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Federal Circuit Patent Bulletin: *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*

May 2, 2017

"[T]he AIA did not change the statutory meaning of 'on sale' in the circumstances involved here. . . . [If] the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale."

On May 1, 2017, in *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Dyk,* Mayer, O'Malley) reversed the district court's judgment that U.S. Patents No. 7,947,724, No. 7,947,725, No. 7,960,424, and No. 8,598,219, which related to intravenous formulations of palonosetron and reducing the likelihood of chemotherapy-induced nausea and vomiting (CINV), were not invalid as on-sale under 35 U.S.C. § 102. The Federal Circuit stated:

[A]pplication of the on-sale bar requires that (1) "the product must be the subject of a commercial offer for sale" and (2) "the invention must be ready for patenting." We first address whether the invention of the '724, '725, and '424 patents was subject to a sale or offer for sale prior to the critical date. "As a general proposition, we will look to the Uniform Commercial Code ('UCC') to define whether . . . a communication or series of communications rises to the level of a commercial offer for sale." A sale occurs when there is a "contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold."

[There are] other factors that are important to this analysis, [but] like the UCC itself, none is determinative individually. [T]he absence of the passage of title, the confidential nature of a transaction, and the absence of commercial marketing of the invention all counsel against

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applying the on-sale bar. [T]hese factors [are] important because they helped shed light on whether a transaction would be understood "in the commercial community" to constitute a commercial offer for sale. But those additional factors are not at issue in this case. . . . We agree with the district court that there was a sale for purposes of pre-AIA § 102(b) prior to the critical date because there was a sale of the invention under the law of contracts as generally understood. . . .

There can be no real dispute that an agreement contracting for the sale of the claimed invention contingent on regulatory approval is still a commercial sale as the commercial community would understand that term. The UCC expressly provides that a "purported present sale of future goods . . . operates as a contract to sell." . . . It has been implicit in our prior opinions that the absence of FDA or other regulatory approval before the critical date does not prevent a sale or offer for sale from triggering the on-sale bar. . . .

At oral argument for the first time, Helsinn contended that applying the on-sale bar would be unfair because it would distinguish between vertically-integrated manufacturers that have in-house distribution capacity and smaller entities like Helsinn that must contract for distribution services from a third party. . . . Such a broad principle would largely eviscerate the on-sale bar provision except as to sales to end users. "[S]tockpiling," including purchases from a supplier, "does not trigger the on-sale bar." We also expressed concern over a policy of "penalizing a company for relying, by choice or by necessity, on the confidential services of a contract manufacturer." . . . Helsinn did not contract for MGI's confidential marketing or distribution services . . . . Instead, the Supply and Purchase Agreement between Helsinn and MGI unambiguously contemplated the sale by Helsinn of MGI's requirements of the claimed invention. It is clear that the Supply and Purchase Agreement constituted a commercial sale or offer for sale for purposes of § 102(b) as to the asserted claims of the '724, '725, and '424 patents. . . .

Before the AIA, § 102(b) barred the patentability of an invention that was "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent." Under that earlier provision, we concluded that, although confidentiality weighs against application of the on-sale bar, that fact alone is not determinative. . . . . By enacting the AIA, Congress amended § 102 to bar the patentability of an "invention [that] was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." . . .

Helsinn argues that . . . the on-sale bar does not apply unless the sale "disclose[s] the invention to the public" before the critical date. It urges that since the 0.25 mg dose was not disclosed, the invention was not disclosed and the on-sale bar does not apply. The suggestion is that Congress required that the details of the claimed invention be publicly disclosed before the on-sale bar is triggered. Requiring such disclosure as a condition of the on-sale bar would work a foundational change in the theory of the statutory on-sale bar. [U]nder our cases, an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public. Our cases explicitly rejected a requirement that the details of the invention be disclosed in the terms of sale. . . . A primary rationale of the on-sale bar is that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs. The patented product need not be on-

hand or even delivered prior to the critical date to trigger the on-sale bar. And . . . we have never required that a sale be consummated or an offer accepted for the invention to be in the public domain and the on-sale bar to apply, nor have we distinguished sales from mere offers for sale. We have also not required that members of the public be aware that the product sold actually embodies the claimed invention. . . . Thus, our prior cases have applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or, even when, upon delivery, members of the public could not ascertain the claimed invention. . . . We do not find that distribution agreements will always be invalidating under § 102(b). We simply find that this particular Supply and Purchase Agreement is.

[T]here are at least two ways in which an invention can be shown to be ready for patenting: "by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." We conclude that the invention here was ready for patenting because it was reduced to practice before the critical date. . . .