

Bargained-Away Rights to File for IPR May Not Be Recovered

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In a precedential opinion, the US Court of Appeals for the Federal Circuit reversed a district court's denial of a plaintiff's requested injunction seeking to force a patent challenger to abandon its petitions for *inter partes* review (IPR). *Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc.*, Case No. 2021-2369 (Fed. Cir. Feb. 8, 2022) (Newman, **Lourie**, Stoll, JJ.)

Nippon Shinyaku and Sarepta Therapeutics executed a mutual confidentiality agreement (MCA) to facilitate discussion of "a potential business relationship relating to therapies for the treatment of Duchenne Muscular Dystrophy." The MCA established a mutual covenant not to sue for "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" during a covenant term. The mutual covenant explicitly "include[d], but [wa]s 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" (emphasis added). The MCA also included a forum selection clause to govern post-term intellectual property disputes between the parties, which stipulated:

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 (emphasis added).

"Potential actions" were defined 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 connection with the Parties' development and commercialization of therapies for Duchenne Muscular Dystrophy (emphasis added).

The day the covenant term ended, Sarepta filed seven petitions for IPR at the Patent Trial & Appeal Board (Board). Nippon Shinyaku filed suit in the US District Court for the District of Delaware for breach of contract, declaratory judgment of noninfringement and invalidity and patent infringement. Nippon Shinyaku motioned for a preliminary injunction to enjoin Sarepta from proceeding with the IPR petitions and to force Sarepta to withdraw them. The district court denied Nippon Shinyaku under each of the preliminary injunction factors (likelihood of success on the merits, irreparable harm in the absence of extraordinary preliminary relief, balance of harms in its favor and relief being in the public interest).

The district court explained that any irreparable harm arguments fell within Nippon Shinyaku's contract interpretation arguments, and that Nippon Shinyaku's balance of hardships and public interest arguments relied on Sarepta's ability to file IPR petitions—all elements that had been contracted between the parties. Nippon Shinyaku timely appealed, and the Federal Circuit heard arguments on an expedited timeline since the Board had granted institution in all the IPRs at issue in the interim.

Under both Federal Circuit and applicable regional circuit (Third) precedent, a showing of likelihood of success on the merits is necessary to establish entitlement to a preliminary injunction. Like the district court, the Court felt that this issue turned entirely on contract interpretation of the MCA, which it reviewed *de novo* before finding that the plain language of the forum selection clause of the MCA resolved the dispute. The MCA's forum selection clause was deemed unambiguous, such that 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 as IPR petitions at the Board. Since the forum selection clause in MCA Section 10 precluded the filing of IPR petitions during the two-year period following the expiration of the covenant term on June 21, 2021, the Court found that Nippon Shinyaku was likely to succeed on the merits of its claim for breach of contract.

The Federal Circuit also agreed with Nippon Shinyaku that absent a preliminary injunction, it would be deprived of its bargained-for choice of forum and forced to litigate its patent rights in multiple jurisdictions. The Court followed its own 2011 precedent of *Gen. Protecht Grp. v. Leviton Mfg.* that such harm constitutes irreparable harm sufficient to meet the standard for a preliminary injunction.

Similarly, the Federal Circuit agreed that the balance of hardships tipped in Nippon Shinyaku's favor since, absent a preliminary injunction, Sarepta would potentially get multiple bites at the invalidity apple (including in a forum it had bargained away). The Court again quoted from *Gen. Protecht*: "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."

Finally, with respect to the public interest, the Federal Circuit rejected the argument that it would be unfair to hold Sarepta to the bargain it had made, citing the 1972 Supreme Court opinion in *M/S Bremen v. Zapata Off-Shore* for the proposition that forum selection clauses "are prima facie valid and should be enforced," and 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."

The Federal Circuit reversed the district court's decision and remanded for entry of a preliminary injunction.

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