IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,	
Plaintiffs,)
v.	
EDWARDS LIFESCIENCES CORPORATION,	
Defendant.	
EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES PVT, INC., and EDWARDS LIFESCIENCES LLC,) C.A. No. 16-275-JFB-SRF REDACTED - PUBLIC VERSION
Counterclaim and Third-Party Plaintiffs,)))
v.	
BOSTON SCIENTIFIC CORPORATION, BOSTON SCIENTIFIC SCIMED, INC., and SADRA MEDICAL, INC.,)))
Counterclaim and Third-Party Defendants.)))

REPORT AND RECOMMENDATION

I. INTRODUCTION

Presently before the court in this patent infringement action is a motion to dismiss the complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(h)(3) filed by defendant Edwards Lifesciences Corporation ("Edwards"). (D.I. 205) For the following reasons, I recommend that the court grant-in-part and deny-in-part Edwards' motion to dismiss.

II. BACKGROUND

A. Parties

Plaintiff Boston Scientific Corporation ("BSC") is a corporation incorporated under the laws of Delaware with its principal place of business in Massachusetts. (D.I. 1 at ¶ 2) Boston Scientific Scimed, Inc. ("BSSI") (together with BSC, "Boston Scientific") is a wholly owned subsidiary of BSC incorporated under the laws of Minnesota with its principal place of business in Minnesota. (Id. at ¶ 3) Boston Scientific Limited ("BSL") is a wholly owned subsidiary of BSC that is an Irish limited company with its registered office in Ireland. (D.I. 207 at 1; D.I. 216 at 8) Defendant Edwards is a corporation organized and existing under the laws of Delaware with its principal place of business in California. (D.I. 1 at ¶ 4)

B. Patent-In-Suit

On June 26, 2009, Sadra Medical, Inc. ("Sadra") filed the application leading to United States Patent No. 8,992,608 ("the '608 patent"), bearing number 12/492,512 ("the '512 Application"), with the United States Patent and Trademark Office (the "USPTO"). (D.I. 1, Ex. A) On March 31, 2015, the USPTO issued the '608 patent, entitled "Everting Heart Valve." (Id.) The '608 patent lists Ulrich R. Huag, Hans F. Valencia, Robert A. Geshilder, Tom Saul, Amr Salahieh, Dwight P. Morejohn, and Kenneth J. Michlitsch as inventors and identifies Sadra as the assignee. (Id.) The '608 patent "provides methods and apparatus for endovascularly replacing a patient's heart valve." (Id.)

C. Facts

Sadra was the original assignee of the application leading to the '608 patent. (D.I. 207, Ex. 4) On January 4, 2011, Boston Scientific acquired Sandra, which became a wholly owned subsidiary of BSSI. (*Id.*, Exs. 6, 7) On the same day, Sadra assigned to BSSI all of its intellectual property, including its "entire right, title and interest in and to" the '512 application

that issued as the '608 patent. (*Id.*, Ex. 8 at 6508, 6515; D.I. 206 at 2-3) On January 4, 2011, BSSI licensed the '512 application to BSL via an Intangible Property License Agreement (the 'License Agreement'). (D.I. 207, Ex. 7) The License Agreement grants BSL a "nonexclusive, worldwide right and license to: (1) manufacture and sell [p]roducts utilizing the [intellectual property acquired from Sadra] and (2) use the [acquired intellectual property] for further research and development." (D.I. 207, Ex. 7 at § 2.01) The License Agreement is subject to the Second Amended and Restated Agreement for Sharing Intangible Development Costs (the "Cost Sharing Agreement"), which BSSI and BSL had previously entered into on January 5, 2009. (D.I. 218, Ex. 21)

D. Procedural History

On April 9, 2016, BSSI and BSC filed the present action against Edwards asserting a cause of action for alleged infringement of the '608 patent. (D.I. 1) Edwards filed a motion to amend its answer on November 30, 2016. (D.I. 65) The court granted Edwards' motion to amend on February 28, 2017. (D.I. 104) Edwards filed a second motion to amend its answer on May 3, 2017. (D.I. 166) On January 10, 2018, the court granted Edwards' motion to amend its answer. (D.I. 299; D.I. 300) On June 21, 2017, Edwards filed the present motion to dismiss for lack of subject matter jurisdiction pursuant to Rules 12(b)(1) and 12(h)(3). (D.I. 205)

III. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of jurisdiction over the subject matter, or if the plaintiff lacks standing to bring its claim. Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to the court's subject matter jurisdiction. See Lincoln Ben. Life Co. v. AEI Life, LLC, 800 F.3d 99, 105 (3d Cir. 2015) (quoting Common Cause of Pa. v. Pennsylvania, 558 F.3d 249, 257 (3d Cir. 2009)). In

reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply. In this regard, the court must accept all factual allegations in the complaint as true, and the court may only consider the complaint and documents referenced in or attached to the complaint. See Church of Universal Bhd. v. Farmington Twp. Supervisors, 296 F. App'x 285, 288 (3d Cir. 2008); Gould Elec., Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000). In reviewing a factual challenge to the court's subject matter jurisdiction, the court is not confined to the allegations in the complaint. See Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977). Instead, the court may consider evidence outside the pleadings, including affidavits, depositions and testimony, to resolve any factual issues bearing on jurisdiction. See Gotha v. United States, 115 F.3d 176, 179 (3d Cir. 1997). Once the court's subject matter jurisdiction over a complaint is challenged, the plaintiff bears the burden of proving that jurisdiction exists. See Lincoln, 800 F.3d at 105; Mortensen, 549 F.2d at 891.

The Supreme Court has announced three requirements for standing which originate out of Article III of the Constitution, all of which must be satisfied for a federal court to entertain a claim. In Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992), the Supreme Court opined:

Over the years, our cases have established that the irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an "injury in fact"—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) "actual or imminent, not 'conjectural' or 'hypothetical." Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be "fairly... trace[able] to the challenged action of the defendant, and not... th[e] result [of] the independent action of some third party not before the court." Third, it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision."

Id. (internal citations and quotation marks omitted). Therefore, to satisfy the constitutional standing requirements, a plaintiff must show that it (1) has suffered or will

immediately suffer an injury, (2) which is fairly traceable to the defendant's conduct, and (3) which is likely to be redressed by a favorable federal ruling on the matter. "[T]he touchstone of constitutional standing in a patent infringement suit is whether a party can establish that it has an exclusionary right in a patent that, if violated by another, would cause the party holding the exclusionary right to suffer legal injury." WiAV Solutions LLC v. Motorola, Inc., 631 F.3d 1257, 1265 (Fed. Cir. 2010).

In addition to the constitutional standing requirements, the federal courts have adopted a set of self-imposed prudential standing limitations on the exercise of federal jurisdiction. "These considerations require that (1) a litigant assert his own legal interests rather than those of third parties, (2) courts refrain from adjudicating abstract questions of wide public significance which amount to generalized grievances, and (3) a litigant demonstrate that her interests are arguably within the zone of interests intended to be protected by the statute, rule or constitutional provision on which the claim is based." Davis by Davis v. Phila. Housing Auth., 121 F.3d 92, 96 (3d Cir. 1997) (citations omitted). These "prudential" limitations are generally designed to prevent courts from deciding broad questions of social import where no individual rights would be vindicated. Id. "Prudential standing to sue for patent infringement derives from 35 U.S.C. § 281: 'A patentee shall have remedy by civil action for infringement of his patent." Int'l Gamco, Inc. v. Multimedia Games, Inc., 504 F.3d 1273, 1276 (Fed. Cir. 2007). The term "patentee" in § 281 "includes the patentee's successors in title." Id. (citing 35 U.S.C. § 100(d)).

Although patent rights are initially held by the named inventor, they may be licensed or assigned, and when "a sufficiently large portion of this bundle of rights is held

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by one individual, we refer to that individual as the owner of the patent, and that individual is permitted to sue for infringement in his own name." Alfred E. Mann Found. for Sci. Research v. Cochlear Corp., 604 F.3d 1354, 1360 (Fed. Cir. 2010). Accordingly, plaintiffs who "hold all legal rights to the patent as the patentee or assignee of all patent rights" can sue in their own name alone. Morrow v. Microsoft Corp., 499 F.3d 1332, 1339 (Fed. Cir. 2007) ("Unquestionably, a patentee who holds all the exclusionary rights and suffers constitutional injury in fact from infringement is one entitled to sue for infringement in its own name.").

Exclusive licensees also have constitutional standing because they hold "exclusionary rights and interests created by the patent statutes, but not all substantial rights to the patent." Morrow, 499 F.3d at 1340. "However, these exclusionary rights 'must be enforced through or in the name of the owner of the patent,' and the patentee who transferred these exclusionary interests is usually joined to satisfy prudential standing concerns." Id. at 1340; see also Propat Int'l Corp. v. Rpost, Inc., 473 F.3d 1187, 1193 (Fed. Cir. 2007). In other words, "unlike an assignee that may sue in its own name, an exclusive licensee having fewer than all substantial patent rights . . . that seeks to enforce its rights in a patent generally must sue jointly with the patent owner." Intellectual Prop. Dev., Inc. v. TCI Cablevision of CA, Inc., 248 F.3d 1333, 1347-48 (Fed. Cir. 2001) (finding "it was proper for IPD, as an exclusive licensee of fewer than all substantial rights in the '202 patent, to add [licensor] as a party plaintiff"). "By contrast, a bare licensee, i.e., a party with only a covenant from the patentee that it will not be sued for infringing the patent rights, lacks standing to sue third parties for infringement of the patent." Propat, 473 F.3d at 1193-94.

