UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

CHR. HANSEN HMO GMBH, Plaintiff and Counterclaim-Defendant, v. GLYCOSYN LLC, Defendant and Counterclaim-Plaintiff. v. ABBOTT LABORATORIES, Third-Party Defendant.

REPORT AND RECOMMENDATION ON ABBOTT'S MOTION FOR SUMMARY JUDGMENT (D. 200)

CABELL, U.S.M.J.

Plaintiff Chr. Hansen HMO GmbH ("Hansen") has brought an action for a declaratory judgment that it has not infringed two patents belonging to defendant Glycosyn LLC ("Glycosyn"), including U.S. Patent No. 9,970,018 ("'018 Patent") and its precursor, U.S. Patent No. 9,453,230 ("'230 Patent"). The patents provide a method of using genetically engineered strains of E. Coli to produce 2'-Fucosyllactose ("2'-FL"), a human milk oligosaccharide ("HMO") used in infant formula. Glycosyn has asserted counterclaims for infringement against Hansen as well as its commercial distributor, Abbott Laboratories ("Abbott"), alleging that Abbott's infant formulas containing 2'-FL infringe upon both the '018 and the '230 Patents. Abbott moves for summary judgment on various grounds. (D. 200). The motion has been referred to the undersigned for a report and recommendation. For the reasons stated below, I recommend that the motion be denied.

I. BACKGROUND

A. Prior Proceedings

In 2018, Glycosyn filed suit against Hansen's predecessor, Jennewein Biotechnologie GmbH ("Jennewein"), in the U.S. District Court for the District of Massachusetts for infringement of the '018 Patent. (D. 1 at 3-4). That same year, Glycosyn also sued Jennewein before the International Trade Commission ("ITC"), asserting infringement of the '018 Patent and the '230 Patent. (D. 1 at 4). As noted, the patents provide a method of using genetically engineered strains of *E. Coli* to produce 2'-FL, an HMO used in infant formula. (D. 291 at 2).

The district court suit was stayed pending final resolution of the ITC action. (D. 201 at 2). During the ITC investigation, Glycosyn withdrew its infringement claims for the '230 Patent. (D. 1 at 4). The ITC determined (and the Federal Circuit affirmed) that Jennewein infringed the '018 Patent when using two strains in

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its production process to make 2'-FL: the #1520 strain and the #1240 strain. (D. 1 at 4-5).

On August 19, 2020, upon Jennewein's request, the Intellectual Property Rights (IPR) Branch of U.S. Customs and Border Protection ("Customs") ruled that 2'-FL made using another strain, the #1242 strain, did not infringe the '018 Patent. (D. 1 at 5-6). Glycosyn then dismissed the district court suit. (D. 201 at 2).

B. The Present Action

On July 7, 2022, Hansen initiated the present action, seeking a declaratory judgment of invalidity and non-infringement regarding the '018 Patent. (D. 1). In response, Glycosyn filed a counterclaim against Hansen and Abbott as its commercial distributor, alleging that Abbott's infant formulas containing 2'-FL infringe upon both the '018 and the '230 Patents. (D. 15).

C. Summary of Relevant Undisputed Material Facts¹

Abbott's principal contention in moving for summary judgment is that Glycosyn legally cannot maintain a suit against Abbott alone, but rather must be joined by Dutch limited liability company

¹ Unless otherwise noted, the facts are taken from the parties' respective statements of material fact filed in connection with the summary judgment motion. The court presents the facts in the light most favorable to Glycosyn as the party opposing the motion.

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Friesland Campina DOMO B.V. ("RFC"), with whom Glycosyn entered into an exclusive licensing agreement in February 2016.

Pertinent here, the licensing agreement, in effect to May 2034, granted RFC: (1) a worldwide, exclusive, royalty-bearing license to exploit the patents to use, make, have made, sell, offer for sale, and import 2'-FL during the term of the agreement; (2) the ability to extend license grants to RFC's affiliates; and (3) the ability to sublicense any of the licensed rights to a third party provided Glycosyn consented. *License and Collaboration Agreement* (the "licensing agreement") (D. 202-1).

Glycosyn retained certain rights under the licensing agreement, however. Among them, Glycosyn retained rights relating to the sale, offering for sale, distribution, and import of 2'-FL for therapeutic use. Glycosyn also retained the right to use, license, and otherwise exploit the patents and the licensed rights for non-commercial purposes. (Id.).

