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Location of Accused Activity Informs Post-Approval Enforceability of "Quality-Control" Process Patents

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On November 10, 2015, the United States Court of Appeals for the Federal Circuit issued its decision in two companion cases: *Momenta Pharms. Inc. v. Teva Pharms. USA Inc.* (14-CV-1274, 14-CV-1277) and *Momenta Pharms. Inc. v. Amphastar Pharms., Inc.* (14-CV-1276, 14-CV-1278). In these cases, the court considered Teva's and Amphastar's manufacture of generic enoxaparin. Both companies' manufacturing processes include a quality-control (or "QC") step which is allegedly covered by a patent assigned to Momenta. Notably, the patented QC step is not directly involved in the making of the finished enoxaparin product, but rather is used to separate "conforming" and "non-conforming" batches of enoxaparin during the manufacturing process. Teva manufactures its generic enoxaparin product in Italy. In contrast, Amphastar manufactures its generic enoxaparin in the United States.

Within the Patent Act, 35 U.S.C. § 271 is the statute which defines acts of infringement. The *Momenta* panel interpreted the scope of two of its subsections, 35 U.S.C. §§ 271(g) and 271(e)(1), in the context of application to QC process patents. An exception to the general rule that infringing acts must occur within the United States — that is, an exception to otherwise non-infringing activity — Section 271(g) provides a cause of action for the owners of process patents against those who practice the invention abroad, but then import a final product of that process into the United States. Conversely, Section 271(e)(1) provides an exception to otherwise infringing activity: it is a "safe harbor" from infringement liability for regulatory-related activities, *e.g.,* seeking FDA approval for generic products. In *Momenta*, the Federal Circuit first held that the use of a patented QC method is not an act of infringement under section 271(g). This issue, however, divided the Federal Circuit panel with a judge dissenting from the majority. Second, the Federal Circuit held section 271(e)(1)'s safe harbor does not shield infringers within the United States who use patented methods to generate "routine" QC information.

The *Momenta* decision thus provides guidance on the enforceability of QC method patents. *Momenta* may be read to suggest that generic pharmaceutical companies can avoid infringing a QC patent by manufacturing its active pharmaceutical ingredient (or whatever other component requires the patented QC step) outside of the United States, while, quite differently, parties conducting the *same* manufacturing activity *within* the United States cannot avoid liability under the safe harbor provision of section 271(e)(1) — at least post-FDA approval.

Background: Generic Enoxaparin and the ’886 Patent

United States Patent No. 7,575,886 (the “’886 patent”) claims methods of analyzing enoxaparin samples.[1] Generally, the ’886 patent claims a QC process used in the manufacture of enoxaparin. Momenta, the first generic manufacturer of enoxaparin to gain FDA approval, is the assignee of the ’886 patent. Momenta asserted the ’886 patent against Teva and Amphastar, competitors in the generic enoxaparin market.

Teva sources its enoxaparin product from an Italian company — Chemi S.p.A. — which manufactures, analyzes, tests, packages, and labels the product before importing it into the United States. Amphastar, on the other hand, manufactures its enoxaparin product in the United States.

Using a Patented Process Limited to “Quality Control” Is Not an Act of Infringement under 35 U.S.C. § 271(g)

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.’”

Here, the Federal Circuit considered whether Teva’s use of Momenta’s patented method in Italy and subsequent importation and sale of the derived end product in the United States constituted an act of infringement under section 271(g). The critical issue was thus whether Teva’s end product is “made by” the claimed method of the ’886 patent — a QC method — within the meaning of the statute. The court determined that it is not.

