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. (collectively, "the plaintiffs") bring suit against Amphastar Pharmaceuticals, Inc. ("Amphastar"), International Medication Systems, Ltd. ("IMS") and Watson Pharmaceuticals, Inc. ("Watson") (collectively, "the defendants") for patent infringement.

On October 28, 2011, this Court allowed plaintiffs' motion for a preliminary injunction based on alleged infringement of U.S. Patent No. 7,575,886 ("the '886 patent"). Before the Court is the defendants' emergency motion to stay or dissolve that preliminary injunction.

III. Analysis

Pursuant to Federal Rule of Civil Procedure 62(c), the Court has discretion to stay enforcement of a preliminary injunction when appropriate. To determine if a stay is warranted, the court considers: (1) whether the moving party has demonstrated a strong showing that he is likely to succeed on the merits, (2) whether the moving party will be irreparably injured absent a stay, (3) whether the stay would substantially injure the other parties, and (4) where the public interest lies. Standard Havens Prods., Inc. v. Gencor Indus., Inc., 897 F.2d 511, 512 (Fed. Cir. 1990). No one factor is determinative and all may be considered on a sliding scale. Id. at 512-13. The Federal Circuit has stated:

> To obtain a stay, pending appeal, a movant must establish a strong likelihood of success on the merits or, failing that, nonetheless demonstrate a substantial case on the merits provided that the harm factors militate in its favor. In deciding whether to grant a stay, pending appeal, this court assesses the movant's chances of success on the merits and weighs the equities as they affect the parties and the public.

Eon-Net, L.P. v. Flagstar Bancorp, Inc., 222 Fed. Appx. 970, 971-72 (Fed. Cir. 2007) (internal citation and quotation omitted).

The Court concludes that defendants have not met their burden to obtain a stay of the preliminary injunction pursuant to Rule 62(c). First, defendants have not demonstrated a strong likelihood of success on the merits. The Court is unpersuaded by defendants' contentions that the legal standard for issuance of a

preliminary injunction was misapplied or that the contested claims were misconstrued. Moreover, for essentially the same reasons stated in the Memorandum and Order issued in conjunction with the Preliminary Injunction, the Court does not agree that the patent's identification of the 1,6-anhydro structure by its associational status raises a substantial question regarding validity.

Second, the Court remains convinced that defendants have failed to demonstrate irreparable injury absent a stay. The significant bond in place ($100,000,000) is adequate protection in the event the patent is later found to be invalid or otherwise not infringed.

Although the defendants motion fails under Fed. R. Civ. P. 62(c), the Court will consider whether relief from the preliminary injunction is warranted under Fed. R. Civ. P. 60(b) because defendants have now proffered new evidence on the issue of irreparable harm. Rule 60(b) states, in relevant part:

> On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons: (5) applying [the judgment] prospectively is no longer equitable; or (6) any other reason that justifies relief.

A preliminary injunction is a "judgment". See Fed. R. Civ. P. 54(a) ("'[J]udgment' as used in these rules includes a decree and any order from which an appeal lies."). According to the First Circuit, Rule 60(b) is "a vehicle for extraordinary relief"

and "motions invoking the rule should be granted only under exceptional circumstances." Silva v. Massachusetts, Nos. 08-1956, 08-2559, 2009 WL 2902712, at *9 (1st Cir. 2009). Rule 60(b)(5) requires a moving party to show it is no longer equitable that the judgment should have prospective application and that there has been a significant change in circumstances. See Concilio de Salud Integral de Loiza, Inc. v. Perez-Perdomo, 551 F.3d 10, 16 (1st Cir. 2008). Rule 60(b)(6) is a catch-all provision which allows relief only in exceptional circumstances. See Aspect Software, Inc. v. Barnett, 787 F. Supp. 2d 118, 132-33 (D. Mass. 2011).

When issuing the preliminary injunction, this Court determined that the plaintiffs had demonstrated a likelihood of success on the merits, applied a presumption of irreparable harm and held that plaintiffs had submitted specific evidence to support a finding of irreparable harm absent such a presumption.[1] It accepted plaintiffs' contention that allowing Amphastar to enter a market in which plaintiffs sold the only generic enoxaparin product would result in harm to plaintiffs in the form

[1] Although not critical to the finding of irreparable harm, application of that presumption was ill-advised. As defendants point out, the Federal Circuit held two weeks prior to the imposition of the preliminary injunction that the Supreme Court's decision in eBay Inc. v. MercExchange, LLC, 547 U.S. 388 (2006) "jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief." See Robert Bosch LLC v. Pylon Mfg. Corp., No. 2011-1096, 2011 WL 4834266, at *4 (Fed. Cir. Oct. 13, 2011).

of price erosion, related loss of customer goodwill, lost market share, loss of market capitalization, reputational injury and threats to both the funding of ongoing research development and the hiring and retention of critical scientific talent. It concluded that although some of the harm alleged was compensable through money damages, allegations of price erosion, loss of goodwill and reputational injury likely were not.

