**United States District Court**
**District of Massachusetts**

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| **MOMENTA PHARMACEUTICALS, INC., SANDOZ INC., Plaintiffs,** | ) | |
| | ) | **Civil Action No. 10-12079-NMG** |
| **v.** | ) | |
| **TEVA PHARMACEUTICALS USA, INC., Defendant.** | ) | |

**MEMORANDUM & ORDER**

**GORTON, J.**

Plaintiffs Momenta Pharmaceuticals, Inc. and Sandoz Inc. (collectively, "Momenta") bring suit against Teva Pharmaceuticals USA, Inc. ("Teva") for infringement of U.S. Patent No. 7,575,886 ("the '886 patent").[1]

## I. Background

In July, 2010, after receiving FDA approval, plaintiffs began to market the first generic version of Lovenox (otherwise known as enoxaparin) in the United States. Enoxaparin is an anticoagulant used to prevent blood clots. In February, 2010, Teva announced its intention to sell a generic enoxaparin as soon as it obtained FDA approval. Chemi S.p.A ("Chemi") an Italian

[1] Momenta originally also asserted infringement of U.S. Patent No. 7,790,466 ("the '466 patent") but indicated in its opposition to defendants' motion for summary judgment that it is withdrawing that claim. Thus, this Court need not address that claim.

company located in Patricia, Italy is responsible for manufacturing, analyzing, testing, packaging and labeling of Teva's generic enoxaparin before Teva imports it into the United States.

Momenta is the assignee of the '886 patent, issued in August, 2009, which is directed at a set of manufacturing control processes that ensure that each batch of generic enoxaparin includes the individual sugar chains characteristic of Lovenox. Momenta alleges that Teva has infringed its patents by making material preparations to sell a generic enoxaparin product that has been manufactured using the methods in plaintiffs' patents.

## II. Procedural History

Plaintiffs filed their complaint on December 2, 2010 and moved for expedited discovery on December 28, 2010. On January 19, 2011, Teva Pharmaceuticals Industries Ltd. was dismissed as a defendant and the following month this Court denied the motion for expedited discovery.

The Court held a joint Markman hearing in this case and Momenta Pharm. Inc, v. Amphastar Pharm., C.A. No. 11-cv-11681-NMG ("Amphastar Litigation"), in May, 2012, and issued a Markman Order in June, 2012. At the joint request of the parties, this case was stayed from August 10, 2012 until January 15, 2013, during an appeal to the Court of Appeals for the Federal Circuit in the Amphastar litigation which raised issues relating to the

so called "safe harbor" provision, 35 U.S.C. § 271(e)(1) ("§ 271(e)(1)"), which is also at issue in this case.

On January 31, 2013, defendants filed a motion for Judgment on the Pleadings or in the alternative Summary Judgment. On March 18, 2013, defendants moved to strike plaintiffs' third amended infringement contentions. Shortly thereafter, plaintiffs filed a cross-motion for leave to amend their infringement contentions. The Court heard oral argument on all three motions at a hearing on July 1, 2013 and took the matter under advisement. The Court now announces its ruling on those three motions.

## III. Motion for Summary Judgment[2]

### A. Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991) (quoting Garside v. Osco Drug, Inc., 895 F.2d 46, 50 (1st Cir. 1990)). The burden is on the moving party to show, through the pleadings, discovery and affidavits, "that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

[2] Defendants filed a motion for Judgment on the Pleadings or in the alternative Summary Judgment. The Court treats the motion as one for Summary Judgment.

A fact is material if it "might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Factual disputes that are irrelevant or unnecessary will not be counted." Id. A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

Once the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most favorable to the non-moving party and make all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). Summary judgment is appropriate if, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists and that the moving party is entitled to judgment as a matter of law.

**B. Application**

In their Complaint plaintiffs allege that Teva must be infringing the '886 patent because the Food and Drug Administration ("FDA") requires Teva to perform the methods claimed in the patent. Defendant moves for summary judgment on the grounds that all of its allegedly infringing activity is

subject to the § 271(e)(1) safe harbor as interpreted by the Federal Circuit in Momenta Pharm. v. Amphastar Pharm., 686 F.3d 1348 (2012) and thus cannot constitute patent infringement. Plaintiffs oppose on several grounds.

