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Federal Circuit Affirms That No Supplier Exception Exists When It Comes To The On-Sale Bar

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On July 2, 2015, the Federal Circuit issued a decision in The *Medicines Company v. Hospira, Inc.*, --- F.3d ---, 2015 WL 4033143 (Fed. Cir. July 2, 2015) reversing the District of Delaware's finding that the asserted claims were not invalid under the on-sale bar. The Federal Circuit held that the actions of the plaintiff and its supplier triggered the on-sale bar because the evidence demonstrated that a sale was made to the commercial benefit of The Medicines Company (TMC).

Pursuant to 35 U.S.C. § 102(b), the on-sale bar applies when, before the critical date, the claimed invention (1) was the subject of a commercial offer for sale; and (2) was ready for patenting. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67-68 (1998).

In *The Medicines Company*, TMC entered into a manufacturing service agreement with Ben Venue Laboratories (BVL) to prepare and supply batches of the drug product at issue. Notably, each invoice identified the services as a "charge to manufacture Bivalirudin lot" and each lot was marked with a commercial product code and customer lot number, and subsequently released to TMC for commercial and clinical packaging. (*The Medicines Company* at *1). The District Court held "that no commercial sale occurred because . . . Ben Venue only sold manufacturing services, not pharmaceutical batches." (*Id.* at *2). The Federal Circuit disagreed: "While the district court is correct that [BVL] invoiced the sale as manufacturing services and title to the pharmaceutical batches did not change hands, that does not end the inquiry." (*Id.*). For avoidance of doubt, the Federal Circuit explained that "we have found the on-sale bar to apply 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 embodiments of the invention." The Court explained that BVL "marked the batches with commercial product codes and customer lot numbers and sent them to [TMC] for commercial and clinical packaging, *consistent with the commercial sale of pharmaceutical drugs*." (*Id.* (emphasis added)). The Federal Circuit held that a finding that a commercial sale did not take place, would allow TMC "to circumvent the on-sale bar simply

because its contracts happened to only cover the processes that produced the patented product-by process." (*Id.* at *3). Further, the Federal Circuit reaffirmed its principle that "no 'supplier' exception exists for the on-sale bar." (*Id.*at *3 (quoting *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001)).

The Federal Circuit, in disagreeing with the District Court, also held that the experimental use exception was not applicable to the product batches produced by BVL because "[t]he batches were prepared for *commercial* exploitation, and this is not the type of 'secret, personal use' described" in prior case law. (*Id.* at *3 (emphasis in original)). The Court explained that "[t]his is not a situation in which the inventor was unaware that the invention had been reduced to practice, and was experimenting to determine whether that was the case. The batches sold [to TMC] satisfied the claim limitations, and the inventor was well aware that the batches" met the claim limitations. (*Id.* at *3).

The Federal Circuit's decision in *The Medicines Company* reaffirms that there is indeed no supplier exception to the on-sale bar. This case is important to alleged patent infringers, in particular those in the pharmaceuticals arena, as it further strengthens the use of the on-sale bar as a method of invalidating patents based on the inventor/assignee's actions before the critical date.

For more information on the matters discussed in this *Locke Lord QuickStudy*, please contact the authors:

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