

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

C.A. No. 21-1015-LPS

UNSEALED ON

OCT. 27, 2021

MEMORANDUM ORDER

On July 13, 2021, Plaintiff Nippon Shinyaku Co., Ltd. (“Nippon Shinyaku”) sued Defendant Sarepta Therapeutics, Inc. (“Sarepta”) for breach of contract and various patent-related claims. (*See generally* D.I. 2, 12) Nippon Shinyaku simultaneously moved for a preliminary injunction, seeking to require Sarepta to withdraw seven petitions for *inter partes* review (“IPR”) pending before the Patent Trial and Appeal Board (“PTAB”). (*See generally* D.I. 4, 13)¹ The Court issued a memorandum order denying Nippon Shinyaku’s request for a preliminary injunction. (*See* D.I. 47) The Court issued the memorandum order the day after Nippon Shinyaku filed a letter requesting expedited oral argument and consideration of its motion, understanding that Nippon Shinyaku believed its motion to be time-sensitive. (*See* D.I. 46) Given the Court’s numerous other commitments, however, the Court was unable to provide

¹ The seven IPR proceedings are IPR2021-01134, IPR2021-01135, IPR2021-01136, IPR2021-01137, IPR2021-01138, IPR2021-01139, and IPR2021-01140. Each of Sarepta’s IPR petitions challenges one of the seven patents that Nippon Shinyaku has asserted in this case: U.S. Patent Nos. 9,708,361, 10,385,092, 10,407,461, 10,487,106, 10,647,741, 10,662,217, and 10,683,322.

a full explanation of its reasoning in the previous memorandum order. (*See* D.I. 47 at 2) The Court stated that it would issue another memorandum that more fully explains its reasoning.

(*Id.*) Having considered the briefing submitted in connection with the motion (*see generally* D.I. 5, 18, 25), and having considered the notice of subsequent authority that Sarepta filed after the Court denied the motion (*see* D.I. 65), the Court now further explicates its reasoning.

1. To obtain a preliminary injunction, the moving party must show (i) “a reasonable probability of eventual success in the litigation” and (ii) “that it will be irreparably injured . . . if relief is not granted.” *Reilly v. City of Harrisburg*, 858 F.3d 173, 176 (3d Cir. 2017). If those two factors are met, then courts also consider (iii) “the possibility of harm to other interested persons from the grant or denial of the injunction” and (iv) “the public interest.” *Id.* “An injunction is ‘mandatory’ if such injunction would alter the status quo by commanding some positive act.” *Doe v. Del. State Univ. Bd. of Trs.*, 2021 WL 2036670, at *2 (D. Del. May 21, 2021) (internal quotation marks omitted). “[A] mandatory injunction is an extraordinary remedy that is only granted sparingly by the courts.” *Trinity Indus., Inc. v. Chi. Bridge & Iron Co.*, 735 F.3d 131, 139 (3d Cir. 2013). When the moving party seeks a mandatory injunction, “the burden on the moving party is particularly heavy.” *Id.* (internal quotation marks omitted). Indeed, the moving party’s “right to relief must be indisputably clear.” *Communist Party of Ind. v. Whitcomb*, 409 U.S. 1235, 1235 (1972) (Rehnquist, J., in chambers).

2. This case involves a mutual confidentiality agreement that the parties signed on June 1, 2020. (*See generally* D.I. 2-1) That agreement is governed by Delaware law. (*Id.* at 6) In Delaware, the construction of contract language presents a question of law. *See Rhone-Poulenc Basic Chems. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192, 1195 (Del. 1992). “The

primary goal of contract interpretation is to attempt to fulfill, to the extent possible, the reasonable shared expectations of the parties at the time they contracted.” *Comrie v. Enterasys Networks, Inc.*, 837 A.2d 1, 13 (Del. Ch. 2003) (internal quotation marks omitted). Under Delaware law’s “objective theory” of contract interpretation, the Court “looks to the most objective indicia” of the parties’ intent, i.e., the words of the agreement itself. *Sassano v. CIBC World Markets Corp.*, 948 A.2d 453, 462 (Del. Ch. 2008). “It is well established that a court interpreting any contractual provision . . . must give effect to all terms of the instrument, must read the instrument as a whole, and, if possible, reconcile all the provisions of the instrument.” *Elliott Assocs., L.P. v. Avatex Corp.*, 715 A.2d 843, 854 (Del. 1998).

