No. 2021-2369

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 No. 1:21-CV-01015, Honorable Leonard P. Stark

RESPONSE TO PETITION FOR REHEARING

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CERTIFICATE OF INTEREST

Case Number 2021-2369

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

Filing Party/Entity Appellant Nippon Shinyaku Co., Ltd.

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Dated: April 15, 2022 /s/ William R. Peterson

William R. Peterson
Counsel for Appellant
Nippon Shinyaku Co., Ltd.

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).	3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. None/Not Applicable
Nippon Shinyaku Co., Ltd.	Not Applicable	None

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).					
□ None/Not Applicable					
Jitsuro Morishita (Morgan, Lewis &	Michael T. Sikora (Morgan, Lewis &				
Bockius LLP)	Bockius LLP)				

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

TABLE OF CONTENTS

			Page
Certi	ficate	of Interest	i
Table	e of C	ontents	iii
Table	e of A	uthorities	iv
Intro	ductio	on	1
Back	groun	d	3
Argu	ıment i	in Response	5
I.		Panel Correctly Applied Delaware Contract Interpretation	5
	A.	Sarepta misreads the panel's opinion and confuses the interpretation and validity of forum selection clauses	6
	В.	Delaware law favors forum-selection clauses and enforces them broadly	8
	C.	The panel correctly enforced the plain and unambiguous language of the parties' agreement.	10
II.		Panel Correctly Held that Nippon Shinyaku Is Entitled to an netion Enforcing the Forum Selection Clause.	13
Conc	clusion	n & Prayer for Relief	18
Certi	ficate	of Compliance	19

TABLE OF AUTHORITIES

	Page(s)
CASES	
Atl. Marine Const. Co., Inc. v. U.S. Dist. Court for W. Dist. of Tex., 571 U.S. 49 (2013)	17
Dodocase VR, Inc. v. MerchSource, LLC, 767 F. App'x 930 (Fed. Cir. 2019)	7
DSU Med. Corp. v. JMS Co., 471 F.3d 1293 (Fed. Cir. 2006)	5
Erie R. Co. v. Tompkins, 304 U.S. 64 (1938)	passim
Estate of Osborn v. Kemp, 991 A.2d 1153 (Del. 2010)	11, 13
Gen. Protecht Grp., Inc. v. Leviton Mfg. Co., 651 F.3d 1355 (Fed. Cir. 2011)	2, 16
Genuine Parts Co. v. Cepec, 137 A.3d 123 (Del. 2016)	9
<i>In re Dillon</i> , 919 F.2d 688 (Fed. Cir. 1990)	5
In re Shorenstein Hays-Nederlander Theatres LLC Appeals, 213 A.3d 39 (Del. 2019)	12
Ingres Corp. v. CA, Inc., 8 A.3d 1143 (Del. 2010)	9
Kannuu Pty Ltd. v. Samsung Elecs. Co., 15 F.4th 1101 (Fed. Cir. 2021)	7, 8
Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487 (1941)	6

TABLE OF AUTHORITIES

(continued)

	Page(s)
Kortum v. Webasto Sunroofs, Inc., 769 A.2d 113 (Del. Ch. 2000)	8
Lorillard Tobacco Co. v. Am. Legacy Found., 903 A.2d 728 (Del. 2006)	11
M/S Bremen v. Zapata Off-Shore Co., 407 U.S. 1 (1972)	17
Manti Holdings, LLC v. Authentix Acquisition Co., 261 A.3d 1199 (Del. 2021)	11, 12
Midwest Indus., Inc. v. Karavan Trailers, Inc., 175 F.3d 1356 (Fed. Cir. 1999)	7
Nat'l Indus. Grp. (Holding) v. Carlyle Inv. Mgmt. L.L.C., 67 A.3d 373 (Del. 2013)	9, 10
Parfi Holding AB v. Mirror Image Internet, Inc., 817 A.2d 149 (Del. 2002)	10
Pullman-Standard v. Swint, 456 U.S. 273 (1982)	15
Rodriguez de Quijas v. Shearson/Am. Exp., Inc., 490 U.S. 477 (1989)	9
Salzberg v. Sciabacucchi, 227 A.3d 102 (Del. 2020)	1, 8, 10
Scherk v. Alberto–Culver Co., 417 U.S. 506 (1974)	10
Sherwood, Inc. v. Cottman Transmission Sys., Inc., No. 6768, 1982 WL 17882 (Del. Ch. Apr. 15, 1982)	18
Sony Elecs., Inc. v. U.S., 382 F.3d 1337 (Fed. Cir. 2004)	5

TABLE OF AUTHORITIES

(continued)

	Page(s)
Trascent Mgmt. Consulting, LLC v. Bouri, 152 A.3d 108 (Del. 2016)	9
RULES	
Fed. R. App. P. 28(j)	17
Other Authorities	
Fed. Cir. IOP 13(2)	5

Introduction

Sarepta's petition neither presents the sort of exceptional issue suitable for en banc rehearing nor identifies an error suitable for panel rehearing.

