Invention details need not be public

THE CASE:
Helsinn Healthcare v Teva Pharmaceuticals
US Court of Appeals for the Federal Circuit
1 May 2017

Do 'secret' sales still trigger the on-sale bar after the America Invents Act?
Michael J Pomianek and **Michelle Nyein** report

On 1 May, the US Court of Appeals for the Federal Circuit issued its highly-anticipated decision in *Helsinn Healthcare v Teva Pharmaceuticals.* This is the court's first case interpreting the scope of the "on-sale bar" under the America Invents Act (AIA) of 2011. Declining to broadly illuminate what types of sales and offers for sale qualify as invalidating prior art under post-AIA 35 USC § 102(a)(1), the Federal Circuit's narrow holding instead sheds only a sliver of light, and from what we can see, it's not clear whether the AIA changed anything at all. Still, there are actions companies can take to preserve their patent rights and avoid triggering the on-sale bar. And, though many answers await further case law developments, there may still prove to be opportunities presented by the AIA to capture patent rights in inventions that would have previously been precluded by prior commercial sale or use activity.

On-sale bar issues are particularly relevant to companies that work with outside vendors to fabricate prototypes or produce development batches of a product for testing, or that enter early-stage supply and distribution agreements to reduce risks associated with high development costs. Such offers and sales, even in the context of internal R&D not involving sales to the public, may still trigger patentability bars and must be closely monitored.

Under pre-AIA law applying to patents and patent applications entitled to priority before 16 March 2013, 35 USC § 102(b) provides that a person is not entitled to a patent on an invention "in public use or on sale in this country" more than one year prior to the filing date of a patent application. In *Pfaff v Wells Electronics, Inc,*[1] the Supreme Court of the US held that two conditions must be met in order for a sale to trigger the one-year bar of § 102(b): (1) there must be a commercial sale or offer for sale of the patented subject matter, and (2) the invention must be ready for patenting. There is no requirement that the sale be public, and the courts repeatedly held that even secret commercial sales – including those whose very existence is kept secret – by patentees can preclude patentability.

"Filing patent applications prior to commercial offers or sales is the safest way to preserve both US and international patent rights."

The AIA, applying to patents and patent applications claiming subject matter first filed on or after 16 March 2013, by contrast provides in § 102(a)(1) that a person is not entitled to a patent on an invention "in public use, on sale, *or otherwise available to the public*" (emphasis added) before the effective filing date of the claimed invention (or more than one year prior to the effective filing date for public use or sale by an inventor or another obtaining the subject matter from an inventor). The addition of "or otherwise available to the public" was widely viewed as indicating that confidential sales would no longer be disqualifying prior art. In fact, in a 2011 Senate hearing, Senator Leahy, one of the AIA's lead sponsors, stated, "subsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the US that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case."

This interpretation of § 102(a)(1) was also adopted by the US Patent and Trademark Office (USPTO). In particular, § 2152.02(d) of the Manual of Patent Examining Procedure (MPEP), which is based on examination guidelines issued by the USPTO, states, "The 'or otherwise available to the public' residual clause of AIA 35 USC 102(a)(1) … indicates that AIA USC 102(a)(1) *does not cover secret sales or offers for sale*. For example, an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor" (emphasis added).

Until *Helsinn*, the courts had not addressed whether the AIA changed the scope of the on-sale bar to exclude secret sales. In *Helsinn*, Teva challenged the validity of four Helsinn patents relating to intravenous formulations of a drug, palonosetron, for reducing chemotherapy-induced nausea and vomiting. Teva asserted that three pre-AIA patents were invalid based on the pre-AIA § 102(b) on-sale bar and that the fourth patent subject to AIA law was invalid based on the post-AIA § 102(a)(1) on-sale bar. At issue were agreements between Helsinn and two contract manufacturing companies (Oread and SP Pharmaceuticals) and between Helsinn and an oncology-focused pharmaceutical company (MGI Pharma). The agreements with

Oread and SP were confidential agreements to manufacture palonosetron formulations for Phase III clinical studies, since Helsinn lacked sufficient in-house manufacturing capabilities. The agreements with MGI included a licence agreement and a supply and purchase agreement in which MGI agreed to purchase the palonosetron formulations exclusively from Helsinn upon Food and Drug Administration approval. Critically, while not disclosing details of the drug formulations, the existence of the MGI agreements was publicly announced in a joint press release and in MGI's Form 8-K filing with the Securities and Exchange Commission (SEC). All of the agreements were entered into more than one year before Helsinn filed any patent applications resulting in the patents in suit.

