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NO SPECIFICATION SUPPORT DOOMS MEANS-PLUS-FUNCTION CLAIM SET

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Advanced Ground Information Systems, Inc., v. Life360, Inc., slip op. 2015-1732 (Fed. Cir. Jul. 28, 2016)

In this appeal from a decision of the United States District Court for the Southern District of Florida, Advanced Ground Information Systems, Inc. (AGIS) appealed the District Court's findings that the claims are indefinite under 35 U.S.C. §112, 2nd paragraph, and that the claims are invalid. The parties stipulated to invalidity based on indefiniteness. AGIS is the owner of U.S. Patent 7,031,728 (the '728 patent) and U.S. Patent 7,672,681 (the '681 patent).

The '728 patent is directed to a cellular communication system allowing multiple users to monitor other users' locations and statuses via display on a map. The locations of other users are indicated by symbols on a displayed map. The symbols represent the latitude and longitude of other users. By touching a displayed symbol on the map, users can perform various functions including calling, sending text messages, or data or pictures. Representative claims of the '728 patent recite a "symbol generator … that can generate symbols that represent each of the participants' cell phones in the communication network on the display screen." Life360 asserted, and the District Court held, that the claim term "symbol generator" invokes means-plus-function claiming and the terms failed to disclose adequate structure and are indefinite.

The Federal Circuit panel found that the term "symbol generator" invokes §112, ¶6 because it fails to describe a sufficient structure. In particular, the Federal Circuit pointed to AGIS' expert's testimony that the term "is a term coined for the purposes of the patents-in-suit"

and is not used in "common parlance or by persons of skill in the pertinent art to designate structure." Further, the fact that the expert testified that the individual terms "symbol" and "generator" are known, "but was unaware of the use of the term "symbol generator" within the field of computer science" was evidence that the words did not "have a sufficiently definite meaning as the name for structure." Thus, the Federal Circuit held the claim terms to be subject to 35 U.S.C. §112, ¶6 and turned to construe the terms by identifying the corresponding structure, material, or acts described in the specification to which the claim terms would be limited.

On this issue, the Federal Circuit found that the specifications failed to disclose an algorithm for the claim elements reciting "symbol generator" and therefore, the claims are indefinite under 35 U.S.C. §112, ¶2.

SUPPLYING AND SHIPPING CONSTITUTE PURPOSEFUL AVAILMENT TO SUPPORT PERSONAL JURISDICTION

By Chih-Kuei (Alex) Hu, Esq. (chu@ipfirm.com)

Polar Electro OY v. Suunto Oy, slip op. 2015-1930 (Fed. Cir. Jul. 20, 2016)

Polar, a Finnish company, sued Suunto, ASWO, and Firstbeat for patent infringement in the United States District Court for the District of Delaware. Suunto is a Finnish company with a principal place of business and manufacturing facilities in Finland, and ASWO is a Delaware corporation with a principal place of business in Utah. Suunto and ASWO are sister companies owned by the same parent company.

ASWO distributes Suunto's products in the US and maintains Suunto's US website. Suunto receives orders from ASWO, and then packages that order at its factory in Finland, and ships to addresses specified by ASWO. The title to the accused goods passes from Suunto to ASWO at a shipping dock in Finland. The issue here is whether US District Court for the District of Delaware has Personal Jurisdiction to Suunto.

The district court considered the Delaware long arm statute and found that under the "dual jurisdiction" theory, Suunto's intent to serve the US market is sufficient to establish its intent to serve the Delaware market. The district court then considered the constitutional due process and found Suunto did not have sufficient contacts with Delaware, because the record only indicated that Suunto had a general intent to serve the US market at large, without any particular focus on Delaware.

Due process requires that the defendant have sufficient "minimum contacts" with the forum state. The United States Court of Appeals for the Federal Circuit reviewed the district court's decision using the three-prong test for specific jurisdiction: (1) whether the defendant purposefully directed activities at residents of the forum; (2) whether the claim arises out of those activities; and (3) whether assertion of personal jurisdiction is reasonable and fair. The Federal Circuit found that Suunto purposefully shipped 94 accused products to Delaware retailers. It was Suunto, not ASWO, who physically fulfilled the orders, packaged the products and prepared the shipment in Finland. Through its own conduct, Suunto purposefully availed itself of the Delaware market. The Federal Circuit also found Suunto bears the burden to prove unreasonableness. However, the district court did not decide the reasonableness prong.

Therefore, the Federal Circuit vacated the district court's determination that it lacked personal jurisdiction over Suunto and remained for the district court to determine whether

exercising jurisdiction over Suunto would be reasonable and fair.