3. While the Court must consider the mutual confidentiality agreement as a whole, several provisions are particularly pertinent.

a. Section 6.1 of the agreement establishes a “Covenant Not to Sue or Initiate a Patent Challenge”:

{E}ach Party . . . hereby covenants and irrevocably agrees that during the Covenant Term it shall not directly or indirectly assert or file any legal or equitable cause of action, suit or claim or otherwise initiate any litigation or other form of legal or administrative proceeding against the other Party . . . other than an action, suit or claim that is statutorily barred from being filed if not filed during the Covenant Term in any jurisdiction in the United States or Japan of or concerning intellectual property in the field of Duchenne Muscular Dystrophy. For clarity, this covenant not to sue includes, but is not limited to . . . patent validity challenges before the U.S. Patent and Trademark Office

(*Id.* at 5) It is undisputed that the Covenant Term ended on June 21, 2021. (*See* D.I. 5 at 3-4; D.I. 18 at 1; D.I. 25 at 5)

b. Section 10 of the agreement, which relates to “Governing Law; Jurisdiction; Attorney’s Fees,” contains a forum selection clause:

[T]he Parties agree that all Potential Actions arising under U.S. law relating to patent infringement or invalidity, and filed within two (2) years of the end of the Covenant Term, shall be filed in the United States District Court for the District of Delaware and that neither Party will contest personal jurisdiction or venue in the District of Delaware and that neither Party will seek to transfer the Potential Actions on the ground of *forum non conveniens*.

(D.I. 2-1 at 7)

c. Section 1 of the agreement defines “Potential Actions” to mean:

[A]ny patent or other intellectual property disputes between [Nippon Shinyaku] and Sarepta, or their Affiliates, other than the [European] Oppositions or [Japanese] Actions, filed with a court or administrative agency prior to or after the Effective Date in the United States, Europe, Japan or other countries in connection with the Parties’ development and commercialization of therapies for Duchenne Muscular Dystrophy.

(*Id.* at 2)

4. On the first factor for a preliminary injunction, Nippon Shinyaku has not shown a reasonable probability that Sarepta breached the mutual confidentiality agreement.

a. In Nippon Shinyaku’s view, Section 10’s forum selection clause prohibits Sarepta from pursuing challenges to the asserted patents before the PTAB (or in any other forum other than this Court) until June 2023. The Court does not agree. To start, Nippon Shinyaku’s opening brief completely ignores Section 6’s covenant not to sue. Under that covenant, the parties explicitly agreed not to initiate any patent challenges, including administrative proceedings such as IPRs, until after the Covenant Term. (*See* D.I. 2-1 at 5) Giving the forum selection clause in Section 10 the broad meaning for which Nippon Shinyaku argues would create tension with Section 6’s covenant not to sue. Although Sections 6 and 10 implicate different time periods, it would be odd if Section 6 *expressly* deferred the filing of IPR petitions for one year and twenty days only for them to be *impliedly* delayed for two additional years,

likely making them time-barred and never available (as further explained below). *See Sonitrol Holding Co. v. Marceau Investissements*, 607 A.2d 1177, 1184 (Del. 1992) (“The cardinal rule of contract construction is that, where possible, a court should give effect to all contract provisions.”) (emphasis omitted). The best reading of Section 6 is that the parties intended to allow IPRs to proceed after the Covenant Term expired.

b. Sarepta also has the better reading of Section 10’s forum selection clause. To be sure, Section 10 obliquely refers to IPR proceedings through its mention of “Potential Actions,” which is defined to include proceedings before administrative agencies such as the PTAB. Read in full context, however, Section 10 applies only to cases filed in federal court. Section 10 refers to “all Potential Actions arising under U.S. law relating to patent infringement or invalidity.” (D.I. 2-1 at 7) The PTAB cannot hear patent infringement disputes, as infringement disputes may only be heard in federal district court.² Moreover, Section 10 states that the parties will not “seek to transfer the Potential Actions on the ground of *forum non conveniens*.” (D.I. 2-1 at 7) While cases in federal court may be transferred for *forum non conveniens*, that doctrine does not apply to administrative proceedings. *See Sinochem Int’l Co. v. Malay. Int’l Shipping Corp.*, 549 U.S. 422, 430 (2007) (explaining that *forum non conveniens* involves trial court declining to exercise jurisdiction). Section 10 also states that the parties will not “contest personal jurisdiction or venue in the District of Delaware.” (D.I. 2-1 at 7) Personal jurisdiction and venue are limitations on suits in federal courts, not proceedings before administrative agencies. *See AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1361

² Indeed, Section 10’s “arising under” language echoes the language that Congress used to vest the federal courts with exclusive jurisdiction over patent cases. *See* 28 U.S.C. § 1338(a).

