

IN THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NIPPON SHINYAKU CO., LTD.,
Plaintiff-Appellant

v.

SAREPTA THERAPEUTICS, INC.,
Defendant-Appellee

On Appeal from the United States District Court for the
District of Delaware in No. 1:21-cv-1015-LPS

**SAREPTA'S COMBINED PETITION FOR PANEL
REHEARING AND REHEARING EN BANC**

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**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
CERTIFICATE OF INTEREST**

Case Number 2021-2369

Short Case Caption Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.

Filing Party/Entity Sarepta Therapeutics, Inc.

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Date: March 10, 2022

Signature: /s/ Michael J. Flibbert

Name: Michael J. Flibbert

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<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al.</i> , IPR2021-01134 (PTAB)	<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al.</i> , IPR2021-01135 (PTAB)	<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al.</i> , IPR2021-01136 (PTAB)
<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al.</i> , IPR2021-01137 (PTAB)	<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al.</i> , IPR2021-01138 (PTAB)	<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al.</i> , IPR2021-01139 (PTAB)
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None/Not Applicable Additional pages attached

TABLE OF CONTENTS

STATEMENT OF COUNSEL	1
POINTS OVERLOOKED OR MISAPPREHENDED BY THE PANEL	2
STATEMENT OF THE CASE.....	4
ARGUMENT	7
I. The Court Should Reverse the Panel Decision, Which Conflicts with <i>Erie</i> 's Requirement for a Federal Court Sitting in Diversity to Apply State Substantive Law.....	7
A. The Panel Overlooked the Delaware Contract Law Principle That There Can Be No Waiver of a Statutory Right Unless the Waiver Is Clearly and Affirmatively Expressed	7
B. The Panel Decision Violates <i>Erie</i> 's Constitutional Limits on Federal Judicial Power	13
II. Alternatively, the Court Should Vacate and Remand This Case to the District Court for Reevaluation and Balancing of the Preliminary Injunction Factors	15
CONCLUSION.....	17

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Acumed LLC v. Stryker Corp.</i> , 483 F.3d 800 (Fed. Cir. 2007)	1, 16
<i>Apple, Inc. v. Samsung Elecs. Co.</i> , 678 F.3d 1314 (Fed. Cir. 2012)	1, 15, 16
<i>Collins v. Mary Kay, Inc.</i> , 874 F.3d 176 (3d Cir. 2017)	13
<i>Dodocase VR, Inc. v. MerchSource, LLC</i> , 767 F. App'x 930 (Fed. Cir. 2019)	9
<i>Erie R. Co. v. Tompkins</i> , 304 U.S. 64 (1938).....	<i>passim</i>
<i>Estate of Osborn v. Kemp</i> , 991 A.2d 1153 (Del. 2010)	11
<i>Gasperini v. Ctr. for Humanities Inc.</i> , 518 U.S. 415 (1996).....	7, 13, 14
<i>General Protecht Grp., Inc. v. Leviton Mfg. Co.</i> , 651 F.3d 1355 (Fed. Cir. 2011)	16
<i>Hanna v. Plumer</i> , 380 U.S. 460 (1965).....	7, 11, 14
<i>Issa v. Delaware State Univ.</i> , 268 F. Supp. 3d 624 (D. Del. 2017).....	8
<i>Jack Guttman, Inc. v. Kopykake Enters., Inc.</i> , 302 F.3d 1352 (Fed. Cir. 2002)	1, 16
<i>Johnson v. American Modern Home Ins. Co.</i> , 259 A.3d 724, 2021 WL 3771825 (Del. Aug. 23, 2021).....	8
<i>Juul Labs, Inc. v. Grove</i> , 238 A.3d 904 (Del. Ch. 2020)	8

<i>Kannuu Pty. Ltd. v. Samsung Elecs. Co.</i> , 15 F.4th 1101 (Fed. Cir. 2021)	10
<i>Kortum v. Webasto Sunroofs, Inc.</i> , 769 A.2d 113 (Del. Ch. 2000)	<i>passim</i>
<i>Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.</i> , No. 1:21-cv-01015-LPS, D.I. 85 (D. Del. Dec. 27, 2021)	17
<i>Pullman-Standard v. Swint</i> , 456 U.S. 273 (1982).....	16
<i>Reilly v. City of Harrisburg</i> , 858 F.3d 173 (3d Cir. 2017)	15
<i>Rohm & Haas Co. v. Adco Chem. Co.</i> , 689 F.2d 424 (3d Cir. 1982)	13
<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.</i> , IPR2021-01134, Paper No. 20 (PTAB Jan. 12, 2022)	6
<i>Sherwood, Inc. v. Cottman Transmission Sys., Inc.</i> , C.A. No. 6768, 1982 WL 17882 (Del. Ch. Apr. 15, 1982)	17
<i>United Mine Workers of Am. v. Gibbs</i> , 383 U.S. 715 (1966).....	13
Statutes	
28 U.S.C. § 1332	13
28 U.S.C. § 1338	12
28 U.S.C. § 1367	13
35 U.S.C. § 315(b)	5
Rules	
Fed. R. Civ. P. 52(a)(2).....	16
Del. Sup. Ct. Rule 14(b)(vi)(B)(2).....	8

STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States and this Court: *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938); *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314 (Fed. Cir. 2012); *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352 (Fed. Cir. 2002); and *Acumed LLC v. Stryker Corp.*, 483 F.3d 800 (Fed. Cir. 2007).

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting questions of exceptional importance:

(1) Does the *Erie* doctrine require this Court to apply state substantive law when deciding an issue of contract interpretation under state law, including a state contract law principle that there can be no waiver of a statutory right unless that waiver is clearly and affirmatively expressed in the agreement?

