International reports

‘Private’ sale of invention bars patents

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On May 1 2017 the Federal Circuit in *Helsinn Healthcare v Teva Pharmaceuticals USA Inc* held that a ‘private’ sale of an invention more than one year before the provisional filing date invalidated the patent for the invention under the on-sale bar provision in 35 USC Section 102. In doing so, the appeals court confirmed that the America Invents Act did not change the pre-America Invents Act statutory meaning of ‘on sale’.

Helsinn owns four patents directed to reducing the likelihood of chemotherapy-induced nausea and vomiting, which is a serious side effect of chemotherapy. Teva Pharmaceuticals filed an abbreviated new drug application seeking approval from the Food and Drug Administration (FDA) to market a generic product that was arguably covered by one or more of the patents. Helsinn filed a lawsuit under the Hatch-Waxman Act asserting infringement of the patents due to the application filing.

Teva asserted that the patents were invalid due to the on-sale bar. Under US patent law, the sale of an invention more than one year before (ie, the ‘critical date’) the effective filing date can invalidate any patent claim to the invention. Some of the statutory language was changed by the America Invents Act and the one-year grace period after the America Invents Act is generally considered less protective for the inventor.

All four patents claim priority to a provisional patent application filed on January 30 2003, thus establishing the critical date as January 30 2002. However, in April 2001, almost two years before applying for a patent, Helsinn had entered into a supply and purchase agreement with MGI Pharma. Under the agreement, MGI agreed to purchase certain dosages of the products covered by the patents, depending on which were approved for sale by the FDA.

During a bench trial, the district court held that Teva infringed all of the patents in question and that all of the patent claims were valid. The district court recognised that the MGI supply and purchase agreement was a contract for the future sale of a commercial product that would constitute a sale under pre-America Invents Act law. However, for three of the patents, it found that the claimed invention was not ready for patenting until after the critical date. The fourth patent was governed under the provisions of the America Invents Act and here the court held that the America Invents Act had changed the meaning of the on-sale bar to require a public sale or offer for sale of the invention. Since the MGI supply and purchase agreement did not publicly disclose the details of the invention, the district court concluded that there was no sale.

The Federal Circuit reversed. With regard to the three pre-America Invents Act patents, it agreed with the district court that there was a sale under pre-America Invents Act law because there was a sale of the invention under the law of contracts as generally understood. However, unlike the district court, it concluded that the invention was ready for patenting as of the critical date because it was reduced to practice before the critical date, thereby invalidating the relevant claims of the three pre-America Invents Act patents.

With regard to the fourth patent, which was governed by the America Invents Act, the Federal Circuit held that the America Invents Act did not change the meaning of the on-sale bar under Section 102. The appeals court agreed with Teva that the America Invents Act’s use of the existing statutory term ‘on sale’ indicated that Congress did not change the meaning of the on-sale bar. Helsinn argued that the inclusion of new language ("or otherwise available to the public") in the statute suggested that the on-sale bar required that the details of the claimed invention be publicly disclosed. The Federal Circuit declined to implement such a foundational change to the theory of the statutory on-sale bar, relying on the Supreme Court's discussion in 1829 of commercial exploitation in *Pennock v Dialogue*. Accordingly, the relevant claims in the fourth patent were invalidated as well.

While patent applicants in the United States have the benefit of a one-year grace period for filing a patent application after novelty-destroying disclosures, *Helsinn* underscores the hazards of relying on that grace period. Recommended practice is to meet the absolute novelty requirements generally applicable worldwide, and thus avoid any issues in the United States as well.

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