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Pre-Patenting Manufacturing and Distribution Agreements—The Public or Secret Weapon Against Your Company's Own Intellectual Property

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Have you or your company ever engaged with anyone else to sell novel products before filing a patent application or engaged someone to manufacture products using novel methods before filing a patent application? If so, then you should ask the million (or possibly multi-million) dollar question: are any patents you have on those products or methods still valid? To the extent you may have thought confidential agreements cannot be a source of invalidating offers for sale, the U.S. Supreme Court's recent decision in *Helsinn* should make you think again.

Any Pre-Patent Sale/Offer for Sale, Including Confidential Ones, Starts the Invalidity Clock

The U.S. Patent Laws prohibit you from obtaining a valid patent if you do not file a patent application within one year from the date when you commercially offered for sale or sold the patent-practicing product while that product was "ready for patenting."[1]

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In addition to patent-practicing products, methods that are offered for sale more than a year before an application for a method patent is filed render the method patent invalid.[2] In some instances, offering for sale a product made by a patented method more than a year before the application for the method patent was filed may result in the method patent's invalidity.[3]

Prior to the Leahy-Smith America Invents Act (AIA), a sale could constitute a bar even if done in secret.[4] Recently, the U.S. Supreme Court held that confidential commercial sales or offers for sale of an invention to a third party may also constitute a bar to obtaining a patent under the AIA.[5] Therefore, you or your company must take extreme caution with respect to agreements with your manufacturers and distributors since even confidential agreements can form an "on-sale" bar to any inventions disclosed in the same.

Have You or Your Business Made an Invalidating "Commercial Sale or Offer"?

The Federal Circuit has held that manufacturing and distribution agreements between a patent owner

and its own manufacturers or distributors can give rise to a finding of patent invalidity. "[T]he on-sale bar does not exempt commercial agreements between a patentee and its supplier or distributor."[6]

In *Medicines I*, the Federal Circuit decision addressed the issue of whether the patent owner's own manufacturing/distribution agreements invalidated its patents. There, the court held that offers for sale relate to "those activities that would be understood to be commercial sales and offers for sale 'in the commercial community,'" as guided by §2-106 and §2-306 of the Uniform Commercial Code (UCC).[7]

On remand from *Medicines I*, the Federal Circuit provided numerous examples of what may qualify as a "commercial sale" in a manufacturing/distribution agreement:[8]

- Agreeing to let the manufacturer/distributor sell the patented product to customers;
- Agreeing to let the customer retain title of the patented product once received from the distributor;
- Agreeing to let the distributor to use "commercially reasonable efforts" to fill purchase orders;
- Agreeing to a sole supplier of product to meet purchase orders;
- Agreeing to a designated purchaser of product within the United States for a fixed duration to receive all product from distributor;
- Agreeing to let the distributor supply worldwide requirements at reasonable times and prices, even though the purchaser was able to purchase products at prices and time schedules which were reasonably competitive with those of other sources; and
- Invoices identifying a product being sold and a transfer of title to the purchaser.

The situation involving manufacturing and distribution agreements can get even more complex when seeking patent protection on methods of making products. For example, in *Equistar Chemicals, LP v. Westlake Chemical Corp.*, a case involving a patented method, the Federal Circuit vacated summary judgment of no invalidity because there were numerous factual disputes over whether the patentee's use of a method prior to the method patent constituted an invalidating offer for sale.[9] The Federal Circuit instructed that six questions be developed on the record on remand to the district court in that case—questions which I would submit should be answered as early as possible in your or your company's quest to secure patent protection of proprietary methods and systems:

- What were the offers for sale of the product made by the patented method, and when were they made?
- Did the offers require the product to be made by the patented method?
- If the offers were accepted, were either you or your company obligated to supply product made by the patented method?
- Before the critical date, did you or your company decide to fill orders using a patented method?
- Before the critical date, could orders be filled with products produced by non-patented methods or was only product produced by a patented method available?
- Was the product produced before the critical date by the patented method made to enable you or your company to make offers before the critical date?[10]

Consider the question of whether "soliciting manufacturing or distribution services alone qualified as an invalidating offer for sale…." In light of *Equistar*, the intent behind such services and agreements may now also be relevant to determine whether orders for patented products were to be filled or whether patented methods had to be used to make the products to be sold. Keep in mind that as the Federal Circuit stated in *Equistar*, resolution of on-sale issues will depend on the facts of each case and on whether the patent right under review is for a product or a method or system.

Conclusion/Recommendations

The safest route to avoiding potential invalidating offers for sale is by filing a patent application well before negotiating or entering into a manufacturing and/or distribution agreement. Remember that the confidential offer for sale is just as much a danger to patenting endeavors as one that is open to the public. Therefore, if manufacturing is necessary before filing, then make sure the agreement is specific to manufacturing services and is not aimed at sales of a product or method; this includes making sure vendor invoices reflect the services and not product sales or title transfer. You may even want to include that the services do not require the patented method to carry out the work or provide optional methods by which the desired services can be rendered.

Additionally, a patent attorney may be of valuable assistance in any negotiations concerning manufacturing or distribution agreements so as to avoid the issues discussed by the Federal Circuit in the *Medicines* and *Equistar* cases. It is better to have advice from an experienced patent attorney during the review of those agreements than to have concerns raised by an accused infringer, a potential acquiring company, a venture capitalist, or an angel investor who looks at those agreements first and then tells you that your patent is not worth the paper on which it is written. Keep apprised of whether the claims you seek to protect are product claims or method claims or both, as this can affect the inquiries that should be made and the analysis of the aforementioned agreements.

If you, as the owner of a subsequently patented product or method, relinquish title to a supplier, you can effectively give authority to the supplier to market that product or disclose it to others. Remember, it is possible that such a transfer to the supplier could be deemed an invalidating offer for sale.

For any existing manufacturing/distribution agreements, it may be prudent to have counsel review those agreements in view of the above concerns.

Innovate onward.

Notes

1. *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67 (1998).
2. *See* Scaltech, Inc. v. Retec/Tetra LLC, 269 F.3d 1321, 1328 (Fed. Cir. 2001)(patentee's offer to use its process for profit "does not take it outside the on sale bar rule.").
3. *See* In re Kollar, 286 F.3d 1326, 1333 (Fed. Cir. 2002) ("[A] sale by the patentee ... of a product made by the claimed process would constitute…a sale because that party is commercializing the patented process in the same sense as would occur when the sale of a tangible patented item takes place.").
4. In re Caveney, 761 F.2d 671, 675 (Fed. Cir. 1985).
5. *See* Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., No. 17-1229, 586 U.S. __, 2019 WL 271945 (Jan 22, 2019).
6. *Caveney*, 761 F.2d at 676 ("The mere fact that a product is delivered to a distributor does not exempt the transaction from 35 U.S.C. § 102(b)."); Medicines Co. v. Hospira, Inc., 827 F.3d 1363, 1373 (Fed. Cir. 2016) (en banc) (Medicines I) (accord).
7. Medicines I, 827 F.3d at 1373 ("[a]n offer for sale is 'one which the other party could make into a binding contract by simple acceptance.").
8. Medicines Co. v. Hospira, Inc., 881 F.3d 1347, 1351-53 (Fed. Cir. 2018).
9. 739 Fed. Appx. 628, 633, 2018 WL 3239710, at *4 (Fed. Cir. July 3, 2018) (unpublished).
10. *Id*. at 8.