

Appeal 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 in No. 1:21-cv-1015-LPS

**SAREPTA'S OPPOSITION TO APPELLANT'S
MOTION TO EXPEDITE ISSUANCE OF THE MANDATE**

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March 18, 2022

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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.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box.** Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

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

Date: March 18, 2022

Signature: /s/ Michael J. Flibbert

Name: Michael J. Flibbert

<p align="center">1. Represented Entities. Fed. Cir. R. 47.4(a)(1).</p>	<p align="center">2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).</p>	<p align="center">3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).</p>
<p>Provide the full names of all entities represented by undersigned counsel in this case.</p>	<p>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.</p>	<p>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.</p>
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<p>Sarepta Therapeutics, Inc.</p>		

Additional pages attached

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 Additional pages attached

Jack B. Blumenfeld	Morris, Nichols, Arsht & Tunnell LLP	
Megan E. Dellinger	Morris, Nichols, Arsht & Tunnell 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).

None/Not Applicable Additional pages attached

<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al., IPR2021-01134 (PTAB)</i>	<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al., IPR2021-01135 (PTAB)</i>	<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al., IPR2021-01136 (PTAB)</i>
<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al., IPR2021-01137 (PTAB)</i>	<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al., IPR2021-01138 (PTAB)</i>	<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al., IPR2021-01139 (PTAB)</i>
<i>Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd., et al., IPR2021-01140 (PTAB)</i>		

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).

None/Not Applicable Additional pages attached

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Appellee Sarepta Therapeutics, Inc. (“Sarepta”) respectfully submits this opposition to the motion by Appellant Nippon Shinyaku Co., Ltd. (“Nippon Shinyaku”) for the Court to expedite issuance of the mandate. D.I. 54 (“Mot.”).

Sarepta timely filed its combined petition for panel and *en banc* rehearing on March 10, 2022. The petition raises important constitutional issues and procedural issues relating to injunctions warranting consideration by this Court. The alleged “continued irreparable harm” that Nippon Shinyaku complains of—i.e., the time and cost of continuing with the IPR proceedings while waiting for the mandate to issue in due course—is obviated by the initial stay of the IPR proceedings through April 24, 2022, that the Board has ordered. *See* Mot., Ex. A at 4. Further, the current stay will not necessarily end on April 24; rather, the parties are simply required to contact the Board at that time “to discuss the posture of the affected cases and how to proceed.” *Id.* Thus, if Sarepta’s rehearing petition remains under consideration by the Court on April 24, the parties can jointly request an extension of the stay in accordance with the Board’s practice in similar cases.

Significantly, however, issuing the mandate immediately would irreparably harm Sarepta because granting Nippon Shinyaku’s request would deprive this Court of jurisdiction over the appeal, immediately ending any further consideration of the petition. Nippon Shinyaku’s motion is thus effectively a request to prematurely deny Sarepta’s petition before it can be fully and fairly considered by the Court. As

explained below, Nippon Shinyaku identifies no factual or legal basis for this request. The Court should therefore deny the motion.

I. The Board’s Stay of the IPRs Precludes Any Alleged Irreparable Harm to Nippon Shinyaku

Nippon Shinyaku argues throughout its motion that it will suffer “continued irreparable harm” by virtue of the IPRs continuing during the rehearing stage. *See, e.g.*, Mot. 2-3, 6. Nippon Shinyaku even postures that “[e]xpeditious issuance of the mandate . . . is the only way to avert this harm to Nippon Shinyaku from [the] IPRs.” *See* Mot. 7. But the Board has stayed all IPR proceedings at the parties’ joint request until **April 24, 2022**. *See id.*, Ex. A at 4. Importantly, this stay will not be automatically lifted on April 24; rather, the parties have been directed to jointly contact the Board at that time to discuss the status of the cases and how to best proceed. *Id.*

If Sarepta’s petition is denied, it may be before April 24; if there is interest from the *en banc* Court, the Board has previously indicated a willingness to stay proceedings for up to six months. *See, e.g., Rohm Semiconductor USA, LLC v. Maxpower Semiconductor, Inc.*, IPR2020-01674, Paper 56 at 2 (PTAB Nov. 22, 2021) (staying the case for up to six months and vacating all pending deadlines while an arbitrator determined whether disputes were subject to arbitration); *Collegium Pharm., Inc. v. Purdue Pharma L.P.*, PGR2018-00048, Paper 45 at 4 (PTAB Oct. 2, 2019) (extending one-year pendency by up to six months for good cause). Sarepta

represents that it would not oppose a further extension request at the Board to allow for this Court's continued *en banc* review of the rehearing petition.