Three of Momenta's arguments in opposition to summary judgment are based on claims that Teva's activities are not subject to the § 271(e)(1) safe harbor. In brief, Momenta contends that: 1) the FDA does not require Teva to use "any particular test" and thus Teva cannot be "required" to perform a test that infringes the '866 patent, 2) the routine commercial manufacturing records kept by Teva are not actually submitted or intended to be submitted to the FDA and 3) the maintenance of records is not "solely" for uses "reasonably related to development and submission of information". Momenta made all three of these arguments in its opposition to summary judgment in the Amphastar case. The Court again rejects them for the reasons explained in its Memorandum and Order in that case. Order on Motion for Summary Judgment (Docket No. 497), Momenta Pharm. Inc, v. Amphastar Pharm., C.A. No. 11-cv-11681-NMG.

Momenta's other arguments in opposition are also unavailing. Momenta asserts that even if the testing done to achieve FDA approval is subject to the § 271(e)(1) safe harbor, Teva's sales activity is a separate form of patent infringement under 35 U.S.C. § 271(g). That statute states in part that

> 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.

Plaintiffs assert that defendants are "liable as...infringer[s]" because they offer to sell and sell a product made by a process patented in the United States.

Momenta's attenuated interpretation of § 271(g) incorrectly relies on the illogical assertion that practicing a process abroad could somehow constitute an act of infringement even though, due to the protections of the safe harbor provision, that same process would not constitute infringement when practiced within the United States. Such a construction of the statute would lead to extra-territorial application of U.S. patent law in a way not intended by Congress. Instead,

> congressional reports make clear that the principal purpose of [§ 271(g)] was to prevent a patent owner's competitors from avoiding the patent by producing products outside the United States and then importing them.

Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d 1306, 1318 (Fed. Cir. 2001), vacated on other grounds, 535 U.S. 1109 (2002). As a result, § 271(g) was "intended to grant patent holders the same protection against overseas infringers as they already enjoyed against domestic entities", not to create a cause of action where none existed domestically. Id. Thus, it would be contrary to Congressional intent if § 271(g) were interpreted to apply in situations in which there would be no domestic

liability.

This Court also agrees with defendants that § 271(g) does not apply in this case because there is no product that is "made" by the accused tests and sold in the United States. Momenta asserts that the testing does result in the product being "made" because it is conducted as part of the broader "manufacturing process." Yet, that argument is without merit because, while the quality control release testing is a regulatory requirement for sale of enoxaparin in the United States, it is not a method for making enoxaparin.

All of the asserted claims of the '866 patent require that an enoxaparin sample exist prior to the allegedly infringing testing. For example, Claim 53 claims a

> method for analyzing an enoxaparin sample for the presence or amount of a non naturally occurring sugar . . . that results from a method of making enoxaparin.

In other words, that claim presupposes that enoxaparin has already been made by a previous method not covered by the patent. Without a pre-existing sample of enoxaparin the allegedly infringing testing could not take place. What is "made" by the process claimed in the '866 patent is 1) a digested sample of enoxaparin and 2) information about that sample, neither of which is subsequently sold by Teva. Thus, § 271(g) is inapplicable and summary judgment of non-infringement is appropriate.

## IV. Cross Motions to Strike and Amend Infringement Contentions

On February 28, 2013, Momenta served its Third Amended Infringement Contentions ("Amended Contentions"). In those Amended Contentions Momenta added a second test, the Disaccharide Building Block Procedure ("DBB test"), that it claimed also infringed the '866 patent. The DBB test is the same as the 15-25% procedure except that it compares the presence and amount of particular digested sub-chains to individual reference standards for those specific sub-chains rather than to the 15-25% reference standard. Teva moved to strike the Amended Contentions on the ground that they were untimely in light of the Court's scheduling order. Momenta then filed a cross motion for leave to file the Amended Contentions.

A scheduling order may be modified only for good cause and with the judge's consent. Fed. R. Civ. P. 16(b)(4). Here the Court finds no good cause to allow a modification to that order. The § 271(e)(1) safe harbor also applies to the DBB test. Thus, for reasons explained in the Court's Memorandum and Order in the Amphastar case, the amendment would be futile.

**ORDER**

In accordance with the foregoing,

1) Defendant's Motion for Summary Judgment (Docket No. 135) is **ALLOWED,**

2) Defendant's Motion to Strike Plaintiffs' Third Infringement Contentions (Docket No. 144) is **ALLOWED,** and

3) Plaintiffs' Motion for Leave to Amend Infringement Contentions (Docket No. 161) is **DENIED.**

**So ordered.**

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated July 19, 2013