The district court, citing the language of the statute, the USPTO's guidelines, the AIA committee report, and Congress' overarching goal of harmonising the US patent system with international counterparts, held that post-AIA § 102(a)(1), unlike the pre-AIA version of the statute, requires a *public* sale or offer for sale of the claimed invention. The district court found that none of the agreements constituted "public sales": the Oread and SP agreements were not public sales because they were subject to confidentiality restrictions, and the MGI agreements did not disclose Helsinn's claimed palonosetron formulations and therefore did not make the claimed invention "available to the public". In contrast, when considering the validity of the patents subject to the pre-AIA on-sale bar – while ultimately holding that none of the sales were invalidating at least for the reason that the invention was not ready for patenting before the critical date – the district court did opine that the MGI supply and purchase agreement could qualify as a barring sale, because there is no requirement under pre-AIA law that a disqualifying sale disclose the invention to the public.

Teva's appeal to the Federal Circuit attracted significant attention, with numerous *amicus* briefs filed. The US government's position, consistent with the USPTO's interpretation, was that the post-AIA on-sale bar was only triggered by sales or offers for sale that made the invention available to the public (eg, by disclosing details of the invention as claimed).

Although *Helsinn* presented the first opportunity for the Federal Circuit to interpret the post-AIA on-sale bar and what, if anything, "or otherwise available to the public" adds as a requirement, the court side-stepped the broader question of whether the post-AIA statute now exempts "secret sales". It held that even if the AIA requires that a sale be public, a question it declined to answer definitively, the MGI supply and purchase agreement would still qualify because the existence of the agreement was made public by the press release and SEC filing. What was clarified was that the details of the invention need not be publicly disclosed in the terms of the agreement for a sale or offer to be considered an invalidating public sale. The court also disagreed with the district court's holding that the invention was not ready for patenting before the critical date and reversed the district court's holding that the asserted patents were not proven invalid.

While *Helsinn v Teva* leaves many questions unanswered, such as whether truly secret sales and offers for sale – ie, those whose very existence is confidential – can preclude patentability under the AIA, or whether secret uses for commercial purposes by patentees continue to be invalidating public uses, the decision suggests that the Federal Circuit may be inclined to interpret sales and public uses under the AIA in line with its pre-AIA case law. As we wait for additional cases to provide clarity, companies would be well advised to exercise caution and diligence regarding the timing of patent application filings in view of sales and offers – even those that are confidential. Filing patent applications prior to commercial offers or sales is the safest way to preserve both US and international patent rights. At the very least, even in situations involving confidential offers or sales, to reduce the risk of loss of US patent rights, patent applications should be filed within one year of such offers or sales. Helsinn does leave open the possibility that under the AIA a truly secret offer or sale may not be invalidating. So companies should, where possible, keep not only the terms but also the existence of offers and sales confidential in situations where preemptive patent applications have not been filed.

In addition, the Federal Circuit's recent *en banc* decision in *The Medicines Company v Hospira, Inc*,[2] holding that sales of only manufacturing services do not constitute a "commercial sale" of an invention directed to the manufactured product, suggests that framing vendor contracts – such as those involving fabrication of prototypes or production of development batches of a product – as a sale of manufacturing services rather than of the manufactured product can avoid an on-sale bar invalidating product claims.

By remaining vigilant regarding the timing of sales and offers (even confidential ones), and by carefully framing the terms of contracts when possible as a purchase of manufacturing, fabrication or prototyping services rather than of the resulting products, companies will be well-positioned to preserve patent rights and avoid triggering on-sale bars – regardless of whether pre-AIA or AIA law applies and where subsequent case law interpreting the AIA leads.

Footnotes

1. 525 US 55 (1998).
2. 827 F.3d 1363 (Fed Cir 2016).

Authors

Michael J Pomianek is a shareholder and Michelle Nyein is an associate at intellectual property law firm Wolf Greenfield.