Published on *The National Law Review* https://natlawreview.com

Federal Circuit Interprets Two Important Infringement Provisions

Article By:

Courtenay C. Brinckerhoff

In a single decision issued for companion cases ***Momenta Pharmaceuticals v. Teva Pharmaceuticals*** and ***Momenta Pharmaceuticals v. Amphastar Pharmaceuticals***, the Federal Circuit interpreted two important sections of the infringement statute, 35 USC § 271. In one portion of its decision, the court adopted a literal interpretation of § 271(g), holding that the statute only applies if the accused product was synthesized by a patented process. In another portion of its decision, the court decided that the post-manufacture testing at issue constituted "routine" post-approval activities that were not protected by the safe harbor of § 271(e)(1). In so doing, the court backpedaled from its 2012 decision in Momenta Pharmaceuticals v. Amphastar Pharmaceuticals, where it held that Amphastar's activities were "anything but routine."

The Patent At Issue

The patent at issue was Momenta's U.S. Patent 7,575,886. According to the recent Federal Circuit decision, Momenta asserts its "method is used … 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]."

The accused products are generic versions of Lovenox® (enoxaparin), an anticoagulant used to prevent blood clots.

The Federal Circuit opinion was authored by Judge Wallach and joined by Judge Moore. Judge Dyk concurred-in-part and dissented-in-part.

"Made By" Under § 271(g)

Momenta asserted infringement under § 271(g), which provides in pertinent part:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.

The district court found no violation of § 271(g), based on its determination that the '866 patent related to "quality control release testing" and was "not a method of making enoxaparin" as the statute required.

On appeal, Momenta argued that the "made by" language of the statute encompasses the entire manufacturing process, and "that its patented method is 'a crucial interim step used directly in the manufacture of [Teva's] product[s] …. to select and separate batches of intermediate drug substance that conform to [USP] requirements for enoxaparin from batches that do not.'" Momenta also cited FDA Good Manufacturing Practice (GMP) regulations that "define '[m]anufacture' and 'processing' of drug products as including 'testing[] and quality control of drug products.'"

The Federal Circuit disagreed with Momenta, and affirmed the district court's decision on this issue:

> 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.

In light of the foregoing, the 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.

Judge Dyk dissented from this portion of the decision.

"Routine" Activities Under § 271(e)(1)

The "safe harbor" of § 271(e)(1) exempts from infringement activities that are "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 or veterinary biological products." In Classen Immunotherapies, Inc. v. Biogen Idec, the court held that "[t]he statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained."

In its 2012 decision in *Momenta v. Amphastar,* the court held that Amphastar's activities were "anything but routine," and so likely fell under the safe harbor. In this decision, the court determined that the "law of the case" did not apply to that determination since it was made at a preliminary stage, and came to a different conclusion:

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."

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.

The court also recognized the inequity of the *Momenta I* decision:

> The conclusion in *Momenta I* that Amphastar's commercial use of Momenta's patented method falls within the safe harbor of § 271(e)(1) would result in manifest injustice. Amphastar points to no case, until *Momenta I*, extending immunity under § 271(e)(1) to encompass activities related to ongoing commercial manufacture and sale.

Thus, the Federal Circuit affirmed the district court decision granting summary judgment in favor of Teva and affirmed-in-part, vacated-in-part, and remanded the district court decision granting summary judgment in favor of Amphastar.

Judge Dyk's Dissent

As noted above, Judge Dyk dissented from the majority's interpretation of 271(g).

> The patent here … is not utilized to identify the product to be made, but rather is used in the manufacturing process. The quality control process of the '886 patent is an intermediate step to determine which batches of putative enoxaparin must be discarded, and which batches may be incorporated in the final drug product. It is distinctly part of the manufacturing process of the product.
>
> *****
>
> [L]imiting "made" in § 271(g) to "the creation or transformation of a product, such as by synthesizing, combining components, or giving raw materials new properties," Maj. Op. at 8, would lead to anomalous results. Patents on purification methods or the quality control method at issue here, which may be integral to the regulatory or commercial viability of a product, but which do not create or transform a product, combine components, or confer new properties, could be freely infringed simply by outsourcing those processes abroad. Congress could not have intended to create this loophole when it sought to protect process patent owners from foreign competitors using U.S. manufacturing processes abroad. *See generally Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1571–72 (Fed. Cir. 1996).

Writing Claims For § 271(g)

Each independent claim of the '866 patent is directed to "[a] method for analyzing an enoxaparin sample." Now that the court has decided that § 271(g) requires "the creation or transformation of a

product” by the patented process, applicants should consider including claims that include *making* steps, even if the invention primarily pertains to other steps.

National Law Review, Volume V, Number 323