Although Sarepta attempts to frame its primary issue as involving *Erie* and "constitutional limits on federal judicial power," the panel correctly applied Delaware law. Sarepta's true argument is simply that the panel erred in applying Delaware law in interpreting the specific forum-selection clause at issue.

Sarepta relies on an alleged "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." But the Delaware Supreme Court has never applied this waiver principle to forum selection clauses. Far from treating these clauses as narrow and disfavored, Delaware "requires courts to give as much effect as possible to forum selection clauses." *Salzberg v. Sciabacucchi*, 227 A.3d 102, 132 (Del. 2020).

And even if Delaware required forum selection clauses to be clear, the panel held that the plain language of the MCA's forum selection clause unambiguously covered IPRs. Even under Sarepta's framing of the issue, the panel was correct.

Sarepta's second question, remedy, is fact-bound and case-specific. Both before the district court and before the panel, all of Sarepta's arguments relied on its own contract interpretation. Sarepta never argued that a preliminary injunction should be denied if Nippon Shinyaku's interpretation of the MCA were correct.

In addition, the panel correctly held that on the facts of this case and in light of this Court's precedent in *Gen. Protecht Grp., Inc. v. Leviton Mfg. Co.*, 651 F.3d 1355, 1363 (Fed. Cir. 2011), the preliminary injunction factors were established as a matter of law. This case-specific ruling, which rests largely on Sarepta's failure to develop any argument to the contrary, is correct and unsuitable for en banc review.

Sarepta's petition for rehearing should be denied as expeditiously as possible in light of the upcoming expiration of the stay ordered by the PTAB.

BACKGROUND

On June 1, 2020, Nippon Shinyaku and Sarepta executed a Mutual Confidentiality Agreement ("MCA"), Appx508, which contains a Delaware choice-of-law clause. Appx513. The MCA also includes a covenant not to sue through June 21, 2021, and a forum selection clause that applies for the following two years. Appx512-14.

The forum selection clause requires that "all Potential Actions arising under U.S. law relating to patent . . . invalidity . . . shall be filed in the United States District Court for the District of Delaware[.]" Appx514. "Potential Actions" is defined broadly and expressly includes intellectual property disputes "filed with a[n] . . . administrative agency." Appx509. The district court held—and Sarepta has never denied—that this definition "literally encompasses IPRs." Appx1231.

After the MCA expired—and within the two-year period covered by the forum selection clause—in June 2021, Sarepta breached the MCA by filing seven IPR petitions challenging various Nippon Shinyaku Patents. Appx867.

Nippon Shinyaku responded with a complaint in the District of Delaware that, *inter alia*, asserted claims for breach of the MCA and for patent infringement. Appx475-506. Nippon Shinyaku also filed a motion for a preliminary injunction, asking the district court to enjoin Sarepta from proceeding with its IPR Petitions. Appx864-876.

The district court denied the preliminary injunction, and Nippon Shinyaku appealed. Following briefing and oral argument, on February 8, 2022, the panel reversed the denial of preliminary injunction in a precedential opinion authored by Judge Lourie.

Both before the district court and before the panel, Sarepta rested all of its arguments on its (incorrect) interpretation of the forum selection clause. *See, e.g.*, Sarepta Br. 36 (arguing that there is no irreparable harm because "Section 10 only relates to potential federal court actions"); Sarepta Br. 40 ("The absence of any breach eliminates any public interest support for an injunction."). After holding that the plain meaning of the forum selection clause controls, the panel recognized that there was no dispute regarding the preliminary injunction factors and rendered judgment ordering that a preliminary injunction be entered to enforce the parties' agreement.

ARGUMENT IN RESPONSE

En banc review is disfavored and granted only if it is necessary to maintain uniformity of this Court's decisions or if the proceeding involves a question of exceptional importance. Fed. R. App. Proc. 35(a); *see* Fed. Cir. IOP 13(2); *Sony Elecs., Inc. v. U.S.*, 382 F.3d 1337, 1339 (Fed. Cir. 2004).

