United States District Court
District of Massachusetts

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

MEMORANDUM & ORDER

GORTON, J.

Plaintiffs Momenta Pharmaceuticals, Inc. ("Momenta") and Sandoz Inc. ("Sandoz") (collectively, and for simplicity, "Momenta") bring suit against Amphastar Pharmaceuticals, Inc. ("Amphastar"), International Medication Systems, Ltd., Actavis, and Watson Pharma, Inc. (collectively, and for simplicity, "Amphastar") for infringement of U.S. Patent No. 7,575,886 ("the '886 patent") and declaratory judgment of infringement.[1]

[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.

I. Background

The facts of this case have previously been extensively described both by this Court and by the United States Court of Appeals for the Federal Circuit and need not be repeated at length here. In brief, 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. Amphastar received FDA approval to market its generic enoxaparin product on September 19, 2011.

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 Amphastar infringes the '886 patent by manufacturing generic enoxaparin for commercial sale using the claimed methods of the patent.

II. Procedural History

Plaintiffs filed the instant action on September 21, 2011, two days after Amphastar received FDA-approval of its generic enoxaparin product. Shortly thereafter, plaintiffs moved for a temporary restraining order and preliminary injunction to prevent Amphastar from marketing its product, which the Court allowed. Defendants appealed that ruling to Federal Circuit. On January

25, 2012, the Federal Circuit stayed the preliminary injunction pending appeal.

This Court held a joint Markman hearing in this case and Momenta Pharm. Inc, v. Teva Pharm., C.A. No. 11-cv-12079-NMG, in May, 2012, and issued a Markman Order in June, 2012. On August 3, 2012, the Federal Circuit vacated the preliminary injunction. Shortly thereafter, on August 14, 2012, at the request of the parties, this Court stayed the case pending an en banc appeal in the Federal Circuit. In November, 2012, the Federal Circuit denied the petition for an en banc hearing. Amphastar then filed a motion to remove the stay. This Court delayed ruling on that motion due to a petition for certiorari to the Supreme Court in Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1303 (Fed Cir. 2011), which also raised issues relating to the so called "safe-harbor" under 35 U.S.C. § 271(e)(1) ("§ 271(e)(1)"). After the Supreme Court denied cert in Classen, this Court lifted the stay in this case on January 15, 2013.

On January 16, 2013, Amphastar moved for Summary Judgment and Judgment on the Pleadings. Recently, Momenta requested leave to amend its infringement contentions and on July 1, 2013 the Court heard oral argument on both motions and took the matter under advisement. The Court now announces its ruling on both motions.

III. Federal Circuit Decision

In overturning this Court's determination that Momenta had proven a likelihood of success on the merits sufficient to warrant a preliminary injunction, the Federal Circuit ruled that the "safe harbor" provision of § 271(e)(1) applied to this case. That provision states that

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

In interpreting § 271(e)(1), the Federal Circuit explained that Congress broadly defined the scope of the safe harbor and thus the protection provided by the safe harbor is not limited to "activities necessary to seek approval of a generic drug", but rather encompasses all "materials the FDA demands in the regulatory process." Momenta Pharm. v. Amphastar Pharm., 686 F.3d 1348, 1356 (2012). Therefore, the Federal Circuit determined that even post-FDA approval activities are covered by the safe harbor, as long as they are "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs." Id. at 1358-60.

Citing the requirements in 21 C.F.R. § 211.180(a) that testing records from each batch of generic enoxoparin must be

"retained for at least 1 year after the expiration date of the batch" and in 21 C.F.R. § 211.180(c) that those records "shall be readily available for authorized inspection" by the FDA, the Federal Circuit held that the requirement to maintain records for FDA inspection satisfies the "requirement that the uses be reasonably related to the development and submission of information to the FDA." The Federal Circuit also held that "the fact that the FDA does not in most cases actually inspect the records does not change" that reasoning. Momenta, 686 F.3d at 1357 (citing § 271(e)(1)).

In light of it's decision the Federal Circuit instructed this Court to consider on remand

> whether Momenta's admission that Amphastar's use of the patented invention is to 'satisfy the FDA's requirements' makes this case amenable to summary judgment of non-infringement in favor of Amphastar.

Momenta Pharma. v. Amphastar Pharma., 686 F.3d 1348, 1361 (Fed. Cir. 2012).

IV. 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

[2] Although defendants filed a motion for Judgment on the Pleadings and Summary Judgment, in light of the fact that the Federal Circuit requested that this Court consider whether the case is "amenable to summary judgment of non-infringement", and the fact that the outcome would be the same, the Court treats the motion as one for Summary Judgment.

