

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 AND ORDER

GORTON, J.

Pending before the Court are three motions arising out of the patent infringement suit filed by plaintiffs Momenta Pharmaceuticals, Inc. and Sandoz Inc. (collectively, and for simplicity, "Momenta") against defendants Amphastar Pharmaceuticals, Inc., International Medication Systems, Ltd., Actavis, Inc. and Watson Pharma, Inc. (collectively, and for simplicity "Amphastar"). Momenta alleges that Amphastar infringes U.S. Patent No. 7,575,886 ("the '886 patent") but has abandoned its claim that Amphastar infringes U.S. Patent No. 7,790,466 ("the '466 patent").

The instant dispute involves the surety bond posted by Momenta to cover Amphastar's damages arising from an October 7,

2011 Temporary Restraining Order and an October 28, 2011 preliminary injunction ("the injunctions"). Amphastar has moved to enforce the bond and Momenta urges the Court to defer consideration of that motion until the United States Court of Appeals for the Federal Circuit reviews the entry of summary judgment in favor of Amphastar. Amphastar also seeks an order requiring Momenta to post an additional surety to account for interest on the bond and other damages caused by the delay.

I. Background and Procedural History

The dispute concerns a generic version of Lovenox (otherwise known as enoxaparin), an anticoagulant used to prevent blood clots. The '886 patent, which issued in 2009 and has been assigned to Momenta, 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.

The Food and Drug Administration ("FDA") approved Momenta's application to market generic enoxaparin in July, 2010 and approved Amphastar's application to market its own generic enoxaparin in September, 2011. Two days after Amphastar received FDA approval, Momenta moved for a temporary restraining order and preliminary injunction to prevent Amphastar from marketing its product on the grounds that Amphastar used

Momenta's patented tests as part of its process for manufacturing generic enoxaparin.

In October, 2011, the Court entered a temporary restraining order against Amphastar and, shortly thereafter, allowed Momenta's motion for a preliminary injunction. The Court found that Momenta had established that it was likely to succeed on the merits of its infringement claim. Moreover, it rejected Amphastar's argument that the allegedly infringing activity fell within the safe harbor provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(1), which provides that

It shall not be an act of infringement to make, use, offer to sell or sell...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....

35 U.S.C. § 271(e)(1). The Court found the safe harbor provision inapplicable based upon a contemporaneous Federal Circuit opinion that held that § 271(e)(1) does not apply to information that "may be routinely reported the FDA, long after marketing approval has been obtained." Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1070 (Fed. Cir. 2011). It reasoned that because Amphastar had already received FDA approval to market the drug, its alleged continuing use of the patented method did not fall within the safe harbor.

The Court's Order enjoined Amphastar from advertising, offering for sale or selling in the United States any generic

enoxaparin product alleged to infringe the '886 patent. As a condition for the injunctive relief, the Court required Momenta to post two surety bonds in the amounts of \$50,000 and \$100,000,000 for the temporary restraining order and the preliminary injunction, respectively. The Court subsequently denied two motions to stay or dissolve the preliminary injunction filed by Amphastar.

Amphastar filed an interlocutory appeal of the Order entering the preliminary injunction and the denial of its motions to stay or dissolve the injunction to the Federal Circuit. The Federal Circuit stayed the preliminary injunction in January, 2012 and vacated it in August, 2012, finding this Court's interpretation of the safe harbor provision to be unduly narrow. It reasoned that Momenta was unlikely to prevail on its infringement case because Amphastar's "release testing" likely fell under the Patent Act's safe harbor provision. The court specifically explained that

Momenta concedes that Amphastar's tests "are conducted in order to satisfy the FDA's requirements that each batch of enoxaparin that is sold commercially after FDA approval is actually the same as the brand name drug." Under a proper construction of 35 U.S.C. § 271(e)(1), the fact that Amphastar's testing is carried out to "satisfy the FDA's requirements" means that it falls within the safe harbor, even though the activity occurs after approval.... The district court's interpretation of § 271(e)(1) was erroneous. Under the correct interpretation, Momenta cannot establish a likelihood of success on infringement and the preliminary injunction must be vacated.

Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1359 (Fed. Cir. 2012) (internal citations omitted).

The Federal Circuit denied Momenta's petition for an en banc hearing in November, 2012. The Supreme Court denied a petition for certiorari in June, 2013.

After the case was remanded and the parties took further discovery, Amphastar moved for summary judgment. Momenta argued in its opposition to that motion that evidence developed subsequent to the preliminary injunction proceedings revealed that 1) Amphastar sold generic enoxaparin made using the process claimed in the '886 patent that rendered Amphastar liable for infringement under 35 U.S.C. § 271(g) and 2) Amphastar used the patented methods in ways that were not required by the FDA and did not keep records of such uses.

