

United States District Court  
District of Massachusetts

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MOMENTA PHARMACEUTICALS, INC.	)	
and SANDOZ INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No.
	)	11-11681-NMG
AMPHASTAR PHARMACEUTICALS, INC.	)	
and INTERNATIONAL MEDICATION	)	
SYSTEMS, LTD.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM & ORDER

GORTON, J.

This is a patent infringement case in which plaintiffs, Momenta Pharmaceuticals, Inc. and Sandoz Inc. (collectively, "Momenta" or "plaintiffs"), claim that defendants, Amphastar Pharmaceuticals, Inc. and International Medication Systems, Ltd., (collectively, "Amphastar" or "defendants"), infringed their '886 patent during the course of defendants' manufacture and sale of generic enoxaparin products.

Pending before the Court is Momenta's motion for judgment as a matter of law under Fed. R. Civ. P. 50(a) on Amphastar's affirmative defenses. Pursuant to Fed. R. Civ. P. 50(a) judgment as a matter of law is warranted when

a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not

have a legally sufficient evidentiary basis to find for the party on that issue[.]

Fed. R. Civ. P. 50. Because the only reasonable conclusion as to the defenses of 1) patent eligible subject matter and 2) indefiniteness is that they are inapplicable, with respect to those two defenses, the motion will be allowed.

The two-step framework for patentable subject matter is described in Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012). First, the Court must determine whether the patent claims are "directed" to a patent-ineligible concept, such as a natural law, natural phenomenon or abstract idea. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting Mayo, 132 S. Ct. at 1296-97). If the claims are not so directed, they are patentable. Id. If the claims are directed to an ineligible concept, then the Court determines whether the elements of the invention "transform" the claims into an application eligible for a patent. Id. Patent eligibility is a question of law. Id.

Because the '886 patent "[is] directed to a new and useful method" of ensuring the quality of enoxaparin and involves a series of laboratory steps rather than a law of nature or abstract idea, this Court concludes that the asserted claims involve patentable subject matter. See CellzDirect, 827 F.3d at 1048. Therefore, with respect to the affirmative defense that

the asserted claims do not involve patent eligible subject matter, Momenta's motion will be allowed.

With respect to the indefiniteness defense, a patent's specification must be sufficiently "definite" so as to include at least one claim that "particularly point[s] out and distinctly claim[s] the subject matter which the applicant regards as [the] invention." 35 U.S.C. § 112 (2002). Pursuant to Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014),

[a] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

Although "[s]ome modicum of uncertainty" is permissible, the "patent must be precise enough to afford clear notice of what is claimed." Trusted Knight Corp. v. Int'l Bus. Machines Corp., No. 2016-1510, 2017 WL 899890, at \*3 (Fed. Cir. Mar. 7, 2017) (quoting Nautilus, 134 S. Ct. at 2128-29).

When a Court evaluates indefiniteness by examining intrinsic evidence, such as the claims and specifications in the patent, indefiniteness is a question of law. Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374, 1378 (Fed. Cir.), cert. denied, 136 S. Ct. 569 (2015).

Amphastar contends that all of the claims are indefinite because they are limited to "the non naturally occurring sugar

associated with peak 9 of FIG. 1" and there is no specific "FIG. 1" in the '886 patent. Based on the intrinsic evidence, however, the "Figure 1" in the patent is composed of Fig. 1A and Fig. 1B. The only figure in the patent with peak 9 is FIG. 1A. Moreover, the claims of the patent involve enoxaparin and the Fig. 1A is titled "Lovenox" which is the brand name for enoxaparin. Furthermore, the "Brief Description of the Drawings" in the patent clarifies that FIG. 1A is a "[c]apillary electrophoresis (CE) profile of enoxaparin (Lovenox™)". Therefore, this Court concludes that the patent "afford[s] clear notice of what is claimed." Trusted Knight Corp., 2017 WL 899890, at \*3 (quoting Nautilus, 134 S. Ct. at 2128-29) and, with respect to the infiniteness defense, the motion for judgment as a matter of law will be allowed.

#### **ORDER**

In accordance with the foregoing, plaintiffs' motion for judgment as a matter of law (Docket No. 1069) is, with respect to the defenses based upon patent eligible subject matter and indefiniteness, **ALLOWED** but otherwise **DENIED without prejudice**.

**So ordered.**

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

Dated July 21, 2017