"Standing must be present at the time the suit is brought." Sicom Sys., Ltd. v. Agilent Techs., Inc., 427 F.3d 971, 975-76 (Fed. Cir. 2005). If a plaintiff lacks standing at that time, the court lacks subject matter jurisdiction and the case must be dismissed pursuant to Rule 12(b)(1). See generally Ballentine v. United States, 486 F.3d 806, 810 (3d Cir. 2007). The party "bringing the action bears the burden of establishing that it has standing." Sicom, 427 F.3d at 976.

IV. DISCUSSION

A. BSSI

Edwards argues that BSSI does not have standing to bring a patent infringement suit because BSSI assigned all substantial rights to BSL. (D.I. 206 at 19) Specifically, Edwards points to Article IV¹ of the License Agreement as support that the "parties intended to, and did in fact, transfer all substantial rights related to the '608 patent from BSSI to BSL." (*Id.* at 20) BSSI contends that it remains the assignee of the '608 patent, holding legal title thereto and all substantial rights therein. (D.I. 216 at 9)

¹ Article IV of the License Agreement addresses the parties' respective rights of ownership and interest in and to the intellectual property. (See D.I. 207, Ex. 7) Section 4.01, which addresses BSSI's rights, states:

Subject to the last sentence of Section 4.02 hereof and to BSS[I]'s right to assign any rights in the ['608 patent] pursuant to Section 7.09, BSS[I] shall hold legal title to the ['608 patent] and shall have all rights not granted to BSL hereunder, included the nonexclusive, worldwide right and license to: (1) manufacture and sell products utilizing the ['608 patent] and (2) use the ['608 patent] for further research and development.

⁽Id. at § 4.01) Section 4.02, which addresses BSL's rights, states:

BSL shall have the nonexclusive, worldwide right and license to: (1) manufacture and sell [p]roducts utilizing the ['608] and (2) use the ['608 patent] for further research and development. BSL may hold legal title to the ['608 patent] to the extent it is deemed necessary for purposes of protecting any intellectual property rights.

Generally, to satisfy prudential standing, a patent infringement plaintiff "must have held legal title to the patent at the time of the infringement." Rite-Hite, 56 F.3d at 1551; see also 35 U.S.C. §§ 100(d), 281. "A conveyance of legal title by the patentee can be made only of the entire patent, an undivided part or share of the entire patent, or all rights under the patent in a specified geographical region of the United States." Id. (citing Waterman v. Mackenzie, 138 U.S. 252, 255 (1891)). "A transfer of less than one of these three interests is a license, not an assignment of legal title." Id. at 1551-52. In circumstances where a patent owner transfers "all substantial rights" to the patents-in-suit, however, "the transfer is tantamount to an assignment of those patents to the exclusive licensee, conferring standing to sue solely on the licensee." Alfred, 604 F.3d at 1358-59. Thus, to sue for infringement in its own name, a plaintiff must either hold (1) "all patent rights—the entire bundle of sticks," or (2) "all substantial rights." Morrow, 499 F.3d at 1339-40. The court has defined "all substantial rights" as those rights sufficient for the licensee or assignee to be "deemed the effective patentee under 35 U.S.C. § 281." Id. (citing Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1377 (Fed. Cir. 2000)). Each license and assignment is unique, therefore the court "must ascertain the intention of the parties and examine the substance of what [the licensing agreement] granted" to determine if it conveys all of the substantial rights in the patent and is sufficient to grant standing to the licensee. Id. Moreover, "whether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name by which it calls itself, but upon the legal effect of its provisions." Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 873 (Fed. Cir. 1991).

The License Agreement in the case at bar does not assign or transfer all substantial rights in the patent from BSSI to BSL. First, Section 4.01 of the License Agreement makes clear that

