

Public Sales Remain Prior Art After AIA Even Without Disclosing Invention

Public sales which do not themselves disclose an invention nonetheless continue to be available as prior art events after the America Invents Act (AIA). Innovators must file US patent applications within one year of any sale or offer for sale of the invention, even if the sale does not itself disclose the invention. The Federal Circuit has re-affirmed this view of the on-sale bar, notwithstanding the change in wording of the patent statutes under the AIA.

The Federal Circuit Monday held in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* that four patents with claims directed to an anti-nausea medication were invalid for violating the on-sale bar. In its first interpretation of the on-sale bar provision in the AIA, the Court ruled that changes to the statutory language did not add a requirement that a sale make the invention available to the public to trigger the bar.

The claims at issue in *Helsinn* are directed to pharmaceutical formulations of palonosetron for reducing or reducing the likelihood of chemotherapy-induced nausea and vomiting (CINV). Teva filed an Abbreviated New Drug Application (ANDA) to market generic palonosetron and Helsinn sued for infringement. Teva asserted the claims were invalid under the on-sale bar provision of 35 U.S.C. § 102, as a pre-filing sale had been publicly announced in a press release and a filing with the Securities and Exchange Commission (SEC). The public documents, however, did not themselves disclose palonosetron dosage levels, which were elements of the claimed invention.

Three of the four patents fell under pre-AIA § 102(b), which bars patentability of an invention that was “in public use or on sale in this country, more than one year prior to the date of the application for patent.” The remaining patent fell under post-AIA § 102(a) (1), which bars patentability of an invention that was “in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”

Helsinn had argued that the addition of the phrase “or otherwise available to the public” in the context of the statute meant that the sale must make the invention available to the

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public to qualify as a barring event.

The Federal Circuit declined to adopt this interpretation, describing such a proposal as a “foundational change in the theory of the statutory on-sale bar.” Prior cases had held that an invention is made available to the public when there is a commercial offer to sell a product embodying the invention and that sale is made public. A requirement that details of an invention be disclosed in the terms of a sale had been explicitly rejected in previous cases. The court found that floor statements by members of Congress during debate on the AIA did not indicate an intent to overrule these precedents.

The Court concluded that “after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale.” Accordingly, whether under pre-AIA or AIA on-sale bar provisions, a supply and purchase agreement between Helsinn and a third party, which was executed more than the permissible one year before the filing date of the priority provisional application, constituted a barring sale prior to the critical date. The agreement had been disclosed in a press release as well as in documents filed with the SEC.

In addition to a sale or offer for sale of the claimed invention, the invention must be ready for patenting to trigger the on-sale bar according to the two-step test articulated by the Supreme Court in *Pfaff v. Wells Electronics, Inc.* The Court found the subject matter of the claims-at-issue was ready for patenting when a Phase II clinical trial report concluded the relevant dose of palonosetron was effective in suppressing CINV. This standard is much lower than that required by the FDA.

Helsinn highlights that, despite revised language in the AIA, the Federal Circuit does not yet recognize new exclusions to the on-sale bar.

Patent applicants should be aware that the AIA on-sale bar may still be triggered by secret offers to sell and public offers that do make the invention available to the public. Conditions precedent to contract performance, such as FDA approval, do not necessarily negate an offer for sale. Reduction to practice for purposes of triggering the bar will often come much earlier than the data necessary to garner FDA approval.