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Early new product/patent steps receive more protection with ruling

By Erin J. Fox and Justin D. DeAngelis

Erin J. Fox is of counsel practicing in the intellectual property law group at Quarles & Brady LLP in the area of patent prosecution and client counseling. Justin D. DeAngelis is an associate practicing in the same group.

The U.S. Patent Act sets forth a number of novelty-destroying events; one such event, which occurs when an invention is "on sale," is a focal point of patent litigation.

Section 102(a)(1) (previously 102(b)) of the act, which includes the "on-sale bar," provides that a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. Section 102(a)(1).

The scope of actions that may trigger the on-sale bar and the subsequent countdown of the allowed one-year grace period, have been topics of conversation for years. The U.S. Court of Appeals for the Federal Circuit recently acted to narrow what is considered a novelty-destroying action under the on-sale bar.

The case of *Medicines Co. v. Hospira Inc.*, 827 F.3d 1363 (Fed. Cir. 2016), involved alleged infringement of multiple patents directed to the production of a pH-adjusted drug comprising bivalirudin, which is used as an anticoagulant during coronary surgery.

Throughout the proceedings, Hospira argued that the MedCo patents were invalid because the on-sale bar had been triggered before the critical date, meaning one year before the patent applications were filed with the U.S. Patent and Trademark Office.

In a decision that has redefined the types of events considered within the scope of the on-sale bar, the Federal Circuit ruled that the patents were not invalid and that the events that occurred before filing of the patent applications did not trigger the on-sale bar.

MedCo filed its patent applications on July 27, 2008, making the critical date July 27, 2007. The appeals court noted that MedCo is a specialty pharmaceutical company that did not have the resources for in-house production, thus requiring MedCo to outsource manufacturing to a third party, Ben Venue Laboratories.

It was not disputed that in the final quarter of 2006, before the critical date, MedCo paid Ben Venue for the production of three batches of the bivalirudin drug having a combined quantity of about 60,000 commercially viable vials.

Each batch of the drug Ben Venue produced included customer lot numbers, commercial product codes and a statement that it was being released to MedCo "for commercial and clinical packaging." Additionally, each batch invoice specified that it was "filled for commercial use."

Effectively, the scope of events that could trigger the on-sale bar has been narrowed, resulting in an expansion in freedom that companies and inventors have before prompting the on-sale bar.

After manufacturing, MedCo sent all of the batches of the drug to be quarantined at Integrated Commercial Solutions, or ICS. MedCo entered into a distribution agreement with ICS on Feb. 27, 2007, which made ICS the exclusive distributor of the drug within the United States.

All communication, agreements and payments between MedCo, Ben Venue and ICS took place before the critical date, so the question became, Why hadn't the on-sale bar been triggered?

The Supreme Court established two conditions that must be met to satisfy the on-sale bar in *Pfaff v. Wells Electronics Inc.*, 525 U.S. 55 (1998). First, "the product must be the subject of a commercial offer for sale," and second, "the invention must be ready for patenting." These conditions have served as guidelines for patent litigation and ineligibility for the years since *Pfaff*. In *Medicines Co.*, the discussion focused on the first condition.

Hospira argued that the MedCo patents were invalid under Section 102(b) because both the MedCo manufacturing orders with Ben Venue and the MedCo distribution contract with ICS were entered into before the critical date. In narrowing what may be considered a novelty-destroying event under the on-sale bar, the Federal Circuit determined that the contracts were for only manufacturing services and that MedCo had maintained sufficient control of the patented invention, its title and the right to market the invention.

Furthermore, the court held that storage of the product by ICS did not trigger the on-sale bar. Thus, the appeals court determined that the on-sale bar was not triggered, rendering the MedCo patents valid.

An important distinction was that MedCo only prepared for a commercial sale, but never actually sold the invention before the critical date.

The *MedCo* decision imparts more clarity about what fits into the Federal Circuit's idea of a "commercial offer for sale." It appears that this decision provides more latitude for companies and inventors to engage in prepatent filing activities that do not have the look and feel of a commercial sale.

While it is still a best practice to file a patent application related to a new invention as soon as possible to preserve both U.S. and foreign rights, entities engaging in prefiling commercial activities may now operate with less fear that such activities, when unrelated to a commercial sale of an invention, will initiate the patent right destroying on-sale bar.

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In a practical sense, this decision provides further autonomy for entities that are evaluating the marketplace and greater de facto exclusivity when deciding to commercially introduce an invention.