

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ICAHN SCHOOL OF MEDICINE AT
MOUNT SINAI,

15 Civ. 9414

Plaintiff,

OPINION

-against-

NEUROCRINE BIOSCIENCES, INC.,

Defendant.

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A P P E A R A N C E S:

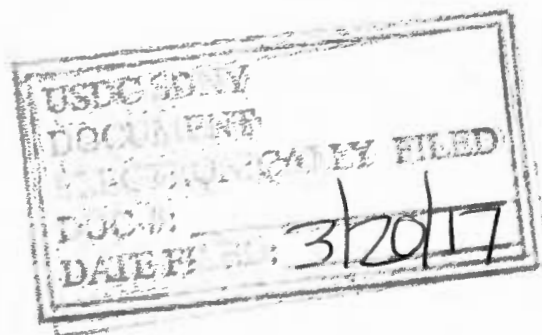
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Sweet, D.J.

The Plaintiff Icahn School of Medicine at Mount Sinai ("Mt. Sinai" or the "Plaintiff") has moved pursuant to F. R. Civ. P. 12(f) to strike Defendant Neurocrine Biosciences, Inc.'s ("Neurocrine" or the "Defendant") affirmative defenses for patent invalidity, non-infringement, and misuse, and moved pursuant to F. R. Civ. P. 12(b)(1) to dismiss Defendant's corresponding declaratory judgment counterclaims. Based on the conclusions set forth below, Plaintiff's motion to strike affirmative defenses 11-14 and to dismiss counterclaims I-IV is granted.

Prior Proceedings

The Defendant's motion to dismiss the complaint was denied on June 13, 2016, finding that Mt. Sinai adequately alleged that Neurocrine had breached and violated the licensing agreement regarding an alleged sublicense to Abbott International Luxembourg S.a.r.l. ("Abbott"), now AbbVie Inc. ("AbbVie"), violated the licensing agreement, created a de facto sublicense, and alleged adequate damages, though it limited the scope of the license to the two patents.

The instant motion to strike affirmative defenses and dismiss counterclaims was heard and marked fully submitted on November 3, 2016.

Pleadings

Plaintiff, formerly known as Mt. Sinai School of Medicine of the City University of New York, is a New York education corporation, organized under the New York Education Law and chartered by the Board of Regents of the State of New York. Its sole member is Mt. Sinai Health System, Inc., a not-for-profit corporation organized under the laws of the State of New York. Mt. Sinai owns and controls certain rights in technology for the identification, discovery, and screening of drug compounds that interact in the human body with receptors for the hormone known as GnRH. Mt. Sinai's drug-discovery tools are foundational in the identification, screening, and development of drugs for the treatment of a number of endocrine disorders, and Mt. Sinai has the exclusive right to grant licenses to the patented technology directed thereto. (Compl., ¶ 20.)

Neurocrine is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12780 El Camino Real, San Diego, CA 92130. Neurocrine is in the business of, among other things, developing pharmaceuticals for use in neurological and endocrine diseases and disorders. (Compl., ¶ 22.)

AbbVie is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is in the business of, among other things, pharmaceutical development, manufacturing and sales.

Mt. Sinai and Neurocrine entered a patent license agreement for certain drug discovery tools on August 27, 1999 including Mt. Sinai's '366 patent and '583 patent, which were issued in May 1998 and November 1999. Both patents have now expired.

The complicated process of discovering and developing new drug treatments requires basic research such as is performed by Mt. Sinai and its scientists. The application of that science to particular conditions such as endometriosis and

uterine fibroids was performed by Neurocrine. The testing, approval, and manufacture of the new drug is performed by a major pharmaceutical company, in this instance Abbott International Luxembourg S.a.r.l. ("Abbott"), now AbbVie.

