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CLIENT ALERT

Was it an Offer for Sale? Law School Nightmare Revisited in Latest "On-Sale Bar" Ruling from the Federal Circuit

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In the latest round of "was that a sale" that would preclude patentability under the Patent Statutes, the Federal Circuit considered (again) the kinds of activities that constitute a contract. Yesterday, the Federal Circuit held that merely offering to enter into a distribution agreement sufficed.

Before the district court, Hospira argued that both patents at issue were invalid because, more than one year prior to the patent application filings, The Medicines Company *offered to sell* Angiomax to its distributor, Integrated Commercialization Solutions, Inc. (ICS), pursuant to a Distribution Agreement between the parties. The district court disagreed, holding that the Distribution Agreement was only an agreement for ICS to be the U.S. distributor of Angiomax and was *not an offer to sell* Angiomax under 35 U.S.C. § 102(b). The decision was appealed to the Federal Circuit.

On February 6, 2018, the Federal Circuit reversed the district court, holding that "the terms of the Distribution Agreement make clear that [T]he Medicines Company and ICS entered into an agreement to sell and purchase the product." *The Medicines Company v. Hospira*, 2014-1469, -1504, slip op. (Fed. Cir. Feb. 6, 2018), p. 6. The relevant terms that led to this conclusion were: 1) a statement that The Medicines Company now desired *to sell* the Product to ICS and ICS desired *to purchase and distribute* the product; 2) the price of the product; 3) the purchase schedule and 4) the passage of title from The Medicines Company to ICS. *Id*.

The court stated that these terms in the Distribution Agreement show it was an offer for sale and that The Medicines Company and ICS "explicitly and purposefully changed their previous distribution services relationship to let ICS take title to the product upon receipt at the distribution center." *Id*. at 7. The Court determined that "the passage of title is a helpful indicator that Angiomax was subject to an offer for sale." *Id*. (internal quotation marks omitted).

The court repeated its position that "a contractual provision concerning the supply of worldwide requirements at reasonable times and prices…constitutes an offer to sell that has been accepted." *Id*. Because the Distribution Agreement designates ICS as The Medicines Company's sole purchasers within the United States for a certain period, The Medicines Company did not enter into an optional sales arrangement that might not qualify as an offer for sale. *Id*. at 7-8. Rather, the exclusive distribution agreement "provided all of the necessary terms and conditions to constitute a commercial offer for sale." *Id*. at 8. According to the court, the terms of the Distribution Agreement clearly demonstrate the "commercial character of the transaction" and, therefore, the Distribution Agreement was a commercial offer for sale. *Id*. at 10.

This decision from the Federal Circuit is a reminder to those drafting such agreements to use clear and unequivocal terms that capture the true intent of the parties, as those terms will largely dictate whether or not the "on-sale bar" is triggered.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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