The purpose of en banc rehearing is not "to second-guess the panel on the facts of a particular case." *In re Dillon*, 919 F.2d 688, 700 n.3 (Fed. Cir. 1990) (Newman, J., joined by Cowen and Mayer, JJ., dissenting). The "rare intervention" of en banc rehearing "should be reserved for real conflicts as well as cases of exceptional importance." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1311 (Fed. Cir. 2006) (Michel, C.J., and Mayer, J., concurring).

That "rare intervention" is unwarranted here. Nor does Sarepta demonstrate any error in the panel's analysis that would warrant panel rehearing.

I. The Panel Correctly Applied Delaware Contract Interpretation Law.

Sarepta frames its first issue as whether "the *Erie* doctrine requires 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." Pet. 1.

Sarepta's framing of the issue misreads the panel's analysis. The panel applied Delaware contract law, and it did so correctly. In Delaware, forum selection clauses are favored and routinely enforced. The MCA is clear, and the panel properly gave effect to the forum selection clauses' plain meaning under Delaware law. These case-specific questions of state law do not warrant en banc review.

A. Sarepta misreads the panel's opinion and confuses the interpretation and validity of forum selection clauses.

Sarepta erroneously accuses the panel of interpreting the contract according to its own "general principle" of contract law rather than Delaware law. Sarepta misreads the opinion. The quoted sentence (the "general principle") concerns whether parties can, in the abstract, agree to forum selection clauses that cover IPRs, not whether Sarepta and Nippon Shinyaku actually made such an agreement in their MCA.

Although the MCA is interpreted under Delaware law,¹ this Court applies its own law to procedural issues that pertain to patent law, including issues that bear an

Sarepta's discussion of *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938)—the centerpiece of its petition—is incomplete. Sarepta mistakenly asserts that the district court was required to interpret the forum selection clause under Delaware law because it was sitting in diversity. *See* Pet. 7-15.

Nippon Shinyaku does not, of course, dispute *Erie*'s venerable rule that federal courts sitting in diversity apply the substantive law of the forum state. But Sarepta overlooks the contract's choice-of-law provision. *Erie* requires that "[t]he conflict of laws rules to be applied by the federal court in Delaware must conform to those prevailing in Delaware's state courts." *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941).

essential relationship to matters committed to this Court's exclusive control and issues that clearly implicate the jurisprudential responsibilities of this Court within its exclusive jurisdiction. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999). These issues governed by this Court's law would include enforceability of the MCA on public policy grounds: whether parties can, in the abstract, agree to a forum selection clause that covers IPRs. Interpretation—whether Nippon Shinyaku and Sarepta, in their MCA in this case, agreed to such a clause—is governed by state contract law.

Sarepta's complaint about the panel's reference to a "general principle" concerns a sentence merely noting that forum selection clauses *can* cover IPRs—the "general principle" is that these agreements are permissible in the abstract:

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

Delaware law applies to the MCA's interpretation—not because of *Erie* and constitutional limits, as Sarepta contends—but because the parties agreed in the contract that Delaware law would apply, and Delaware choice-of-law rules (which apply under *Erie*) give effect to that provision.

holding in *Kannuu* was an understanding that a differently worded forum selection clause would preclude the filing of IPR petitions.

Op. 13. This sentence—and the discussion quoted above—stand simply for the proposition that parties *can* agree to a forum selection clause that requires invalidity challenges to be raised in district court.

Serapta does not actually appear to dispute this general principle. Sarepta has never denied that parties *can agree* to a forum selection clause that would cover IPRs—Sarepta only denies that *it did agree* to such a clause.

Sarepta cannot transform the panel's (apparently undisputed) observation about forum selection clauses into the panel somehow violating *Erie* by applying federal contract law to interpreting the MCA.

B. Delaware law favors forum-selection clauses and enforces them broadly.

When it addresses Delaware law, Sarepta faults the panel for not applying a Delaware trial-level case involving a shareholder waiving its right to inspect corporate documents. Pet. 8 (citing *Kortum v. Webasto Sunroofs, Inc.*, 769 A.2d 113 (Del. Ch. 2000)). Sarepta's argument assumes that Delaware law treats a forum selection clause as a waiver of substantive rights requiring a clear statement.