Gonadotropin releasing hormone ("GnRH") is implicated in numerous endocrine diseases including prostate cancer, ovarian cancer, breast cancer, and endometriosis. (Compl. ¶¶ 3, 38, 40-43.) Stuart C. Sealton, M.D., a world-renown neurologist at Mt. Sinai, was the first to make stable cell lines expressing the cloned receptor for GnRH ("GnRH-R") and invented a method to identify drug compounds that modulate the receptor's molecular signaling using the cell lines. (Id. ¶¶ 39-40.) Dr. Sealton's patented inventions, assigned to Mt. Sinai, are foundational drug-discovery tools. Both Parties recognized the Sealton tools as essential for Neurocrine to identify and develop new drugs that inhibit GnRH activity and can be used to treat endocrine disorders. (Id. ¶¶ 5, 40-46, 50.)

The parties, on August 27, 1999, entered into a Nonexclusive License Agreement ("License Agreement") which provided that Neurocrine may "grant sublicenses under the License only with the prior written consent" of Mt. Sinai.

(Compl. Ex. 1, D.I. 1-1 ("License Agreement") § 2.1(c).) Mt. Sinai alleges that during their negotiations, the Parties recognized that if Neurocrine identified a promising drug candidate, Neurocrine likely would sublicense (for additional consideration to Mt. Sinai) the remainder of the drug development efforts, which require expensive Phase 3 clinical trials, to a major pharmaceutical corporation. (Compl. ¶¶ 47, 54, 57.)

Neurocrine allegedly used the licensed Sealfon tools to identify "Elagolix" as a strong candidate for treating endocrine disorders. (Compl. ¶ 58.) Neurocrine had contractual obligation to provide annual development reports, including a "complete written list of Licensed Products discovered in the previous year" (License Agreement § 3.5; which it breached; Compl. ¶¶ 67-76), Neurocrine allegedly discovered Elagolix not later than early 2001 (Compl. ¶ 60).

In June 2010, Neurocrine entered an agreement with AbbVie allegedly regarding some of the rights under Neurocrine's license agreement with Mt. Sinai to further develop Elagolix. On June 15, 2010, Neurocrine and AbbVie publicly announced their agreement, under which "Abbott will receive worldwide exclusive

rights [from Neurocrine] to develop and commercialize Elagolix and all next-generation GnRH antagonists, for women's and men's health." (Compl. ¶ 77 and Compl. Ex. 2, D.I. 1-2 ("Press Release") at 1.) Neurocrine did not seek or obtain Mt. Sinai's consent before entering the agreement with AbbVie. (*Id.* ¶¶ 54-57, 71).

Elagolix is currently undergoing FDA testing and has not yet been approved for sale in the United States. The parties dispute whether Mt. Sinai is seeking royalties from future sales of Elagolix, or damages from a breach of the contract for what would have been reasonable compensation for the breach in 2010.

Applicable Standard

On a motion to strike pursuant to Rule 12(f), the Court "may order stricken from [a] pleading any insufficinet defense or any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." *Pony Pal, LLC. v. Claire's Boutiques, Inc.*, No. 05 Civ. 2355 (CSH), 2006 WL 846354, at *2 (S.D.N.Y. Mar. 31, 2006). A motion to strike may be granted where there is no question of fact and no substantial

question of law, the "resolution of which could allow the defense to succeed." *S.E.C. v. Toomey*, 866 F. Supp. 719, 722 (S.D.N.Y. 1992). However, "Motions to strike affirmative defenses are generally disfavored and should be denied unless there is a clear showing that the challenged defense has no bearing on the subject matter and that permitting the defense to stand would prejudice the plaintiff." *Emmpresa Cubana del Tabaco v. Culbro Corp.*, 213 F.R.D. 151, 154-155 (internal citations omitted).

Courts dismiss a case "for lack of subject matter jurisdiction under Rule 12(b)(1) when [they] lack[] the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). The Court only has subject matter jurisdiction over claims that present an "actual controversy" and not hypothetical claims. *Nike, Inc. V. Already, LLC*, 663 F.3d 89, 95 (2d cir. 2011), *aff'd*, 133 S.Ct. 721 (2013). The party seeking declaratory relief "bears the burden of proving subject matter jurisdiction by a preponderance of the evidence." *Aurecchione v. Schoolman Transp. Sys., Inc.*, 426 F.3d 635, 638 (2d Cir. 2005).