Nippon Shinyaku gives no reason why the Board would not extend the stay if jointly requested by the parties. To the contrary, Nippon Shinyaku and Sarepta jointly cited the Board's stay of proceedings for up to six months in *Rohm Semiconductor* as an example of the Board's authority to stay Sarepta's IPRs. *See Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.*, IPR2021-01134, Ex. 3006 (PTAB Feb. 17, 2022) (February 17, 2022, email from Nippon Shinyaku and Sarepta to the Board jointly requesting a stay) (Ex. 1).

Nippon Shinyaku argues that Federal Rule of Appellate Procedure 41(b) allows this Court to shorten the time for issuing its mandate. Mot. 3-4. But neither of Nippon Shinyaku's cited cases used that rule to cut short the Court's consideration of a timely filed petition for rehearing. In *Armstrong v. United States*, No. 21-2141, 2021 WL 5994371 (Fed. Cir. Dec. 15, 2021), the Court dismissed a pro se appeal, and concurrently issued the mandate, because the appellant had *prevailed* in the lower tribunal. *Id.* at *1. There was no possibility of the appellant petitioning for rehearing. Similarly, in *Senate Manor Properties, LLC v. U.S. Department of Housing and Urban Development*, 315 F. App'x 235 (Fed. Cir. 2008), the appellee HUD *agreed* with the disposition of the appeal and thus the Court "anticipate[d] no petition for rehearing." *Id.* at 238. The Court therefore shortened the time for any

petition for rehearing and issuance of the mandate so that the case could be promptly transmitted back to the district court. *Id.* Here, by contrast, Sarepta disputes the disposition of this appeal and has timely filed a petition for rehearing. Nothing in the rules or case law supports issuing the mandate prematurely before that petition can be fully considered.

Nippon Shinyaku implicitly concedes that this motion has little to do with “irreparable harm.” Its motion refers to a \$400,000 estimate for preparation of its Patent Owner’s response, the deadline for which has been stayed and may be further extended. *See* Mot. 7 (“The time and expense of preparing the Patent Owner’s response in all seven pending IPRs would be significant. Counsel anticipates that the costs would exceed \$400,000 . . .”). Nothing else is identified that would allegedly constitute “irreparable harm” to be averted by the immediate issuance of a mandate. *See id.* Nor does this potential future expense constitute irreparable harm. *See, e.g., Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301, 1301-02 (2014) (Roberts, C.J., in chambers) (finding no irreparable harm where money damages were potentially available).

II. Immediately Issuing the Mandate Would Irreparably Harm Sarepta

Nippon Shinyaku argues (with no citation) that issuing the mandate before the full Court has even considered Sarepta’s rehearing petition would “not moot” the petition or “prevent Sarepta from pursuing its rehearing request.” Mot. 8. This is

plainly incorrect. “Issuance of the mandate formally marks the end of appellate jurisdiction.” *Johnson v. Bechtel Assocs. Prof'l Corp.*, 801 F.2d 412, 415-16 (D.C. Cir. 1986). Thus, granting Nippon Shinyaku’s motion would deprive the Court of jurisdiction over the appeal, immediately *ending* any further consideration of the timely filed petition.

Nippon Shinyaku’s representation that it “would not oppose Sarepta’s refiling of any withdrawn IPR petitions by July 13, 2022, in the unlikely event that this Court reverses the panel’s decision on rehearing” is meaningless. Mot. 8. If the Court grants Nippon Shinyaku’s motion and issues its mandate immediately, this case will be returned to the district court for the entry of a preliminary injunction before the full Court can even consider the merits of Sarepta’s petition in accordance with this Court’s Rules of Practice and Internal Operating Procedures. *See* Fed. Cir. R. 35(j), 40(d); Fed. Cir. IOPs #12-14. The Court should reject this unsupported and unreasonable request, which would irreparably harm Sarepta.

