party 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." *Id.* at 1367 (citing *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed.Cir.1995) (*en banc*)). "By

the same token, if the patentee allows others to practice the patent in the licensee's territory, then the licensee is not an exclusive licensee." *Id.*

OMI is not an exclusive licensee. The first and most obvious evidence for that conclusion is that the license, by its terms, is only "semi-exclusive," which is the functional equivalent of "less than exclusive." Of more significance than the label used in the license, however, is the substance of the rights granted to OMI and reserved to Purdue and others. Although the "semi-exclusive license" OMI received from Purdue grants OMI the right to practice the '887 patent in the United States, the license does not preclude Labopharm from doing the same. OMI's license explicitly states that it does not interfere with Labopharm's license to practice the '887 patent in the United States or Purdue's right to grant an additional license to practice the '887 patent [redacted] That reservation of rights is sufficient to undermine OMI's claim of standing, since the Federal Circuit has held that a licensee lacks standing to sue when even one other entity has the patentee's permission to practice the patent in the applicable territory, irrespective of whether others might be excluded. *Id.* at 1368 ("Because we find that MEI was not an exclusive licensee as a result of Mars's licence to MEI-UK, we need not consider the effect of the other licenses... .").[4]

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[4]The OMI Agreement allows OMI to participate in any infringement litigation initiated by Purdue. (D.I. 277 Ex. 1 at ¶ 6.3.) As both parties rightfully note, such a contractual provision cannot confer standing.

> [A] right to sue clause cannot negate the requirement that, for co-plaintiff standing, a licensee must have beneficial ownership of some of the patentee's proprietary rights. A patentee may not give a right to sue to a

OMI argues that it has standing to sue as a co-plaintiff because its license grants it an exclusive field of use, namely, the exclusive right under the '887 patent to a single entity extended release tramadol product. (D.I. 281 at 3.) *See Int'l Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273, 1276-80 (Fed. Cir. 2007) (recognizing that a licensee with an exclusive field-of-use license may have standing to be a co-plaintiff with the patentee). Even if OMI could successfully argue that a single entity extended release tramadol product encompasses a distinct field of use sufficient to provide co-plaintiff standing, and I am not convinced that it could,[5] OMI has not shown that it in fact has an exclusive license to that field. On the contrary, by specifying explicitly that the "semi-exclusive license" to OMI did not prevent Purdue from maintaining its license with Labopharm, the parties acknowledged that the Biovail product and the Labopharm product, which itself is defined as a once daily solid oral dosage formulation, might use the '887 patent in an overlapping field. Likewise, Purdue and Labopharm seem to have been concerned that the Biovail and Labopharm products occupied the same field when

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> party who has no proprietary interest in the patent. ... Here, being only a nonexclusive licensee, Ortho has no inherent or implied right to sue which the clause regulates as between the parties. Thus, we conclude the right to sue clause has no effect on Ortho's standing, one way or the other.

Ortho Pharmaceutical Corp. v. Genetics Inst., Inc., 52 F.3d 1026, 1034 (Fed. Cir. 1995) (citations omitted).

[5]For example, it is not at all clear that the '887 patent sets forth claims that can be sensibly divided into separate and distinguishable fields of use. *Compare Int'l Gamco*, 504 F.3d 1276-80 (noting that at least one of the claims was directed toward the field of use carved out in the license at issue).

they amended the Labopharm Agreement. And the covenant not to sue among Purdue, Labopharm, OMI, and Biovail defines both the Labopharm product and the Biovail product as a "single entity extended release tramadol product ... in all dosage strengths," providing further support for the proposition that the two products are not distinct instantiations of the '887 patent. (D.I. 277 Ex. 5 at PUR1107024.)

The burden is on OMI to establish that it has standing, and it has failed to do so. Because OMI has not shown that it has an exclusive license, or even that it has an exclusive license to a particular field of use, it does not have standing to be a co-plaintiff in this suit.[6]

III. Conclusion

For the reasons stated above, the defendants' motion to dismiss OMI as a party will be granted.

[6]OMI does not claim a license to the '430 patent or assert it as a basis for standing independent from the '887 patent.