United States District Court
District of Massachusetts

MOMENTA PHARMACEUTICALS, INC. and SANDOZ INC.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 11-11681-NMG**
AMPHASTAR PHARMACEUTICALS, INC., INTERNATIONAL MEDICATION SYSTEMS, LTD., ACTAVIS, INC. and WATSON PHARMA, INC.,	)	
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., International Medication Systems, Ltd., Actavis, Inc. and Watson Pharma, Inc. (collectively, "Amphastar" or "defendants") infringed their patent during the course of defendants' manufacture and sale of generic enoxaparin products.

Pending before the Court is Momenta's renewed motion for leave to amend its infringement contentions with respect to the Disaccharide Building Block Procedure ("DBB test"). For the following reasons, that motion will be allowed.

I. Background

In July, 2010, after receiving approval from the United States Food and Drug Administration ("the FDA"), Momenta 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. Momenta is the assignee of U.S. Patent No. 7,575,886 ("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.

Amphastar received FDA approval to market its generic enoxaparin product in September, 2011. Momenta initiated this lawsuit two days later by filing a complaint alleging that Amphastar infringed its '886 patent by manufacturing generic enoxaparin for commercial sale using the patented methods.

In October, 2011, this Court allowed Momenta's motion for injunctive relief by enjoining Amphastar from advertising, offering for sale or selling allegedly infringing enoxaparin products. That decision included a preliminary finding that the safe harbor provision in 35 U.S.C. § 271(e)(1) did not protect Amphastar's infringing activities because it used the patented process to test products after it had already obtained FDA

approval, such that the use was not "reasonably related to the development and submission of information" to the FDA.

Momenta served Amphastar in February, 2012 with its initial infringement contentions which accused two Amphastar procedures: the "Approved 15-25% Procedure" which Amphastar performed at the time of FDA approval and the "Revised 15-25% Procedure" which it adopted after FDA approval.

In August, 2012, the Federal Circuit Court of Appeals ("the Federal Circuit") vacated this Court's preliminary injunction and found that this Court applied "an unduly narrow interpretation" of the safe harbor provision. Momenta Pharm., Inc. v. Amphastar Pharm, Inc., 686 F.3d 1348, 1349 (Fed. Cir. 2012)("Momenta I"). It explained that Amphastar's post-approval use of the patented process to run quality control tests on its products fell within the scope of the safe harbor provision because its use generated information for records that Amphastar needed for continued FDA approval. Id. at 1357-61.

In mid-August, 2012, this Court stayed the case pending the completion of appellate proceedings and denied all outstanding motions without prejudice. The Federal Circuit denied Momenta's petition for a rehearing en banc in November, 2012.

This Court removed the stay in mid-January, 2013. Amphastar moved for summary judgment. Momenta served Amphastar with amended infringement contentions in February, 2013 which

additionally accused the DBB test and a "Batch-to-Batch Procedure". In May, 2013, Momenta served Amphastar with its second amended infringement contentions adding "further documentary support" for its DBB and Batch-to-Batch contentions based upon Amphastar's delayed production of the testing records and Abbreviated New Drug Application ("ANDA") materials. Momenta did not seek leave to amend its infringement contentions on either occasion but did so in June, 2013.

In July, 2013, this Court entered summary judgment in Amphastar's favor, finding that its activities were protected by the safe harbor provision and therefore did not infringe. The Court also denied Momenta leave to amend the infringement contentions with respect to the DBB test as "futile" because Amphastar's use of that test fell within the safe harbor provision pursuant to 35 U.S.C. § 271(e)(1).

The Federal Circuit vacated this Court's grant of summary judgment to Amphastar in November, 2015 and held this time that the safe harbor provision did not apply to its infringing activities. Momenta Pharm., Inc. v. Teva Pharm. USA Inc., 809 F.3d 610, 613 (Fed. Cir. 2015).[1] The Federal Circuit also suggested that:

[1] In that decision, the Federal Circuit addressed the findings of this Court in both the instant case, in which Momenta alleges that Amphastar infringed the '886 patent, and the companion case, in which Momenta alleged that Teva Pharmaceuticals USA Inc. infringed the '886 patent. Id.

> Given our vacation of summary judgment on the reach of § 271(e)(1), the district court may choose to reconsider on remand its denial of leave [to amend the infringement contentions] in light of our holding.

Id. at 622.

Momenta now renews its motion for leave to amend its infringement contentions with respect to the DBB test, having failed to seek leave prior to serving the amended and second amended infringement contentions as required by the scheduling order in this case (Docket No. 139).

II. Motion to amend infringement contentions

A. Legal standard

A scheduling order may be modified only for good cause and with the court's consent. Fed. R. Civ. P. 16(b)(4). In determining whether to grant leave to amend after a deadline in the scheduling order has expired, a court may consider 1) the explanation for the movant's failure to move timely for leave to amend 2) the importance of the amendment 3) the potential for prejudice caused by allowing the amendment and 4) the opportunity to cure such prejudice. E.g. S&W Enters., L.L.C. v. SouthTrust Bank of Alabama, NA, 315 F.3d 533, 536 (5th Cir. 2003).

B. Application

Momenta seeks to amend its infringement contentions to accuse Amphastar's use of the DBB test as an infringing

activity. It contends that 1) the scheduling order allowed it to amend its preliminary infringement contentions, as of right, within 30 days of the Court's ruling on claim construction, 2) the 30-day period expired on February 11, 2013, 3) "[n]othing substantive occurred between February 11 and 12, 2013 that could have possibly prejudiced Amphastar" and 4) it served Amphastar with the amended infringement contentions on February 12, 2013. Momenta further submits that it promptly served Amphastar with the second amended infringement contentions, which added further support for the existing contentions but not new theories of liability, after receiving Amphastar's delayed disclosures.

Momenta's motion to amend will be allowed. The Court remains concerned by Momenta's allegations that Amphastar intentionally withheld and concealed, perhaps in violation of a court order, the documents necessary for Momenta to discover Amphastar's use of the DBB test. Given the Federal Circuit's finding that the safe harbor provision does not protect Amphastar from liability, the Court no longer deems the proposed amendment "futile". Momenta credibly asserts that the amendment will not unduly prejudice Amphastar because 1) it does not affect the fact discovery conducted after the belated disclosure, 2) no expert discovery has yet occurred and 3) Amphastar will have the opportunity to address the amended infringement contentions at the summary judgment stage.

Defendants' statement that the amended contentions would "substantially" broaden the scope of the claims and present new issues of claim construction is unpersuasive. As the Court found when it considered Momenta's prior motion to amend, the DBB test uses a different reference standard but is otherwise the same as the two 15-25% procedures identified in the initial set of infringement contentions.

Accordingly, Momenta's renewed motion to amend with respect to the DBB test will be allowed.

ORDER

For the foregoing reasons, plaintiffs' renewed motion for leave to amend its infringement contentions with respect to the DBB test (Docket No. 624) is **ALLOWED**.

So ordered.

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

Dated June 21, 2016