Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc., 25 F.4th 998 (Fed. Cir. 2022) (Newman, Lourie, Stoll)

BY WILLIAM H. MILLIKEN

Nippon Shinyaku and Sarepta entered into a Mutual Confidentiality Agreement to facilitate discussions about a potential business relationship related to muscular dystrophy therapies. Section 6.1 of the MCA contained a mutual covenant not to sue that lasted for a period defined as the "Covenant Term." The covenant expressly encompassed "challenges before the U.S. Patent and Trademark Office." Section 10 of the MCA was a forum-selection clause providing that, for two years following the Covenant Term, "all Potential Actions arising under U.S. law relating to patent infringement or invalidity" must be filed in the U.S. District Court for the District of Delaware. "Potential Actions" were defined as "any patent or other intellectual property disputes" between the parties "filed with a court or other administrative agency."

The day the Covenant Term expired, Sarepta filed IPR petitions against several Nippon Shinyaku patents. Nippon Shinyaku sued Sarepta in the U.S. District Court for the District of Delaware, arguing that Sarepta's filing the IPR petitions breached the MCA's forum-selection clause. Nippon Shinyaku also sought a preliminary injunction requiring Sarepta to withdraw the petitions.

The district court denied the request for injunctive relief, concluding that Nippon Shinyaku was not likely to succeed on the merits. The court held that the forum-selection clause did not apply because "Potential Actions" was "best understood as limited to cases in federal district court." *First*, the district court reasoned, because the covenant not to sue "expressly deferred the filing of IPR petitions for" the Covenant Term, it would be "odd" to read the forum-selection clause as "impliedly" delaying them for two more years. *Second*, the district court observed that the forum-selection clause included a waiver of contests to personal jurisdiction or venue—concepts that relate only to district-court litigation and do not apply at the Board. *Third*, the district court noted that interpreting the forum-selection clause to apply to IPRs could have the effect of barring IPRs altogether, given the one-year time bar of 35 U.S.C. § 315.

A forum-selection clause that encompasses "any patent or other intellectual property disputes" between the parties "filed with a court or other administrative agency" can preclude post-grant proceedings at the U.S. Patent and Trademark Office.

The Federal Circuit reversed. The "the plain language for the forum selection clause," the court held, resolved the dispute in favor of Nippon Shinyaku. The MCA defined "Potential Actions" to include disputes "filed with a court *or administrative agency*," meaning it "literally encompasse[d]" IPRs before the Board.

The Federal Circuit rejected each of the rationales the district court had provided for its contrary result. *First*, the court concluded that there was no tension between the covenant not to sue and the forum selection clause. The former merely prohibited litigation of any kind (regardless of forum) during the Covenant Term, while the latter channeled litigation filed after that term into a specific forum. *Second*, the court rejected the proposition that the forum-selection clause's mention of jurisdiction and venue evidenced an intent by the parties "to categorically exclude IPRs." *Third*, the court noted that "parties are entitled to bargain away their rights to file IPR petitions, including through the use of forum-selection clauses," and that in any event the interpretation of MCA's forum-selection clause should not turn on the possibility of an event (the filing of a district-court complaint) occurring long after the parties entered into the agreement.

With respect to the remaining preliminary-injunction factors—irreparable harm, balance of hardships, and the public interest—the court likewise found in favor of Nippon Shinyaku. Nippon Shinyaku's loss of its bargained-for forum constituted irreparable harm. The balance of hardships tipped in Nippon Shinyaku's favor because a preliminary injunction would merely require Sarepta to litigate its invalidity challenges in the chosen forum rather than before the Board. With respect to the public interest, there was nothing "unfair about holding Sarepta to its bargain." To be sure, "Congress desired to serve the public interest by creating IPRs to allow parties to quickly and efficiently challenge patents," but, the court concluded, "it does not follow that it is necessarily against the public interest for an individual party to bargain away its opportunity to do so."

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