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ALERTS

Intellectual Property Law Alert - Federal Circuit Provides Guidance On When Outsourcing Manufacturing Constitutes A Patent-Invalidating Sale

July 12, 2016 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

On July 11, the full U.S. Court of Appeals for the Federal Circuit held in *The Medicines Company v. Hospira Inc.* (case number 2014-1469) that the on-sale bar under 35 U.S.C § 102(b), which prohibits patenting an invention that was on sale more than one year prior to filing a patent application, applies only when the patented product is "the subject of a commercial sale or offer for sale."

The court relied on the Uniform Commercial Code § 2-106(1), which states, "A sale consists in the passing of title from the seller to the buyer for a price" to find that The Medicine Company's (MedCo) manufacturing of the patented product by a third-party provider was not a sale of the product under § 102(b), and thus, was not fatal to MedCo's patents.

The patents at issue, U.S. Patents 7,582,727 and 7,598,343, claim products-by-processes. MedCo does not have its own manufacturing facilities so it relied on a third-party provider to produce commercial quantities of a bivalirudin drug (tradename Angiomax®) pursuant to the patented technology. The product was stockpiled by MedCo's distributor pending FDA approval.

The issues on appeal included:

Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b)?

> (i) Was there a sale for the purposes of § 102(b) despite the absence of a transfer of title?
> (ii) Was the sale commercial in nature for the purposes of § 102(b) or an experimental use?

Judge Kathleen O'Malley, writing for the full court stated, "stockpiling' by the purchaser of manufacturing services is not improper commercialization under § 102(b)," further noting, "The on-sale bar is triggered by actual commercial marketing of the invention, not preparation for potential or eventual marketing." Judge O'Malley opined that for a §102(b) on-sale bar to apply, "the transaction must be one in which the product is 'on sale' in the sense that it is "commercially marketed." The court pointed out as significant in the present case that "only manufacturing services were sold to the inventor—the invention was not." That the inventor retained title to the claimed products and did not authorize its third-party service provider to use or sell the product to others was highlighted by the court as reflecting an absence of commercial marketing of the product by the inventor.

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The Federal Circuit concluded, “a contract manufacturer’s sale to the inventor of manufacturing services where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under § 102(b).”

In most instances, the court’s ruling provides one set of rules applicable to entities that outsource their manufacturing and those that have in-house production capabilities. However, the Federal Circuit cautions inventors using third-party vendors by commenting, “While the fact that a transaction is between a supplier and inventor is an important indicator that the transaction is not a commercial sale, understood as such in the commercial marketplace, it is not alone determinative…even a transfer of product to the inventor may constitute a commercial sale under § 102(b). The focus must be on the commercial character of the transaction, not solely on the identity of the participants.” The court also indicated that whether the patent claims are directed to a product or a method can lead to a different result under similar facts regarding whether the sale of manufacturing services to an inventor creates an on-sale bar to patenting an invention.

For more information, contact the Barnes & Thornburg attorney with whom you work or a member of the firm’s Intellectual Property Law Department in the following offices: Atlanta (404-846-1693), Chicago (312-357-1313), Columbus (614-628-0096), Dallas (214-258-4200), Delaware (302-300-3434), Elkhart (574-293-0681), Fort Wayne (260-423-9440), Grand Rapids (616-742-3930), Indianapolis (317-236-1313), Los Angeles (310-284-3880), Minneapolis (612-333-2111), South Bend (574-233-1171), Washington, D.C. (202-289-1313).

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