"BSS[I] shall hold legal title to the ['608 patent]." (D.I. 207, Ex. 7 at § 4.01) BSSI also retained a "nonexclusive, worldwide right and license to: (1) manufacture and sell products utilizing the ['608 patent] and (2) use the ['608 patent] for further research and development." (Id.) Because the License Agreement grants BSL only a "nonexclusive license," BSSI, therefore, also retained the right to grant additional licenses to the '608 patent. (Id. at § 2.01) BSL could not assign, delegate, or otherwise transfer "any and all of its rights or obligations" to any party other than an "entity directly or indirectly owned or controlled by Boston Scientific Corporation" without the consent of BSSI. (Id. at § 7.09) BSSI, not BSL, was responsible for maintaining the '608 patent and was responsible for the function of "IP Registration and Defense," and "IP Protection and Infringement risks." (D.I. 218, Ex. 21 at App'x A) BSL was granted two rights: (1) a nonexclusive, worldwide right and license (i) to manufacture and sell products utilizing the '608 patent and (ii) to use the '608 patent for further research and development; and (2) a contingent title to the '608 patent only "to the extent it is deemed necessary for purposes of protecting any intellectual property rights." (D.I. 207, Ex. 7 at § 4.02) Because there was not a complete transfer of rights, the License Agreement gives BSL a license, not an assignment. As such, BSSI holds legal title to the '608 patent.

Conversely, Edwards argues that "the only affirmative right granted to BSSI by [Article IV] is a nonexclusive license and any other right not granted to BSL by Section 4.02." (D.I. 206 at 20) Edwards argues that "the single mention of the paramount right to exclude (i.e. enforce the patent) comes in the last sentence of Section 4.02, which grants BSL legal title...." (Id.) The court is not persuaded by Edwards' interpretation of the License Agreement. Although Section 4.02 states that "BSL may hold legal title to the ['608 patent] to the extent it is deemed necessary for purposes of protecting any intellectual property rights," this does not alter BSSI's legal title

to the '608 patent as it relates to this case. (D.I. 207, Ex. 7 at § 4.02) The License Agreement only grants contingent title to BSL, and such a clause may be found in licensing agreements in order to prevent a failure of justice -e.g., to prevent the grantor from infringing the grantee's license. Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1131 (Fed. Cir. 1995) (internal citations omitted) ("when a patent owner grants only a license, title remains in the owner of the patent and suit cannot be brought 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"). Absent those limited circumstances, the License Agreement makes clear that BSSI holds legal title to the '608 patent. (See D.I. 207, Ex. 7 at § 4.01) This intent is further reflected in the recitals of the License Agreement, which state that "Sadra transferred ownership of the ['608 patent] to BSS[I]" and "the ['608 patent] [is] being made available to BSL." (Id. at Recitals (5)-(6)) When examining that License Agreement as a whole, it is clear that legal title remains with BSSI, and BSL is instead granted a nonexclusive license and only a contingent title to the '608 patent in limited circumstances. Moreover, this finding does not run afoul of the general rule that an assignee has standing to bring suit but a licensee does not in order to "prevent the possibility of two suits on the same patent against a single infringer." Vaupel, 944 F.2d at 875 (citing Crown Die & Tool Co. v. Nye Tool & Mach. Works, 261 U.S. 24, 38 (1923)). This policy is not undercut here because the right to sue rested solely with BSSI. As previously discussed, BSL only has a contingent title only under certain conditions that have not occurred in the present case -i.e., only to the extent such transfer is "deemed necessary" to enforce the patent. (D.I. 207, Ex. 7 at § 4.02) Any contingent title is not necessary for Boston Scientific to enforce the '608 patent against Edwards. Because BSL does not have standing to bring an action against Edwards, Edwards must defend itself in only one suit in which the '608 patent is asserted – the present action.

Edwards also argues that the intent to assign the rights to the '608 patent is further

bolstered by the fact that BSL paid BSSI in up-front consideration for the intellectual property rights, in addition to future royalty payments. (D.I. 206 at 22) Edwards contends that this up-front consideration (Id.) However, pursuant to the Cost Sharing Agreement between BSSI and BSL, this was the amount due "in accordance with the reasonably anticipated benefits to be derived by each [p]arty from use of the [d]eveloped [t]echnology in manufacturing, selling, and/or licensing [p]roducts over the full useful life of the cost-shared intangibles." (D.I. 218, Ex. 21 at Art. IV(A)) Whether BSL overpaid for what it received is irrelevant, and the clear language of the License Agreement

On August 14, 2017, Edwards submitted a letter to the court supplementing its opening and reply briefs with "newly discovered facts in support of Edwards' Motion to Dismiss" (the "letter"). (D.I. 253) In the letter, Edwards cites to relevant portions of Joanne Rapchuck's, Boston Scientific's Rule 30(b)(6) designee, deposition, which occurred on July 27, 2017, as

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² Federal Rule of Civil Procedure 30(b)(6) requires that a named organization designate one or more officers, directors, managing agents, or designate other persons who consent to testify on its behalf; and it may set out the matters on which each person designated will testify. Fed. R. Civ. P. 30(b)(6). The persons designated must testify about information known or reasonably available to the organization. *Id.* A Rule 30(b)(6) witness's testimony is binding on the corporation, and as such a corporation has an affirmative duty to produce a representative who can answer questions that are within the scope of the matters described in the notice. *Harris v. New Jersey*, 259 F.R.D. 89, 92 (D. N.J. 2007).

further evidence that BSL, not BSSI, holds legal title to the '608 patent. Edwards' specific arguments in the letter will now be addressed in turn.³

First, Edwards argues that a key distributorship agreement defining the relationship between BSC and BSL in this case confirms that "(1) BSL owns the '608 patent and (2) BSC has no license to the '608 patent." (D.I. 253 at 1-2) However, BSSI is not a party to this distributorship agreement, and it was executed six years before Boston Scientific's acquisition of Sadra and the '608 patent. (D.I. 253, Ex. 12) As such, the distributorship agreement does not define nor alter the ownership and licensing of the '608 patent. Edwards also cites to a single "whereas" clause in the distributorship agreement that states "the products that are the subject of this [a]greement consist primarily of products manufactured by BSL's contract manufacturers using BSL's intellectual property." (*Id.* at 1) However, reliance on this clause is unavailing because the clause itself makes clear that the products subject to the distributorship agreement consist only "primarily of," not entirely of, products using BSL's intellectual property.

Moreover, "BSL's intellectual property" does not preclude that property licensed to BSL.

Second, Edwards contends that Ms. Rapchuck testified that "only BSL receives residual profits under the Cost Sharing Agreement for the manufacture of the Lotus Valve products" (which Plaintiffs have identified as covered by the '608 patent). (D.I. 253 at 2) (emphasis in original). However, the residual profit on Lotus products is retained by the manufacturer of the products, which is either BSSI or BSL, depending on where the final assembly of that particular Lotus product took place. (D.I. 256, Ex. 21 at 28-30) The cost sharing agreement specifies that BSSI and/or its designees will manufacture products in the United States, and that BSL will

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³ In reviewing a factual challenge to the court's subject matter jurisdiction, the court is not confined to the allegations in the complaint. *See Mortensen*, 549 F.2d at 891. Instead, the court may consider evidence outside the pleadings, including affidavits, depositions and testimony, to resolve any factual issues bearing on jurisdiction. *See Gotha*, 115 F.3d at 179.

manufacture products outside the United States. (Id.) The portion of Ms. Rapchuck's deposition testimony cited to by Edwards does not state that "only BSL receives residual profits under the Cost Sharing Agreement." (D.I. 253, Ex. 11 at 200:19-201:13) Rather, Ms. Rapchuck testified that BSL earned such a residual profit when Galway was manufacturing the finished product. (Id.)

Third, Edwards contends that Ms. Rapchuck "confirmed that the

by BSL under the agreement was for the entirety of Sadra's intangibles, and not just a portion as Plaintiffs had asserted without support, and she was

"(D.I. 253 at 2) However, Ms. Rapchuck testified as to the method by which Boston Scientific determined the payment price, which was a "prescribed method in the transfer pricing regulations...called the acquisition price method." (D.I. 253, Ex. 11 at 214:16-215:21) She testified that "the value of that intangibles payment is what BSL made to BSSI." (Id. at 215:18-21) Meaning, BSL's payment was the value of only its portion of the reasonably anticipated benefits of Sadra's intangible property. (D.I. 256 at 5)

Fourth, Edwards argues that "as even further financial evidence confirming BSL's ownership, [Ms. Rapchuck] could not dispute that BSL had, as Edwards noted, further received Irish tax breaks on this (D.I. 253 at 3)

Neither Ms. Rapchuck nor Boston Scientific disputes that Irish tax laws are favorable compared to United States tax laws. (D.I. 256 at 5) However, this fact alone does not have bearing on ownership of the '608 patent.

Finally, Edwards questions why it was Mr. Peter Gafner who submitted a declaration if only Ms. Rapchuck was identified by Plaintiffs as knowledgeable about the relevant corporate entity issue. (D.I. 253 at 3) Although Plaintiffs identified Ms. Rapchuck as a designee in response to interrogatories concerning the entity involvement in manufacturing, marketing, distributing, and selling the Lotus Valve products, and the flow of sales revenues and profits from the manufacture, distribution, and sales of such products, Mr. Gafner was specifically offered to testify on "standing issues." (D.I. 256, Ex. 21 at 25-30; Ex. 20 at 2-4) His deposition was not taken because the parties could not agree as to what specific topics Mr. Gafner would testify. (D.I. 253, Ex. 5) This fact is not dispositive, and in regards to standing, the License Agreement is still controlling. As such, whether Mr. Gafner was or was not deposed gives no support to either party.

Because the License Agreement vests legal title in the '608 patent with BSSI and grants BSL only a nonexclusive license, BSSI has standing to sue for infringement of the '608 patent. Therefore, the court recommends denying Edwards' motion to dismiss as to BSSI's claims.

