Federal Circuit Report
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The Federal Circuit recently denied a petition for rehearing and a petition for rehearing en banc of a precedential panel decision regarding forum selection clauses. *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc. [FK1]*, 2021-2369, Order (Fed. Cir. May 3, 2022). The panel decision found that a forum selection clause in a confidentiality agreement could be used to prevent inter partes review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB). The rehearing denial affirms the panel decision. This affirmation is good news for patent owners who have similar clauses in their agreements.

Some quick takeaways from the decision:

- Forum selection clauses in agreements can be used to exclude patent validity challenges before the PTAB.
- The agreement does not have to be a patent license agreement.

The confidentiality agreement in *Nippon* was entered into by Nippon Shinyaku Co. Ltd. (“Nippon Shinyaku”) and Sarepta Therapeutics, Inc. (“Sarepta”) in pursuit of a potential business relationship related to therapies for treating Duchenne muscular dystrophy. The agreement included a two-year covenant not to sue. The covenant not to sue specifically identified “patent validity challenges before the U.S. Patent and Trademark Office or Japanese Patent Office.” After the two-year covenant period expired, a forum selection clause governed all potential actions arising under U.S. law relating to patent infringement or invalidity. The forum selection clause stated that all such actions that are filed within two years of the expiration of the term of the covenant not to sue shall be litigated in the U.S. District Court for the District of Delaware. Although the forum selection clause did not specifically identify patent validity challenges before the U.S. Patent and Trademark Office, “potential actions” were specifically defined in the agreement to include “patent or other intellectual property disputes...filed with a court or administrative agency.”

The very day that the covenant not to sue period expired, or June 21, 2021, Sarepta filed seven IPR petitions with the PTAB; Nippon Shinyaku responded by suing Sarepta in the U.S. District Court for the District of Delaware for breach of contract, requesting a declaratory judgment of non-infringement and invalidity regarding Sarepta’s patents, and alleging infringement of Nippon Shinyaku’s patents. Nippon Shinyaku filed a motion for preliminary injunction with its complaint in which it alleged that Sarepta breached the confidentiality agreement by filing the IPR Petitions. The district court (Judge Stark) denied the preliminary injunction, finding that Sarepta had not breached the confidentiality agreement because the forum selection clause did not relate to IPRs. The district court seemed to base its conclusion on what it considered the parties meant rather than what the agreement actually stated.

Overturning the decision by the district court, the Federal Circuit panel concluded that the forum selection clause precluded the filing of IPR petitions for two years after the expiration of the covenant not to sue period. *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*, 2021-2369, slip opinion (Fed. Cir. February 8, 2022) [FK1]. The panel's conclusion was not the first time that the Federal Circuit had found, either explicitly or implicitly, that forum selection clauses could preclude the filing of IPR petitions. (See page 13 of the slip opinion.) It was, however, the first time it did so in a precedential opinion. The panel decision was unanimous.

The full Court of Appeals for the Federal Circuit, with the exception of Judge Stark, denied rehearing and rehearing en banc. The Order was issued per curiam, meaning “for the court,” i.e., not signed. Although it is possible that Sarepta may petition the Supreme Court for writ of certiorari, it does not seem likely that certiorari will be granted. The forum selection clauses are bargained for by parties to an agreement. Nothing prevents the parties from including, or excluding, particular jurisdictions.

The ability to prevent opposing parties from challenging patents
before the PTAB provides patent owners with a distinct benefit. The burden of proof for proving a patent is invalid is higher in district court than before the PTAB. The burden of proof for proving invalidity before district courts is “clear and convincing evidence,” which means “substantially more likely true than untrue.” This standard requires a firm belief that it is highly probable that the factual contentions are true. The burden of proof for proving invalidity before the PTAB, however, is “a preponderance of the evidence,” which means “more likely true than untrue.” This standard is much easier to meet, and only requires a slightly greater than 50 percent probability that the factual contentions are true.

In light of the foregoing, patent owners should review any agreements they have with a party whom they may be contemplating suing over patent rights to see if that agreement has a similar forum selection clause. The agreement does not have to be a patent license agreement — the agreement at issue in Nippon was a confidentiality agreement. In addition to patent license agreements and confidentiality agreements, such clauses may also be present in nondisclosure agreements, material transfer agreements, joint research/development agreements, consulting agreements, or even employment agreements. The clause itself does not have to state explicitly that IPRs are included, as long as it uses broad language that can be interpreted to include IPRs, and/or IPRs are not specifically excluded. Patent owners should also consider including such clauses in future agreements.

Doreen Y. Trujillo is a seasoned patent lawyer who represents her clients in numerous facets of patent law, including prosecution and counseling, opinion preparation, licensing, due diligence, and litigation. As a Partner in Saul Ewing Arnstein & Lehr LLP’s Intellectual Property practice, Doreen has prosecuted patent applications in the United States and abroad, and has experience handling patent interferences, reissues, reexaminations, ex parte appeals, and appeals before the Court of Appeals for the Federal Circuit.