CONTRACT MANUFACTURING SERVICES DOES NOT TRIGGER ON-SALE BAR UNDER 35 U.S.C. §102(B)

By Yi Suo, Intern (ysuo@ipfirm.com)

An *en banc* rehearing was affirmed in *Medicines Company v. Hospira, Inc.*, slip ops. 2014-1469 and 2014-1504 (Fed. Cir. Jul. 11, 2016).

On August 19, 2010, MedCo sued Hospira in the United States District Court for the District of Delaware, alleging that Hospira's two ANDA filings infringed claims of US patent no. 7,582,727 (the '727 patent) and claims of US patent no. 7,598,343 (the '343 patent). The district court found the patents valid and not infringed. Hospira also sued MedCo alleging several grounds of invalidity of MedCo's claims. Hospira argued that the invention was sold or offered for sale before the critical date under §102(b). The district court held that the asserted claims are not invalid. The Federal Circuit affirmed the district court's holding.

MedCo is a pharmaceutical company that is not capable of making its products in-house. The Bivalirudin active pharmaceutical ingredient is too acidic for patients' injection, and MedCo had attempted to develop manufacture methods to overcome this issue. The resulting patent applications were filed on July 27, 2008, making July 27, 2007, the critical date for determining whether the patents were invalid under the on-sale bar. MedCo paid Ben Venue Laboratories to manufacture three batches of bivalirudin using the claimed methods in 2006 and the three batches were delivered to an exclusive distributor, Integrated Commercial Solutions (ICS), under a distribution agreement. The batches were not released for sale until August 2007, after the critical date.

In the *en banc* rehearing, the Federal Court considered whether The Medicines Company's use of third-party services to manufacture the patented products triggered the on-sale bar.

The Federal Circuit identified three main reasons for upholding the validity of the patents. First, "only manufacturing services were sold to the inventor—the [present] invention was not." Second, "the inventor maintained control of the invention, as shown by the retention of title to the embodiments and the absence of any authorization to [the manufacturing service provider] to sell the product to others." Third, "'stockpiling,' standing alone, does not trigger the on-sale bar."

The Court concluded that "to be 'on sale' under § 102(b), a product must be the subject of a commercial sale or offer for sale, and that a commercial sale is one that bears the general hallmarks of a sale pursuant to Section 2-106 of the Uniform Commercial Code." The Court found that "no such invalidating commercial sale occurred in this case," and "no reason to treat MedCo differently than [it] would a company with in-house manufacturing capabilities."

The Federal Circuit remanded the appeal to the original panel for further proceedings concerning additional issues in the case relating to claim construction, infringement, and validity.

NOTICE AND EXCLUSION PERIODS UNDER THE BPCIA

By Greg Brummett, Esq. (gbrummett@ipfirm.com)

Amgen inc. v. Apotex Inc., slip op. 2016-1308, (Jul. 5, 2016).

Apotex had an application pending before the United States Food and Drug Administration ("FDA") under the provisions of the Biologics Price Competition and Innovation Act of 2009 ("Biologics Act" or "BPCIA") seeking permission to market a product allegedly "biosimilar" to Amgen's FDA-approved Neulasta®. Amgen's product includes an engineered protein that stimulates bone marrow to produce additional white blood cells, and thereby reduce the chance of infection in patients with compromised immune systems.

The BPCIA lays out a step-by-step process for both the FDA applicant and the sponsor of the previously approved reference product. This process requires that the parties provide various notices, exchange specific information, and address patent issues relevant to the application. As a result of their participation in this process, Amgen has filed an action for patent infringement alleging that Apotex's proposed marketing would infringe Amgen's patent rights.

The current appeal, however, is unrelated to the merits of the infringement action, but relates instead to Amgen's motion for preliminary injunction to enforce a provision of the BPCIA requiring an applicant to give at least 180 day's notice before commercially marketing its FDA-licensed biosimilar product. 42 U.S.C. §262(l)(8)(A).

In light of the Federal Circuit's opinion in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357–58 (Fed. Cir. 2015), holding that the 180-day notice period is calculated from delivery of the post-licensure notice, the district court granted Amgen's motion.

On appeal, Apotex argued that that the grant of the preliminary injunction should be rejected

> 1) because notice under §262(l)(2)(A) is effective in satisfying the requirements of §262(l)(8)(A);
>
> 2) in order to avoid adding 180 days or more to the 12-year exclusivity period already provided under §262(l)(7); and
>
> 3) because §262(l)(9) establishes a declaratory judgment action as the exclusive remedy for failure to provide the required §262(l)(8)(A) notice of commercial marketing.