(2) When a district court denies a preliminary injunction motion based on the movant's failure to establish the first two "gateway" factors, and this Court reverses those determinations on appeal, is the appropriate remedy to vacate and remand for further proceedings to allow the district court to reevaluate and balance the four preliminary injunction factors before entering any injunction?

/s/ Michael J. Flibbert
Michael J. Flibbert
Attorney for Appellee

POINTS OVERLOOKED OR MISAPPREHENDED BY THE PANEL

Nippon Shinyaku's preliminary injunction motion sought to require Sarepta to withdraw its petitions for *inter partes* review ("IPR petitions" or "IPRs") challenging Nippon Shinyaku's patents based on a forum selection clause in the parties' confidentiality agreement. In denying that motion, the Delaware district court applied Delaware state contract interpretation principles in concluding that Nippon Shinyaku was unlikely to establish any breach of the agreement. Appx1227-1231. It also found that Sarepta, not Nippon Shinyaku, would be irreparably harmed by an injunction because it would likely lose its statutory right to pursue its IPR challenges. Appx1232.

In reversing the district court's decision and remanding for entry of a preliminary injunction, the panel interpreted the "plain language" of the forum selection clause in isolation as encompassing IPRs. Slip Op. at 9-10. The panel decision, however, conflicts with Supreme Court and Federal Circuit precedent. The Court should therefore grant rehearing for two independent reasons:

First, by reaching an outcome that differs substantively from how a Delaware state court would have resolved the same issues of contract interpretation, the panel decision violates the constitutional limits on federal judicial power set forth in *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). Under Delaware contract law, there can be no waiver of a statutory right "unless that waiver is clearly and affirmatively

expressed” in the agreement. *Kortum v. Webasto Sunroofs, Inc.*, 769 A.2d 113, 125 (Del. Ch. 2000). This interpretive canon has been applied consistently by both the Delaware Chancery Court and the Delaware Supreme Court. The district court properly applied this principle in interpreting the agreement. *See* Appx1231 (applying *Kortum*). It found that, when read as a whole, the agreement does *not* clearly and affirmatively express any waiver of statutory rights. Appx1231-1233. Rather, the district court found that the parties carefully *preserved* their statutory rights when drafting the agreement. Appx1231.

The panel, however, never addressed *Kortum* or the Delaware contract principle that any waiver of statutory rights must be explicit. Slip Op. at 7-16. Nor did the panel address the district court’s findings concerning the absence of any explicit waiver of the statutory right to file IPRs. *Id.* Instead, the panel devised its own “general principle” of contract law that “parties are entitled to bargain away their rights to file IPR petitions, including through the use of forum selection clauses.” Slip Op. at 13. But the panel’s purported “general principle” conflicts with settled *Delaware* contract law requiring that any such waiver of statutory rights be clearly and affirmatively expressed in the agreement. Moreover, *Erie* prohibits federal courts from devising federal common law based on “general” principles—precisely what the panel did here. *Erie*, 304 U.S. at 78 (“There is no federal general common law.”). The Court should therefore correct the panel’s overreach of

constitutional authority *en banc*, reverse the panel decision, and affirm the district court's denial of a preliminary injunction.

Second, the panel decision remanding the case to directly enter a preliminary injunction conflicts with this Court's prior decisions vacating and remanding for further proceedings in similar circumstances. Thus, if the Court does not reverse the panel decision, it should, at a minimum, vacate and remand this case to the district court to complete its findings and balance the preliminary injunction factors in light of the panel's interpretation of the agreement.

STATEMENT OF THE CASE

Sarepta and Nippon Shinyaku entered into a Mutual Confidentiality Agreement (“MCA”), governed by Delaware law, to confidentially engage in patent settlement discussions. Appx508-516. In Section 6 of the MCA, entitled “Covenant Not to Sue or Initiate a Patent Challenge,” the parties expressly agreed to defer bringing any patent invalidity challenges with the USPTO until after the “Covenant Term” expired. Appx512 at § 6.1; Appx509; Appx513 at § 7. After the agreed-upon Covenant Term expired, Sarepta filed seven IPR petitions with the Patent Trial and Appeal Board (“Board”), challenging the patentability of the claims of seven Nippon Shinyaku patents. Appx882; Appx888.

Nippon Shinyaku sued Sarepta in the District of Delaware for breach of contract and patent infringement. Appx475-506. It moved for a preliminary

injunction seeking to require Sarepta to withdraw its IPR petitions. Appx861-863. Nippon Shinyaku's motion did not mention the covenant not to sue of Section 6, which expressly addressed the timing of IPR petitions. Instead, Nippon Shinyaku argued that a forum selection clause in Section 10 of the MCA implicitly precluded Sarepta from filing its IPRs. Appx513-514.

The district court denied Nippon Shinyaku's motion in Orders dated September 24, 2021, and October 25, 2021. Appx5-6; Appx1226-1233. The district court first determined that, under the covenant not to sue provisions of Section 6, the parties intended to allow IPRs to proceed after the Covenant Term expired. Appx1229-1230.

The district court then held that, read in full context, the forum selection clause of Section 10 was best understood as limited to cases filed in federal district court. Appx1230-1231. It rejected Nippon Shinyaku's contention that Sarepta had waived its statutory right to pursue IPRs:

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.”).

Appx1231. The district court similarly found that “the parties were not explicit about the elimination of any statutory right.” Appx1233.

In addition, contrary to any express waiver of the statutory right to file IPRs, the district court found that “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).” Appx1231. It concluded that Nippon Shinyaku had not shown a reasonable probability that Sarepta breached the MCA. Appx1231.

The district court also found that Nippon Shinyaku had failed to show irreparable harm. Appx1231-1232. It held that Sarepta would be irreparably harmed by an injunction because it would be deprived of its statutory right to pursue IPR challenges to Nippon Shinyaku’s patents. Appx1232. It denied Nippon Shinyaku’s motion. Appx1233.