(Fed. Cir. 2019) (“Article III requirements do not apply to administrative agencies.”). Thus, while the definition of “Potential Actions” in Section 1 literally encompasses IPRs, the use of that term in Section 10 is best understood as limited to cases in federal district court.

c. Nippon Shinyaku’s interpretation of Section 10 would also have the unusual effect of precluding Sarepta from filing any IPRs against the asserted patents. By statute, a patent challenger must file any IPR petition no later than one year after the challenger is served with a complaint alleging infringement of the patent. 35 U.S.C. § 315(b). Because Sarepta was served with the complaint in this case on July 14, 2021 (*see* D.I. 9), any IPR petitions must be filed by July 14, 2022. If Sarepta is forced to wait until June 2023, as Nippon Shinyaku insists, then its IPR petitions will be time-barred. The mutual confidentiality agreement as a whole does not evince a shared expectation and intent that Sarepta was waiving its right to file IPR petitions. *See Kortum v. Webasto Sunroofs, Inc.*, 769 A.2d 113, 125 (Del. Ch. 2000) (“There can be no waiver of a statutory right unless that waiver is clearly and affirmatively expressed in the relevant document.”). Indeed, while drafting the mutual confidentiality agreement, the parties were careful to preserve their rights to initiate proceedings that would be statutorily barred (by excluding them from Section 6’s covenant not to sue). (*See* D.I. 2-1 at 5) Overall, then, Nippon Shinyaku has not shown a reasonable probability that Sarepta breached the mutual confidentiality agreement by filing IPR petitions.

5. On the second factor, Nippon Shinyaku has also failed to show that it will suffer irreparable harm if the Court does not grant a preliminary injunction. According to Nippon Shinyaku, in the absence of a preliminary injunction, “it will be deprived of its bargained-for choice of forum.” (D.I. 5 at 8) As the Court explained above, however, Nippon Shinyaku

ignores or misreads the relevant provisions of the mutual confidentiality agreement; it did not bargain to prevent Sarepta from filing all timely IPR petitions against the asserted patents. Nippon Shinyaku also argues that it will suffer irreparable harm because “it will be forced to litigate the issues of patent invalidity . . . on multiple fronts with the possibility of inconsistent results.” (*Id.*) Again, this argument depends on the faulty assumption that Nippon Shinyaku contracted itself out of that potential situation. Furthermore, absent an agreement to refrain from pursuing an IPR, there is nothing irreparably harmful (or unusual) in district court and PTAB proceedings moving in parallel. *See, e.g., Kannuu Pty. Ltd. v. Samsung Elecs. Co.*, 2021 WL 195163, at *5 (S.D.N.Y. Jan. 19, 2021) (“While [the plaintiff] may be concerned about inconsistent rulings or duplicative proceedings, those factors alone do not rise to the level of irreparable harm, especially in light of the fact that the parties can . . . ask[] for a stay in this proceeding.”), *aff’d*, 2021 WL 4617967 (Fed. Cir. Oct. 7, 2021). Contrary to Nippon Shinyaku’s arguments, it is Sarepta that would be irreparably harmed if the Court entered an injunction because Sarepta would then be “deprived of its statutory right to pursue IPR challenges” to the asserted patents. (D.I. 18 at 18)

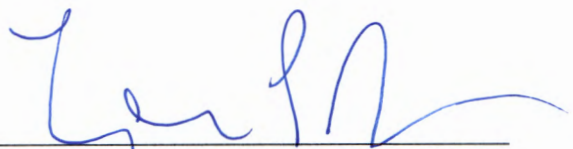
6. Given the Court’s conclusions on the first two factors, the Court need not reach the balance of the equities or the public interest. *See Reilly*, 858 F.3d at 176. It is worth pointing out, nonetheless, that Nippon Shinyaku’s arguments for these third and fourth factors depend, yet again, on the flawed presumption that Sarepta’s IPR petitions cannot be filed until June 21, 2023. (*See* D.I. 5 at 9; D.I. 25 at 9-10) Additionally, in the Court’s view, the public interest generally requires that if parties are going to contractually agree to eliminate the statutory right to pursue an IPR, they should be explicit about it. *See, e.g., Kannuu Pty. Ltd. v.*

Samsung Elecs. Co., 2021 WL 461967, at *6 (Fed. Cir. Oct. 7, 2021) (crediting district court's finding that public interest favored permitting litigation of patent validity before PTAB). Here, the parties were not explicit about the elimination of any statutory right.

7. Nippon Shinyaku did not meet its burden on any of the factors it must establish in order to obtain a preliminary injunction. Accordingly, the Court denied Nippon Shinyaku's motion for a preliminary injunction. (*See* D.I. 47)

Because the Court has issued the instant memorandum order under seal, **IT IS HEREBY ORDERED** that the parties shall meet and confer and, no later than October 26, submit a proposed redacted version of it, should they believe that they can meet the applicable legal standards to support such redactions. If so, they shall submit a memorandum providing such support. If no version with proposed redactions is timely submitted, the Court will unseal this memorandum order.

October 25, 2021
Wilmington, Delaware



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE