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A Sign of Future Biosimilars Litigation?

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On October 28, 2011, the U.S. District Court for the District of Massachusetts granted plaintiffs Momenta Pharmaceuticals, Inc. and Sandoz Inc.'s motion for preliminary injunction against defendants Amphastar Pharmaceuticals, Inc., International Medication Systems, Ltd., and Watson Pharmaceuticals, Inc. *See Momenta Pharmaceuticals, Inc., et al. v. Amphastar Pharmaceuticals, Inc., et al.*, No. 1:11-cv-11681-NMG (D. Mass. Oct. 28, 2011) ("*Momenta* Opinion"). The *Momenta* plaintiffs had previously brought suit for infringement of Momenta's patents concerning quality control methods for generic versions of sanofi-aventis's branded drug Lovenox® (enoxaparin). And while the patent claims at issue covered methods developed to meet an FDA requirement regarding approval of generic enoxaparin products, the *Momenta* court ruled, in granting a preliminary injunction, that the § 271(e)(1) safe harbor did not permit the defendants to continue to infringe such claims ***after*** FDA approval.

Lovenox® (enoxaparin sodium injection) is a low molecular weight heparin, a complex polysaccharide comprising sugar chains of varying lengths and compositions. On July 23, 2010, in response to a Citizen's Petition, the FDA established five criteria that would be required for a generic enoxaparin product to demonstrate active ingredient "sameness" to Lovenox®. These criteria include, *inter alia*, evaluating "the nature and arrangement of components that constitute enoxaparin." On the same day that the FDA issued these guidelines, it approved an ANDA for a generic enoxaparin product developed in collaboration between Momenta and Sandoz.

Prior to approval of its generic enoxaparin product, Momenta had obtained U.S. Patent No. 7,575,886 ("the '886 patent"), with claims directed to methods of analyzing a sample of enoxaparin to ensure its conformity with an enoxaparin reference standard. The *Momenta* plaintiffs subsequently asserted these claims against the defendants, potential competitors who had filed their own ANDAs for generic versions of enoxaparin. In moving for a preliminary injunction against the defendants, the *Momenta* plaintiffs alleged that the quality control methods to be used by the defendants would infringe the '886 patent. In response, the defendants asserted that the '886 patent was invalid and the asserted claims did not cover the defendants' processes. The defendants further argued that their alleged infringing activity fell within the safe harbor of 35 U.S.C. § 271(e)(1), a statutory provision that protects otherwise infringing activity when used "solely for uses reasonably related to the development and submission of information" under FDA law.

Judge Nathaniel M. Gorton found that the *Momenta* plaintiffs demonstrated a likelihood of success on the merits of their claims that the asserted claims of the '886 patent are valid and infringed. The court further rejected defendants' claims to safe harbor under § 271(e)(1), holding that "although the safe harbor provision permits otherwise infringing activity that is conducted to obtain regulatory approval

of a product, it does not permit a generic manufacturer to continue in that otherwise infringing activity after obtaining such approval . . . ." *See Momenta* Opinion at 23. Because the defendants would continue use Momenta's claimed testing methods on each commercial batch of enoxaparin after FDA approval, their infringing activities could not be shielded by § 271(e)(1).

Judge Gorton also found that plaintiffs had submitted evidence demonstrating long-term irreparable harm because plaintiffs market the "only" generic enoxaparin,[1] and defendants' entry into this market would have caused price erosion, reputational injury, and loss of goodwill. *See Momenta* Opinion at 24-27. The court also emphasized that generic enoxaparin is Momenta's only product, and entry of another generic would have drastic effects of the market's valuation of the company. *See id.* at 26. Further finding that the balance of hardships and the public interest weighed in favor of the plaintiffs, Judge Gorton granted plaintiffs their requested preliminary injunction. *See id.* at 27-30.

Although the approval of generic equivalents to Lovenox® is regulated under the Hatch-Waxman Act, and not the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), the FDA's "sameness" requirements for generic enoxaparin products may bear a resemblance to future FDA guidelines for approval of biosimilar products under the BPCIA. Likewise, it can be expected that developers of biosimilars could try to patent their proprietary methods for meeting the quality control benchmarks required to establish biosimilarity, and those patents could be asserted against competing biosimilars applicants. As in the *Momenta* case, if the competitors must use patented quality control methods for each commercial batch after approval, the § 271(e)(1) safe harbor would likely not protect them against patent infringement suits.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

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[1] The *Momenta* court appeared to be unaware that earlier in October 2011, sanofi-aventis launched its own authorized generic version of Lovenox® through its division Winthrop U.S.