Nippon Shinyaku appealed. During the appeal, the Board granted all seven of Sarepta’s IPR petitions. The Board held in each Institution Decision that Sarepta had “demonstrated a reasonable likelihood of success in proving that the challenged claims of the [patent] are unpatentable.” *See, e.g., Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.*, IPR2021-01134, Paper No. 20 at 43 (PTAB Jan. 12, 2022) (Decision Granting Institution); *see also* ECF No. 47.

In reversing the district court, the panel interpreted the plain language of the forum selection clause in isolation as encompassing IPRs. Slip Op. at 9-10. The panel did not address the Delaware contract principle that any waiver of statutory rights must be explicit or the district court’s findings concerning the absence of any such explicit waiver in the MCA. *Id.* at 7-16. Instead, the panel articulated its own “general principle” of contract law that parties are entitled to bargain away their rights to file IPR petitions. *Id.* at 13.

ARGUMENT

I. The Court Should Reverse the Panel Decision, Which Conflicts with *Erie*’s Requirement for a Federal Court Sitting in Diversity to Apply State Substantive Law

As explained below, the Court should grant rehearing because the panel’s creation of a “general principle” of contract interpretation conflicts with Delaware law and thus violates *Erie*’s constitutional limits on federal judicial power.

A. The Panel Overlooked the Delaware Contract Law Principle That There Can Be No Waiver of a Statutory Right Unless the Waiver Is Clearly and Affirmatively Expressed

Under *Erie*, when a federal court is exercising jurisdiction based on diversity, the outcome of the litigation should be substantially the same, insofar as legal rules determine the outcome, as if the case were tried in state court. *Erie*, 304 U.S. at 78; *Gasperini v. Ctr. for Humanities Inc.*, 518 U.S. 415, 428 (1996); *see also Hanna v. Plumer*, 380 U.S. 460, 465 (1965) (*Erie* held that federal courts sitting in diversity cases, when deciding questions of substantive law, are “*bound by state court*

decisions as well as state statutes”) (emphasis added). The panel decision departs from these constitutional constraints.

As the district court held, under Delaware contract law there can be no waiver of a statutory right “unless that waiver is clearly and affirmatively expressed” in the agreement. *Kortum*, 769 A.2d at 125; *Juul Labs, Inc. v. Grove*, 238 A.3d 904, 909 (Del. Ch. 2020) (citing *Kortum* in finding no waiver of statutory inspection rights). This principle of Delaware contract law has been consistently applied by both the Delaware Chancery Court and the Delaware Supreme Court. *See also Johnson v. American Modern Home Ins. Co.*, 259 A.3d 724, 2021 WL 3771825, at *2 (Del. Aug. 23, 2021) (“Delaware law permits a party to a contract to waive its statutory rights. But such waiver must be ‘clearly and affirmatively expressed in the relevant document.’”) (quoting *Juul Labs*, 238 A.3d at 909, and *Kortum*, 769 A.2d at 125).¹

The district court properly applied this Delaware legal principle in interpreting Section 10 of the MCA. *See* Appx1231 (applying *Kortum*). It found, for example, no explicit waiver by the parties of their statutory right to file IPRs. Appx1233. On the contrary, it found that in drafting the MCA, the parties were careful to *preserve* their rights to initiate proceedings that would be statutorily barred by excluding them

¹ Although *Johnson* is an unpublished decision, it is properly citable as precedent. *See* Del. Sup. Ct. Rule 14(b)(vi)(B)(2); *Issa v. Delaware State Univ.*, 268 F. Supp. 3d 624, 631 n.1 (D. Del. 2017) (discussing Delaware practice of permitting citation of unpublished Delaware decisions as precedent).

from Section 6’s covenant not to sue. Appx1231; Appx512 (“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”). The district court recognized that Section 10’s reference to IPRs was “oblique[]” at best—not an express waiver of the right to file IPRs. Appx1230; Appx1233.

The panel, however, failed to apply this state law requirement; for example, it never cited or addressed *Kortum* or the Delaware contract principle that any waiver of statutory rights must be explicit. Slip Op. at 7-16. Nor did the panel address the district court’s findings concerning the absence of any explicit waiver of the statutory right to file IPRs in the MCA. *Id.* Instead, the panel devised its own “general principle” of contract law (apparently under Federal Circuit law) that “parties are entitled to bargain away their rights to file IPR petitions, including through the use of forum selection clauses.” Slip Op. at 13.

In support of this purported “general principle,” the panel cited *Dodocase VR, Inc. v. MerchSource, LLC*, 767 F. App’x 930, 935 (Fed. Cir. 2019) (non-precedential). But, apart from the fact that it was a non-precedential decision, *Dodocase* was decided under California law, not Delaware law. *Dodocase*, 767 F. App’x at 934 (“We therefore apply California state law to interpret the MLA.”). *Dodocase* did not address (much less distinguish) *Kortum* or the principle of

Delaware contract law that there can be no waiver of a statutory right unless the waiver is clearly and affirmatively expressed in the agreement.

The panel distinguished *Kannuu Pty Ltd. v. Samsung Electronics Co.*, 15 F.4th 1101, 1106-10 (Fed. Cir. 2021), where a forum selection clause in a confidentiality agreement was held not to extend to IPRs, on the basis that the decision turned on the “specific language” of the forum selection clause. Slip Op. at 13. The panel stated that inherent in *Kannuu*’s holding was “an understanding that a differently worded forum selection clause would preclude the filing of IPR petitions.” *Id.* But while that may be true, it is irrelevant: *Kannuu* was decided under New York law; it did not involve Delaware law or the Delaware principle that there can be no waiver of a statutory right unless the waiver is clearly and affirmatively expressed.