In July, 2013, this Court entered summary judgment in Amphastar's favor, finding that its accused tests fell under the safe harbor provision and therefore did not infringe. It rejected Momenta's argument that the FDA did not require the particular test at issue because the Federal Circuit had explicitly held in its opinion vacating the preliminary injunction that the safe harbor "does not mandate the use of a noninfringing alternative when one exists." Momenta, 686 F.3d at 1359. It also found Momenta's § 271(g) argument inapplicable because the Federal Circuit has interpreted that provision to

require importation or sale of a product manufactured through the practice of a patented process abroad. The Court entered final judgment on Momenta's infringement claims in January, 2014 and the parties' cross-appeals are pending before the Federal Circuit.

In December, 2013, Amphastar moved to enforce liability on the surety bonds ("the bond motion"). Shortly thereafter, before its responsive pleading was due, Momenta filed an emergency motion to defer consideration of Amphastar's motion pending exhaustion of Momenta's appeal ("the motion to defer"). This Court heard argument on those motions at a January, 2014 hearing and took the matter under advisement. It later informed the parties the deadline for Momenta to respond to Amphastar's bond motion was suspended pending resolution of Momenta's motion to defer.

In February, 2014, Amphastar filed a renewed motion to enforce liability on the bonds in which it requests that the Court order Momenta to post an additional bond to compensate Amphastar for interest and other damages attributable to the delay ("the renewed bond motion").

II. Motions with respect to Momenta's liability on the bonds

Momenta submits that the bond motion will not be ripe for resolution until the Federal Circuit decides Momenta's appeal and, even if the issue is ripe, the Court should exercise its

discretion and defer its consideration until the Federal Circuit resolves the matters currently on appeal. It also maintains that it is entitled to conduct discovery on damages before it can be required to respond to Amphastar's bond motion.

A. Jurisdiction over the bond motion

1. Legal standard

The bond at issue in this case was provided pursuant to Fed. R. Civ. P. 65(c) which states, in relevant part, that

The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.

Fed. R. Civ. P. 65(c) (emphasis added). The United States Court of Appeals for the First Circuit has held that a party is wrongfully enjoined when it had the right to do all along what it was enjoined from doing. Global NAPs, Inc. v. Verizon New England, Inc., 489 F.3d 13, 22 (1st Cir. 2007).

Fed. R. Civ. P. 65.1, in turn, governs proceedings against a surety bond and provides that "[t]he surety's liability may be enforced on motion without an independent action." Fed. R. Civ. P. 65.1. The First Circuit has described Fed. R. Civ. P. 65.1 as providing a "summary procedure for the enforcement of liability against a surety." Id. at 20. Moreover, the surety requirement and the summary procedure for enforcing liability on the surety are generally understood to serve the purpose of

assur[ing] the enjoined party that it may readily collect damages from the funds posted or the surety provided in the event that it was wrongfully enjoined, without further litigation and without regard to the possible insolvency of the assured

Id. at 21 (quoting Continuum Co. v. Inceptis, Inc., 873 F.2d 801, 803 (5th Cir. 1989)).

2. Application

Momenta argues that the bond motion is not ripe for consideration at this time because Momenta's appeal of this Court's decision to award summary judgment to Amphastar is pending before Federal Circuit. It maintains that a decision by the Federal Circuit on the merits in favor of Momenta would mean that Amphastar was not "wrongfully enjoined" in the first place.

Amphastar responds that the Federal Circuit resolved the question of whether Amphastar was "wrongfully enjoined" when it vacated the preliminary injunction in August, 2012 on the grounds that it was based on an incorrect interpretation of the § 271(e)(1) safe harbor provision. It adds that even if the initial order vacating the injunction was insufficient, rulings subsequent to that order were more than sufficient, namely, 1) the Federal Circuit's denial of the request to rehear the case en banc, 2) the Supreme Court's denial of certiorari and 3) this Court's entry of summary judgment in favor of Amphastar.

The parties appear to agree that the controlling precedent is Global NAPs, Inc. v. Verizon New England, Inc., 489 F.3d 13

(1st Cir. 2007), but they disagree about the nature of that precedent and its bearing upon this case.

a. Global NAPs

Global NAPs arose out of the failure of Global NAPs to make required payments to Verizon and Verizon's threats to terminate its services as a result. In 2005, following an initial merits appeal to the First Circuit, the district court entered a preliminary injunction, conditioned on the posting of a surety bond, to prevent Verizon from disconnecting services to Global NAPs until the court resolved the merits of the parties' claims. Id. at 16. The court ultimately entered summary judgment in favor of Verizon and against Global NAPs and later confirmed that the ruling on summary judgment dissolved the preliminary injunction. Id. It allowed a motion by Global NAPs for an injunction pending appeal, however, and Global NAPs posted an additional security. Id. at 16-17.