The Court found that Apotex's notice to Amgen under §262(l)(2)(A) provided a factual distinction, but not a legally material distinction, between the current dispute and that previously addressed in *Amgen v. Sandoz*.

The Court noted that §262(l)(8)(A) provides that the "applicant ***shall*** provide notice … not later than 180 days before the date of the first commercial marketing of the [licensed] biological product," (emphasis added) and that the word "shall" generally indicates that the directive is mandatory. The Federal Circuit noted further that the language of (8)(A) contains no suggestion that the notice requirement depends on whether or not the applicant previously provided notice under §262(l)(2)(A). Accordingly, the Federal Circuit found that the notice requirements under 8(A) are neither optional nor conditional.

The Federal Circuit also rejected Apotex's argument that giving §262(l)(8)(A) its plain meaning effectively extends, by at least six months, the 12-year exclusivity period already provided to the sponsor of the reference product under § 262(k)(7). The Federal Circuit found that the plain language of §262(k)(7) establishes the 12-year date is only the ***earliest***

date on which a FDA-issued biosimilar license can take effect. Even in those instances in which an applicant's market entry is delayed by at least 180 days under the provisions of (8)(A), the Federal Circuit found this result to be consistent with the terms of §262(k)(7).

In addressing Apotex's argument that §262(l)(9) limits the remedy for violations of 8(A) to a declaratory-judgment action, the Federal Circuit noted that the federal courts' equitable jurisdiction is not limited absent a legislative command to that effect, whether the command is explicit or inferred. Applying that standard, the Federal Circuit found no language or inference in §262(l)(9) that provided a declaratory-judgment action as the sole remedy for violating (8)(A).

The district court's grant of the preliminary injunction was affirmed accordingly.

JURY'S PREFERENCE FOR PATENTEE'S EXPERT BOLSTERED BY COPIOUS SECONDARY CONSIDERATIONS

By Thomas S. Auchterlonie, Esq. (tauchterlonie@ipfirm.com)

In *WBIP, LLC v. Kohler Co.*, slip ops. 2015-1038 and 2015-1044 (Fed. Cir. Jul. 19, 2016), the Federal Circuit affirmed, among other things, the denial of defendant Kohler's two motions for judgment as a matter of law (JMOL) that plaintiff WBIP's two asserted patents were invalid. The jury had found that Kohler infringed all claims of plaintiff WBIP's two asserted patents, and Kohler had defended the infringement on the basis that the patent claims were invalid on two grounds, (1) obviousness and (2) inadequate written description.

Obviousness was not decided *de novo*. Rather, the Federal Circuit determined whether the district court had correctly decided if the jury's finding of non-obviousness was reasonably supported by evidence. In doing so, the Federal Circuit assessed (1) evidence produced during the 'battle of experts' (relative to Kohler's assertion that it would have been obvious to have modified the prior art Phipps reference in view of 'standard coolant elements') and (2) an unusually large amount of evidence of secondary considerations of obviousness (including evidence of long-felt need, initial industry skepticism, subsequent industry praise, copying and commercial success). In the battle of experts, though not literally stated, the Federal Circuit clearly favored the testimony of plaintiff WBIP's expert over that of defendant Kohler's expert. For example, instead of couching his testimony in terms of how the ordinarily skilled artisan WOULD have modified motivated to modify the Phipps reference and why, the Federal Circuit regarded (unfavorably) Kohler's expert as having testified, in effect, that a skilled artisan COULD have modified the Phipps reference as asserted if she had been asked to do so. By contrast, the Federal Circuit regarded (favorably) WPIB's expert as having testified, in effect, that there was no motivation to have modified the Phipps reference as asserted, and as having provided reasons why there were no such motivations.

Similarly, adequacy of the written description was not decided *de novo*. Rather the Federal Circuit determined whether the district court had correctly decided if the jury's finding (that Kohler had failed to prove an inadequate written description) was reasonably supported by the evidence and arguments which had been presented to the jury. In contrast to the detailed arguments presented in Kohler's appeal, the Federal Circuit found that Kohler had provided only conclusory statements and no detailed arguments to the jury regarding inadequate written description.

The Federal Circuit also affirmed the finding that the infringement was willful under the new (and easier) *Halo* standard, which replaced the old (and more difficult) *Seagate*

standard. In addition, the Federal Circuit affirmed vacated the denial of WBIP's motion for a permanent injunction and remanded the case for further consideration.

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