Teva used the method claimed by the ’886 patent “to select and separate batches of intermediate drug substance that conform to [United States Pharmacopeial Convention] requirements for enoxaparin from batches that do not.” Relying on dictionary definitions of the word “make,” the court ruled that section 271(g)’s scope “extends to the creation or transformation of a product, such as by synthesizing, combining components, or giving raw materials new properties.” In contrast, section 271(g) “does not extend to testing to determine whether an already synthesized drug substance possesses existing qualities or properties.” In other words, section 271(g) covers only “the actual ‘mak[ing]’ of a product” and does not extend to “methods of testing a final product or intermediate to ensure that the intended product or substance has in fact been made.”

The court’s interpretation seemingly excludes patents claiming QC methods from section 271(g)’s scope. The court accordingly concluded that Teva’s use of the QC method claimed in the ’886 patent in Italy does not provide Momenta with a cause of action under section 271(g).

Describing this construction of section 271(g) as “too limited,” Judge Dyk dissented from the majority of the panel (Judges Wallach and Moore) on this point and urged that courts “should resolve the question of whether a product [is] ‘made by’ a process on a case-by-case basis,” rather than treat, as law, that QC is not part of a manufacturing process for purposes of the statute. Among other things, Judge Dyk opined that the majority’s construction “would lead to anomalous results,” including a “loophole” whereby QC patents “could be freely infringed simply by outsourcing [accused] processed abroad.”

Parties That Infringe a Patented Process for Generating “Routine” Information Are Not Entitled to Safe Harbor under 35 U.S.C. § 271(e)(1)

Section 271(e)(1) provides a safe harbor for parties that perform what would otherwise be infringing activity, if that activity is “solely for uses reasonably related to the development and submission of information” under Federal law.

In a previous appeal, the Federal Circuit vacated a preliminary injunction on grounds that Momenta was unlikely to succeed on the merits of an infringement claim against Amphastar because Amphastar was entitled

[1] See *Momenta Pharms. v. Amphastar Pharms. Inc.*, 686 F.3d 1348, 1351 (Fed. Cir. 2012) (“*Momenta I*”) (The claims of the ’886 patent “generally require digestion of an enoxaparin sample with a heparin degrading enzyme, followed by the use of a separation method to detect the presence of the non-naturally occurring sugar resulting from the B-eliminative cleavage. The signal corresponding to the non-naturally occurring sugar can then be used to analyze the test sample based on a comparison with a reference standard.”).

to section 271(e)(1)'s safe harbor protection. In this subsequent appeal, after the district court granted summary judgment of non-infringement in favor of Amphastar, the Federal Circuit, with the benefit of further briefing from the parties, reversed course.

The court considered whether Amphastar's manufacture, including the use of the QC step in the '886 patent claims, and subsequent sale of enoxaparin in the United States infringed Momenta's '886 patent, or whether instead the activity is protected under 271(e)(1). The court noted that the type of information generated by the QC method of the '886 patent is that which "is routinely (i.e., habitually, regularly, and repeatedly) recorded and retained." According to the Federal Circuit, unlike non-routine submissions that occur pre- and post-approval, such as "investigational new drug applications ('INDs'), new drug applications ('NDAs'), supplemental NDAs, or other post-approval research results" which enjoy section 271(e)(1)'s safe harbor protection, use of the method claimed in the '886 patent merely generates data associated with "routine record retention requirements associated with testing and other aspects of the commercial production process." The *Amphastar* panel emphasized that the generation of such "routine" information is **not** protected by 271(e)(1).

The court thus held that section 271's safe-harbor provision does not exempt Amphastar from infringement liability for use of the QC method claimed in the '886 patent. The court accordingly vacated the district court's grant of summary judgment of non-infringement for Amphastar to the extent it was based on a determination that Amphastar's acts were within the safe-harbor of 271(e)(1). It bears considering, however, that the outcome may have been different had Amphastar not yet received FDA approval to market its generic product. Under such facts — that is under a *pre*-approval scenario — the decision suggests that Amphastar may have argued successfully that its use of the same claimed QC method was "related to obtaining FDA approval," *e.g.*, by virtue of the inclusion of the resulting data in Amphastar's Abbreviated New Drug Application.

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