In April, 2006, the First Circuit affirmed the district court's award of summary judgment to Verizon (Global NAPs II). Id. at 17. Shortly thereafter, the First Circuit vacated the injunction that had been entered pending appeal and later denied Global NAPs' motion to reconsider the motion to vacate the injunction. Id. On the same day that the injunction was vacated, Verizon moved the district court to release the security. Id. at 18. One week later, the First Circuit denied

Global NAPs' petition for rehearing and rehearing en banc. Id. at 17 n.2. In May, 2006, the First Circuit issued its mandate. Id. at 18. The district court allowed Verizon's motion the following day and released the full \$16 million security to Verizon. Global NAPs appealed both rulings. Id.

On appeal, the First Circuit first clarified that a party is wrongfully enjoined when "it had a right all along to do what it was enjoined from doing." Id. at 22. In so ruling, it rejected the argument that a party is wrongfully enjoined only if the court that entered the injunction abused its discretion in doing so. Id. Applying that rule to the injunction at issue, the court found that

the issue of whether Verizon was wrongfully enjoined was determined when we issued our opinion in [Global NAPs II] and rejected [Global NAPs'] arguments on the merits of its position. We then vacated the injunction because Verizon was entitled, and had been entitled all along, to cut off services to [Global NAPs].

Id. at 23 (emphasis added). The First Circuit also rejected Global NAPs' argument that the district court erred in releasing the entire \$16 million security to Verizon before the First Circuit addressed, on appeal, whether Verizon was in fact entitled to \$16 million in damages based on the wrongful injunction. It explained that

[d]issolution of an injunction is itself a final determination which permits a party to seek security posted with respect to the injunction.

Id. at 22 n.6.

b. Arguments

Momenta argues that Global NAPs held that a party is deemed to be “wrongfully enjoined” only when all issues relating to the merits of the case have been decided on appeal. It relies upon the First Circuit’s statement that the issue of whether Verizon was wrongfully enjoined was

determined when we issued our opinion in [Global NAPs II] and rejected [Global NAPs’] arguments on the merits of its position.

Id. at 23. Momenta adds that the posture of this case requires the Federal Circuit to reach the merits of this Court’s summary judgment ruling. First, it notes that the Federal Circuit’s ruling that vacated the preliminary injunction 1) was made on an interlocutory appeal, 2) was based on an incomplete record and 3) did not resolve all issues in the case. Furthermore, it notes that it raised new factual and legal arguments on summary judgment that were not previously considered by the Federal Circuit and that, if resolved in Momenta’s favor, would show that Amphastar was not wrongfully enjoined from selling its generic enoxaparin product in the first place.

Amphastar responds that Fed. R. Civ. P. 65(c) and 65.1 do not require a party to exhaust all potential appeals on the merits before enforcing a security bond and Global NAPs does not

require otherwise. Instead, it suggests, Global NAPs should be read as requiring only that the injunction be dissolved, regardless of whether the injunction is dissolved by an adverse decision on the merits, as in Global NAPs, or by a ruling vacating the injunction as improvidently granted, as in this case. In support of its position, it points to the First Circuit's explanation that dissolving an injunction is a "final determination" that permits a party to enforce liability on the bond that secured the injunction. Id. at 22 n.6.

c. Analysis

This case presents a close call where 1) the Federal Circuit held in no uncertain terms that Momenta was not entitled to the preliminary injunction awarded by this Court, 2) Momenta's requests for further review were denied by the Federal Circuit and the Supreme Court and 3) this Court awarded summary judgment in favor of Amphastar based on the Federal Circuit's interpretation of the safe harbor provision. Nevertheless, the Court agrees with Momenta that it lacks jurisdiction to consider Amphastar's motion until the Federal Circuit resolves Momenta's appeal on the merits. Momenta raised new factual and legal arguments on remand that, if decided in its favor, would establish that it was entitled to the injunction in the first place because Amphastar never had a right to do what it was enjoined from doing. Thus, the ruling vacating the injunction

was, on these facts, not decisive of whether Amphastar was “wrongfully enjoined.”