But a forum selection clause does not "waive" a party's substantive rights. "[F]orum-selection provisions 'are process-oriented,' and are not substantive." *Salzberg*, 227 A.3d at 136. Sarepta retains its ability to challenge the validity of

Nippon Shinyaku's patents. *See* Reply Br. 16–18. The forum selection clause simply requires Sarepta to raise these arguments in the parties' chosen forum. Like an arbitration provision, by agreeing to a forum selection clause, "a party does not forgo the substantive rights afforded by the statute; it only submits to their resolution in [a specific] forum." *Rodriguez de Quijas v. Shearson/Am. Exp., Inc.*, 490 U.S. 477, 481 (1989).

The Delaware Supreme Court has adopted the United States Supreme Court's favorable treatment of forum selection clauses. *Ingres Corp. v. CA, Inc.*, 8 A.3d 1143, 1145 (Del. 2010). These clauses are "presumptively valid" and should be "specifically enforced." *Id.* at 1146.

The Delaware Supreme Court regularly discusses forum selection clauses. See, e.g., Trascent Mgmt. Consulting, LLC v. Bouri, 152 A.3d 108, 113 n.21 (Del. 2016); Genuine Parts Co. v. Cepec, 137 A.3d 123, 148 (Del. 2016); Nat'l Indus. Grp. (Holding) v. Carlyle Inv. Mgmt. L.L.C., 67 A.3d 373, 381 (Del. 2013). In analyzing them, it has never once applied (or mentioned) the "clear statement" principle relied upon by Sarepta.

Far from treating forum selection clauses as disfavored and reading them narrowly, the Delaware Supreme Court "requires courts to give as much effect as possible to forum-selection clauses." *Salzberg*, 227 A.3d at 132.²

Sarepta's theory that Delaware treats a forum selection clause as waiving a substantive right has no support in Delaware law, and its argument that these clauses are construed narrowly directly conflicts with the Delaware Supreme Court's direction that courts must give them "as much effect as possible."

C. The panel correctly enforced the plain and unambiguous language of the parties' agreement.

Even if a clear statement were required, the MCA provides it. The panel correctly held that "[u]nder 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." Op. 10.

There is no other reasonable interpretation of the language used by the parties: "The MCA's forum selection clause is thus unambiguous, and we must 'give effect

² This is consistent with Delaware's treatment of arbitration provisions, which are "in effect, a specialized kind of forum-selection clause." *Nat'l Indus. Grp.* (*Holding*), 67 A.3d at 384 n.41 (quoting *Scherk v. Alberto–Culver Co.*, 417 U.S. 506, 519 (1974)). When interpreting an arbitration clause, Delaware courts "resolve any doubt as to arbitrability in favor of arbitration." *Parfi Holding AB v. Mirror Image Internet, Inc.*, 817 A.2d 149, 155–56 (Del. 2002).

to the plain meaning of [its] terms." Op. 10 (quoting *Estate of Osborn v. Kemp*, 991 A.2d 1153, 1159-60 (Del. 2010)).

The panel's holding is correct. The definition of "Potential Actions" literally encompasses IPRs (a truth that Sarepta has never disputed), and it cannot seriously be denied that IPRs "arise under U.S. law relating to patent . . . invalidity." This plain language clearly and unambiguously applies to IPRs.

Indeed, Sarepta has never actually proposed an alternative interpretation of the MCA's language. Before the district court and in its briefing to this Court, Sarepta argued that courts should rely on the parties' "intent" rather than the plain language of their contract. *See* Reply Br. 6-7 (rebutting the argument).

Sarepta's arguments conflict with Delaware law, which mandates that a court interpreting a contract is "constrained by a combination of the parties' words and the plain meaning of those words[.]" *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006) "When the language of a . . . contract is clear and unequivocal, a party will be bound by its plain meaning." *Id.* The panel correctly gave effect to "the plain language of the forum selection clause in Section 10 of the MCA." Op. 10.

This plain and unambiguous language would easily satisfy the standard for waiver of a substantive right under Delaware law. In *Manti Holdings, LLC v.*Authentix Acquisition Co., the Delaware Supreme Court considered whether a

contract waived a stockholder's statutory right of appraisal, a waiver that the court stated "must be clear to be enforceable." 261 A.3d 1199, 1210-1211 (Del. 2021). The contract satisfied this standard because waiver was "[t]he only reasonable interpretation" of the parties' agreement. *Id.* Refusing to enforce the plain language "would undermine the objective intent of the bargain the parties struck." *Id.* at 1212.

