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# Federal Circuit Patent Bulletin: *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*

November 11, 2015

*"[A] product is not 'made by' a patented process within the meaning of § 271(g) if it is used merely to determine whether the intended product of a separate and perhaps separately-patented process has in fact already been manufactured."*

On November 10, 2015, in *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, the U.S. Court of Appeals for the Federal Circuit (Dyk, Moore, Wallach*) affirmed-in-part, vacated-in-part, and remanded the district courts summary judgments, *inter alia*, that neither Teva nor Amphastar infringed U.S. Patent No. 7,575,886, which related to the anticoagulant enoxaparin for preventing blood clots marketed as Lovenox, under 35 U.S.C. § 271(g), and that Amphastar's activities fall within the § 271(e)(1) safe harbor. The Federal Circuit stated:

Section 271(g) prohibits the unauthorized importation into the United States, or sale or use within the United States, of a "product which is made by a process patented in the United States." A key issue on appeal is therefore whether Teva'sand Amphastar's enoxaparin products are "made by" Momenta's patented process within the meaning of § 271(g). We conclude they are not.

Momenta argues that "made" means "manufactured," and that its patented method is "a crucial interim step used directly in the manufacture of [Teva's] product[s]." Specifically, Momenta asserts its "method is used [by Teva] to select and separate batches of intermediate drug substance that conform to [United States Pharmacopoeial Convention] requirements for enoxaparin from batches that do not," and that selected batches are then "further process[ed]." . . . Although Momenta's arguments are not without merit, it is more consonant with the language of the statute, as well as with this court's precedent, to limit § 271(g) to the actual "ma[king]" of a product, rather than extend its reach to methods of testing a final product or intermediate substance to ensure that the intended product or substance has in fact been made. [T]he ordinary meaning of "made" as used in § 271(g) means "manufacture," and extends to the creation or transformation of a product, such as by synthesizing, combining components, or giving raw materials new properties. However, "ma[king]" does not extend to testing to determine whether an already-synthesized drug substance possesses existing qualities or properties. . . .

The samples of enoxaparin that are the subject of testing are "exhaustively digest[ed]" into "sub-chains" and the sub-chains are then separated. Based on the test performed on this sample, an enoxaparin batch from which the samples were extracted may be selected for incorporation into the finished product. No assertion is made, however, that the enoxaparin samples on which tests are performed are themselves incorporated into the finished product or imported into the United States, nor do the tests create or give new properties to the enoxaparin substance in batches that are selected for further processing.

[A] product is not "made by" a patented process within the meaning of § 271(g) if it is used merely to determine whether the intended product of a separate and perhaps separately-patented process has in fact already been manufactured. All of the asserted claims of the '886 patent are directed to "[a] method for analyzing an enoxaparin sample." Use of the word "analyzing" indicates practicing the claimed invention requires that the enoxaparin already be "made." . . . The ordinary meaning of the term "made by"—rather than an FDA definition of "manufacture" crafted for purposes unrelated to incentivizing invention—therefore controls. For these reasons, Teva's and Amphastar's enoxaparin products are not "made by" Momenta's patented process for purposes of § 271(g). Because Momenta's infringement claims against Teva are based on § 271(g), the district court's grant of summary judgment in favor of Teva is affirmed.

Section 271(e)(1) provides that it is not infringement for a party to use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." "Though the contours of [§ 271(e)(1)] are not exact in every respect," "[t]here is no dispute as to the statutory purpose," namely, "to facilitate market entry upon patent expiration." . . . The language of § 271(e)(1) is "sufficiently broad" to "leave[] adequate space for experimentation and failureon the road to regulatory approval." The breadth of the exemption extends even to activities the "actual purpose" of which may be "promot[ional]" rather than regulatory, at least where those activities are "consistent with the collection of data necessary for filing an application with the [FDA] . . . for approval." Moreover, notwithstanding the legislative focus on activities occurring prior to the approval of generic drugs, the § 271(e)(1) exemption applies to medical devices, and "is not restricted to pre-approval activities," Section 271(e)(1) thus "provides a wide berth for the use of patented drugs in activities related to the federal regulatory process."

Despite the broad contours of the exemption, some activities are outside its protection. For example, § 271(e)(1) "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." In addition, research tools or devices that are not themselves subject to FDA approval may not be covered. . . .

With the benefit of additional briefing in the current appeals, which reflects the full district court record developed by all parties after the preliminary injunction phase, we conclude Amphastar's submissions are appropriately characterized as "routine." Webster's defines the adjective form of "routine" as "o fa commonplace or repetitious character." . . . These definitions aptly describe the patented quality control method. "[T]he '886 patent . . . is directed at a set of manufacturing control processes that ensure that each batch of generic enoxaparin" meets quality standards. The information generated as each batch of drug substance is tested is routinely (i.e., habitually, regularly, and repeatedly) recorded and retained as required

by regulation.

The routine record retention requirements associated with testing and other aspects of the commercial production process contrast with non-routine submissions that may occur both pre-and post-approval, such as the submission of investigational new drug applications ("INDs"), new drug applications ("NDAs"), supplemental NDAs, or other post-approval research results. The routine quality control testing of each batch of generic enoxaparin as part of the post-approval, commercial production process is therefore not "reasonably related to the development and submission of information" to the FDA, and it was clearly erroneous to conclude otherwise.