The licensing agreement also set out RFC and Glycosyn's respective rights and obligations in cases of suspected infringement of the licensed patent rights. Specifically, each party was obligated to notify the other party of the possible infringement. RFC was also obligated to take legal action against suspected infringers when commercially reasonable, and Glycosyn,

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as appropriate, would provide a power of attorney to RFC or join RFC's suit as a plaintiff. (Id.).

The licensing agreement also gave RFC the first option to bring a suit against a suspected infringer. In litigation matters initiated by RFC, Glycosyn would receive 20% of any proceeds recovered by RFC; would also retain the right to review relevant legal documents monitor the action; and would retain the right to approve any settlement. Glycosyn was obligated to act reasonably in this regard but was not obligated to agree to a resolution that went against its interests or required a license, a covenant not to sue for future use, or any other grant of future rights. (Id.).

In the event RFC declined to bring a legal action within 120 days after notification of suspected infringement, Glycosyn could take legal action and enjoy or suffer the full impact of the outcome of the proceedings. (Id.).

Further, even in matters initiated by RFC, RFC could not as part of any settlement grant to any infringer or third party a license, covenant not to sue for future use, or authorize any use or exploitation of any technology or right under any "Glycosyn Patent Right, Strain, Proprietary Production Technology trade secret, or any other Glycosyn intellectual property." (Id.).

II. LEGAL STANDARD

Summary judgment is appropriate when the movant shows, through the pleadings, discovery, and declarations of fact, that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); Amax, Inc. v. ACCO Brands Corp., 268 F.Supp.3d 301, 304 (D. Mass. 2017). If the moving party has met its burden, the burden shifts to the nonmovant to show that there is a genuine, triable issue. Amax, 268 F.Supp.3d at 304. When evaluating a summary judgment motion, the court makes all reasonable inferences in favor of the nonmoving party. Cabot v. Lewis, 241 F.Supp.3d 239, 247-248 (D. Mass. 2017).

III. ANALYSIS

Abbott argues that Glycosyn legally cannot maintain a suit against Abbott without also having RFC as a party. Abbott's argument rests on three grounds. It argues first that Glycosyn itself has not suffered an injury-in-fact because it licensed its commercial rights in the patents to RFC and therefore had no "exclusionary rights" under the licensing agreement, and thus lacks Article III standing to sue Abbott. It argues next that, even assuming Glycosyn has constitutional standing to sue, it still cannot sue Abbott on its own because the law providing for a remedy

for patent infringement, 35 U.S.C. § 281, applies only to a "patentee," and Glycosyn is not a patentee here where it gave all its substantial rights to RFC under the licensing agreement. Finally, and alternatively, Abbott argues that RFC is a necessary and indispensable party and the failure to join them as a party here merits dismissal. The court addresses each argument in turn.

A. Article III Standing

Abbott argues that Glycosyn lacks Article III standing (hereafter referred to as "constitutional standing") to assert its patent infringement counterclaim because it has not suffered an injury-in-fact. An injury-in-fact is an "invasion of a legally protected interest, which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-561 (1992). To have constitutional standing, a plaintiff must have suffered an injuryin-fact that is traceable to the defendant's conduct and redressable by a favorable decision. *Id.* Abbott argues that Glycosyn lacks standing here because, even though it holds the patents, it does not possess an "exclusionary right" in them.

Exclusionary rights include, in essence, the rights to affect the commercial use of a patent and/or the course of litigation concerning suspected infringement of the patent. *Morrow* v. *Microsoft Corp.*, 499 F.3d 1332, 1339-1340 (Fed. Cir. 2007).

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Patent owners hold exclusionary rights in their patents unless they have transferred all exclusionary rights away. Intell. Tech LLC v. Zebra Technologies Corp., 101 F.4th 807, 814-816 (Fed. Cir. 2024. For purposes of having constitutional standing to sue a suspected infringer, all that is required is that the patent holder retain an exclusionary right. Intell. Tech, 101 F.4th at 813; Univ. of S. Fla. Rsch. Found., Inc. v. Fujifilm Med. Sys. U.S.A., Inc., 19F.4th 1315, 1323 (Fed. Cir. 2021).

Abbott argues that Glycosyn could not sue it here because Glycosyn transferred all its relevant rights to RFC under the licensing agreement. As Abbott notes, the licensing agreement gave RFC the exclusive right to "use, make, have made, sell, offer for sale and import" 2'-FL made using the patented technology. Abbott argues that this transfer of rights gave RFC the sole ability to grant Abbott a sublicense to forgive any alleged infringement.

