Goodmans LLP Update

Stop That Sale!

The first U.S. Supreme Court patent-related decision of 2019 has confirmed the long standing rule that commercial exploitation of a patentable invention may bar the issuance of a patent in the U.S., *even* where there is no public disclosure of the invention!

Background

The facts of *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. et al.* are relatively simple. Helsinn Healthcare S.A., a Swiss pharma company, partnered with MGI Pharma, Inc. to market and distribute in the U.S. 0.25 mg and 0.75 mg doses of palonosetron, a treatment for chemotherapy-induced nausea and vomiting. Helsinn and MGI signed two agreements, each requiring MGI to keep all proprietary information confidential. The existence of the agreements was publicly announced.

In January 2003, nearly two years after the agreements were entered into, Helsinn filed a provisional patent application covering a .25 mg dose of palonosetron (the "**'219 Patent**"). Over the next 10 years, Helsinn filed four patent applications that claimed priority dating back to January 2003. One of those patent applications was in respect of the '219 Patent and was filed in 2013.

The respondents, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "**Teva**"), sought marketing approval for a generic version of palonosetron. Helsinn sued for infringement of the '219 Patent. Teva countered that the '219 Patent was invalid because the .25 mg dose was "on sale" more than one year before Helsinn filed the provisional patent application. This, they argued, contravened the *Leahy-Smith America Invents Act* (the "**AIA**"), which generally precludes a person from obtaining a patent on an invention that was "in public use, on sale, or otherwise available to the public" more than one year before the inventor filed an application for the patent.

The Supreme Court was tasked with determining whether the .25 mg dose was "on sale" within the meaning of the AIA provision, invalidating the '219 Patent. Specifically, it had to consider whether the catchall phrase "or otherwise available to the public" in the AIA provision modified the "on sale" bar in that provision. That is, would a "secret" sale (one where the invention was *not* publically disclosed) invalidate patentability? Notably, the catchall language was added to the AIA in 2011, though the "on sale" bar had existed in U.S. jurisprudence since the 1800s.

The District Court agreed with Helsinn that the catchall language modified earlier jurisprudence, holding the invention was not "on sale" unless the sale or offer was made to the public. The Federal Circuit reversed the District Court's decision, concluding that the details of the invention need not be publicly disclosed as long as a sale took place. The Supreme Court granted leave and affirmed the Federal Circuit decision, holding that a sale made before the one-year grace period can qualify to invalidate a patent even where the sale was not disclosed to the public.

Implications for U.S. Patents

To avoid a successful "on sale" attack, U.S. inventors and their attorneys should take care to avoid transactions and agreements regarding patentable inventions that could be interpreted as a "commercial sale or offer for sale". This may prove difficult in practice given agreements regarding inventions are often entered into well before patent applications are filed (for example, in respect of clinical trials, manufacture of active ingredients for regulatory submissions, *etc.*).

Canadian Perspective

Paragraph 28.2(1)(a) of the *Patent Act* provides a “statutory bar” to the issuance of a patent in circumstances where the claimed invention in the patent application was disclosed more than one year before the filing date by the applicant in such a manner that the subject matter became available to the public in Canada or elsewhere.

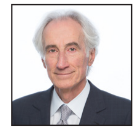
The Federal Court of Appeal has held that, for the prior disclosure statutory bar to apply so as to prevent the issuance of a patent (or to invalidate a patent), there must be public use or public sale of the invention, anywhere in the world, that amounts to an enabling disclosure (*Canwell Enviro-Industries Ltd. et al. v. Baker Petrolite Corp. et al.*, 2002 FCA 158). Enabling disclosure has been defined as disclosure that would allow a person skilled in the art to derive or reverse engineer the invention from the sold product without exercising inventive skill or undue burden.

Key Takeaway

Even though an “on sale” bar may preclude the issuance of a U.S. patent in the case of a “secret sale”, it may nonetheless be possible to obtain a Canadian patent for the invention if the sale or offer to sale is not an enabling disclosure. For example, a sale in the U.S. one year before the filing of the application under a non-disclosure agreement would likely trigger the “on sale” bar, while such a sale in Canada may not constitute enabling disclosure and thus not trigger the commencement of the one-year grace period.

For further consideration of these and other issues, including the effect of the AIA on Canadian or U.S. filings, please contact any member of our Intellectual Property Group.

Authors



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