III. Sarepta's Petition Raises Important Constitutional and Procedural Issues that Warrant Consideration by this Court

Nippon Shinyaku accuses Sarepta of using its timely filed rehearing petition for “dilatory tactics” and “nullifying this Court’s decision.” Mot. 6, 8–9.¹ Nippon Shinyaku is wrong. This Court’s rules provide a brief period before the mandate issues to give the parties an opportunity to raise important issues and to allow the Court time to consider whether corrective action is necessary. *See Bell v. Thompson*, 545 U.S. 794, 806 (2005) (rehearing provides a mechanism for correcting errors in the federal courts of appeals before Supreme Court review is requested). This brief pause benefits the Court by ensuring that it has a full and fair opportunity to consider and address the issues raised in a rehearing petition.

Sarepta’s petition raises the important issue of whether the constitutional limits on the federal judiciary under the *Erie* doctrine were violated in this appeal. D.I. 53 at 1–3. Second, Sarepta’s petition argues that 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.

¹ Nippon Shinyaku also suggests that Sarepta is improperly delaying issuance of the preliminary injunction by requesting briefing on the scope of the injunction and the amount of the bond. *See* Mot. 5. But both elements are essential prerequisites for entry of any injunction under Rule 65. *See* Fed. R. Civ. P. 65(c)-(d).

Id. at 4. Nippon Shinyaku has failed to identify any legal or practical reason for the extraordinary step of expediting issuance of this Court's mandate, thus precluding full consideration by the Court of these important issues.

IV. Conclusion

For these reasons, the Court should deny Nippon Shinyaku's motion to expedite issuance of the mandate.

Date: March 18, 2022

Respectfully submitted,

/s/ Michael J. Flibbert

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ADDENDUM

Ex.	Description
1	February 17, 2022, e-mail from Nippon Shinyaku and Sarepta to the Board jointly requesting a stay

EXHIBIT 1

From: [Bregman, Dion M.](#)
To: [Trials](#)
Cc: [NS-IPRs-Service](#); [Lipton, Alissa](#); [Raich, William](#)
Subject: IPR2021-01134 to 01140 / Joint Request to Suspend Due Dates
Date: Thursday, February 17, 2022 3:37:36 PM

CAUTION: This email has originated from a source outside of USPTO. **PLEASE CONSIDER THE SOURCE** before responding, clicking on links, or opening attachments.

Your Honors,

The parties met and conferred on Monday (2/14) concerning a potential **motion to suspend all due dates** for the seven captioned IPRs. As indicated in prior correspondence, the Federal Circuit panel in Case No. 2021-2369 ordered the District Court for the District of Delaware to enter a preliminary injunction relating to the above-captioned IPRs. The parties now jointly request that the Board **suspend all due dates for the captioned IPR proceedings**, and propose that the **suspension should be reconsidered after (1) the Federal Circuit issues its mandate in Case No. 2021-2369; and (2) the District Court for the District of Delaware thereafter enters an order concerning the preliminary injunction.**

The Board has authority to grant this jointly-requested suspension pursuant to 37 C.F.R. § 42.5, and has previously exercised this authority to suspend due dates in other prior PTAB cases. See, e.g., IPR2018-00494, Paper 49 (suspending the oral hearing date until issuance of a Federal Circuit mandate); IPR2020-01674, Paper 56 (staying the case for up to six months and vacating all pending deadlines while an arbitrator determined whether disputes were subject to arbitration); IPR2019-01410, Paper 8 (suspending all due dates pending Supreme Court decision on a petition for writ of certiorari). The parties will notify the Board as soon as there are further pertinent developments at the Federal Circuit or district court.

The parties also request guidance as to whether a joint motion needs to be filed or whether this joint email request will suffice. We note that in the above-cited IPR2018-00494, no motion was filed before the Board's suspension order.

Should the Board wish to discuss any of the above, the parties are available on Friday, February 18th from 11 AM – 3 PM EST for a conference call.

Respectfully and Jointly Submitted,

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Lead Counsel for Petitioner

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

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

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

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Date: 03/18/2022

Signature: /s/ Michael J. Flibbert

Name: Michael J. Flibbert