However, the licensing agreement also provides that Glycosyn retained the right to sue, which is an exclusionary right. See Lone Star Silicon Innovations LLC v. Nanya Tech. Corp., 925 F.3d 1225, 1234 (Fed. Cir. 2019). Abbott acknowledges as much but argues that the right never manifested here because Glycosyn never notified RFC of Abbott's alleged infringement, as required by the licensing agreement. Glycosyn has adduced evidence, however, that

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it did in fact provide RFC with timely notice of Abbott's suspected infringement by letter and email. (D. 232-2). Assuming that fact were credited, it would mean that Glycosyn, at the time it brought suit, had an exclusionary right under the licensing agreement to do so.

Accordingly, there is a basis in the record to find that Glycosyn had the right under the licensing agreement to sue Abbott for infringement. As a minimum, there is a dispute of material fact as to whether it could do so. Moreover, even though the licensing agreement gave RFC the first right to sue, RFC could not on its own resolve any potential suit or forgive any infringement, and Glycosyn alone retained the right to grant a license to an infringer.² See Morrow, 499 F.3d at 1342 ("The right to license third parties is an important patent right because implicit in the right to exclude is the right to waive that right; that is, to license activities that would otherwise be excluded.").

Per the foregoing, the court finds that Glycosyn retained an exclusionary right in its patents under the licensing agreement and therefore has constitutional standing to assert a claim for suspected patent infringement.

 $^{^2\,{\}rm The}$ licensing agreement provides that "RFC is not granted the right to, and shall not, in connection with a legal action, . . . grant a license . . . to any infringer or suspected infringer." (D. 202-1).

B. 35 U.S.C. § 281

Under 35 U.S.C. § 281, "[a] patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281. Abbott argues that, assuming Glycosyn is found to have constitutional standing to sue, it still cannot sue under the patent laws because it is not a patentee/patent owner³ within the meaning of section 281. This is so, Abbott contends, because Glycosyn effectively assigned the patents to RFC by transferring to RFC "all substantial rights" in the patents. This argument is unpersuasive.

To begin, Abbott is correct in stating that an exclusive licensee may effectively become the patentee if the original patent owner transfers "all substantial rights" in the patents such that it is "tantamount to an assignment." Alfred E. Mann Found. for Sci. Rsch. v. Cochlear Corp., 604 F.3d 1354, 1359 (Fed. Cir. 2010). An exclusive licensee must hold "all substantial rights" to bring suit in its own name and must otherwise join the patentee as a party if it does not. See Lone Star, 925 F.3d at 1229.

But critically, "all" means "all" in this context. An original patentee, even one such as Glycosyn that has licensed substantial rights in the patent to an exclusive licensee, will

 $^{^{\}scriptscriptstyle 3}$ The terms are used interchangeably for purposes of this opinion.

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continue to be viewed as a patentee under section 281 as long as it retains *any* substantial rights under section 281. *See id.* at 1231 ("The relevant question here is whether AMD's rights, however retained or reacquired, include any substantial rights."). If Glycosyn retains *any* substantial rights, it remains the patentee and has the right to sue for infringement. *Id.* at 1229.

Courts generally examine the totality of the licensing agreement when determining whether a patent owner transferred all substantial rights in the patented technology. *See id*. In *Lone Star*, the court identified two key rights in a patentee's bundle of sticks: the right to enforce and the right to alienate. *See Lone Star*, 925 F.3d at 1229. Glycosyn retained both here.

First, Glycosyn, as noted, retained the right to sue suspected infringers if RFC declined to do so, and always retained the sole right to settle any litigation even if RFC did choose to sue. By the same token, this means that RFC could never sue as a patentee because it did not have "all" substantial rights to the patent. See, e.g., AsymmetRx, Inc. v. Biocare Med. LLC, 582 F.3d 1314, 1317, 1320 (Fed. Cir. 2009) (explaining that exclusive licensee AsymmetRx could not sue as a "patentee" because its right to sue was not exclusive given that the original patent owner could sue and settle if AsymmetRx declined).

Glycosyn also retained the right to exert influence over the use of the patents where the licensing agreement required RFC to obtain Glycosyn's prior written consent to sublicense the patents to (non-affiliate) third parties or settle a claim by granting a license. Glycosyn thus effectively maintained "control [on] how the patents are asserted," which "is fundamentally inconsistent with a transfer of all substantial rights." *Lone Star*, 925 F.3d at 1233. Further, Glycosyn retained the rights to exploit the patents for non-commercial purposes and therapeutic use. As such, RFC's "exclusive license to some, but not all, fields of use under the patents in suit mandat[es] the legal conclusion that [RFC] holds less than all substantial patent rights." *A123 Systems, Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1217 (Fed. Cir. 2010).

