

Practice Update

Waiting to File for a Patent? A Cautionary Tale

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A patent can provide incredible benefits. When a patent is infringed, the patent owner may be entitled to damages from the infringer. Also, the patent owner may be able to receive an injunction against the infringer, protecting the patent owner's market share.

Unfortunately, these benefits may only be available if a patent owner files for the patent early on. In the United States, a patent owner is barred from receiving a patent if the patent owner waits more than one year after disclosing the idea. This means that the actions (and inactions) of a patent owner can ruin a valuable patent. The recent United States Supreme Court decision in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 586 U.S. ___, 2019 WL 271945 (2019) provides one such cautionary tale.

In this case, Helsinn Healthcare S.A. developed a drug that utilized 0.25 mg of palonosetron to treat chemotherapy-induced nausea. Helsinn then entered into various sales agreements for the drug. These agreements were made public, but the dosage information was kept a secret. Nearly two years later, Helsinn finally filed for, and received, a patent for its idea. With patent in hand, Helsinn sued Teva Pharmaceuticals USA, Inc. for patent infringement.

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At trial, Teva argued that Helsinn's own sales agreements invalidated the patent because the 0.25 mg dosage of palonosetron was "on sale" for more than one year before Helsinn filed its patent application. Helsinn denied this, arguing that the "on sale" bar was not applicable. The district court agreed with Helsinn, finding that the Leahy-Smith America Invents Act (AIA) changed the "on sale" bar to only apply to sales that publicly disclose the details of the invention. Based on this, the district court held that the patent was valid, and that Teva had infringed the patent. On appeal, the Federal Circuit disagreed, finding that the AIA did not change the "on sale" bar. On further appeal, and in an unanimous decision, the United States Supreme Court agreed with the Federal Circuit, holding that there was no persuasive evidence that Congress intended to change the long understood "on sale" bar.

Ultimately, Helsinn lost its patent, and its infringement case – all because of its own actions. If Helsinn had filed its patent application earlier, such a result may have been avoided. The Helsinn case is just one more reminder that patent protection should be applied for early, not later. Specifically, a patent application should be filed before an invention is ever (1) disclosed, (2) offered for sale, or (3) sold. If that is not an option, the patent application should be filed within one year of such an occurrence, at the very latest. Anything later could destroy the patent.

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