B. BSC

i. Implied License

Edwards argues that BSC's claims must be dismissed because BSC has no exclusionary rights in the '608 patent, and thus no standing to sue Edwards for infringement. (D.I. 206 at 16) Further, Edwards argues that "simply because BSC is the parent to a corporate entity that

⁴ Edwards also argues that, as to BSC's standing, Ms. Rapchuck "repeatedly confirmed that BSC, BSL, and BSSI are each separate and distinct corporate legal entities," in contradiction of Plaintiffs' corporate control theory. (D.I. 253 at 3) Boston Scientific argues that this "proposition does not establish the BSC lacks an implied license to the '608 patent owned by its affiliates." (D.I. 256 at 5) However, for reasons discussed *supra*, § IV(B), BSC does not have standing and, therefore, the court does not need to address this supplemental argument.

possesses the rights to enforce the '608 patent does not itself give BSC standing to maintain the present action." (*Id.* at 23) BSC argues that it has standing to sue because it is the implied exclusive licensee of the '608 patent and it may assert equitable claims against Edwards. (D.I. 216 at 20)

The court recommends dismissal for lack of standing because BSC is not an implied exclusive licensee of the '608 patent. 35 U.S.C. § 261 states in relevant part:

Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.

The Federal Circuit has concluded that both assignments and "virtual assignments" (i.e., exclusive license agreements that convey all substantial rights) must be in writing for a party to have standing to sue in its own name. Aspex Eyewear, Inc. v. Altair Eyewear, Inc., 288 F. App'x 697, 705-06 (Fed. Cir. 2008) (citing Enzo APA & Son, Inc. v. Geapag A.G., 134 F.3d 1090, 1093 (Fed. Cir. 1998)). The Federal Circuit has also concluded that an exclusive license need not be in writing for the exclusive licensee to have standing to sue with the patentee as a co-plaintiff. Id. (citing Waymark Corp. v. Porta Sys. Corp., 334 F.3d 1358, 1364 (Fed. Cir. 2003); Weinar v. Rollform, Inc., 744 F.2d 797, 806-07 (Fed. Cir. 1984)). But, "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." Rite-Hite, 56 F.3d at 1552.

This court agrees with Edwards that Plaintiffs have failed to establish that BSC has standing to join BSSI's infringement suit. The evidence of record shows that BSSI owns the '608 patent, as discussed *supra* § IV(A), and Plaintiffs ask the court to infer, based on the fact that BSC is the parent corporation of BSSI, that BSSI made an implied promise to exclude all

other entities other than BSC from practicing the '608 patent. To the contrary, in claiming that BSSI had legal title to the '608 patent, Plaintiffs argued, and the court agrees, that the License Agreement gives BSSI the right to grant additional licenses to the '608 patent. (D.I. 207, Ex. 7 at §§ 2.01, 4.01) Moreover, Section 7.10 of the License Agreement states that "except as expressly provided herein, no third party is intended, or shall be deemed, to be a beneficiary of any provision of this Agreement." (Id. at § 7.10) BSC is not expressly included as a beneficiary to the Agreement.5 (See id.) Plaintiffs have not produced any other evidence to support the contention that BSC has an implied exclusive license. At best, BSC has a bare license. The court cannot recommend that standing exists on these facts, for "this would mean that any company related to a patent owner could be treated as an exclusive licensee, so long as the patent owner allows only that company to practice the patent, regardless of any actual agreement as to exclusivity." Spine Sols., Inc. v. Medtronic Sofamor Danek USA, Inc., 620 F.3d 1305, 1318 (Fed. Cir. 2010) abrogated on other grounds by Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923 (2016). This is contrary to case law, which specifies that a "bare license ... even if it is the only license granted by the patentee, does not provide standing without the grant of a right to exclude others." Rite-Hite, 56 F.3d at 1553.

Given that Plaintiffs fail to point to any evidence other than its current "organization" to show that BSC is an exclusive licensee, the court recommends finding that Plaintiffs have failed to meet their burden of establishing that BSC has standing to bring suit.

ii. Equitable Standing

⁵ The only time BSC is named in the License Agreement, besides the defined terms, is in Section 7.09, wherein the parties (BSSI and BSL) agree that either party has the right or power to assign, delegate, or otherwise transfer any or all of its rights or obligations under the Agreement to "any entity directly or indirectly owned or controlled by BSC." (D.I. 207, Ex. 7 at § 7.09)

BSC also argues that, as a parent corporation to BSSI, it has standing to join BSSI in its equitable claims against Edwards. (D.I. 206 at 20)

