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Further Clarity For the On-Sale Bar

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The Federal Circuit, in an *en banc* decision, held that to be "on sale" under pre-AIA § 102(b), a product 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. In particular, the Court clarified that the mere sale of manufacturing services by a contract manufacturer to an inventor, to create embodiments of a patented product for the inventor, does not constitute a "commercial sale" of the invention. The Court further clarified that "stockpiling" by the purchaser of manufacturing services is not improper commercialization under § 102(b). Notably, commercial benefit—even to both parties in a transaction—is not enough to trigger the on-sale bar of § 102(b). Rather, the transaction must be one in which the product is "on sale" in the sense that it is "commercially marketed."

The suit arose from the submission of two Abbreviated New Drug Applications ("ANDAs"), by Defendant Hospira, Inc. ("Hospira"), to sell generic bivalirudin drug products before the expiration of the patents-in-suit covering Angiomax, the trade name of a form of bivalirudin that Plaintiff MedCo markets in the United States. MedCo is a specialty pharmaceutical company that does not have its own manufacturing facilities and is not capable of making its products in-house. Instead, MedCo contracts with Ben Venue Laboratories ("Ben Venue") for the manufacture commercial quantities of bivalirudin.

The manufacturing protocol between MedCo and Ben Venue governing the three batches at issue stated that "the solution will be filled for commercial use" and that the three batches "will be placed on quality hold until all testing has been successfully completed." Each batch received a "Commercial Product Code," a customer lot number, and each stated that the batch was released to MedCo for commercial and clinical packaging. Once manufactured by Ben Venue, the batches were placed in quarantine with MedCo's distributor and logistics coordinator pending FDA approval. Only after the critical bar-date did MedCo release the three batches from quarantine and make them available for sale.

In an earlier appeal, a panel decision of the Federal Circuit concluded these activities were sufficient to trigger the on-sale bar under § 102(b). The panel acknowledged that "Ben Venue invoiced the sale as manufacturing services and title to the pharmaceutical batches did not change hands," but disagreed with the district court's conclusion that Ben Venue's sale of services did not constitute a commercial sale of the claimed product. The panel explained that, "where the evidence clearly demonstrated that the inventor commercially exploited the invention before the critical date, even if the inventor did not transfer title to the commercial embodiment of the invention," the on-sale bar applies.

In the current appeal, the Federal Circuit reached the opposite conclusion for three primary reasons: (1) only manufacturing services were sold to the inventor; (2) the inventor maintained control of the invention and retained title to the batches; and (3) "stockpiling," standing alone, does not trigger the on-

sale bar. Notably, MedCo paid Ben Venue only about 1% of the ultimate market value of the product manufactured, which indicated only laboratory services were being sold. Since Ben Venue lacked title, it was not free to use or sell the claimed products or to deliver the patented products to anyone other than MedCo, nor did it do so. Section 2-106(1) of the Uniform Commercial Code describes a "sale" as "the passing of title from the seller to the buyer for a price." Accordingly, the Court found that these circumstances did not result in a "sale" under § 102(b), which only occurs when the parties give and pass rights of property for consideration.

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