Neurocrine Is Estopped from Challenging the Validity of the Patents and the Twelfth and Thirteenth Affirmative Defenses Are Stricken

Neurocrine argues that its patent invalidity defenses are relevant and cause no prejudice because if the patents are invalid, then neither Neurocrine nor AbbVie needed Mt. Sinai's permission to use the Mt. Sinai tools to develop the GnRH receptor. Citing *Myriad Genetics*, Neurocrine concludes that Mt. Sinai's patents are "naturally occurring" sequences of the GnRH-R gene. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116-19 (2013). Further, Neurocrine argues the patents are invalid for anticipation, obviousness, and/or written description and enablement. 35 U.S.C. §§ 102, 103, 112.

However, this motion does not involve the merits of the patent invalidity issue. Instead, Mt. Sinai seeks to estop Neurocrine from asserting the patent invalidity defense because Neurocrine has already enjoyed the benefits of the patent license. The parties agree that a licensee is estopped from asserting invalidity as a defense to contractual obligations and royalties already owed at the time of the suit, however the parties dispute whether the relief requested by Mt. Sinai here for obligations that may accrue in the future.

The Supreme Court has held that a licensee cannot be estopped from challenging the validity of a patent merely because it benefitted from a license agreement. *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). This is because the licensee "may often be the only individual[] with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification." *Id.*

The Federal Circuit has found an exception to the *Lear v. Adkins* rule for circumstances in which the licensee is seeking to avoid contractual obligations that the licensee already owes under the agreement. *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997), *cert denied*, 522 U.S. 996, 118 S.Ct. 560, 139 L.Ed.2d 401 (1997) ("this court must prevent the injustice of allowing Shell to exploit the protection of the contract and patent rights and then later to abandon conveniently its obligations under those same rights") ("*Shell Oil*"); see also *Advanced Card Techs., LLC v. Versatile Card Tech., Inc.*, 410 F. Supp. 2d 158, 161 (S.D.N.Y. 2006) (estopping a party from challenging the validity of a patent for "royalty payments that were not made in respect

of sales accruing prior to the filing of this action"); *Revson v. Claire's Stores, Inc.*, 120 F. Supp. 2d 322, 326-27 (S.D.N.Y. 2000) (same).

The parties dispute how to characterize the relief that Mt. Sinai seeks. It is undisputed that Neurocrine is "not [] precluded from raising a defense of patent invalidity against" a claim "to recover royalties for time periods after the filing of the Answer in this case." *Pony Pal, LLC. v. Claire's Boutiques, Inc.*, No. 05 Civ. 2355 (CSH), 2006 WL 846354, at *3 (S.D.N.Y. Mar. 31, 2006).

Mt. Sinai claims that it is not seeking future royalties for Elagolix. Instead, Mt. Sinai claims that it seeks the value of an unlawful sublicense measured in 2010 at the time Neurocrine allegedly sublicensed the rights to the patents to AbbVie without obtaining Mt. Sinai's contractually required consent. *Schonfeld v. Hilliard*, 218 F.3d 164, 176 (2d Cir. 2000) ("When the defendant's conduct results in the loss of an income-producing asset with an ascertainable market value, the most accurate and immediate measure of damages is the market value of the asset at the time of breach—not the lost profits that the asset could have produced in the future."). Neurocrine

argues that only past royalties are compensable under the relevant caselaw cited above. If the damages Mt. Sinai alleges are distinct from royalties on Elagolix, then they are permissible damages because "there is [not] a relevant distinction between unpaid royalties and other types of damages flowing from the breach of the Licensing Agreement." *Esoterix Genetic Laboratories LLC v. Qiagen Inc.*, 133 F.Supp.3d 349, 362 (D. Mass. 2015). "The Federal Circuit's holding in *Shell Oil* is not obviously limited to royalties and can be read to stand for the broader principle that a licensee may not avoid liability for damages arising out of its breach of a license agreement, assuming that the breach occurred prior to the date that the licensee first challenged the validity of the patent claims." *Id.*

Neurocrine argues that even if the estoppel argument is permitted with respect to non-royalty contractual damages, Neurocrine must be permitted its invalidity affirmative defense to prevent injustice based on the unclean hands doctrine.