Based on the foregoing, the court finds that Glycosyn retained substantial rights regarding the patents at issue and therefore is a patentee for purposes of 35 U.S.C § 281. Accordingly, the court finds that Glycosyn has both constitutional and statutory standing to sue Abbott for infringement, rendering summary judgment on these grounds inappropriate.

C. Joinder of a Necessary Party

Alternatively, Abbott argues that dismissal is warranted under Fed R. Civ. P. 19 because RFC is a necessary and indispensable party to this suit that cannot feasibly be joined.

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Courts generally treat joinder issues raised in summary judgment motions as motions to dismiss for failure to join a necessary party pursuant to Rule 12(b)(7). See Alexander v. Nat'l Fire Ins. of Hartford, No. CIV.A. 03-1511, 2004 WL 765639, at *8 (E.D. Pa. Mar. 3, 2004); NLFC, Inc. v. Devcom Mid-Am., Inc., No. 93 C 0609, 1994 WL 16484076, at *3 (N.D. Ill. Jan. 4, 1994).

To that end, courts must order the joinder of any necessary⁴ and indispensable⁵ parties; when joinder is not possible, the court must determine whether the action should proceed among the existing parties or be dismissed. Fed. R. Civ. P. 19(a)(2); *Merrill Lynch*, *Pierce, Fenner & Smith, Inc. v. Flanders-Borden*, 11 F.4th 12, 17 (1st Cir. 2021); *See Lone Star*, 925 F.3d at 1238 ("Rule 19 is

Fed. R. Civ. P. 19(a)(1).

 $^{\rm 5}$ When determining whether a party is indispensable, the court must consider various factors, which are:

Fed. R. Civ. P. 19(b).

⁴ Rule 19(a)(1) provides that an absent party is necessary if:

⁽A) [I]n that person's absence, the court cannot accord complete relief among existing parties; or (B) the person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may: (i) as a practical matter, impair or impede the person's ability to protect the interest, or (ii) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest.

⁽b) (1) [T]he extent to which a judgment rendered in that person's absence might prejudice the person or the existing parties; (2) the extent to which any prejudice could be lessened or avoided[;]...
(3) whether a judgment rendered in the person's absence would be adequate; and (4) whether the plaintiff would have an adequate remedy if the action were dismissed for nonjoinder.

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mandatory and so it applies whether a defendant invokes Rules 12(b)(1), (6), (7), or none of the above."). Here, the court finds that Rule 19 does not require RFC's joinder as a necessary and indispensable party.⁶

As a threshold matter, Abbott cites to Federal Circuit caselaw for the proposition that exclusive licensees are necessary parties to infringement suits and thus are subject to Rule 19 joinder. See, e.g., Aspex Eyewear, Inc. v. Miracle Optics, Inc., 434 F.3d 1336, 1344 (Fed. Cir. 2006); Indep. Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459, 466 (1926). That said, the Federal Circuit itself has noted that this circuit's law rather than its own should apply to questions of joinder. See, e.g., Gensetix, Inc. v. Bd. of Regents of Univ. of Texas Sys., 966 F.3d 1316, 1321 (Fed. Cir. 2020) (Regional circuit law governs Rule 19 joinder decisions); Univ. of Utah v. Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V., 734 F.3d 1315, 1320, 1327 (Fed. Cir. 2013) (same); Katz v. Lear Siegler, Inc., 909 F.2d 1459, 1461 (Fed. Cir. 1990) (same). In that regard, the First Circuit has not addressed whether an exclusive licensee is a necessary party to an infringement suit. See e.g., Amgen, Inc. v. Hoffman-LaRoche Ltd.,

 $^{^{\}rm 6}$ The court assumes solely for the sake of this issue that RFC would have standing to sue Abbott for patent infringement.

456 F.Supp.2d 267, 283 (D. Mass. 2006) ("The Federal Circuit in *Aspex* did not give any indication that it was making such a significant statement regarding the law of patent standing."). In the absence of controlling precedent instructing otherwise, the court declines to hold that RFC is a necessary party as a matter of law simply because it is an exclusive licensee.

More, a consideration of Rule 19 itself supports the notion that RFC should not be deemed a necessary party merely because it is an exclusive licensee. Under Rule 19(a)(1)(A), a necessary party is one that in that person's absence, the court cannot accord complete relief among existing parties. Fed. R. Civ. P. 19(a)(1)(A). Here, the court does not need to join RFC as a party to the present suit because, as noted above, RFC lost the right to seek or enjoy any proceeds from this lawsuit once it decided not to sue and ceded that right to Glycosyn. Put more simply, RFC is not a necessary party here because it is not entitled to any relief.⁷ See § 281; Part B, supra.