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).

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

i. 35 U.S.C. § 271(e)(1)

In their Complaint plaintiffs alleges that Amphastar must be infringing the '886 patent because the Food and Drug Administration ("FDA") requires Amphastar to perform the methods claimed in the patent. Defendants move for summary judgment on the grounds that all of their allegedly infringing activity is subject to the § 271(e)(1) safe harbor and thus cannot constitute patent infringement. Plaintiffs oppose on several grounds.

First, plaintiffs argue that summary judgment is not appropriate because the safe harbor does not apply if the FDA has not mandated the use of the particular infringing test. Momenta contends that "Amphastar's use of Momenta's patented process was entirely voluntary" because the FDA has not specifically required Amphastar to use the test covered by the '866 patent. This argument is unavailing. There is no language in § 271(e)(1) that limits the application of the safe harbor to situations in which the FDA has expressly required an applicant to use a particular infringing test. Instead, the Federal Circuit construed the safe harbor such that it provides a "wide berth." Id. at 1356. Thus,

> as long as the use of the patented invention is done to generate information that will be submitted pursuant to a relevant federal law, that use falls within the safe harbor.

Id.

Furthermore, the Federal Circuit explicitly held that the safe harbor "does not mandate the use of a noninfringing alternative when one exists." Momenta, 686 F.3d at 1359. The Court further noted that Momenta is

> incorrect that the possibility that the FDA would accept the use of other, non-patented, testing methods for the development and submission of information precludes Amphastar from relying on the safe harbor in this case.

Id. at 60. Moreover, if the safe harbor covered only infringing tests that are required by the FDA, it would be in conflict with the Supreme Court's holding in Merck v. Integra Lifesciences I, LTD, 545 U.S. 193 (2005). In that case the Court held that pre-filing tests that were not ultimately submitted to the FDA were still covered by the safe harbor because such pre-filing tests could never have been required by the FDA.

Second, plaintiffs argue that Amphastar's "[r]outine, post-approval recordkeeping" is not "submission of information" to the FDA because Amphastar does not actually "submit" these results and thus such maintenance is not covered by the safe harbor. Plaintiffs cite numerous dictionary definitions to attempt to distinguish "submission" from mere "maintenance". These definitions do not, however, negate the fact that the Federal Circuit expressly held that the maintenance of records for FDA inspection "satisfies the requirement that the uses be reasonably related to the development and submission of information to the

FDA." Id. at 1357 (emphasis added). The Court further noted that "the fact that the FDA does not in most cases actually inspect the records does not change" the fact that the records are reasonably related to "submission" of information to the FDA. Id. (citing Merck, 545 U.S. 193 at 207).

Momenta also avers that Amphastar's alleged use of the patented method during manufacturing "so that it can sell [enoxaparin] and earn profit" makes that use not "solely" for "uses reasonably related to the development and submission of information" to the FDA. Plaintiffs assert that Amphastar's routine commercial manufacturing conducted "long after FDA approval" therefore makes that use "well beyond" the reach of the safe harbor. Unfortunately for plaintiffs, the Federal Circuit found that such an argument is "not a tenable reading of the statute" and is "contrary to precedent." Id. at 1360. For example, the Federal Circuit has previously held that "alternate uses [of test data] are irrelevant to [the] qualification to invoke the section 271(e)(1) shield" because the safe harbor allows alleged infringers to use test data for "more than FDA approval." Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1030 (Fed. Cir. 1997). Defendants' activities are thus protected by the safe harbor.

ii. 35 U.S.C. § 271(g)

Momenta also asserts that summary judgment of non-

infringement is inappropriate on the ground that defendants are conducting infringing activity under 35 U.S.C. § 271(g). That statute provides, in relevant 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 argue 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.

Plaintiffs rely on the plain language of 35 U.S.C. § 271(g) to contend that the statute "makes no distinction between the use of a patented process inside or outside the United States." Such an argument ignores the fact that the Federal Circuit has explicitly stated that § 271(g)

> requires importation or sale of the product of a patented process practiced abroad, before infringement can be established under that provision.

Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 576 F.3d 1348, 1369 (Fed. Cir. 2009). That reasoning is supported by the language of § 271(g) which provides that it is only applicable to the infringement of a process patent if "there is no adequate remedy under this title for infringement." Section 271(a) applies to the making or use of a patented invention within the United States, and therefore § 271(g) would not apply in those circumstances. Because there is no suggestion that Amphastar manufactures enoxaparin abroad, § 271(g) is inapplicable in this

case. As a result, Amphastar cannot be liable for infringement pursuant to § 271(g).