First, Neurocrine asserts that Mt. Sinai sat on its rights for more than five years before bringing this claim. However, it is undisputed that the claim was brought within the

statute of limitations period for breach of contract in New York. As Neurocrine argued, a party cannot assert an equitable defense related to the other party's delay where it also contributed to that delay. *King v. Innovation Books*, 976 F.2d 824, 833 (2d Cir. 1992); *Clarke v. Comm. Workers of Am.*, 318 F. Sup. 2d 48, 57-58 (E.D.N.Y. 2004). However, this line of cases is inapplicable here because Mt. Sinai is not claiming that Neurocrine unlawfully delayed any action since 2010; Mt. Sinai is asserting that it wants damages from an alleged breach that occurred in 2010.

Neurocrine is estopped from asserting patent invalidity to avoid its prior obligations arising under the License Agreement and its twelfth and thirteenth affirmative defenses are stricken. Accordingly, Mt. Sinai is precluded from asserting a claim for royalties on sales of Elagolix and may only claim damages for what it could have reasonably obtained at the time of the alleged breach in 2010.

Neurocrine's Eleventh Affirmative Defense for Non-Infringement is Stricken

Neurocrine attempts to bring an affirmative defense for non-infringement of the patents despite the fact that Mt.

Sinai did not bring a claim for infringement. Neurocrine brings this defense so that it can assert that it "will not owe royalties based on sales of Elagolix." (Opposition Brief ("Oppn. Br.") at 16.) For the reasons that follow, this defense cannot be brought since Mt. Sinai did not seek a claim for infringement, though Neurocrine will not owe any royalties based on sales of Elagolix.

Neurocrine has at all relevant times been licensed to use the Mt. Sinai patented technology, and there is no claim for infringement. The statute dictates that there can only be a claim for infringement when a party "without authority makes, uses, offers to sell, or sells any patented invention." 35 U.S.C. § 271(a). Neurocrine seeks to use non-infringement as a method to challenge the breach of contract action, which is not permissible.

Neurocrine has relied on *Pony Pal*. However, unlike the instant affirmative defense, the action in *Pony Pal* was for a declaratory judgment that "products sold by Defendant do not fall within the scope of the Patent claims, and that, therefore, Defendant is not in breach of the Agreement." *Pony Pal, LLC. v. Claire's Boutiques, Inc.*, 2006 WL 846354, at *5. Here, the

Defendant is not yet selling any products that are allegedly violating the patents. The claim in this action is for breach of contract for not obtaining Mt. Sinai's permission before forming the agreement with AbbVie. The counterclaim for non-infringement, Counterclaim Eleven, is stricken.

Neurocrine's Fourteenth Affirmative Defense for Patent Misuse is Stricken

Neurocrine also seeks to assert an affirmative defense of patent misuse because Mt. Sinai is allegedly seeking impermissible royalties on sales of Elagolix even though Mt. Sinai does not own any patents for Elagolix and those royalties extend beyond the life of the two drug discovery patents relevant in this case. *Kimble v. Marvel Entertainment, LLC*, 135 S.Ct. 2401, 2407 (2015); *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S.Ct. 843, 851-52 (2014).

Again, the issue is whether Mt. Sinai is claiming royalties on future sales of Elagolix or is seeking damages for Neurocrine's breach by allegedly sublicensing with AbbVie without obtaining Mt. Sinai's permission, as is required under Section 2.1(c) of the License Agreement. As discussed above,

Mt. Sinai is precluded from bringing any claims for royalties of future sales of Elagolix.