The panel also stated that “the practical effect that Sarepta’s IPRs will now be time barred is *irrelevant* to determining the parties’ intent at the time they included the forum selection clause in the MCA.” Slip Op. at 14 (emphasis added). But this was based on the panel’s speculation that “it seems possible that if Sarepta had not first filed its IPR petitions, Nippon Shinyaku never would have filed its complaint.” *Id.* Nippon Shinyaku itself never advanced any such argument and the district court found no such facts. Nor did the district court simply consider the “practical effect” of Sarepta being barred from pursuing its IPRs—it instead correctly applied the

Delaware legal principle that there can be no waiver of a statutory right unless clearly and affirmatively expressed. Appx1231.

Thus, Sarepta’s potential loss of its statutory right to pursue IPRs was not “irrelevant” to a proper contract interpretation as the panel held—to the contrary, it was squarely relevant to a proper interpretation under Delaware law. *See Kortum*, 769 A.2d at 125; *Hanna*, 380 U.S. at 465 (*Erie* held federal courts sitting in diversity are “bound by state court decisions” when deciding questions of state substantive law). *Nippon Shinyaku* did not address *Kortum* or the district court’s application of *Kortum* to the case in either of its appeal briefs and thus has failed to challenge the district court’s proper reliance on *Kortum* in interpreting the forum selection clause. Blue Br. 22-23 (arguing, without addressing *Kortum*, that Sarepta waived its right to file IPR petitions for two years after the Covenant Term).

The panel relied on *Estate of Osborn v. Kemp*, 991 A.2d 1153 (Del. 2010), as allegedly supporting its “plain meaning” interpretation of the MCA’s forum selection clause. Slip Op. at 9-10. But *Osborn* involved a *one-sentence* contract for the purchase of a beach house. *Osborn*, 991 A.2d at 1156. It did not address a more complex agreement, as here, containing multiple sections that needed to be reconciled. Nor did *Osborn* suggest that giving effect to the plain meaning of contract terms should supersede the Delaware requirement that there can be no waiver of a statutory right unless it is express.

The panel, in light of *Kortum*, should have interpreted Section 10 in a way that was consistent with the parties' intent to preserve their statutory rights. The district court did precisely that, identifying *several* reasons for interpreting Section 10 as only referring to cases filed in federal court. Appx1230-1231. The term "Potential Actions," for example, is modified by the phrase "*arising under U.S. law relating to patent infringement or invalidity,*" consistent with the language of 28 U.S.C. § 1338, which confers jurisdiction on federal courts in patent cases. Appx1230 n.2 (emphasis added). The district court noted this parallel to section 1338, but the panel never addressed it. *Id.*; Slip Op. at 2-14.

The panel decision, if not reversed, will irreparably harm Sarepta by effecting an implied waiver of Sarepta's statutory right to pursue its IPR challenges to Nippon Shinyaku's patents in contravention of state law. Appx1232 (district court finding that Sarepta would be irreparably harmed by an injunction). That outcome is impermissible under Delaware law because as the district court found, when read as a whole, the MCA does *not* clearly and affirmatively express any waiver of the statutory right to file IPRs. Appx1231-1233.

B. The Panel Decision Violates *Erie*'s Constitutional Limits on Federal Judicial Power

Federal jurisdiction over Nippon Shinyaku's breach of contract claim under Delaware law is based on diversity under 28 U.S.C. § 1332(a). *See* Appx477 at ¶ 8.² For this state law claim, “[f]ederal diversity jurisdiction provides an alternative forum for the adjudication of state-created rights, but it does not carry with it generation of rules of substantive law.” *Gasperini*, 518 U.S. at 426. Rather, “[u]nder the *Erie* doctrine, federal courts sitting in diversity apply state substantive law and federal procedural law.” *Id.* at 427; *Erie*, 304 U.S. at 78.

Issues of contract interpretation are considered quintessentially substantive, rather than procedural, under *Erie*. *E.g.*, *Collins v. Mary Kay, Inc.*, 874 F.3d 176, 182 (3d Cir. 2017). This holds true for the interpretation of forum selection clauses in contracts. In *Collins*, for example, the Third Circuit found “no reason under this Circuit’s precedent or the *Erie* doctrine to apply federal common law to interpret the forum selection clauses” at issue and thus applied “state contract law to assess the scope of the clauses.” *Id.* at 183 (holding that the *interpretation* of contractual terms

² Although Nippon Shinyaku also alleged supplemental jurisdiction over this claim under 28 U.S.C. § 1367(a), its state law claim (breach of contract) is governed by Delaware law regardless. *See United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 726 (1966) (federal court “bound to apply state law” to pendent state law claims under *Erie*); *Rohm & Haas Co. v. Adco Chem. Co.*, 689 F.2d 424, 429 (3d Cir. 1982) (rejecting a district court’s application of federal common law and applying state law to pendent trade secret claim).

on forum selection is a matter of state law as distinct from wider *enforceability* questions). This appeal similarly involves a question of the proper interpretation (not enforceability) of a forum selection clause and thus mandates application of state substantive law in accordance with *Erie*. *See id.*

By reaching an outcome, however, that differs from how a Delaware state court would have resolved the same issues of contract interpretation, the panel decision violates *Erie*'s constitutional requirements. *Gasperini*, 518 U.S. at 428; *Hanna*, 380 U.S. at 467 (“The *Erie* rule is rooted in part in a realization that it would be unfair for the character or result of a litigation materially to differ because the suit had been brought in a federal court.”).