Here, the only reasonable interpretation of the MCA's forum selection clause is that Sarepta promised to raise any invalidity challenges in the District of Delaware (and not in administrative proceedings). Op. 11-12. Failing to enforce the plain and unambiguous language of the parties' agreement would undermine "the objective intent of the bargain the parties struck." Even if Delaware required forum selection clauses to be "clear," this standard was satisfied by the MCA.

Sarepta also errs by repeatedly referring to the district court's "findings" about the MCA's meaning. See Pet. 3 (faulting the panel for not "address[ing] the district court's findings concerning" the MCA's meaning); Pet. at 7 (same); Pet. at 9 (same). But the interpretation of an unambiguous contract is a question of law reviewed de novo. In re Shorenstein Hays-Nederlander Theatres LLC Appeals, 213 A.3d 39, 56 (Del. 2019). There are no "findings" about the meaning of an unambiguous contract. The MCA's interpretation is a question of law, and the district court was not owed any deference.

The language of the MCA is clear and unambiguous. The panel properly gave "effect to the plain meaning of the [its] terms." Op. 10 (quoting *Estate of Osborn v. Kemp*, 991 A.2d 1153, 1159–60 (Del. 2010)). The plain contract language has only one reasonable meaning. No greater clarity was—or could be—required. And in any event, the question whether the panel correctly applied Delaware law on the facts of this case is unsuitable for en banc review.

II. The Panel Correctly Held that Nippon Shinyaku Is Entitled to an Injunction Enforcing the Forum Selection Clause.

After concluding that Nippon Shinyaku showed a likelihood (indeed, a certainty) of success because Sarepta breached the MCA by filing IPR petitions, the panel considered the other three preliminary injunction factors.

On all three factors, the district court rejected Nippon Shinyaku's arguments only because the district court misinterpreted the MCA. Op. 14-15; *see also* Reply Br. 5 (detailing the findings).

Like the district court, all of Sarepta's arguments opposing an injunction were based on its (erroneous) interpretation of the MCA. Sarepta did not—in its brief at trial or on appeal—say anything like, "In the alternative, even under Nippon Shinyaku's interpretation of the MCA, a preliminary injunction should denied."

Case: 21-2369 Document: 60 Page: 21 Filed: 04/15/2022

On every factor, Sarepta based its arguments on its interpretation of the MCA:³

- Irreparable Harm: "Because Nippon Shinyaku cannot establish a breach of the MCA, it cannot show irreparable harm[.]" Appx898 (trial court); Sarepta Br. 36 (same).
- Balance of the Equities: "The MCA does not reflect Sarepta's alleged waiver of its right to pursue *any* IPRs against Nippon Shinyaku's patents." Appx900 (emphasis in original); Sarepta Br. 39 (arguing that the balance of the equities favors Sarepta because there was no breach).
- **Public Interest:** "The absence of any breach eliminates any public interest support for an injunction." Appx900-901; Sarepta Br. 41 (same).

Having made the strategic decision to rest all of its preliminary injunction arguments on its contract interpretation, Sarepta cannot complain when its arguments on the other preliminary injunction factors fall along with its contract interpretation. Raising these arguments for the first time on rehearing comes far too late.

Sarepta also cannot claim surprise. Nippon Shinyaku's opening brief made clear the relief it sought: "[T]his Court should reverse the district court's denial of Nippon Shinyaku's preliminary injunction and remand this case to the district court with instructions to enter the preliminary injunction and order Sarepta to withdraw

³ The parties also discussed this point at oral argument. *See* Oral Argument at 33:36, Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc. (No. 2021-2369), https://cafc.uscourts.gov/01-11-2022-2021-2369-nippon-shinyaku-co-ltd-v-sarepta-therapeutics-inc-audio-uploaded/ (explaining that Sarepta's arguments against a preliminary injunction have always rested entirely on Sarepta's contract interpretation).

its IPR Petitions." Opening Br. 32. Nonetheless, Sarepta's brief did not address remedy or argue for a remand if the panel reversed the district court's contract interpretation.

In any event, remand is unnecessary when "the record permits only one resolution of the factual issue[s]." *Pullman-Standard v. Swint*, 456 U.S. 273, 292 (1982). The panel correctly held that "Nippon Shinyaku has satisfied the remaining preliminary injunction factors in this case as a matter of law." Op. 15.

