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Supreme Court moves goalposts of the on-sale bar

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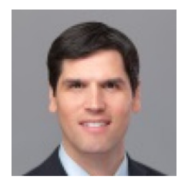

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The slightest change in language can have significant legal implications. Before the adoption of the America Invents Act, 35 USC Section 102(b) provided that a person was entitled to a patent unless "the invention was... in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States". This provision has long been referred to as the "on-sale bar". Under this, a patent was held invalid if, before the critical date, the product was the subject of a commercial offer for sale in the United States and the invention was ready for patenting (for further information, please see *Pfaff v Wells Elecs Inc* 525 US 55, 67 1998).

In 2011 Congress enacted the America Invents Act, which amended 35 USC Section 102. Section 102 now provides that:"[a] person shall be entitled to a patent unless... the claimed invention was... in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." It provides a one-year grace period for disclosures made directly or indirectly by the inventor.

The act added the phrase "or otherwise available to the public" as a basis for the on-sale bar. It has been argued that the addition of this phrase suggests that "otherwise available to the public" implies that sales that are made in private and do not disclose the invention should not trigger the on-sale bar. In 2017 the Federal Circuit decided *Helsinn Healthcare SA v Teva Pharms USA Inc* (855 F3d 1356 (Federal Circuit 2017)). Helsinn alleged that Teva was infringing four of its patents related to intravenous medications. Teva defended itself by arguing that the asserted claims were invalid under the on-sale bar. Approximately two years before Helsinn applied for a patent, it entered into an agreement with a pharmaceutical marketing and distributing company. These agreements were announced in a joint press release and in the distributor's Form 8-K filing with the Securities and Exchange Commission (SEC) and the redacted versions of the agreements were published. While the agreement specified the price, method of payment and method of delivery, the SEC disclosure did not include all of the details that were claimed in Helsinn's patent, such as dosage levels for the drug.

The district court had determined – with respect to three of the patents – that the pre-America Invents Act law applied and ultimately concluded that they were not invalid under the on-sale bar. With respect to the last-filed patent, the district court determined that the act applied and that the agreement was not a public sale because the agreement or SEC disclosure did not publicly disclose the dosage levels of the drug. The district court held that the remaining patent was also not invalid under the on-sale bar.

On appeal, the Federal Circuit reversed the district court's decision with regard to the three pre-America Invents Act patents. With respect to the last-filed patent, the Federal Circuit held that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale" for the sale to be invalidating under Section 102. As a result, the Federal Circuit found the patent to be invalid.

Helsinn sought – and was granted – Supreme Court review on a single issue: whether, under the America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention. Helsinn's argument focuses on the construction of the new catch-all language in Section 102 ("or otherwise available to the public"). The United States has filed an *amicus curiae* brief in support of Helsinn's position, arguing that the on-sale bar does not invalidate Helsinn's patent. This matter will be discussed on 4 December 2018.

The Supreme Court's decision could have multiple notable implications. A Supreme Court ruling in Helsinn's favour could be used to effectively permit patent owners to extend the length of the exclusive rights protected by patent law. For example, patent owners could enter into a confidential, exclusive sales and distribution agreement for a certain period of time and then later seek patent protection over the invention. A ruling in Teva's favour could be viewed as unfairly advantageous to privately-held companies and companies who do business with privately-held companies that do not have the same SEC reporting obligations as publicly-held companies. To add to the list of considerations, there is support for Helsinn's interpretation in the legislative history of the act. In addition, because the act shifted from a first-to-invent to first-to-file rule of patent priority, inventors should still be incentivised to file for patent protection rather than enter into secret sales agreements and extend the duration of their monopolies.

While a bright-line rule could provide some guidance on the boundaries and importance of the phrase "or otherwise available to the public" alone or in conjunction with the on-sale bar, absent such a ruling the phrase is likely to be heavily litigated in the future as a meaningful invalidity avenue under Section 102.

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