The *Erie* doctrine was designed to *prohibit* federal courts from unconstitutionally devising federal common law based on “general” principles. *Erie*, 304 U.S. at 78 (“There is no federal general common law. Congress has no power to declare substantive rules of common law applicable in a state whether they be local in their nature or ‘general,’ be they commercial law or a part of the law of torts. And no clause in the Constitution purports to confer such a power upon the federal courts.”). Congress vested in the Federal Circuit the ability to ensure uniformity in federal patent law, but this Court cannot fashion its own “general” principles of state contract law as it did here. *See Slip Op.* at 13 (devising a “general principle” that

parties are entitled to bargain away their rights to file IPR petitions). This overreach of constitutional authority should be corrected *en banc*.

The Court should therefore grant rehearing to correct the panel’s failure to follow controlling Delaware contract law in violation of *Erie*. Further, since the panel’s reversal of the district court’s decision was based on its legally erroneous contract interpretation (*see* Slip Op. at 2-16), the Court should reverse the panel decision and affirm the district court’s decision denying a preliminary injunction.

II. Alternatively, the Court Should Vacate and Remand This Case to the District Court for Reevaluation and Balancing of the Preliminary Injunction Factors

In denying a preliminary injunction, the district court explained that because Nippon Shinyaku had not established the first two preliminary injunction “gateway” factors, it did not have to “reach the balance of the equities or the public interest.” Appx1232 (citing *Reilly v. City of Harrisburg*, 858 F.3d 173, 176 (3d Cir. 2017)). Although the district court briefly addressed “Nippon Shinyaku’s arguments” on the third and fourth preliminary injunction factors, it never addressed *Sarepta’s* arguments on those factors. Appx1232-1233.

The panel’s remand “for entry of a preliminary injunction” conflicts with prior decisions of this Court, which have vacated and remanded for further proceedings in analogous situations. *See, e.g., Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1332 (Fed. Cir. 2012) (“Because the district court has not yet weighed the balance

of hardships to the parties and the public interest factors, we do not have a sufficient basis for concluding that the failure to enter an injunction was an abuse of discretion.”); *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 811 (Fed. Cir. 2007) (vacating permanent injunction and remanding for district court to reconsider the four-factor test); *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1362-63 (Fed. Cir. 2002) (vacating denial of preliminary injunction and remanding for further proceedings).

Further, in view of the district court’s reasoning, it never had a need to *balance* the preliminary injunction factors. Appx1232-1233. The “balancing of the four factors, of course, rests within the discretion of the trial court, not the appellate court.” *Guttman*, 302 F.3d at 1363. The panel usurped the district court’s role as factfinder in ruling that the second, third, and fourth preliminary injunction factors were established “as a matter of law” without permitting the district court to complete its analysis or balance the four factors. Slip Op. at 15; *Apple*, 678 F.3d at 1332; Fed. R. Civ. P. 52(a)(2); *see also Pullman-Standard v. Swint*, 456 U.S. 273, 291-92 (1982) (“the usual rule is that there should be a remand for further proceedings to permit the trial court to make the missing findings”).

General Protecht Group, Inc. v. Leviton Manufacturing Co., 651 F.3d 1355 (Fed. Cir. 2011), cited by the panel (Slip Op. at 15-16), affirmed the grant of a preliminary injunction (finding it was not an abuse of discretion)—it did not address

any issues relating to the reversal of a district court's denial of a preliminary injunction, at issue here.

The district court has not yet addressed Sarepta's public interest arguments. *See, e.g.*, Appx1232-1233; Red Br. 40-41. In addition, after denying a preliminary injunction (and after briefing in this appeal was completed), the district court found that *Nippon Shinyaku violated the MCA* by improperly disclosing the substance of the parties' confidential business discussions in its complaint. *See Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*, No. 1:21-cv-01015-LPS, D.I. 85 at 31-34 (D. Del. Dec. 27, 2021). That violation of the core protections of the MCA by Nippon Shinyaku could support denying Nippon Shinyaku any equitable relief.³ Thus, if the Court does not reverse the panel decision, it should nonetheless allow the district court to reevaluate the *current* circumstances of the case on remand before entering any injunction.

CONCLUSION

Sarepta respectfully requests rehearing for the Court to reverse the panel decision and affirm the district court's denial of a preliminary injunction. Alternatively, the Court should return this case to the district court for reevaluation and balancing of the preliminary injunction factors.

³ *See, e.g., Sherwood, Inc. v. Cottman Transmission Sys., Inc.*, C.A. No. 6768, 1982 WL 17882, at *2 (Del. Ch. Apr. 15, 1982) (denying injunctive relief to plaintiff due to its own breach of contract).

Date: March 10, 2022

Respectfully submitted,

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ADDENDUM

**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

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

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

relate to federal district court litigation and are categorically inapplicable to IPR proceedings at the Board. *Id.* The court thus concluded that, “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.” *Id.*

The district court’s third reason was based on the practical effects of interpreting Section 10’s forum selection clause as precluding IPRs for two years following the Covenant Term. In light of the timing of Nippon Shinyaku’s complaint for patent infringement in this case, the court noted that “[i]f Sarepta is forced to wait until June 2023 [to file IPR petitions], as Nippon Shinyaku insists, then its IPR petitions will be time-barred” under 35 U.S.C. § 315(b). *Id.* The court found that “the [MCA] as a whole does not evince a shared expectation and intent that Sarepta was waiving its right to file IPR petitions.” *Id.*

The district court then turned to the remaining preliminary injunction factors. For the second factor, the court found that “Nippon Shinyaku has also failed to show that it will suffer irreparable harm if the [c]ourt does not grant a preliminary injunction.” *Id.* The court essentially found that Nippon Shinyaku’s irreparable harm arguments fell with its contract interpretation arguments regarding the forum selection clause. *Id.* (“[T]his argument depends on the faulty assumption that Nippon Shinyaku contracted itself out of that potential situation.”). Similarly, with respect to the third and fourth preliminary injunction factors—the balance of hardships and public interest—the court found that Nippon Shinyaku’s arguments “depend, yet again, on the flawed presumption that Sarepta’s IPR petitions cannot be filed until June 21, 2023.” *Id.* at *4. Thus, the court concluded that “Nippon Shinyaku did not meet its burden on any of the factors it must establish in order to obtain a preliminary injunction.” *Id.*

III. The Instant Appeal

Nippon Shinyaku filed this appeal on September 29, 2021—five days after the district court’s original order denying the preliminary injunction motion, and a month before the district court issued its order explaining its reasoning. Nippon Shinyaku immediately moved for expedited briefing on October 1, 2021, and then filed its opening brief on October 4, 2021. After the district court issued its memorandum order explaining its reasoning, Sarepta filed its responsive brief on November 2, 2021 and Nippon Shinyaku filed its reply on November 9, 2021.

