On Sale Bar

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Publicly disclosing an invention will (generally speaking) eliminate foreign patent rights and begin the 1-year grace period to file in the US. "Offers to sell" the invention can likewise begin this process. As you can imagine, though, an "offer to sell" is a somewhat nebulous standard that's caused some issues in the caselaw (is a "nod and a wink" sufficient?). Pfaff v. Wells (S. Ct.) and some other cases do provide some guidance (there's a nice history beginning on page 14 of today's opinion), but it can still be a challenge depending upon the facts. Pfaff offered a two-part test that restates the sale determination in the first step.

> *"Pfaff clarified that the on-sale bar under 35 U.S.C. § 102(b) applies when, before the critical date, the claimed invention (1) was the subject of a commercial offer for sale; and (2) was ready for patenting."*

The CAFC's Hospira opinion today will hopefully resolve some of that ambiguity (clarifying part one of the Pfaff test). Hospira deals with ANDA applications (deserving a separate post in their own right), but specifically decides whether MedCo's payment to Ben Venue to manufacture Angiomax and a distribution agreement with ICS were "offers to sell" sufficient to invalidate MedCo's patents (MedCo made it clear to Ben Venue and ICS that it wanted to manufacture for commercial purposes).

To summarize the result, it makes a difference whether your invention is a process/method or a product. Here, the invention was a product, so agreements concerning a process for its manufacture

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don't carry quite the same implications. The Uniform Commercial Code is a group of laws regarding the sale of goods, so the court looked to it for guidance.

> *"[a] tangible item is on sale when . . . the transaction 'rises to the level of a commercial offer for sale' under the Uniform Commercial Code," "[a] process, however, is a different kind of invention . . . [and] thus[is] not sold in the same sense as is a tangible item."*

What about product-by-process inventions and things blending this line? Well, the court gave a lot of weight to the "transfer of title", so that's usually a good sign-post for your analysis.

> *"The absence of title transfer further underscores that the sale was only of Ben Venue's manufacturing services. The absence of title transfer further underscores that the sale was only of Ben Venue's manufacturing services . . . A 'sale' under §102(b) "occurs when the parties . . . give and pass rights of property for consideration.'"*

So this is all helpful, but it's still a pretty fact-intensive inquiry. Note that just because something turns out not to be a "sale" doesn't mean it won't be a public "disclosure" (hiring someone to manufacture an invention outside in public view).

> *"Like the absence of title transfer, the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature"*

So in conclusion, like many areas of law, it may be better to address multiple factors, rather than try to abide by a single "bright-line" rule. As more of the factors are hit (a good rather than a process, confidential rather than public, title retained, etc.) the chances of passing the first part of the two-part test improve.

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