⁷Conversely, if RFC were suing, it would not be able to obtain complete relief without joining Glycosyn because it would not be able to sue as a patentee under 35 U.S.C. § 281. Moreover, only Glycosyn would be able to settle the case, and it would also be entitled to a portion of the proceeds.

Further, RFC would not be a necessary party under Rule 19(a)(1)(B) because it does not claim an interest in this action.⁸ See United States v. San Juan Bay Marina, 239 F.3d 400, 406-407 (1st Cir. 2001) (holding that compulsory joinder under Rule 19(a)(2) is only appropriate where the person claims an interest relating to the subject of the action); Ferrofluidics Corp. v. Advanced Vacuum Components, Inc., 968 F.2d 1463, 1472 (1st Cir. 1992) (concluding that third party was not a necessary party under Rule 19 because it did not claim an interest in the outcome of the action); Duggan v. Martorello, 596 F.Supp.3d 195, 204 (D. Mass. 2022) ("For purposes of this Rule, 'the issue is whether the Tribal entities claim an interest, not whether they have one."") (emphasis in original); cf. STC.UNM v. Intel Corp., 754 F.3d 490 (Fed. Cir. 2014) (a patent co-owner that has expressed its desire to not join an infringement case may not be involuntarily joined under Rule 19(a)).

On the contrary, the court may reasonably infer that RFC consciously disclaimed any interest in seeking any relief it otherwise could have obtained in Glycosyn-initiated litigation where the record provides a basis to find that RFC received notice

 $^{^8}$ "A person . . . must be joined as a party if . . . that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may . . ."). Fed. R. Civ. P. 19(a)(1)(B)

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of Abbott's suspected infringement but declined to bring suit within 120 days of receiving that notice. The licensing agreement supports this, as it provides that RFC would have no entitlement to any damages or relief Glycoysn might recover. (D. 202-1, § 9(b)(iv)). Relatedly, RFC has not attempted to intervene as a party plaintiff, suggesting further that it does not claim an interest in this litigation. *See Ferrofluidics*, 968 F.2d at 1472 (party's failure to intervene showed its disinterest in the action, supporting the conclusion that it was not a necessary party).

In short, since Glycosyn is legally wholly entitled to bring this suit to enforce its patent rights and can be accorded complete relief, and where RFC has not expressed any interest in joining the suit (and arguably has disclaimed its interest), it is not necessary to join RFC as a party to this suit under Rule 19(a) (1), even though it is an exclusive licensee. See Duggan, 596 F.Supp.3d at 204 ("Where a party is aware of an action and chooses not to claim an interest, the district court does not err by holding that joinder is unnecessary."). Therefore, the court does not need to reach the issue of whether RFC is indispensable under Rule 19(b). See Pujol v. Searson Am. Exp., Inc., 877 F.2d 132, 134 (1st Cir. 1989) (If a person is a necessary party but joinder is not feasible, the court must then determine whether the party is

indispensable). Dismissal is therefore not warranted on these grounds.

IV. CONCLUSION

In light of the foregoing, Abbott's Motion for Summary Judgment That Glycosyn Alone Cannot Maintain Its Patent Infringement Claims (D. 200) should be denied.⁹

> /s/ Donald L. Cabell DONALD L. CABELL, U.S.M.J.

DATED: March 14, 2025

⁹ The parties are hereby advised that under the provisions of Federal Rule of Civil Procedure 72(b), any party who objects to this recommendation must file specific written objections thereto with the Clerk of this Court within 14 days of the party's receipt of this Report and Recommendation. The written objections must specifically identify the portion of the proposed findings, recommendations, or report to which objection is made and the basis for such objections. The parties are further advised that the United States Court of Appeals for the First Circuit has repeatedly indicated that failure to comply with Rule 72(b) will preclude further appellate review of the District Court's order based on this Report and Recommendation. See Keating v. Secretary of Health and Human Servs., 848 F.2d 271 (1st Cir. 1988); United States v. Emiliano Valencia-Copete, 792 F.2d 4 (1st Cir. 1986); Park Motor Mart, Inc. v. Ford Motor Co., 616 F.2d 603 (1st Cir. 1980); United States v. Vega, 678 F.2d 376, 378-379 (1st Cir. 1982).