On January 10, 2022, Nippon Shinyaku submitted a letter pursuant to Fed. R. App. P. 28(j) advising us that the Board granted institution in two of the seven IPR proceedings that Nippon Shinyaku seeks to enjoin. We held argument in the case the following day on January 11, 2022, during which counsel for Nippon Shinyaku advised us that the deadlines for the Board to issue institution decisions in the remaining IPR proceedings were approaching. As of January 13, 2022, the Board has granted institution in all seven IPRs at issue in this case.

Because Nippon Shinyaku appeals from an interlocutory order of the district court in a case in which a party has asserted a claim arising under an Act of Congress relating to patents, we have jurisdiction under 28 U.S.C. § 1292(c)(1). *See also* 28 U.S.C. § 1292(a)(1); 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

We generally review a denial of a preliminary injunction using the law of the regional circuit, here the Third Circuit. *See Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1363 (Fed. Cir. 2016) (citing *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014)). “However, the Federal Circuit has itself built a body of

precedent applying the general preliminary injunction considerations to a large number of factually variant patent cases, and gives dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues.” *Id.* (quoting *Trebro*, 748 F.3d at 1165). Both the Federal Circuit and the Third Circuit review a denial of a preliminary injunction for abuse of discretion. *See id.*; *see also Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484 (3d Cir. 2000). Under that standard, we review underlying questions of law *de novo*. *Antares Pharma, Inc. v. Medac Pharma Inc.*, 771 F.3d 1354, 1357 (Fed. Cir. 2014).

District courts generally consider four factors in evaluating a motion for a preliminary injunction: (1) whether the moving party has shown a reasonable likelihood of success on the merits; (2) whether the moving party will suffer irreparable harm in the absence of a preliminary injunction; (3) whether the balance of hardships tips in the moving party’s favor; and (4) the impact of a preliminary injunction on the public interest. *See, e.g., Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1352 (Fed. Cir. 2016) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)); *Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014). However, under both Federal Circuit and Third Circuit precedent, the first factor—*i.e.*, likelihood of success on the merits—is a necessary showing to establish entitlement to a preliminary injunction. *See, e.g., Somerset Pharm., Inc. v. Dudas*, 500 F.3d 1344, 1346 (Fed. Cir. 2007) (citing *Nat’l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1324–25 (Fed. Cir. 2004)); *Holland v. Rosen*, 895 F.3d 272, 286 (3d Cir. 2018) (citing *In re Revel AC, Inc.*, 802 F.3d 558, 568 (3d Cir. 2015)).

Here, the district court’s finding that Nippon Shinyaku did not show it was likely to succeed on the merits turned entirely on the court’s interpretation of the MCA. The parties agreed that the MCA “shall be governed by and interpreted in accordance with the laws of the State of Delaware.” J.A. 513 (MCA § 10). Therefore, this appeal

NIPPON SHINYAKU CO., LTD. v. SAREPTA THERAPEUTICS, INC. 9

presents “a question of contract interpretation under Delaware law, which we review *de novo*.” *Studiengesellschaft Kohle, m.b.H. v. Hercules, Inc.*, 105 F.3d 629, 632 (Fed. Cir. 1997) (citing *Cyrrix Corp. v. Intel Corp.*, 77 F.3d 1381, 1384 (Fed. Cir. 1996)); *see also Volt Info. Sciences, Inc. v. Bd. of Trustees of Leland Stanford Junior Univ.*, 489 U.S. 468, 474 (1989) (“[T]he interpretation of private contracts is ordinarily a question of state law”); *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1347 (Fed. Cir. 2008) (“Construction of a contract is an issue of law that we review without deference.” (citing *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1361 (Fed. Cir. 2003))).

II

In interpreting a contract, “Delaware adheres to the ‘objective’ theory of contracts, i.e. a contract’s construction should be that which would be understood by an objective, reasonable third party.” *Estate of Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (quoting *NBC Universal v. Paxson Commc’ns*, No. 650-N, 2005 WL 1038997, at *5 (Del. Ch. Apr. 29, 2005)). Under Delaware law, we must “read a contract as a whole” and “give each provision and term effect, so as not to render any part of the contract mere surplusage.” *Id.* (quoting *Kuhn Constr., Inc. v. Diamond State Port Corp.*, 990 A.2d 393, 396–97 (Del. 2010)). Importantly, “when the contract is clear and unambiguous, we will give effect to the plain-meaning of the contract’s terms and provisions.” *Id.* at 1159–60 (citing *Rhone-Poulenc Basic Chem. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192, 1195 (Del. 1992)).

In this case, the plain language of the forum selection clause in Section 10 of the MCA resolves the dispute. Section 10 states clearly 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.” J.A. 513–14. The express

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

definition of “Potential Actions” includes “patent or other intellectual property disputes . . . filed with a court *or administrative agency*,” J.A. 509 (emphasis added), and the district court acknowledged that the “definition of ‘Potential Actions’ in Section 1 literally encompasses IPRs.” *Decision*, 2021 WL 4989489, at *3. Sarepta does not contend otherwise. The MCA’s forum selection clause is thus unambiguous, and we must “give effect to the plain meaning of [its] terms.” *Estate of Osborn*, 991 A.2d at 1159–60.