If Mt. Sinai is successfully able to establish that Neurocrine breached the License Agreement by failing to ask for permission to sublicense the patents to AbbVie and Abbvie employed Mr. Sinai's technology, Neurocrine argues that Mt. Sinai's alleged damages force "Neurocrine at gunpoint, conditioning its sublicense (and, according to Mount Sinai, its ability to close the AbbVie deal) on Neurocrine's agreement to pay an exorbitant and unprecedented royalty." (Oppn. Br. at 17.) However, Mt. Sinai will only be permitted to seek what it reasonably could have bargained for at the time of the breach, namely the value of the sublicense, and not future Elagolix royalties. *Schonfeld v. Hilliard*, 218 F.3d at 176.

Neurocrine's Affirmative Defenses Would Prejudice Mt. Sinai

In order to establish if the moving party would suffer prejudice, if "the defense is insufficient as a matter of law, the defense should be stricken to eliminate the delay and unnecessary expense from litigating the invalid claim." *Fed. Deposit Ins. Corp. v. Eckert Seamans Cherin & Mellott*, 754 F. Supp. 22, 23 (E.D.N.Y. 1990). Here, the delay and "unnecessary

expense" of litigating the validity of the underlying patents would greatly expand the scope of this case and would cause the Plaintiff prejudice because these issues are far outside of the scope of the breach of contract claim. *Id.* Some of the additional costs leading to this prejudice include numerous additional technical, factual, and legal issues that would lead to additional fact discovery, expert discovery, and substantial motion practice. For these reasons, there is sufficient prejudice shown and affirmative defenses 11 through 14 are stricken.

The Declaratory Judgment Counterclaims Are Dismissed for the Same Reasons the Affirmative Defenses Are Stricken

The parties dispute whether the declaratory judgment claims for patent invalidity, non-infringement, and misuse are ripe since they may depend on sales of Elagolix, which is not yet on the market. The Second Circuit's standard for ripeness of declaratory judgment actions is that "there is a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Inc. v. St. Paul Fire & Marine Ins. Co.*, 411 F.3d 384, 388 (2d Cir. 2005) (internal citations omitted).

Here, the dispute about whether a successful challenge to the patents would impact Mt. Sinai's damages for future sales of Elagolix is a substantial controversy. The question is whether it is of sufficient immediacy as Elagolix is not yet commercially available. However, while the question of ripeness is one of degree, "the fact that liability may be contingent does not necessarily defeat jurisdiction of a declaratory judgment action." *Associated Indem. Corp. v. Fairchild Indus.*, 961 F.2d 32, 35 (2d Cir. 1992) (internal citations omitted). Here, despite the contingent question of whether Elagolix will ever be sold publically, Neurocrine's claims are ripe and it is more efficient to resolve them in this action. *Dish Network, LLC v. Am. Broad. Cos.*, No. 12 Civ. 4155, 2012 WL 2719161, at *3 (S.D.N.Y. July 9, 2012) ("One of the primary purposes of declaratory relief is to promote efficiency-i.e., to allow one action to define the legal relationships and adjust the attendant rights and obligations at issue between the parties") (internal citations omitted).

While the declaratory judgment claims are ripe, they are dismissed for the same reasons articulated above in deciding the parallel claims to strike affirmative defenses. The underlying claims for the declaratory judgment counterclaims for

patent invalidity, non-infringement, and misuse are the same substantive legal claims as the affirmative defense claims discussed above and are dismissed for the same reasons.


Conclusion

Based on the conclusions set forth above, Plaintiff's motion to strike affirmative defenses 11-14 and to dismiss counterclaims I-IV is granted.

It is so ordered.

New York, NY

March 17, 2017

A handwritten signature in cursive script, appearing to read "Sweet", is written over a horizontal line.

ROBERT W. SWEET

U.S.D.J.