THE MEDICINES COMPANY v. HOSPIRA, INC., Appeal Nos. 2014-1469 and 2014-1504 (Fed. Cir. July 11, 2016). Before Prost, Newman, Lourie, Dyk, Moore, O'Malley, Reyna, Wallach, Taranto, Chen, Hughes, and Stoll (*en banc*). Appealed from D. Del. (Judge Andrews).

Background:

The Medicines Company ("MedCo") sued Hospira, Inc. ("Hospira") alleging that Hospira's two ANDA filings infringed claims of its patents. Hospira argued that MedCo's patents were invalid because the invention was sold or offered for sale before the critical date under §102(b) when MedCo paid Ben Venue to manufacture three batches of the drug according to MedCo's patents before the critical date. MedCo does not have its own manufacturing facilities.

The district court applied the two-step framework of *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), which requires that the claimed invention was (1) the subject of a commercial offer for sale, and (2) ready for patenting. The district court concluded that the first prong of *Pfaff* was not met because the batches were not made for commerical profit, but were for experimental purposes, and thus the batches Ben Venue manufactured for Medco did not trigger the on-sale bar. Hospira appealed.

On appeal, a Federal Circuit panel reversed the district court's ruling regarding the applicability of the on-sale bar. MedCo petitioned for rehearing en banc, which was granted.

Issue/Holding:

Did the district court err in holding that the transactions between MedCo and Ben Venue were not invalidating under §102(b)? No, affirmed.

Discussion:

With respect to the first prong of *Pfaff*, the Federal Circuit held that there was no commercial sale of the invention. The Federal Circuit indicated that the most natural conclusion to draw from the evidence is that Ben Venue sold contract manufacturing services, and not the patented invention. Instead, the Federal Circuit stated that Ben Venue acted as a pair of "laboratory hands" to reduce MedCo's invention to practice. The Federal Circuit stated that their holding was further underscored by the fact that Ben Venue's invoices indicated a charge for manufacturing services and title to the pharmaceutical batches did not change hands.

In rejecting Hospira's position that not applying the on-sale bar "would improperly permit an inventor to commercially stockpile his invention," the Federal Circuit held that stockpiling, or building inventory, is mere pre-commercial activity in preparation for future sale, and the on-sale bar is triggered by actual commercial marketing of the invention. The Federal Circuit also stated that while there is not a blanket "supplier exception" to the on-sale bar, the fact that a transaction is between a supplier and inventor is an important indicator, but not determinative alone that the transaction is not a commercial sale, as understood in a commercial marketplace. The focus of analysis must be on the commercial character of the transaction, and not solely on the identity of the participants. The Federal Circuit did not reach the question of experimental use or the second prong of *Pfaff*.