The Court is not persuaded by Amphastar’s argument that the Federal Circuit’s ruling vacating the injunction was dispositive of whether the injunction was wrongfully entered. It disagrees with Amphastar that Global NAPs established that “dissolution of an injunction is itself a final determination” permitting a district court to release a security posted to secure the injunction. See id. That language must be read in its proper context which is the First Circuit’s rejection of Global NAPs’ argument that the security could not be released until the First Circuit considered on appeal whether Verizon was in fact entitled to the full amount in damages. It does not establish that a dissolved injunction was necessarily wrongfully issued.

Nor is the Court convinced that its subsequent entry of judgment on the merits in favor of Amphastar resolved the matter. Global NAPs suggests that the issue was ripe only after the First Circuit upheld the district court’s merits ruling. Other decisions from outside of the First Circuit do not persuade the Court that its interpretations of Global NAPs and Fed. R. Civ. P. 65(c) and 65.1 are incorrect. See, e.g., Nokia Corp. v. InterDigital, Inc., 645 F.3d 553, 559 (2d Cir. 2011) (explaining that “[n]either party seems to dispute that InterDigital was wrongfully enjoined” in appeal from district

court's release of the surety after dismissing the case on remand where Second Circuit had previously vacated an injunction and the record was unchanged on remand to the district court); Blumenthal v. Merrill Lynch, 910 F.2d 1049, 1054-55 (2d Cir. 1990) (holding that arbitrators' decision to vacate injunction entered by district court was an "ultimate decision on the merits" that compelled the conclusion that the preliminary injunction was "wrongful"); Pro Edge L.P. v. Gue, 451 F. Supp. 2d 1026, 1023 & n.3 (N.D. Iowa 2006) (noting that conclusion that bond motion was ripe was bolstered by the Eighth Circuit's "succinct denial of the plaintiff's petition for permission to file an interlocutory appeal"); but see Pabst Brewing Co. v. Corrao, 999 F. Supp. 1242, 1243-44 (E.D. Wis. 1998) (declining to release surety as matter of discretion but finding jurisdiction over the matter despite pending appeal of order vacating injunction).

To be clear, in so holding, the Court declines to adopt a per se rule that a party cannot be said to have been "wrongfully enjoined" under Fed. R. Civ. P. 65(c) until the party that posted the security has exhausted all of its appeals on the merits of the case. It holds only that, on these facts, the issue of whether Amphastar was wrongfully enjoined is not ripe.

Furthermore, even if this Court had jurisdiction over the bond motion at this time, it would be inclined to defer

consideration to the extent that it had the discretion to do so. See Pabst Brewing Co. v. Corrao, 999 F. Supp. 1242, 1243-44 (E.D. Wis. 1998) (declining to release surety as matter of discretion in light of pending appeal of order vacating injunction). Given the possibility that this Court's Order of summary judgment could be reversed on appeal, which would obviate the need to litigate the pending motion to enforce liability, the Court believes that it would be appropriate to avoid the time and expense involved by deferring consideration until the Federal Circuit decides Momenta's appeal.

B. Conclusion

Because the Court finds that Amphastar's motion is not ripe for consideration and declines to exercise jurisdiction in any event, it forgoes the issue of whether Momenta is entitled to additional discovery before it can be required to file a responsive pleading. Momenta's motion to defer consideration will be allowed and Amphastar's motion to enforce liability on the bonds will be denied without prejudice. Amphastar may renew its motion after the Federal Circuit resolves Momenta's appeal from this Court's entry of final judgment.

III. Amphastar's request for an additional bond

In a subsequent "renewed motion" to enforce Momenta's liability on the bonds, Amphastar requests that the Court order Momenta to post an additional security "to account for the lost

interest and delay damages" that continue to accrue. The Court declines to do so, because:

1) Local Rule 62.2 is inapplicable in that the bond has yet to be reduced to a money judgment and

2) modification of the bond or security pursuant to Local Rules 67.1(h) and 67.1(i) is unwarranted. The Court concludes that requiring an additional bond would not be in keeping with the purpose of Fed. R. Civ. P. 65(c) to "provide the plaintiff with notice of the maximum extent of its potential liability." Global NAPS, 489 F.3d at 21 (citing Continuum, 873 F.2d at 803).

ORDER

In accordance with the foregoing,

- 1) Defendants' motion to enforce liability on bonds for damages arising from wrongfully-issued TRO and preliminary injunction (Docket No. 521) is **DENIED WITHOUT PREJUDICE**;
- 2) Plaintiffs' motion to defer consideration of motion to enforce liability on the bonds (Docket No. 530) is **ALLOWED**; and
- 3) Defendants' renewed motion to enforce liability on the bonds (Docket No. 594) is **DENIED**.

So ordered.

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

Dated March 12, 2014