This case-specific holding does not present a conflict with the prior decisions of this Court, as Sarepta contends (at 15-16). In other cases, the preliminary injunction factors were not satisfied as a matter of law, and remand was necessary. In this case, the factors were satisfied as a matter of law, and remand was unnecessary. There is no "conflict" when different facts and a different record lead to different results.⁴ And none of the cases described by Sarepta as "analogous" involved a forum selection clause.

Sarepta does not demonstrate any error in the panel's conclusion. Its rehearing petition says nothing about irreparable harm, and the panel followed this Court's "binding precedent" that litigating in violation of a forum selection clause

⁴ And unlike Sarepta, other appellees specifically briefed the appropriate remedy and argued for a remand. *See Apple, Inc. v. Samsung Elecs. Co., Ltd.*, No. 2012-1105, Brief of Appellee at 73, 2012 WL 454641 (Fed. Cir. 2012) ("Should this Court disagree with the district court's ruling, its order should not be reversed but instead should be vacated and remanded for further consideration.").

"constitutes irreparable harm sufficient to meet the standard for a preliminary injunction." Op. 15 (citing *Gen. Protecht*, 651 F.3d at 1363).

Given this harm to Nippon Shinyaku (and the absence of any harm to Sarepta), the balance of the equities necessarily favors Nippon Shinyaku. "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." Op. 15 (quoting *Gen. Protecht*, 651 F.3d at 1365).

And the public interest favors the enforcement of forum selection clauses: "[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." Op. 16 (quoting *Gen. Protecht*, 651 F.3d at 1366).

On remand, the district court would have been bound by *General Protecht*. Although *General Protecht* reviewed the grant, not the denial, of a preliminary injunction, its legal analysis of forum selection clauses and the preliminary injunction factors binds district courts and subsequent panels. Remand would have been futile.

Because, as a matter of law and this Court's precedent, every factor favors

Nippon Shinyaku on this record, there was nothing for the district to "balance."

Sarepta forfeited any argument based on Nippon Shinyaku supporting its declaratory judgment claim with threats made by Sarepta during the MCA. See

Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015, Dkt. 85 at 31-34 (D. Del. Dec. 27, 2021) (striking paragraphs of the complaint). Sarepta never argued to the district court or the panel that the contents of Nippon Shinyaku's complaint were relevant to the preliminary injunction. If Sarepta believed that the district court's ruling at the hearing was somehow relevant to the pending appeal, it should have alerted the panel. Cf. Fed. R. App. P. 28(j). Having failed to do so, Sarepta should not be heard to raise the argument on rehearing.

The argument is also meritless. The public interest overwhelmingly favors enforcement of forum selection clauses: "In all but the most unusual cases, . . . 'the interest of justice' is served by holding parties to their bargain [in a forum selection clause]." *Atl. Marine Const. Co., Inc. v. U.S. Dist. Court for W. Dist. of Tex.*, 571 U.S. 49, 66 (2013); *see also M/S Bremen v. Zapata Off-Shore Co.*, 407 U.S. 1, 12 (1972) ("[A]bsent some compelling and countervailing reason [a forum selection clause] should be honored by the parties and enforced by the courts."). Sarepta identifies no case in which any court has identified a binding and enforceable forum selection clause and yet refused to grant an injunction enforcing it for reasons unrelated to the clause itself.

The sole case cited by Sarepta on this point (at 17 n.3) is a decades-old, unpublished decision of the trial-level Delaware Chancery court, involving alleged wrongful termination of a franchise agreement, when evidence showed that the

plaintiff breached the franchise agreement before the defendant terminated it. *Sherwood, Inc. v. Cottman Transmission Sys., Inc.*, No. 6768, 1982 WL 17882, at *2 (Del. Ch. Apr. 15, 1982). Not only does Delaware law not control this issue, but *Sherwood* is unrelated to enforcement of a forum selection clause.

CONCLUSION & PRAYER FOR RELIEF

The panel's fact-bound, case-specific decision is entirely correct and, in any event, presents no issue warranting en banc review. Rehearing should be denied.

Dated: April 15, 2022 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Case Number: 2021-2369 Short Case Caption: Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc. The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following: the filing has been prepared using a proportionally-spaced typeface $\overline{\mathbf{V}}$ and includes 3,848 words. the filing has been prepared using a monospaced typeface and includes _____lines of text. the filing contains _____ pages / ____ words / ____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____). Dated: April 15, 2022 /s/ William R. Peterson William R. Peterson