Under the plain language of Section 10, Sarepta was required to bring all disputes regarding the invalidity of Nippon Shinyaku’s patents—including the allegations and contentions contained in Sarepta’s IPR petitions—in the District of Delaware. Sarepta instead brought those disputes in the form of IPR petitions at the Board, which contravened the plain language of the forum selection clause in Section 10 of the MCA.

III

Sarepta makes a number of arguments in support of the district court’s interpretation of the forum selection clause in Section 10 of the MCA. We address these arguments below.

We first consider Sarepta’s suggestion that our reading of Section 10’s forum selection clause would lead, not to a preclusion of IPRs, but rather to a requirement that IPR petitions must be filed in the federal district court in Delaware. We reject that suggestion because such a requirement would not fall within what an “objective, *reasonable* third party” would have understood from the language of the forum selection clause. *See Estate of Osborn*, 991 A.2d at 1159 (emphasis added). Any such nonsensical result stems from the parties’ decision to define the future-tense term “*Potential* Actions” using past-tense language about where such disputes may have been “filed.” *See* J.A. 509 (emphasis added). But the choice of wording in the “Definitions” section of the MCA does not upend our reasonable

NIPPON SHINYAKU CO., LTD. v. SAREPTA THERAPEUTICS, INC. 11

interpretation of the forum selection clause. *See Falcon Steel Co. v. Weber Eng'g Co.*, 517 A.2d 281, 285–86 (Del. Ch. 1986) (refusing to incorporate by reference terms which made a reasonable reading of the contract nonsensical).

We next turn to Sarepta's arguments in defense of the district court's reasoning. Sarepta first echoes the district court's concern about the supposed "tension" between Sections 6 and 10 of the MCA, stressing the legal requirement that we give effect to all terms of the contract and "if possible, reconcile all the provisions of the instrument." *See Alta Berkeley VI C.V. v. Omneon, Inc.*, 41 A.3d 381, 385–86 (Del. 2012) (quoting *Elliott Assoc., L.P. v. Avatex Corp.*, 715 A.2d 843, 854 (Del. 1998)); *see also O'Brien v. Progressive N. Ins. Co.*, 785 A.2d 281, 287 (Del. 2001) (a court must consider the contract as a whole rather than "any single passage in isolation" (citing *Aetna Cas. and Sur. Co. v. Kenner*, Del. Supr., 570 A.2d 1172, 1174 (1990))). Nippon Shinyaku responds that, absent some ambiguity in the plain language of Section 10, there was no reason for the court to look at Section 6 at all. Moreover, Nippon Shinyaku argues that the two provisions are not in conflict with each other because they apply at different times, which the district court acknowledged. *See Decision*, 2021 WL 4989489, at *2 ("Sections 6 and 10 implicate different time periods . . .").

We agree with Nippon Shinyaku that there is no conflict or tension between the two sections of the MCA. During the Covenant Term, Section 6 prohibited the parties from "directly or indirectly assert[ing] or fil[ing] any legal or equitable cause of action, suit or claim or otherwise initiat[ing] any litigation or other form of legal or administrative proceeding . . . of or concerning intellectual property in the field of Duchenne Muscular Dystrophy." J.A. 512 (MCA § 6.1). In essence, the covenant not to sue broadly prohibited the parties from litigating any issue relating to patents, regardless of the forum. *See id.* (expressly clarifying that the covenant not to sue includes "patent infringement litigations, declaratory judgment actions, [and]

patent validity challenges before the U.S. Patent and Trademark Office”). Upon the expiration of the Covenant Term, however, Section 6’s covenant not to sue was no longer in effect, and the parties were thus no longer prohibited from asserting claims relating to patent infringement or invalidity. At that point, to the extent either party wished to assert or file any such claims, Section 10’s forum selection clause merely required that such claims “arising under U.S. law relating to patent infringement or invalidity” be filed in “the United States District Court for the District of Delaware.” J.A. 514 (MCA § 10). This framework—which reflects harmony, not tension, between Sections 6 and 10 of the MCA—is entirely consistent with our interpretation of the plain meaning of the forum selection clause, as set forth above.

Sarepta next defends the district court’s reasoning that other language in Section 10 indicates that the forum selection clause is best read as limited only to federal district court litigation. We disagree. To be sure, the district court was correct that issues of patent infringement, *forum non conveniens*, and jurisdiction challenges are inapplicable to IPR proceedings. *See Decision*, 2021 WL 4989489, at *3 (citing *Sinochem Int’l Co. v. Malay. Int’l Shipping Corp.*, 549 U.S. 422, 430 (2007); *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1361 (Fed. Cir. 2019)). But it does not follow that the parties’ inclusion of those issues in the forum selection clause means that they intended to categorically exclude IPRs. We think the better reading of Section 10 recognizes the parties’ agreement that, after one party files an action relating to patent infringement or invalidity in the District of Delaware—as a filing party is required to do—the other party will not “contest personal jurisdiction or venue in the District of Delaware” or “seek to transfer . . . on the ground of *forum non conveniens*.” J.A. 514.

