En Banc Federal Circuit Clarifies Application of On-Sale Bar to Contract Manufacturing

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On July 11, 2016, the Federal Circuit, sitting en banc in *The Medicines Company v. Hospira*, held that a contract manufacturer's sale of manufacturing services to an inventor did not constitute a sale of the patented invention for purposes of the on-sale bar. The decision is welcome news for entities that lack manufacturing capabilities and rely on contract manufacturers to make their products.

The appeal concerned two patents relating to Angiomax®, an anticoagulant drug sold by The Medicines Company ("MedCo"). MedCo does not have its own manufacturing facilities and does not itself manufacture Angiomax®. Instead, it contracted with a third party, Ben Venue Laboratories, to manufacture the drug.

After Ben Venue manufactured two batches having excessive amounts of a particular impurity, MedCo developed a new manufacturing process and obtained two patents containing product and product-by-process claims. It would later assert the patents against Hospira's generic version of Angiomax®. Hospira defended on the ground that the patents were invalid under the on-sale bar, because more than one year before MedCo filed the patent applications, it paid Ben Venue to make three batches of Angiomax® according to the asserted patents. The district court rejected the defense, but a merits panel of the Federal Circuit reversed.

The en banc Federal Circuit vacated the panel decision and ruled unanimously that the on-sale bar did not apply. The court began its analysis by comparing the patented invention (*i.e.*, pharmaceutical batches) to what was sold (*i.e.*, contract manufacturing services) and concluded that the "invention" was not sold. Citing the Uniform Commercial Code's definition of "sale," the court also stressed that Ben Venue lacked title to the Angiomax® it manufactured for MedCo and could not use or sell the product or deliver it to anyone other than MedCo. The absence of title transfer is not dispositive, the court explained, but it is "significant because, in most instances, that fact indicates an absence of commercial marketing of the product by the inventor." Similarly, the confidentiality of the Ben Venue transaction, while not dispositive, weighed against finding a commercial sale.

The court rejected Hospira's argument that the on-sale bar is triggered by the mere stockpiling of a patented invention by the purchaser of manufacturing services. The bar is triggered "by actual commercial marketing of the invention, not preparation for potential or eventual marketing."

The Federal Circuit recognized that applying the on-sale bar to the Ben Venue transaction would have penalized companies that use contract manufacturers. As the Court put it, "[t]here is no room in the statute and no principled reason raised by the parties or any of the amici to apply a different set of on-sale bar rules to inventors depending on whether their business model is to outsource manufacturing or to manufacture in-house."

Companies should note that this case was decided under the pre-AIA version of the on-sale bar, and the court explicitly left open whether the same analysis would apply post-AIA. Accordingly, while companies should take the court's reasoning into account when structuring contract manufacturing agreements to minimize the risk of triggering the on-sale bar, future cases will have to determine the impact of the AIA amendments on the reach of the on-sale bar.

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