

United States Supreme Court Confirms the “On Sale” Bar Is Triggered Even If a Sale or Offer for Sale Does Not Make the Invention Publically Available

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Helsinn Healthcare (“Helsinn”) is the maker of certain treatments for chemotherapy-induced nausea (the “Palonosetron Products”). During the development process, Helsinn entered into two third party agreements for distribution of the Palonosetron Products. These distribution agreements contained confidentiality provisions requiring the distributors to keep Helsinn’s proprietary information confidential.

Approximately two years after Helsinn entered into the distribution agreements, it filed its first provisional patent application. Helsinn filed several more patent applications over the next ten years, claiming priority back to this first provisional application, with its fourth patent (the “’219 Patent”) application being filed in 2013. Due to its 2013 filing date, the ‘219 Patent is subject to the Leahy-Smith America Invents Act (the “AIA”).

Teva Pharmaceuticals (“Teva”) sought to market a generic palonosetron drug. Helsinn responded with claims that Teva’s generic drug infringed its patents, including the ‘219 Patent, and filed suit for patent infringement. Teva countered that the ‘219 Patent was invalid under the “on sale” bar of the AIA.

Under the “on sale” bar, no patent may be obtained if the invention was “in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”^[1] So, the invalidity of the ‘219 Patent depended on whether or not the two distribution agreements, which were entered into two years prior to the filing of Helsinn’s first patent application, constituted a sale or offer for sale under the AIA even though they contained confidentiality obligations.

The Court held that a sale or offer for sale does not need to make the invention publically available for the “on sale” bar to be triggered. So, even though the distributors were obligated to keep the details of the proprietary Palonosetron Products confidential, the fact that the distribution agreements were executed was enough to start the one year clock under the AIA. This case highlights the importance of tracking any business negotiations and agreements for sale of inventions and to ensure a patent application is filed within the one year grace period provided by that AIA.

The full Opinion can be found here: https://www.supremecourt.gov/opinions/18pdf/17-1229_2co3.pdf

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[1] 35 U.S.C. §102(a)(1)