LANE POWELL

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Mitigating Risk at the Intersection of Business and Patents

Intellectual Property and Technology Legal Update

Public sales and offers to sell can trigger the on sale bar without a public disclosure of the invention

Since its enactment in 2011, many practitioners (and the U.S. Patent and Trademark Office (USPTO) itself) have treated the changed language of 35 USC § 102 — relating to the on-sale bar section of the America Invents Act (AIA) — as a requirement that a sale or offer to sell includes a publically available description of the claimed invention in order to trigger the bar. The on sale bar prevents an applicant from obtaining a patent if a patent application claiming an invention was filed more than one year after the sale or offer of sale. However, the Federal Circuit recently held that no such public disclosure of the claimed invention is required to trigger the on sale bar. A result of the decision is that under the AIA, the on sale bar might prohibit obtaining patent protection for all inventions involved in qualifying public sales that were "ready for patenting" at the time of the sale or offer.

Over the last six years since its enactment, confusion around the changed statutory language of the on-sale bar in the AIA led to issued patents that may be vulnerable and examiners that currently (and may continue to) issue patents that should be barred by a qualifying sale or offer to sell. Further, businesses may currently be relying on established internal procedures that do not provide necessary safeguards for identifying and mitigating risk of sales and offers for sale that might bar patent rights.

Counsel and businesses must first understand the current state of the law for the on-sale bar, including the impact of the recent *Helsinn* decision, and the statutory language of the AIA. Here, we provide that explanation

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and then distill its application into practical business advice to better enable an understanding of the intersection between business and patents and to help mitigate the risk that sales and offers to sell products or services incorporating inventions can have on a business.

The Helsinn opinion and the AIA.

On May 1, 2017, the Federal Circuit issued a much-anticipated opinion in *Helsinn Healthcare v. Teva Pharmaceuticals (Helsinn)* that clarified aspects of how sales and offers to sell patented inventions are interpreted under the AIA. Generally, an applicant may not be awarded a patent or an issued patent may be challenged as being invalid if a public disclosure, sale or offer to sell the claimed invention occurred more than one year before the filing of a patent application. *Helsinn* reinforced that the standard for determining whether the on-sale bar prohibited patent protection was a two-step analysis: (1) determine whether the sale or offer to sell qualified as a commercial sale under the Uniform Commercial Code (UCC); and (2) determine whether the claimed invention was "ready for patenting." If both of these events or conditions occurred more than one year prior to the filing of a patent application, then an issued patent that resulted from that application would be invalid.

Helsinn involved a supply and purchase agreement publicized by a redacted 8-K filing and press release. The agreement included a description of the invention, which was a pharmaceutical used to treat side effects of radiation and chemotherapy. The agreement also included dosing specifics that were redacted and pricing schedules, payment terms, and performance requirements for both parties. Further, the agreement included a condition precedent that only required performance of the contract terms if the subject pharmaceutical was approved by the Food & Drug Administration (FDA) to treat patients using the redacted dosing values. It also included a clause that the supplier was required to approve all purchase orders. In the event the supplier was unable or chose not to fulfil a purchase order, it was required to contract a third party to fulfill the request. The *Helsinn* court held that the supply and purchase agreement triggered the on sale bar of the AIA and thus the patent protecting the drug was invalid because the agreement occurred more than one year prior to the date the patent application was filed.

The AIA changed some key statutory language of 35 USC § 102 that defines the types of sales activities that bar applicants from being able to obtain patent protection for their inventions. The changed language caused confusion as to whether activities such as the public sale that occurred in *Helsinn* — where the claimed invention was not disclosed — could act to bar patent protection under the AIA. *Helsinn* held that sales activities do not require public disclosure of the invention itself if the sale or offer of sale qualified as a commercial transaction under the UCC and the invention was "ready for patenting," although the opinion expressly stated that the holding was limited to the facts of the case. Even with the statutory language change, *Helsinn* explained that the on-sale bar under the AIA did not substantially change from its pre-AIA predecessor.

Mitigating risk at the intersection of business and patents.

It is important for businesses to understand how a potential or actual deal may intersect with the ability to obtain a patent; that is, how *Helsinn* impacts best business practices. Businesses can mitigate risk in deals surrounding their innovations in many ways, ranging from general practice changes by patent counsel to more specific tools that promote collaboration across multi-disciplinary teams. Business leaders and practitioners should avoid overstating the impact of *Helsinn* or underreacting to its practical meaning. Instead, they should engage in meaningful dialogue about the intersection of business deals and patents and how that intersection impacts the business' strategic plan to protect ideas in an increasingly innovation-centric economy.

Patent prosecution attorneys should evaluate their current practice related to sales and offers to sell to adopt the on-sale bar guidance from *Helsinn*. Practitioners should not await formal guidance from the USPTO's Office of General Counsel before making changes to their practice. Business leaders and in-house counsel should discuss the on-sale bar developments with their patent counsel and reinforce internal and external procedures for communicating about sales activities.

The impact of *Helsinn* was limited to its specific facts, most notably that the deal involved a public company with disclosure requirements which resulted in an 8-K filing and a press release about the sales agreement that concerned the invention. The holding does not extend to privately-held companies that do not publicize their distribution agreements

although privately-held businesses should adopt similar procedures to public companies to best mitigate risk because deals can be publicized in many different ways beyond an 8-K filing and press release. Further, the subject invention is a pharmaceutical that required clinical trials and FDA approval, both of which tested the efficacy of the claimed dosing for the drug through a lengthy regulatory compliance process. Even though the lengthy regulatory compliance process is unique to pharmaceuticals and was specifically addressed in the agreement in *Helsinn*, unregulated businesses still often have sales and offers to sell that arise prior to filing for patent protection and should understand this risk both generally and specific to their internal business culture.

Nevertheless, *Helsinn* impacts the way in which business deals intersect with patents. To best mitigate the risk, businesses and counsel alike across all industries should consider adopting some or all of the following best practices:

- Create a multi-disciplinary team of stakeholders that are trained to identify and mitigate on-sale bar risks.
- Stakeholders might include corporate, securities, regulatory compliance and patent counsel along with business development, contract reviewers, marketing, sales and public relations professionals.
- Understand the lifecycle of the business deal in the unique corporate culture of the business — the timing, mechanics and meaning.
- Coordinate communication between stakeholders, both internal and external to the company, through customized teams for deal-specific or client-specific projects.
- Consider creating team- or project-based internal webpages that promote transparency and greater disclosure about business deals among team members.
- Incorporate on-sale bar analysis into all due diligence for patent enforcement pre-litigation analysis, mergers and acquisitions, and strategic patent portfolio development.
- Develop appropriate internal habits for all stakeholders to enable them to appreciate and understand the impact of each step along the deal lifecycle.
- Create customizable confidentiality and template agreement language vetted by those trained in mitigating on-sale bar risks.

Anticipate pressure points caused by a process for review of business deals that may be viewed as frustrating and that might discourage engagement of the legal team — alleviate those pressure points with efficient support and solutions-focused responses.