V. Motion to Amend Infringement Contentions

In their preliminary Infringement Contentions served on February 7, 2012, plaintiffs accused two of Amphastar's procedures: the "Approved 15-25% Procedure" which Amphastar performed at the time of FDA approval, and its "Revised 15-25% Procedure" which it adopted after FDA approval. In its Amended Infringement Contentions served on February 12, 2013, Momenta accuses two additional Amphastar procedures. The first is the Disaccharide Building Block Procedure ("DBB test"). The DBB test is the same as the two 15-25% procedures 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. The second test plaintiffs seek to add is the "Batch-to-Batch" procedure. This method seems to involve a simple comparison between the results obtained through one of the other three tests on a particular batch of enoxaparin and the results obtained on another batch.

In its Second Amended Infringement Contentions served on May 24, 2013, Momenta added further documentary support for the newly added infringement contentions. Momenta now seeks leave from the Court for both its Amended and Second Amended Infringement Contentions having failed to seek leave prior to serving them as

required by the scheduling order in this case (Docket No. 139).

A. Standard

A scheduling order may be modified only for good cause and with the judge's consent. Fed. R. Civ. P. 16(b)(4). In determining whether to grant leave to amend, a court generally considers 1) the explanation for the 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 Enterprises, L.L.C. v. SouthTrust Bank of Alabama, NA, 315 F.3d 533, 536 (5th Cir. 2003).

B. Application

The Court is concerned by Momenta's allegations that the documents necessary to discover the additional tests were intentionally concealed by defendants, possibly in violation of a court order. Despite those concerns, however, the Court will deny the motion to amend because the proposed amendments would be futile in any event.

First, the reasoning of this Court's summary judgment holding that the 271(e)(1) safe harbor provision applies to the 15-25% procedures also applies to the DBB test. Despite plaintiffs contention that the "FDA has no requirement that Amphastar use a method that infringes the '886 patent" the FDA did actually require defendants to perform the DBB test as part

of their ANDA application, in addition to performing the 15-25% tests. Thus, such testing as required by the FDA cannot constitute infringement. Any post-approval DBB testing is also covered by the safe harbor because, as explained by the Federal Circuit, the resulting maintenance of test records for FDA inspection "satisfies the requirement that the uses be reasonably related to the development and submission of information to the FDA." Momenta, 686 F.3d at 1357.

Second, plaintiffs' proposed amendment to add the batch-to-batch test would also be futile. Plaintiffs assert that because no records are kept, and thus there is no possible submission of information to the FDA, the batch-to-batch test does not qualify for the 271(e)(1) safe harbor and as such assert that the amendment would not be futile.

This Court is, however, skeptical that the so called batch-to-batch test is even a separate testing procedure. It apparently involves a simple comparison of results of previously conducted release tests across multiple batches of enoxaparin to identify trends. No records are created precisely because no additional testing is conducted. Because the "test" simply involves comparing data that has already been produced it cannot possibly require repeating all of the steps of the '866 patent that would be required for infringement. E.g. EMI Group N. Am., Inc. v. Intel Corp., 157 F.3d 887, 896 (Fed.Cir.1998)("For

infringement of a process invention, all of the steps of the process must be performed, either as claimed or by an equivalent step.") As a result, a mere comparison of already produced data could not possibly infringe the '866 patent.

Plaintiffs argue that the declaration of their expert Dr. Jian Liu provides "a detailed, step-by-step explanation of why the Batch-to-Batch Procedure infringes claim 1 of the '866 patent." Yet, his declaration states only that Amphastar conducts a "batch to batch comparison of its release test results." Noticeably Dr. Liu does not even refer to that step as a separate "batch-to-batch test" nor does he distinguish it as a separate test rather than a procedure conducted following the 15-25% analysis.

Finally, it is illogical to suggest that conducting the original release tests is not an act of infringement due to the safe harbor but simply looking at the data produced by those tests is somehow an act of infringement. Therefore, plaintiffs proposed amendment would be futile and the motion will be denied.

ORDER

In accordance with the foregoing,

1) Defendants' Motion for Summary Judgment (Docket No. 346) is **ALLOWED**, and

2) Plaintiffs' Motion for Leave to Amend Infringement Contentions (Docket No. 456) is **DENIED.**

So ordered.

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

Dated July 19, 2013