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Federal Circuit Provides Guidance On When An Agreement For Services Triggers The On-Sale Bar

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On July 11, 2016, the Federal Circuit, *en banc*, overruled the merits panel and affirmed the District of Delaware's decision in T*he Medicines Company v. Hospira, Inc.* finding that an assignee's entry into a manufacturing services contract to produce product for stockpiling the invented product where title to the product did not pass hands does not trigger the on-sale bar under 35 U.S.C. § 102(b). *The Medicines Company v. Hospira, Inc.*, C.A. No. 2014-1469, -1504, slip op. at 33 (Fed. Cir. July 11, 2016).

Pursuant to 35 U.S.C. § 102(b), the on-sale bar applies when, before the critical date, the claimed invention (1) was the subject of a commercial offer for sale; and (2) was ready for patenting. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67-68 (1998).

The issue for the Federal Circuit in *The Medicines Company* concerned the first prong in *Pfaff*, and considered "the circumstances under which a product produced pursuant to the claims of a product-by-process patent is 'on sale' under 35 U.S.C. § 102(b)." Slip op. at 3 and 18. Specifically, the circumstances of interest were that The Medicines Company (TMC) entered into a manufacturing service agreement with Ben Venue Laboratories (BVL) whereby BVL would prepare and supply batches of the drug product at issue for commercial and clinical packaging, and TMC would stockpile the batches in order to fulfill orders. *Id.* at 5-7.

In holding that the transaction between TMC and BVL did not trigger the on-sale bar, the Federal Circuit made the following findings:

- A supplier's sale of manufacturing services to create embodiments of the patented product for the inventor does not constitute a "commercial sale" because the sale is not for the product itself, and title to the product did not transfer to the supplier (*i.e.*, BVL acted as a pair of "laboratory hands") (*id.* at 19-22);
- Stockpiling of, or preparation for the sale of, a patented product by an inventor is not improper commercialization under § 102(b) (*id.* at 19, 26-29); and
- Commercial benefit alone is not sufficient to trigger the on-sale bar, rather a triggering transaction must be one wherein the patented product is actually on sale—*i.e.*, commercially marketed—and BVL was not given permission to commercially market the patented product (*id.* at 19, 22-26).

In addition, of particular importance is the Federal Circuit's confirmation that while a "no supplier exception" continues it is not a "blanket 'supplier exception' to what would otherwise constitute a commercial sale." *Id.* at 31. In determining whether a transaction with a supplier constitutes a commercial sale, Courts should determine if (1) the supplier received title to the patented product or process, (2) the supplier received total authority to market the patented product or disclose the patented process, and (3) the transaction is for the sale of the product at full market value. *Id.* "The focus must be on the commercial character of the transaction, not solely on the identity of the participants." *Id.*

The Medicines Company provides some clarity as to when a transaction between a patent holder and a manufacturer/supplier is a commercial sale such that the patent-at-issue may be invalid under 35 U.S.C. § 102(b) because the patented product or process was "on sale in this country, more than one year prior to the date of application for patent in the United States." The Federal Circuit's decision may result in fewer findings of a commercial sale to support an on-sale bar when manufacturers or suppliers to an inventor are involved; however, this decision does not preclude the triggering of an on-sale bar based on such transactions. In view of *The Medicines Company*, parties accused of patent infringement should seek to find details of passing of title or other indications of a commercial sale under the U.C.C. when attempting to assert the on-sale bar defense.

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