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# Why confidentiality may not be enough to safeguard your US patent prospects

In Helsinn Healthcare S.A. et al. v. Teva Pharmaceuticals USA, Inc. , No. 17-1229, the US Supreme Court held that the assessment of whether an invention had been put "on sale", and had therefore entered the prior art, was the same under the America Invents Act (AIA) as under pre-AIA law. An important consequence is that even confidential sales or offers for sale may constitute prior art under the AIA.

**Background**

The novelty statutes of both the AIA and pre-AIA law define similar categories of prior art events, including where a claimed invention was "patented, described in a printed publication", was "in public use", or was "on sale". However, the AIA added to this list the catch-all category "or otherwise available to the public". Helsinn (the patentee) argued that the addition of this phrase should result in the other categories of prior art events – and in particular the "on sale" category (often referred to as the "on-sale bar") – being interpreted as requiring that the invention had been made "available to the public".

**Decision**

The Supreme Court disagreed with Helsinn's interpretation of the statute, holding that the addition of the broad catch-all phrase "or otherwise available to the public" was not sufficient to upset the "well-settled meaning" of the words "on sale". Thus, as under pre-AIA law, sales or offers for sale – even where made in secret – may constitute prior art.

**Comment**

European and other non-US applicants should pay particular attention to this decision, given that the on-sale bar under the AIA has worldwide effect. (By contrast, the pre-AIA novelty statute required that an invention was "on sale in this country", i.e. in the US.) Thus, commercial activities carried anywhere in the world, including European or other non-US countries, could constitute prior art against later US patent filings – even where such activities are covered by non-disclosure agreements.

European and other non-US applicants should therefore be aware that simply keeping an invention confidential prior to filing is not enough to safeguard their US patent prospects. Accordingly, they should be wary of engaging in any commercial activity that might be considered to put an invention "on sale" until initial patent applications to have been filed.

It should be noted in this regard that the "on-sale bar" encompasses activities not typically thought of as sales or offers for sale of an invention. For example, where a contract manufacturer is commissioned to produce a specific number of prototypes of an invention, for the purposes of the "on-sale bar", the commissioning of the prototypes may be considered a sale of the invention by the contract manufacturer to the commissioning company, depending on the circumstances.

Particular caution is therefore warranted in situations where research and development tasks are outsourced to another company. In such cases, it may be advisable to structure the agreement with the R&D company so that payments are expressly made in return for the services provided by the R&D company – and are not tied, for example, to delivery of prototypes.

Furthermore, avoiding triggering the "on-sale bar" may be especially challenging where software is commissioned. In such cases, there may be little practical distinction between paying for the service of developing the software, and paying for the software itself – which could be considered a sale of any inventions embodied in the software.

If you have questions regarding any issues raised by this article, please do get in touch with one of the EIP team.

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