

United States Court of Appeals for the Federal Circuit

NIPPON SHINYAKU CO., LTD.,
Plaintiff-Appellant

v.

SAREPTA THERAPEUTICS, INC.,
Defendant-Appellee

2021-2369

Appeal from the United States District Court for the District of Delaware in No. 1:21-cv-01015-LPS, Judge Leonard P. Stark.

Decided: February 8, 2022

WILLIAM R. PETERSON, Morgan, Lewis & Bockius LLP, Houston, TX, argued for plaintiff-appellant. Also represented by CHRISTOPHER JOHN BETTI, MARIA DOUKAS, KRISTA VINK VENEGAS, AMANDA SCOTT WILLIAMSON, Chicago, IL; AMY M. DUDASH, Wilmington, DE.

MICHAEL J. FLIBBERT, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for defendant-appellee. Also represented by AARON GLEATON CLAY; CHARLES E. LIPSEY, J. DEREK MCCORQUINDALE, Reston, VA; ALISSA KEELY LIPTON, Boston, MA.

2 NIPPON SHINYAKU CO., LTD. v. SAREPTA THERAPEUTICS, INC.

Before NEWMAN, LOURIE, and STOLL, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Nippon Shinyaku Co., Ltd. (“Nippon Shinyaku”) appeals from the decision of the United States District Court for the District of Delaware denying its motion for a preliminary injunction. *See Nippon Shinyaku Co.v. Sarepta Therapeutics, Inc., No. 21-cv-1015, 2021 WL 4989489 (D. Del. Oct. 25, 2021) (“Decision”); see also J.A. 5–6.* For the reasons provided below, we reverse the decision of the district court, and remand for entry of a preliminary injunction.

BACKGROUND

I. The Mutual Confidentiality Agreement

On June 1, 2020, Nippon Shinyaku and Sarepta Therapeutics, Inc. (“Sarepta”) executed a Mutual Confidentiality Agreement (“MCA”). J.A. 508–16. As stated in the MCA, the purpose of the agreement was for the parties “to enter into discussions concerning the Proposed Transaction,” which the MCA defined as “a potential business relationship relating to therapies for the treatment of Duchenne Muscular Dystrophy.” J.A. 508–09.

The MCA established a “Covenant Term,” which was “the time period commencing on the Effective Date and ending upon twenty (20) days after the earlier of: (i) the expiration of the Term, or (ii) the effective date of termination.” J.A. 509. Section 6 of the MCA contained a mutual covenant not to sue, whereby each party agreed 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 . . . in any jurisdiction in the United States

NIPPON SHINYAKU CO., LTD. v. SAREPTA THERAPEUTICS, INC. 3

or Japan of or concerning intellectual property in the field of Duchenne Muscular Dystrophy.

J.A. 512 (MCA § 6.1). Section 6 further stated:

For clarity, this covenant not to sue includes, but is not limited to, patent infringement litigations, declaratory judgment actions, patent validity challenges **before the U.S. Patent and Trademark Office** or Japanese Patent Office, and reexamination proceedings before the U.S. Patent and Trademark Office

Id. (emphasis added).

As noted, the covenant not to sue was time limited and applied only during the Covenant Term. *Id.* Importantly, the MCA also included a forum selection clause to govern patent and other intellectual property disputes between the parties after the expiration of the Covenant Term. The forum selection clause in Section 10 of the MCA states in relevant part:

[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*.

J.A. 513–14 (MCA § 10) (emphases added). “Potential Actions” is defined in Section 1 of the MCA as “any ***patent or other intellectual property disputes*** between [Nippon Shinyaku] and Sarepta, or their Affiliates, other than the EP Oppositions or JP 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

4 NIPPON SHINYAKU CO., LTD. v. SAREPTA THERAPEUTICS, INC.

connection with the Parties’ development and commercialization of therapies for Duchenne Muscular Dystrophy.” J.A. 509 (MCA § 1) (emphases added).

The Covenant Term ended on June 21, 2021, at which point the two-year forum selection clause in Section 10 of the MCA took effect. Yet, on June 21, 2021—the same day the Covenant Term ended—Sarepta filed seven petitions for *inter partes* review (“IPR”) at the Patent Trial and Appeal Board (“the Board”).

II. Proceedings in the District of Delaware

On July 13, 2021, Nippon Shinyaku filed a complaint in the U.S. District Court for the District of Delaware asserting claims against Sarepta for breach of contract, declaratory judgment of noninfringement and invalidity with respect to Sarepta’s patents, and infringement of Nippon Shinyaku’s patents. See J.A. 475. In its breach of contract claim, Nippon Shinyaku alleged that Sarepta breached the MCA by filing seven IPR petitions, which “directly contravenes the MCA’s forum selection clause, which requires that Sarepta and Nippon Shinyaku bring any such patent challenges in the United States District Court for the District of Delaware.” J.A. 475–76. In conjunction with its complaint, Nippon Shinyaku filed a motion for a preliminary injunction asking the court to enjoin Sarepta from proceeding with its IPR petitions and to require that Sarepta withdraw the petitions. See J.A. 861.

On September 24, 2021, the district court denied Nippon Shinyaku’s motion for a preliminary injunction. J.A. 5–6. Referencing the four well-established preliminary injunction factors, the court stated:

Nippon Shinyaku has failed to persuade the Court that it is likely to succeed on the merits, that it will suffer cognizable irreparable harm in the absence of extraordinary preliminary relief, that the

NIPPON SHINYAKU CO., LTD. v. SAREPTA THERAPEUTICS, INC. 5

balance of harms tips in its favor, or that the public interest warrants the relief that it seeks.

J.A. 6. The court concluded by noting that “[i]n due course, the Court will issue a memorandum that more fully explains its reasoning.” *Id.*

On October 25, 2021, the district court issued its memorandum order explaining its reasoning for denying Nippon Shinyaku’s preliminary injunction motion. The court focused the bulk of its analysis on the first preliminary injunction factor, explaining three primary reasons why Nippon Shinyaku “has not shown a reasonable probability that Sarepta breached the mutual confidentiality agreement.” *Decision*, 2021 WL 4989489, at *2.

The district court’s first reason was based on a perceived “tension” that would exist between Sections 6 and 10 of the MCA if the forum selection clause were interpreted to preclude IPRs. *Id.* The court reasoned that, “[a]lthough 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.” *Id.* (emphases in original). Thus, the court stated, “[t]he best reading of Section 6 is that the parties intended to allow IPRs to proceed after the Covenant Term expired.” *Id.*

The district court’s second reason was based on other language in Section 10 of the MCA. The court acknowledged that “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.” *Id.* at *3. But, the court reasoned, “[r]ead in full context, however, Section 10 applies only to cases filed in federal court.” *Id.* The court emphasized Section 10’s discussion of patent infringement disputes, venue transfers on the basis of *forum non conveniens*, and contesting of venue and personal jurisdiction, all of which

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.