

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NOVARTIS PHARMECEUTICALS :
CORPORATION, NOVARTIS PHARMA :
AG, and NOVARTIS INTERNATIONAL :
PHARMECEUTICAL LTD., :
 :
Plaintiffs, :
 :
v. :
 :
TEVA PHARMECEUTICALS USA, INC. :
 :
Defendant. :

Hon. Dennis M. Cavanaugh

OPINION

Civil Action No. 05-CV-1887
(DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motion by Defendant, Teva Pharmaceuticals USA, Inc., to dismiss the claims of Plaintiffs, Novartis Pharmaceuticals Corporation (“NPC”) and Novartis Pharma, AG (“NPAG”) (collectively “Plaintiffs”), for lack of Article III standing. Pursuant to Fed. R. Civ. P. 78, no oral argument was heard. After considering the submissions of the parties, and based upon the following, it is the decision of this Court for the reasons herein expressed that Defendant’s motion to dismiss is **denied**.

I. BACKGROUND

Teva Pharmaceuticals USA, Inc. (“Defendant”) concedes that, insofar as the patent at issue is found to be valid and enforceable, Defendant’s famciclovir product infringes that patent. The issues presented for trial include whether U.S. Patent No. 5,246,937 (the “937 patent”) is invalid as obvious or unenforceable as a consequence of inequitable conduct before the United States Patent

and Trademark Office.

The '937 patent was issued on September 21, 1993 to Michael R. Harnden and Richard L. Jarvest, with Beecham Group PLC as the assignee. In an Asset Sale Agreement, dated August 30, 2000, purchasers, NPAG and NPC purchased certain "Purchased Assets (as hereinafter defined) related to Famciclovir and Penciclovir" from sellers, SmithKline Beecham PLC, SmithKline Beecham Corporation and SmithKline Beecham (Cork) Limited ("SKB"). Section 2, subtitled Assets to Be Sold and Purchased, delineates the following:

Upon the terms and subject to the conditions of this Agreement, [seller] agrees to sell, assign, transfer, convey and deliver to Purchaser and Purchaser agrees to purchase from [seller], at the Closing, all rights title and interest, within the Territory, of [seller] and its Affiliates in and to the following assets, regardless of where such assets are situated (the "Purchased Assets"), free and clear of all Encumbrances:

- (i) all Product Intellectual Property;

On December 20, 2000, Novartis International Pharmaceutical Ltd. ("NIP") acquired title to the '937 patent, pursuant to an assignment, between SKB and NIP. Under that assignment, "[e]ach assignor d[id] hereby sell, transfer, convey and assign unto Assignee such Assignor's entire right, title and interest in and to the Product Patents which are owned by such Assignor . . ."

II. LEGAL STANDARD

Pursuant to 35 U.S.C. § 281, a patentee is entitled to bring a civil action for infringement of his patent. "[P]atentee" includes "not only the patentee to whom the patent was issued but also the successors in title to the patentee." Id. "Those provisions of the Patent Act have been interpreted to require that a suit for infringement of patent rights ordinarily be brought by a party holding legal title to the patent." Propat Int'l Corp. v. RPost US, Inc., 473 F.3d 1187, 1189 (Fed. Cir. 2007) (citing Sicom Sys. Ltd. v. Agilent Techs.Inc., 427 F.3d 971 (Fed. Cir. 2005)).

“[W]here there has been a transfer of the right to make, use and vend the invention throughout the United States, or a specified part of the United States, it amounts to an assignment, irrespective of the name which is affixed to the agreement, vesting in the assignee title in that much of the patent with a right to sue infringers in the[ir] name alone.” Hook v. Hook & Ackerman, Inc., 187 F.2d 52 (3d Cir. 1950) (citing Waterman v. Mackenzie, 138 U.S. 252 (1891)). “The assignment of legal title in a patent can be conveyed in the form 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 (a so called ‘grant’).” Enzo APA & Son v. Geapag A.G., 134 F.3d 1090, 1094 (Fed. Cir. 1998). However, “[w]hat purports to be an assignment may be a license only, and the court will examine the ‘license’ or ‘assignment’ to determine the legal effect of the transfer agreement.” Hook, 187 F.2d at 57. “The owner of a patent, who grants to another the exclusive right to make, use, or vend the invention, which does not constitute a statutory assignment, holds the title to the patent in trust for such a licensee, to the extent that he must allow the use of his name as plaintiff in any action brought at the instance of the licensee in law or in equity to obtain damages for the injury to his exclusive right by an infringer.” Id. (citing Independent Wireless Tel. Co. v. Radio Corp. of America, 269 U.S. 459 (1926)). The position articulated by Independent Wireless has been interpreted as meaning, “an exclusive licensee has a sufficient interest in the patent to have standing to sue under Article III of the Constitution.” Id. at 1193. “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.” Id.

III. DISCUSSION

Defendant contends that Plaintiffs, NPC and NPAG, lack standing under Article III of the

United States Constitution. Defendant asserts that NPC and NPAG are neither the title holders nor the exclusive licensees of the patent at issue. Defendant points to Plaintiffs failure to produce written license agreements between the named Plaintiffs and failure to identify NPC and NPAG as exclusive licensees in either the interrogatories or initial complaint, acknowledging Plaintiffs as licensees.

By contrast, despite the absence of the explicit terminology, “exclusive license,” Plaintiffs claim that the Asset Sale Agreement, dated August 30, 2000 between SKB, as seller, and NPC and NPAG, as purchasers, vests Plaintiffs with exclusive licenses under the patent. In the alternative, Plaintiffs argue that, if the Court does not interpret the Asset Sale Agreement as vesting NPC and NPAG with exclusive licenses, the relationship and course of conduct between NIP, NPC and NPAG establishes an implied exclusive license. Finally, Plaintiffs urge that, given the sufficient evidence suggestive of at least an implied exclusive license, a disputed issue of fact arises requiring the issue to be tried before a jury.

A. Exclusive License

"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." Aspex Eyewear, Inc. v. Miracle Optics, Inc., 434 F.3d 1336,1340 (Fed. Cir. 2006) (quoting Waterman, 138 U.S. at 256). "To determine whether an agreement to transfer rights to a patent at issue amounts to an assignment or a license, we must ascertain the intention of the parties and examine the substance of what was granted."Id. (citing Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 875 (Fed. Cir. 1991)).

Pursuant to the assignment dated December 20, 2000, the parties do not dispute that NIP

holds title to the '937 patent. Although Plaintiffs concede that the Asset Sale Agreement lacks the particular language, "exclusive license," Plaintiffs propose that such agreement vests in NPC and NPAG exclusive licenses. If, as Plaintiffs contend, the Asset Sale Agreement was characterized as vesting an exclusive license in NPC and NPAG, the existence of such licenses would arise as consequence of the relationship between SKI and, NPC and NPAG, but not a relationship between NIP and NPC and NPAG. While the predominant language of the agreement is more indicative of an assignment than a license, the subsequent assignment, identifying NIP as assignee of the "entire right, title and interest in and to the Product Patents" indicated in the Asset Sale Agreement, negates conveyance of any interest NPC and NPAG claim to have obtained formerly pursuant to the initial Asset Sale Agreement. A different reading potentially renders the assignment to NIP subject to the alleged and undefined exclusive licenses held by NPC and NPAG, and, dependent upon the scope of the claimed former licenses, potentially reduces the assignment to a mere license.¹ Indeed, even if the Court were to find that the Asset Sale Agreement confers some form of licensing, the contours of the alleged licenses evidencing exclusivity are entirely absent. Therefore, to the extent that named Plaintiffs, NPC and NPAG, hold exclusive licenses pursuant to the Asset Sale Agreement, dated August 30, 2000, an issue of fact arises concerning the scope and definition of such licenses.

B. Implied Exclusive License

A "patent license agreement is in essence nothing more than a promise by the licensor not

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"The patentee has no more right to practice his patent in a field of use where an exclusive license has been given, than does a stranger." Sanofi, S.A. v. Med-Tech Veterinarian Products, Inc., 565 F. Supp. 931, 937 (D.N.J. 1983) (citing Littlefield v. Perry, 88 U.S. 205, 223 (1874)). Therefore, if the exclusive license has been violated by the patentee, the patentee may be sued for infringement. Id. (citing Research Frontiers, Inc. v. Marks Polarized Corp., 290 F. Supp. 725, 727 (E.D.N.Y. 1968)).

to sue the licensee” for infringement. Medtronic AVE Inc. v. Advanced Cardiovascular Sys., 247 F.3d 44, 59 (3d Cir. 2001) (citing Spindelfabrik Suessen-Schurr Stahlecker, v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft, 829 F.2d 1075, 1080 (Fed. Cir. 1987)). Inasmuch as implied licenses are generally asserted as a defense, “[c]ourts grant implied licenses in order to preclude patent holders from suing purchasers for infringement where, at the time of sale, the patentee led the purchaser to believe that his manufacture, use, or sale of the patented article was permissible.” Monsanto Co. v. Good, 2003 U.S. Dist. LEXIS 27217, *21 (D.N.J. July 23, 2003) (citing Bandag, Inc. v. Al Bolser's Tire Stores, Inc., 750 F.2d 903, 925 (Fed. Cir. 1984)). The existence of an implied license is a matter of inference, deduced from the particular circumstances.² Id. “The party seeking invocation of the implied license doctrine must demonstrate ‘any language used by the owner of the patent or any conduct on his part exhibited to another, from which that other may properly infer that the owner consents to his use of the patent’” Lever Bros. Co. v. Procter & Gamble Distributing Co., 668 F. Supp. 924, 940 (D.N.J. 1987) (citing Lukens Steel Co. v. American Locomotive Co., 197 F.2d 939, 941 (2d Cir. 1952)). In Aspex Eyewear, Inc. v. E'Lite Optik, Inc., the Federal Circuit concluded that the “existence of an oral or implicit license is not a pure question of law, but likely involves fact finding.” 2005 U.S. App. LEXIS 4803, *12 (Fed. Cir. Mar. 24, 2005).

Although transfer by assignment requires a writing, a license may be oral. Waymark Corp. v. Porta Sys. Corp., 334 F.3d 1358, 1364 (Fed. Cir. 2003). At the same time, “it is true that only in

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By way of example, “[a] mere sale does not import a license except where the circumstances plainly indicate that the grant of a license should be inferred.” Monsato, at *21. “Moreover, where the circumstances of a sale do not indicate that a license should be implied, the defendant must show that no non-infringing uses of the patented article exist in order to benefit from the implied license doctrine. Id. at *22.

extremely limited circumstances can the holder of an oral transfer of patent rights sue for infringement in its own name.” Id. Although “a license may be written, verbal, or implied, if the license is to be considered a virtual assignment to assert standing, it must be in writing.” Enzo APA & Son v. Geapag A.G., 134 F.3d 1090, 1093 (Fed. Cir. 1998). “The limited exception we have provided conferring standing on licensees is restricted to virtual assignees.” Id. “As such, the licensing arrangement conferring such must, logically, resemble an assignment in both form and substance.” Id. However, the Federal Circuit has 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.” Aspex Eyewear, Inc. v. Altair Eyewear, Inc., 2008 U.S. App. LEXIS 16344, *22 (Fed. Cir. Aug. 1, 2008) (citing Waymark, 334 F.3d at 1364)).

In stressing the existence of an implicit exclusive license, Plaintiffs underscore the fact that these “three entities constitute the sole authorized production and distribution chain for every famciclovir tablet sold in the United States.” (Pls. Br. at 11). In fact, Plaintiffs contend that NPAG operates as the exclusive manufacturer of famciclovir tablets, selling only to NPC. (Pls. Br. at 5). In turn, NPC operates as the sole authorized distributor of famciclovir tablets sold in the U.S. Id. Further, Plaintiffs underscore NPC’s and NPAG’s ability to sublicense their rights to ‘937 patents.

At the same time, the Court recognizes the inconsistency underscored by Defendants. In particular, in response to an interrogatory, Plaintiffs indicated the following:

Without waiving its objections, Novartis contends that Novartis International Pharmaceuticals Ltd. purchase all rights to tile '937 patent from Beecham Group P.L.C. Novartis Pharma AG was granted a license from Novartis International Pharmaceuticals Ltd. to manufacture, use, and sell the invention claimed in the '937 patent in the United States. Novartis Pharmaceuticals Corporation was granted a license from Novartis Pharma AG to manufacture, use, and sell the invention claimed in the '937 patent in the United States.

(Def. Br. at 5). Defendants also point out that in a hearing before the Honorable Mark Falk, U.S.M.J., Plaintiffs asserted that despite an inability to locate licenses, granted between the Novartis entities, under the '937 patent, corporate agreements may exist between the various entities delineating technology transfers.

In light of the public policy “favor[ing] [the] prevent[ion] of multiple lawsuits on the same patent against the same accused infringer,” the Court declines to dismiss NPC and NPAG for lack of Article III standing at this time. Miracle Optics, Inc., 434 F.3d at 1343. As a consequence of the implicit recognition afforded NPC and NPAG by the title holder to the '937 patent, the Court finds that an implicit license exists between NIP and, NPC and NPAG. However, an inconsistency arises with regard to whether licenses constitute exclusive licenses or merely bare licenses. In the absence of affirmative and concrete evidence supporting the existence of individual licenses held by NPC and/or NPAG to the exclusion of all others, the Court declines render a finding with respect to the Article III standing of NPC and NPAG at this time. The Court recognizes that Plaintiffs have put forth sufficient evidence to create an issue of fact concerning whether NPC and NPAG hold exclusive licenses or, rather, maintain only bare licenses. At this time, there is insufficient evidence to render a finding whether NPC and NPAG hold exclusive licenses permitting standing in this matter. Therefore, this issue of fact will be resolved before the trier of fact in this case.

C. Parent/Subsidiary Relationship

At the same time, if each entity holding an interest in the patent is a wholly owned subsidiary of the parent corporation, resolution of this issue may not be of immediate need. “Another policy consideration is to prevent a party with lesser rights from bringing a lawsuit that may put the licensed patent at risk of being held invalid or unenforceable in an action that did not involve the patentee[.]” or by extension, the parties with a right to relief under the patent. Id. Therefore, if each entity

controls a divided, but undefined interest in the patent, policy favoring the prevention of multiple lawsuits and inconsistent judgments disfavors dismissal of NPC and NPAG at this time.

D. Available Remedies

Defendant contends that upon dismissal of NPC and NPAG, if Teva is found liable, NIP's remedies will be limited. Defendant argues that Plaintiff, as a mere holding company, will be precluded from obtaining injunctive relief. Defendant suggests it is unlikely that NIP that will be able to demonstrate the requisite showing of irreparable harm or the inadequacy of legal remedies.³ Further, Defendant argues that to recover lost profit damages, Plaintiff must have been selling the product patented. By contrast, NIP claims that as a manufacturer of famciclovir, it is not merely a holding company and in fact, incurs irreparable harm as a consequence of Defendant's potentially infringing activity. Further, NIP argues that lost profits arise as a consequence of the loss of royalties caused by Defendant's potentially infringing conduct. Although the Court acknowledges this point of contention, the Court will not speculate as to the scope of remedies available in this matter until the foregoing issues of fact have been resolved.

³Injunctive relief requires the following: (1) a reasonable probability of success on the merits; (2) irreparable injury; (3) the improbability of harm to other interested persons; and (4) the public interest. Apple Computer, Inc. v. Franklin Computer Corp., 714 F.2d 1240, 1246 (3d Cir. 1983). "In order to demonstrate irreparable harm the plaintiff must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial." Airfreight Co. v. C.F. Airfreight, Inc., 882 F.2d 797, 801 (3d Cir. 1989).

IV. CONCLUSION

Based on the foregoing, this Court finds insufficient evidence to determine whether the claims of Plaintiffs, NPC and NPAG, should be dismissed for lack of standing at this time. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Dated: October 21, 2009
Original: Clerk
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
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