"The general rule is that one seeking to recover money damages for infringement of a United States patent (an action 'at law') must have held the legal title to the patent during the time of infringement." Arachnid, Inc. v. Merit Industries, Inc., 939 F.2d 1574, 1579 (Fed. Cir. 1991). In contrast, "[a]n owner of the equitable title may seek redress against an infringer in a court of equity" where he may only seek equitable relief. Id. at 1580 (citation omitted). "The fact that a corporate parent's subsidiary owns a patent is not enough to establish that the parent has a legal ownership interest in the subsidiary's patent." Digitech Image Techs., LLC v. Newegg Inc., 2013 WL 1871513, at *4 (C.D. Cal. May 3, 2013) (emphasis in original). Accord, Abraxis Bioscience, Inc. v. Navinta LLC, 625 F.3d 1359, 1366 (Fed. Cir. 2010). Moreover, "the mere fact that a corporation's subsidiary owns a patent is insufficient to establish that the corporation has equitable title to the patent." Digitech, 2013 WL 1871513, at *4 (emphasis added). Accord, Top Victory Electronics v. Hitachi Ltd., 2010 WL 4722482, at *4 (N.D. Cal. Nov. 15, 2010) (the fact that the companies are "closely intertwined by virtue of their parent/subsidiary relationship" is insufficient to establish standing); Merial Ltd. v. Intervet, Inc., 430 F. Supp. 2d 1357, 1361-63 (N.D. Ga. 2006) ("standing under the Patent Act cannot be based on the mere fact that [the subsidiary] is a wholly owned subsidiary of [the parent company]"); Beam Laser Sys., Inc. v. Cox Communications, Inc., 117 F.Supp.2d 515, 521 (E.D. Va. 2000) (ownership of corporate stock does not create equitable title in that corporation's property); and Site Microsurgical Sys., Inc. v. Cooper Cos., 797 F. Supp. 2d 333, 338 (D. Del. 1992) (finding

⁶ "Equitable title may be defined as 'the beneficial interest of one person whom equity regards as the real owner, although the legal title is vested in another." Digitech, 2013 WL 1871513, at *3 (citation omitted).

mere fact of a parent-subsidiary relationship did not confer standing on parent). See also, Spine Solutions, 620 F.3d at 1317-18 (standing not established based on a corporate "understanding" that one subsidiary owned and enforced the patent and a second subsidiary was the only entity that made and sold products practicing the patent).

The issue of standing is rooted in the facts of each case. Hologic, Inc. v. Minerva Surgical, Inc., 163 F. Supp. 3d 118, 122 (D. Del. 2016). The "mere fact" of stock ownership or of a corporate relationship does not alone establish standing, and the record at bar is not sufficient to demonstrate "that boundaries between the corporations [at bar] have been breached." Id. (citing Top Victory, 2010 WL 4722482, at *3). In Hologic, for example, the court found that "the record reflects that at the time the original complaint and the motion for preliminary relief were filed, [the subsidiary] owned the patents-in-suit and [the parent] owned and "exercised ... complete control over [the subsidiary]," including control over all of the subsidiary's business decisions and the subsidiary's patent enforcement, assignment, and licensing policies. Hologic, 163 F. Supp. 3d at 122. Moreover, according to the parent, "[b] ecause of the structure of this corporate relationship and [the parent]'s complete control over [the subsidiary]'s patent licensing and enforcement policies, [the parent] has had control over the [p]atents-in-[s]uit, and has enjoyed exclusive rights thereunder." Id. The court, therefore, found that, under those circumstances, the parent had established its equitable standing to pursue injunctive relief. Id. Here, however, the pleadings have not asserted in detail, as did the pleadings in Hologic, that BSC exercised complete control over all of BSSI's business decisions, including patent enforcement, assignment and licensing policies, such that the "boundaries between the corporations had been breached." Top Victory, 2010 WL 4722482, at *3.

BSC argues that "under circumstances similar to this case, courts have routinely found that the parent had standing to join as a co-plaintiff," and cites to Pipe Liners, Inc. v. Am. Pipe & Plastics, Inc., Cognex Corp. v. Microscan Sys., Inc., Atmel Corp. v. Authentec, Inc., and Steelcase, Inc. v. Smart Techs., Inc. as support. (D.I. 216 at 22) However, these cases do not lend support to BSC's position. In Pipe Liners, the court held that a parent corporation had standing to seek equitable remedies relating to a patent owned by its subsidiary. Pipe Liners, Inc. v. Am. Pipe & Plastics, Inc., 893 F. Supp. 704, 706 (S.D. Tex. 1995). Although the court noted that the presence or absence of the parent corporation would not change the case, primarily because the subsidiary held legal title to the patent and there was no claim that the parent held any legal right in the patent, the court found "no reason why [the parent] cannot be joined in the equitable remedies of declaratory and injunctive relief." Id. In so finding, the court relied on the fact that the parent corporation owned 100% of all the subsidiary-patent owner's assets, including the disputed patents. *Id.* at 705. The board members of the two corporations substantially overlapped, the parent's employees were responsible for marketing, sales, and licensee assistance for the subsidiary-patent owner, and the parent was actively involved in the subsidiary's management. Id. Here, BSC argues that "in addition to owning BSSI, BSC and BSSI share common leadership and BSC is involved in the manufacturing, distribution, and research and development of common products with BSSI, and it was BSC's decision to file the present lawsuit." (D.I. 216 at 20-21) However, these facts do not rise to the level of involvement as found in Pipe Liners.