Finally, Sarepta argues that the district court correctly determined that neither party intended to bargain away its

NIPPON SHINYAKU CO., LTD. v. SAREPTA THERAPEUTICS, INC. 13

right to file IPR petitions, which, due to the time bar in 35 U.S.C. § 315(b), would be the practical effect of our reading of the forum selection clause. Again, we disagree with Sarepta and the district court. As a general principle, this court has recognized that parties are entitled to bargain away their rights to file IPR petitions, including through the use of forum selection clauses. For example, in *Dodocase VR, Inc. v. MerchSource, LLC*, 767 F. App'x 930, 935 (Fed. Cir. 2019) (non-precedential), we affirmed a district court's grant of a preliminary injunction on the basis that a defendant had likely violated a forum selection clause by filing IPR petitions, even though the forum selection clause did not explicitly mention IPRs. Even in *Kannuu Pty Ltd. v. Samsung Electronics Co.*, 15 F.4th 1101, 1106–10 (Fed. Cir. 2021), where we determined that the parties' forum selection clause did not extend to IPRs, that determination was based on the specific language in the forum selection clause at issue in that case. Inherent in our holding in *Kannuu* was an understanding that a differently worded forum selection clause would preclude the filing of IPR petitions. *See id.* In the case before us now, we have such a forum selection clause, which uses a defined term that the district court acknowledged “literally encompasses IPRs.” *Decision*, 2021 WL 4989489, at *3.

Moreover, it is apparent that the practical effects about which the district court was concerned—*i.e.*, that Sarepta's IPRs will be time barred by the time the forum selection clause expires—resulted from Nippon Shinyaku's filing of a patent infringement complaint, not from the parties' entry into the MCA itself. We are not persuaded that our interpretation of the forum selection clause should be impacted by Nippon Shinyaku's filing of a complaint, which was an event that occurred more than a year after the parties entered into the MCA. *Cf. Osram Sylvania, Inc. v. Townsend Ventures, LLC*, No. 8123-VCP, 2013 WL 6199554, at *19 (Del. Ch. Nov. 19, 2013) (“The courts will not imply terms to ‘rebalanc[e] economic interests after

events that could have been anticipated, but were not, that later adversely affected one party to a contract.” (quoting *Nemec v. Shrader*, 991 A.2d 1120, 1128 (Del. 2010)). At the time the parties entered into the MCA, it was not a given that Nippon Shinyaku would file a complaint for patent infringement during the period governed by the forum selection clause; indeed, it seems possible that if Sarepta had not first filed its IPR petitions, Nippon Shinyaku never would have filed its complaint. Under our interpretation of the forum selection clause, if Nippon Shinyaku had not filed a complaint for patent infringement—or even if Nippon Shinyaku had filed a complaint, but had done so more than a year after the Covenant Term ended—Sarepta would have had time to file its IPR petitions after the expiration of the forum selection clause and before they were time barred by 35 U.S.C. § 315(b). Thus, the practical effect that Sarepta’s IPRs will now be time barred is irrelevant to determining the parties’ intent at the time they included the forum selection clause in the MCA.

For the foregoing reasons, we are unpersuaded by Sarepta’s arguments that the district court correctly interpreted Section 10 of the MCA as allowing the filing of IPR petitions. We conclude as a matter of law that the forum selection clause in Section 10 of the MCA precludes the filing of IPR petitions during the two-year period following the expiration of the Covenant Term on June 21, 2021. Because Sarepta filed IPR petitions during that time in violation of the forum selection clause in Section 10, Nippon Shinyaku is likely to succeed on the merits of its claim for breach of contract.

IV

Having determined that Nippon Shinyaku is likely to succeed on the merits of its breach of contract claim, we turn to the other three factors relevant to the preliminary injunction analysis. As noted above, the district court determined that Nippon Shinyaku’s arguments with respect

NIPPON SHINYAKU CO., LTD. v. SAREPTA THERAPEUTICS, INC. 15

to all three factors rose and fell with its arguments regarding likelihood of success on the merits. We agree, and for the following reasons we find that Nippon Shinyaku has satisfied the remaining preliminary injunction factors in this case as a matter of law.

With regard to irreparable harm, Nippon Shinyaku has argued that, absent a preliminary injunction, it will be deprived of its bargained-for choice of forum and forced to litigate its patent rights in multiple jurisdictions. We have held that such harm constitutes irreparable harm sufficient to meet the standard for a preliminary injunction. *See Gen. Protecht Grp., Inc. v. Leviton Mfg. Co.*, 651 F.3d 1355, 1363 (Fed. Cir. 2011). Our binding precedent compels the same result here.

We also agree with Nippon Shinyaku that the balance of hardships tips in its favor. Without a preliminary injunction, Nippon Shinyaku will suffer the irreparable harm previously described, and Sarepta will potentially get multiple bites at the invalidity apple, including in a forum it bargained away. In contrast, if a preliminary injunction is entered, Sarepta will still have an opportunity to litigate the invalidity of Nippon Shinyaku's patents, but it will have to do so only in the District of Delaware rather than also at the Board. Again, our holding in *General Protecht* is directly on point: "Having contracted for a specific forum, [Sarepta] should not be heard to argue that the enforcement of the contract into which it freely entered would cause hardship." 651 F.3d at 1365.

Finally, with respect to the public interest, we reject the notion that there is anything unfair about holding Sarepta to its bargain. While it is certainly true that Congress desired to serve the public interest by creating IPRs to allow parties to quickly and efficiently challenge patents, it does not follow that it is necessarily against the public interest for an individual party to bargain away its opportunity to do so. It is well established that forum

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

selection clauses “are prima facie valid and should be enforced,” *M/S Bremen v. Zapata Off-Shore Co.*, 407 U.S. 1, 10 (1972), and we have held that “[t]here is no public interest served by excusing a party’s violation of its previously negotiated contractual undertaking to litigate in a particular forum.” *Gen. Protecht*, 651 F.3d at 1366.

CONCLUSION

We have considered Sarepta’s remaining arguments but we find them unpersuasive. For the foregoing reasons, we conclude that Nippon Shinyaku has shown that all four preliminary injunction factors weigh in its favor. Accordingly, we reverse the decision of the district court, and we remand for entry of a preliminary injunction.

REVERSED AND REMANDED

COSTS

Costs against Appellee.

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2021-2369

Short Case Caption: Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.

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