

Federal Circuit Clarifies What Counts as an On-Sale Bar to Patentability

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As a general rule, inventions are not eligible for patent protection after they have become publicly known, such as by being sold to the public. In *The Medicines Company v. Hospira, Inc.*, Fed. Cir., No. 2014-1469 (Fed. Cir. 2016) (en banc), the Federal Circuit, in an *en banc* decision, clarified that an offer for sale of a product must be a commercial offer for sale as understood by the Uniform Commercial Code (UCC), in accordance with the Supreme Court *Pfaff* decision.

The Medicines Company (MedCo) invented a process for making the drug bivalirudin (Angiomax, an anti-coagulant) that produces a batch of the drug with less than 0.6 % of an impurity. They received two patents for the product that was made by the new process. Prior to filing the patent (and the grace period) MedCo contracted Ben Venue Labs to make several batches of bivalirudin using the new process.

The question before the Federal Circuit was whether the purchase of the manufacturing services for bivalirudin from Ben Venue were considered a sale, which would invalidate the patents. The Federal Circuit explained that for an activity to be considered a sale it must be one in which the product is "on sale" in the sense that it is "commercially marketed." What MedCo purchased from Ben Venue was not the drug bivalirudin—i.e. the patented invention—but contract manufacturing services. This was evidenced by the facts that MedCo only paid about 1% of the ultimate market value of bivalirudin to Ben Venue, the transaction was invoiced as the sale of manufacturing services, and title to the bivalirudin batches did not change hands.

The Federal Circuit emphasized that they will look to the UCC for guidance when evaluating whether an action is considered a sale. While the UCC will not be definitive, it will inform the analysis. The goal is to prevent "inventors from filing patents a year or more after the invention has been commercially marketed."

Finally, the Federal Circuit emphasized that there is no "supplier exception" to the on-sale bar. "While the fact that a transaction is

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between a supplier and inventor is an important indicator that the transaction is not a commercial sale," […] "the focus must be on the commercial character of the transaction, not solely on the identity of the participants."

While this case is for a pre-America Invents Act (AIA) patent, it may be informative to cases for AIA patents because the legislative history of the AIA does not indicate that Congress intended to change the on-sale bar standard. However, it is possible that private sales may not be considered public disclosures under the AIA.

For more information, please contact Scott Conley or any attorney in Frost Brown Todd's Intellectual Property Law and Litigation Practice Group.

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