THE MEDICINES COMPANY v. HOSPIRA, INC., Appeal Nos. 2014-1469, -1504 (Fed. Cir. July 2, 2015). Before Dyk, Wallach and Hughes. Appealed from D. Del. (Judge Andrews).

Background:

The Medicines Company (TMC) purchases pharmaceutical batches of Angiomax from Ben Venue Laboratories for sale to the public. In 2005, TMC discovered defects in the process of manufacturing Angiomax which resulted in batches having impurities exceeding the FDA's approved amounts. TMC investigated the causes of the defects and discovered improvements to the process of manufacturing Angiomax that substantially minimized the presence of impurities. TMC subsequently filed and obtained two patents claiming the improvement to the process in the form of product-by-process claims.

In 2010, TMC sued Hospira because Hospira submitted abbreviated new drug applications (ANDA) that allegedly infringe the claims of TMC's patents. During the course of litigation, it was discovered that TMC hired Ben Venue to prepare pharmaceutical batches of Angiomax using an embodiment of the patented method more than one year prior to the filing date of TMC's patents. After a bench trial, the District Court held that TMC's patents were not infringed and not invalid as obvious, indefinite, or under the on-sale bar. Hospira and TMC appealed.

Issue/Holding:

Did the District Court err in holding that TMC's patents are not invalid under the on-sale bar? Yes, reversed.

Discussion:

The on-sale bar under 35 U.S.C. §102(b) applies when, before the one year critical date, the claimed invention was: (i) the subject of a commercial offer for sale; and (ii) ready for patenting. The District Court found that the claimed invention was ready for patenting but not commercially offered for sale prior to the critical date. The District Court concluded that no commercial sale occurred because: (a) Ben Venue only sold manufacturing services, and not pharmaceutical batches; and (b) the pharmaceutical batches fall under the experimental use exception.

The Federal Circuit asserted that in order to ensure that the on-sale bar doctrine is not easily circumvented, the on-sale bar applies when the evidence clearly demonstrates that the inventor commercially exploited the claimed invention before the critical date, even if the inventor did not transfer title to the commercial embodiment of the invention. Here, the Federal Circuit disagreed with the District Court, and held that there is no distinction between the commercial sale of products and the commercial sale of services that result in the patented product-by-process being performed. That is, TMC paid Ben Venue for performing services that resulted in the patented product-by-process being performed, and thus a "sale" of services occurred. Further, Ben Venue delivered the pharmaceutical batches to TMC with commercial product codes and customer lot numbers for commercial and clinical packaging, consistent with the commercial sale of pharmaceutical drugs. Thus, the Federal Circuit held that the experimental use exception did not apply because the batches were prepared for commercial exploitation. Accordingly, the Federal Circuit held that TMC's patents were invalid under the on-sale bar.