In Cognex, the court found that the parent corporation had standing where the decision to bring suit was made by the parent, the parent set the licensing policies for the subsidiary's intellectual property, and the parent had presented ample evidence that supported the existence of an exclusive implied license between the parent and subsidiary. Cognex Corp. v. Microscan Sys., Inc., 2014 WL 2989975, at *5 (S.D.N.Y. June 30, 2014). Although BSC argues here that it decided to bring this lawsuit, not BSSI, BSC has not produced ample evidence to support the existence of an exclusive implied license between it and BSSI, discussed supra §IV(B)(i). (D.I. 216 at 21)

In Atmel, the court found that the parent company had standing where the subsidiary had never allowed any third party to practice the patent, the parent had the implicit right to make, use, and sell the patented inventions, and the parent controlled the enforcement of the patent rights. Atmel Corp. v. Authentec, Inc., 490 F. Supp. 2d 1052, 1055 (N.D. Cal. 2007). The court relied on the fact that the parent corporation was found to be the only entity that practices and enforces the patent in the United States, and that the parent and subsidiary were "essentially one and the same." Id. (citing Mi–Jack Products, Inc. v. The Taylor Group, Inc., 1997 WL 441796, *8 (N.D. Ill. 1997) (finding standing based upon the "extremely close" relationship between the parent patent holder and the wholly owned subsidiary licensee)). Again, BSC has not produced ample evidence to support the existence of an exclusive implied license between it and BSSI, discussed supra §IV(B)(i), as was found in Atmel, nor has it produced evidence to support a finding that BSC and BSSI are "essentially one in the same."

In Steelcase, the court found that the parent corporation had standing to prosecute a suit on the patent-in-suit. Steelcase, Inc. v. Smart Techs., Inc., 336 F. Supp. 2d 714, 718 (W.D. Mich. 2004). Specifically, the subsidiary, who owned the patent, was a wholly owned subsidiary of the parent. Id. There was no written license agreement between the two, but the parent was found to be the sole licensee of the patent, the subsidiary permitted the parent to exclusively practice the patent, and the subsidiary granted the parent the right to enforce the patent. Id. Moreover, there

was no evidence that since the subsidiary had acquired the patent-in-suit that it ever granted rights in the patent to any party other than the parent. Id. Because the parent and subsidiary were found to be "one and the same," the court held that the parent had standing. Id. (citing Mi-Jack, 1997 WL 441796. Again, no such facts are present here, besides BSC owning BSSI. Moreover, the fact of corporate ownership alone was not sufficient to confer standing and the court reached a different conclusion for the grandparent corporation. The court rejected the grandparent corporation's reliance on Pipe Liners and, instead, agreed with the analysis in Beam Laser Systems, wherein the court found the Pipe Liners decision unpersuasive because "[o]wnership of corporate stock does not create equitable title in that corporation's property." Id. at 719 (citing Beam Laser Systems, 117 F. Supp. 2d at 521). The court, therefore, dropped the grandparent corporation as a party because "a parent does not have equitable title in a patent solely by virtue of its ownership of the subsidiary." Id. Here, BSC's general averment of its involvement in activities with its affiliates and its unspecified purported sharing of some common leadership with its affiliates does not render it a corporate alter ego of BSSI or BSL resulting in equitable standing.

Because BSC has not provided enough evidence to show that it and BSSI are "one and the same," the court recommends dismissal of BSC's claims for its lack of standing.

V. CONCLUSION

For the foregoing reasons, the court recommends granting-in-part and denying-in-part Edwards' motion to dismiss for lack of subject matter jurisdiction pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(h)(3). (D.I. 205) Specifically, the court recommends dismissal of BSC's claims, but recommends denying the motion to dismiss the claims of BSSI.

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties should jointly submit a proposed redacted version by no later than **February 23, 2018**. The court will subsequently issue a publicly available version of its Report and Recommendation.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation.

Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. See Sincavage v. Barnhart, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); Henderson v. Carlson, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: February 16, 2018

United States Magistrate Judge