ARE Patent Law Alert:
In The Medicines Company, Federal Circuit Clarifies the Meaning of Offer For Sale

Author(s):

The United States Court of Appeals for the Federal Circuit, sitting *en banc*, held that to invalidate a patent under the "on sale" bar of 35 U.S.C. § 102(b), the claimed invention "must be the subject of a commercial sale or offer for sale, and that a commercial sale is one that bears the general hallmarks of a sale pursuant to Section 2-106 of the Uniform Commercial Code." *The Medicines Company v. Hospira, Inc.*, No. 14-1469 (Fed. Cir. July 11, 2016) (*en banc*).

The Supreme Court established a two part test for determining whether a patent is invalid due to an on-sale bar in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998)--whether the claimed invention (1) was the subject of a commercial offer for sale; and (2) was ready for patenting. In *Pfaff* the Supreme Court delved into the question of when an invention was ready for patenting. Now the Federal Circuit has analyzed what constitutes a commercial offer for sale under § 102(b).

In *The Medicines Company*, the patent owner contracted with a non-party to manufacture the claimed invention more than one year before the filing date of the patent application. The patent owner ordered commercial quantities of the claimed invention from the contract manufacturer and stockpiled them, although the stockpiled product was not sold until after the one year bar date. The defendant argued that the patent either of these acts constituted an invalidating sale under § 102(b). The Federal Circuit rejected these arguments.

First, the Federal Circuit concluded that a contract for the manufacture of a claimed invention does not trigger the on sale bar. The court looked at the transaction between the patent owner and the manufacturer and applied standard commercial law. Among the reasons for concluding that the on-sale bar was not triggered was that title to the finished product never changed hands. The lack of title transfer underscored the fact that the transaction between the patent owner and the manufacturer was for manufacturing services, not for the sale of goods. The court also took into account that the manufacturing agreement provided for confidentiality, further indicating that the parties to the agreement did not consider it to be a commercial sale.

Second, the Federal Circuit rejected the defendant's stockpiling argument. Preparing for commercial sales by building inventory, etc. does not trigger the on-sale bar. Simply because the patent owner's activities have a commercial benefit does not necessarily implicate the on-sale bar. "The on-sale bar is triggered by actual commercial marketing of the invention."

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(page 26).

The holding of *The Medicines Company* allows companies to prepare for commercial sales before the clock starts to tick for § 102(b). We will continue to monitor developments in this area and report on them. In the meantime, if you have questions, please feel free to contact one of our attorneys.

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