Intellectual Property Alert:

Federal Circuit Avoids "Foundational Change in the Theory of the Statutory On-Sale Bar"

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May 4, 2017 — On May 1, 2017, the U.S. Court of Appeals for the Federal Circuit reached its ruling in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*, No. 16-1284. As we wrote back in October 2016, this case is important because it could affect how selling a product or offering to sell a product can count as invalidating prior art against a patent under 35 U.S.C. § 102 of the America Invents Act (AIA).

Procedural History

Briefly, Helsinn brought an infringement suit under the Hatch-Waxman Act, alleging that Teva's proposed generic drugs infringed four of its patents for a chemotherapy-related drug. Prior to patenting, the drug underwent various Food and Drug Administration (FDA) trials. During this time, Helsinn entered into a publicly disclosed supply and purchase agreement, which prescribed an ordering procedure and pricing scheme for any drug formulations that the FDA ultimately approved. However, while the sale of the drug was publicly disclosed in a Securities and Exchange Commission (SEC) filing, the dosage amounts to be used were not disclosed. After the drug was approved, Helsinn proceeded with patent filings covering various embodiments of the drug and was granted four patents, one of which was governed by the AIA.

The district court concluded that the patents-in-suit were valid and infringed. While Teva challenged the validity of the AIA patent based on the on-sale bar, the court disagreed, holding that the AIA had changed how the on-sale bar worked. In particular, the court held that 35 U.S.C. 102(a)(1) now requires a *public* sale or offer for sale of the claimed invention for the on-sale bar to apply. Because the public disclosure of the contract at issue did not publicly disclose the precise dosage levels claimed in the patents, the district court concluded that the contract did not trigger the on-sale bar. The district court further concluded that the patented invention was not ready for patenting at the time of the alleged sale because the claimed invention had not been reduced to practice by that time.

Holding

The Federal Circuit reversed the district court and held that the asserted claims were invalid due to an invalidating sale prior to the critical date. In particular, the Court reasoned that a contract contingent on FDA approval was still an invalidating sale even though the details of the invention were not publicly disclosed through the disclosure of the contract. If the details of the sale were public, as was the case here, the Court reasoned that "the details of the invention need not be

publicly disclosed in the terms of the sale." The Court further held that the asserted claims *were* ready for patenting prior to the critical date.

What It Means

For decades, courts have held that secret, confidential, or non-public sales or offers for sale trigger the on-sale bar if the invention is ready for patenting by the time of the sale. While Helsinn argued that the AIA's addition of a new category of prior art that is "otherwise available to the public" now meant that secret sales were no longer invalidating, the Court disagreed. Helsinn further argued that applying the on-sale bar in this case was 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." However, the Court rejected Helsinn's argument, concluding that it "would largely eviscerate the on-sale bar provision except as to sales to end users."

The Court relied heavily on contract law principles to reach its decision and noted that the contract at issue "bears all the hallmarks of a commercial contract" because it includes specific terms relating to price, method of payment, and method of delivery. The Court further concluded that "[t]here 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 the term." This structure, the Court noted, is called a condition precedent in the law of contracts.

The Court's holding means that the AIA does not overturn decades of judicial precedent by changing the interpretation of the on-sale bar – a change the Court referred to as a "foundational change in the theory of the statutory on-sale bar." Because the Court did not find any evidence of legislative intent to support the notion that sales documents must publicly disclose the details of the claimed invention before the critical date, the Court concluded that Congress did not intend to change settled law related to the on-sale bar. Indeed, the Court noted: "If Congress had intended to work such a sweeping change to our on-sale bar jurisprudence and 'wished to repeal … [these prior] cases legislatively, it would do so by clear language.'"

Perhaps leaving open the door for such legislative action, the Court was cautious in extending the reach of its holding, stating that it "declined the invitation by the parties to decide this case more broadly than necessary." In fact, the Court conceded that several legislators had frowned upon the "extreme results" generated by secret *uses* deemed to be invalidating and made sure to point out that determining whether an invaliding sale occurred must necessarily involve a fact-specific analysis. Indeed, the Court pointed out that it does "not find that distribution agreements will always be invalidating under § 102(b)." Rather, under the specific facts of this case, this particular supply and purchase agreement was found to be an invalidating sale.

Finally, in determining that the drug at issue was ready for patenting even though it was still undergoing FDA testing, the Federal Circuit made clear that the relevant question is still whether the invention has been reduced to practice or whether the inventor had prepared drawings or other descriptions of the inventions that were sufficiently specific to enable a person skilled in the art to practice the invention by the critical date. This question does <u>*not*</u> depend on whether a regulatory agency, such as the FDA, has approved the invention's use in the market. Rather, an invention is

reduced to practice when "the inventor (1) constructed an embodiment … that met all the limitations and (2) determined that the invention would work for its intended purpose." Indeed, the Court noted that the "district court clearly erred by applying too demanding a standard" because "[t]he completion of Phase III [FDA] studies and final FDA approval are not pre-requisites for the invention to be ready for patenting."

Thus, it seems that the pre-AIA law related to the on-sale bar is safe, at least for now. Moreover, this case confirms the importance of filing a patent application as early as possible and certainly prior to any public disclosure or sale.

Click here to read the Federal Circuit's opinion in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*

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