HELSINN HEALTHCARE S.A. v. TEVA PHARM. USA, INC., Appeal Nos. 2016-1284, -1787 (Fed. Cir. May 1, 2017). Before Dyk, Mayer, O'Malley. Appealed from D.N.J. (Judge Cooper).

Background:

Helsinn Healthcare sued Teva Pharmaceuticals for allegedly infringing Helsinn's patents directed to intravenous formulations of a drug for reducing the likelihood of chemotherapy-induced nausea and vomiting. The formulations included the drug at a specific concentration.

Teva countered that Helsinn's patents were invalid under the on-sale bar because Helsinn and a third party entered into a supply and purchase agreement prior to the critical date. The agreement was announced in a press release, but the dosage was not mentioned in the release.

The district court held that the patents were not invalid because the invention was not "ready for patenting" before the critical date. Its finding was based on the fact that Helsinn failed to establish efficacy under FDA standards prior to the critical date. The district court also held that the sale did not trigger the on-sale bar under the AIA (which governed one of the patents) because the sale did not disclose all the details of the invention (including the dosage). The court's interpretation of the on-sale bar under the AIA was based on floor statements made by members of Congress.

Issues/Holding:

Did the district court err in concluding that the invention was not ready for patenting before the critical date? Yes.

Did the district court apply the correct standard for determining a qualifying sale under the AIA? No.

Reversed.

Discussion:

The Federal Circuit determined that the invention was reduced to practice and therefore ready for patenting well before the critical date. Reports dating before the critical date demonstrated that the claimed dosage delayed the onset of nausea and vomiting for a short length of time after a patient was administered the drug. Although the studies were insufficient to meet stricter FDA standards, they nonetheless demonstrated that the invention worked "beyond a probability of failure" for its intended purpose of reducing the likelihood of chemotherapy-induced nausea and vomiting. This was sufficient to establish reduction to practice for purposes of determining whether the invention was "ready for patenting."

The court also disagreed that AIA §102 requires a sale to publicly disclose the details of the invention, noting that this interpretation "would work a foundational change in the theory of the statutory on-sale bar," and Congress would not have instituted this change absent clear language to that effect. Additionally, such a disclosure requirement would encourage an inventor to unfairly extend his monopoly by delaying filing while commercializing the invention, and would withdraw inventions that have been placed in the public domain through commercialization once the patent is ultimately granted.

The Federal Circuit declined to decide whether the AIA eliminated "secret sales" as prior art because the existence of the sale at issue was made public. The court discounted the floor statements made by individual members of Congress as being "not reliable as indicators of congressional intent," and in any case suggested that the statements referred only to congressional intent to eliminate secret *use* as prior art. The court's statements suggest that the on-sale bar will continue to apply to secret sales.