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Federal Circuit Patent Bulletin: *The Medicines Co. v. Hospira, Inc.*

July 6, 2015

"If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."

On July 2, 2015, in *The Medicines Co. v. Hospira, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Dyk, Wallach, Hughes*) reversed the district court's judgment that U.S. Patents No. 7,582,727 and No. 7,598,343, which related to the synthetic peptide bivalirudin used as an anti-coagulant and marketed by The Medicines Co. as Angiomax®, was invalid under 35 U.S.C. § 102(b). The Federal Circuit stated:

The on-sale bar under 35 U.S.C. § 102(b) 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. The district court found that the claimed invention was ready for patenting but not commercially offered for sale before the critical date. Hospira disputes the district court's finding that the claimed invention was not commercially offered for sale, and The Medicines Company disputes the district court's finding that the claimed invention was ready for patenting.

The district court concluded that no commercial sale occurred because: (1) Ben Venue only sold manufacturing services, not pharmaceutical batches; and (2) the batches fall under the experimental use exception. While the district court is correct that Ben Venue invoiced the sale as manufacturing services and title to the pharmaceutical batches did not change hands, that does not end the inquiry. As we have explained, "the intent of [invalidating claims under the on-sale bar] is to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed." To ensure the doctrine is not easily circumvented, 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 embodiment of the invention. . . .

The Medicines Company paid Ben Venue for performing services that resulted in the patented product-byprocess, and thus a "sale" of services occurred. [T]he sale of the manufacturing services here provided a commercial benefit to the inventor more than one year before a patent application was filed. Ben Venue's services were performed to prove to the FDA that The Medicines Company's product met the already-

approved specifications for finished bivalirudin product. Additionally, Ben Venue marked the batches with commercial product codes and customer lot numbers and sent them to The Medicines Company for commercial and clinical packaging, consistent with the commercial sale of pharmaceutical drugs. This commercial activity was not insignificant; The Medicines Company admits that each batch had a commercial value of over $10 million. Accordingly, we find that the district court clearly erred in finding the Ben Venue sale of services did not constitute a commercial sale. To find otherwise would allow The Medicines Company to circumvent the on-sale bar simply because its contracts happened to only cover the processes that produced the patented product-byprocess. This would be inconsistent with our principle that "no 'supplier' exception exists for the on-sale bar."

This is not a case where the inventors have requested another entity's services in developing products embodying the invention without triggering the on-sale bar. The batches were prepared for commercial exploitation, and this is not . . . "secret, personal use" . . . . Indeed, the preparation of the batches was described as an "Optimization Study," and was performed because "several opportunities for further optimization of the formulation process were identified" after "successful[] validat[ion] in a previous validation study."

Moreover, "[i]f a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics." There is no dispute that the batches had the levels of Asp9-bivalirudin required by the claims. Thus, it is irrelevant whether The Medicines Company knew that the process limitations of the asserted claims reliably and consistently produced levels of Asp9-bivalirudin below 0.6%.

The district court also clearly erred in finding that the experimental use doctrine bars the application of the on-sale bar to the Ben Venue batches. "[E]xperimental use cannot occur after a reduction to practice." The Medicines Company asserts that it had not reduced the invention to practice when the batches were made because it did not appreciate the maximum impurity level limitation of the claimed invention until after twenty-five batches of bivalirudin were manufactured according to The Medicine Company's new process. "However, we have held that where an invention is on sale, conception is not required to establish reduction to practice." In other words, "[t]he sale of the [invention] in question obviates any need for inquiry into conception." [T]he experimental use defense may be available even if the invention had been reduced to practice if the inventor was unaware that the invention had been reduced to practice (i.e., worked for its intended purpose) and continued to experiment. This 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 satisfied the claim limitations, and the inventor was well aware that the batches had levels of Asp9-bivalirudin well below the claimed levels of 0.6%.

An invention is ready for patenting when, before the critical date, the invention is reduced to practice; or is depicted in drawings or described in writings of sufficient nature to enable a person of ordinary skill in the art to practice the invention. The Medicines Company argues that the district court erred in finding its invention was ready for patenting because there was no reduction to practice and the inventors had not prepared drawings or written descriptions sufficient to enable a person skilled in the art to practice the invention. But

because the invention was sold, . . . we find that the Ben Venue batches reduced the invention to practice. Thus, the district court did not clearly err in finding the invention was ready for patenting.