Intellectual Property Law
500 W. Madison Street, Suite 1130
Chicago, IL 60661-2562
T (312) 876-1800
F (312) 876-2020
www.woodphillips.com

Manufacturing Services is not a Commercial Sale

Under § 102(b) of Title 35 of the United States Code, if an invention was "on-sale" more than one year prior to filing an application for patent, then the invention was barred from being patented. The purpose of this law is to prevent inventors from profiting from their invention for an extended period of time prior to seeking exclusive rights to that invention. In 1998, in the case of *Pfaff v. Wells Electronics, Inc.*, the Supreme Court of the United States set out a two-prong test to determine if an invention was "on-sale" such that it barred patentability. 525 U.S. 55 (1998). According to the *Pfaff* test, an invention was "on-sale" if the invention was "1) the subject of a commercial offer for sale; and 2) ready for patenting."

In *The Medicines Company v. Hospira, Inc.*, the Court of Appeals for the Federal Circuit ("Federal Circuit") determined that the mere sale of manufacturing services to the inventor while the inventor maintains control of the invention does not constitute a commercial offer for sale. Nos. 2014-1469, 2014-1504 (Fed. Cir., July 11, 2016.)

The Federal Circuit further ruled that "stockpiling" by the inventor of the manufactured product, by itself, does not constitute a sale.

In The Medicines Company v. Hospira, Inc., Hospira contended that The Medicines Company's ("MedCo") patents to its anti-coagulant medication, Angiomax®, were invalid because Angiomax® was "on-sale" more than one year prior to filing of the applications. Specifically, Hospira contended that the following events, which all took place more than one year prior to MedCo filing its patent applications, constitutes a sale: 1) MedCo contracted with Ben Venue Pharmaceuticals to manufacture Angiomax®; 2) Ben Venue finished manufacturing and provided Angiomax® to MedCo; who then 3) stockpiled ready to sell versions of the drug. The Federal Circuit cited several facts in determining that these activities did not constitute a sale or an offer for sale. First, MedCo retained title to the invention throughout the manufacturing process. Second, the contract was for the manufacture of the drug product and not for the product itself, which is supported by the fact that the contract price was only 1.5% of the commercial worth of the drug product. Third, MedCo did not authorize Ben Venue to sell the product to others.

Wood Phillips will continue to monitor case law and take the necessary steps to ensure that our clients' inventions will remain fully protected. If you have any questions about patenting an invention, please contact an attorney at Wood Phillips.