That decision was reached on October 28, 2011. Defendants now direct the Court's attention to a press release issued by Momenta on October 24, 2011 confirming that Sanofi-Aventis ("Sanofi"), the manufacturer of the brand-name product, Lovenox, launched an authorized generic in the fourth quarter of 2011 through its generic arm, Winthrop Pharmaceuticals ("Winthrop"). The effect of such a launch was two-fold: first, Momenta's share from sales of generic enoxaparin shifted from a partnership to a hybrid royalty/profit sharing arrangement, and second, the authorized generic was offered at a significantly lower price than plaintiffs' generic product. Plaintiffs apparently had to match that lower price to retain at least one major customer.

Defendants contend that these new circumstances warrant a dissolution or stay because 1) the injunction against them did not prevent the launch of an authorized generic as plaintiffs had said it would and 2) the injunction unfairly places defendants' in a "deep-freeze" while the authorized generic alters market

dynamics.

Indeed, plaintiffs have repeatedly asserted that such an authorized generic would be introduced into the market if defendants were not enjoined and would significantly add to their risk of irreparable harm. In early October, plaintiffs stated that "[p]reliminary indications are that sales by Winthrop are imminent" and that the introduction of an authorized generic would permanently and irretrievably alter the enoxaparin market to plaintiffs' detriment. Two weeks later, in support of their motion for a preliminary injunction, plaintiffs declared that the risk of irreparable harm, including the risk that Sanofi would "begin selling" an authorized generic, remained unchanged.

It now appears, however, that Sanofi, through Winthrop, made significant sales of a generic enoxaparin prior to the issuance of either the temporary restraining order or the preliminary injunction. Winthrop apparently made inroads with two major distributors (CVS and McKesson Corporation) and almost a third (Walgreens) just as the temporary restraining order was entered. Sandoz retained the third only by matching Winthrop's price. Then, four days before the Court issued the pending preliminary injunction but after oral argument on plaintiffs' motion, plaintiffs issued a press release announcing that Sanofi was launching an authorized generic. They acknowledge that the launch triggered a change in their collaboration agreement.

Plaintiffs, nevertheless, oppose the dissolution or stay of the preliminary injunction because, they say, 1) defendants' evidence is not "newly discovered" insofar as plaintiffs' announcement was made four days before the injunction was entered, 2) the new information does not relate to any of the reasons stated by the Court for its finding of irreparable harm and 3) sales of the authorized generic have been suspended since the Court enjoined the defendants.

The first two of plaintiffs' arguments are unavailing. First, evidence need not be "newly discovered" to relieve a party of a final judgment under Fed. R. Civ. P. 60(b)(6) or even 60(b)(5), which requires only a significant change in circumstances.[2] Second, the information relates directly to 1) the estimated 85% decline in company-wide revenues that would allegedly result from defendants' launch, 2) Momenta's reputation in the investment community and 3) price erosion and loss of customer goodwill. Indeed, the Court's harm analysis proceeded on the premise that Sandoz marketed the only generic enoxaparin. Plaintiffs' arguments to the contrary are disingenuous.

The third of plaintiffs' arguments does, however, counsel

[2] Plaintiffs' additional contention (that defendants "said nothing about Winthrop's conduct or Momenta's press release" in a post-hearing memorandum filed Wednesday, October 26, 2011) is misleading because the five-page memorandum filed on that date was limited by Court order to a discrete claim construction issue.

against dissolution of the preliminary injunction. Plaintiffs consistently represented to the Court that defendants' sales activity, if not enjoined, would precipitate the launch of an authorized generic which would, in turn, irrevocably alter the status quo to plaintiffs' detriment. Apparently, Sanofi's initial sales were in response to the FDA's approval of Amphastar's generic product and the suspension of such sales has been in response to the injunction. Although those sales have, no doubt, had some effect on the market, it is presumed that a full-blown launch of defendants' generic would have a substantially greater effect.

The Court concludes that, as the record now stands, it is prudent to maintain the status quo during the pendency of this litigation. It will not, therefore, dissolve the preliminary injunction at this juncture. Defendants' motion will be denied without prejudice.

ORDER

In accordance with the foregoing, defendants' motion to stay or dissolve the preliminary injunction pending appeal (Docket No. 96) is **DENIED** without prejudice.

So ordered.

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

Dated November 23, 2011