UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 10-20526-CIV-MORENO

VALEANT INTERNATIONAL (BARBADOS) SRL,

Plaintiff,

vs.

WATSON PHARMACEUTICALS, INC., and WATSON LABORATORIES, INC. -- FLORIDA, and WATSON PHARMA, INC.,

Defendants.
_____/

ORDER DENYING MOTION FOR INJUNCTIVE RELIEF

Valeant International (Barbados), SRL, the prevailing Plaintiff in this patent case is seeking to amend the Court's judgment in its favor to include injunctive relief. Because the Court finds the judgment in this case sufficiently protects the Plaintiff's patents, the Court finds an award of injunctive relief unnecessary.

THIS CAUSE came before the Court upon Plaintiff's Motion for Injunctive Relief **(D.E. No. 187)**, filed on **February 22, 2012**.

THE COURT has considered the motion, the response, and the pertinent portions of the record, and being otherwise fully advised in the premises, it is

ADJUDGED that the motion for injunctive relief is DENIED for the reasons stated in this order and all other pending motions are DENIED as moot.

I. Background

A bench trial was conducted in this dispute in June 2011, and an entry of final judgment was entered in favor of Valeant in November 2011. On December 2, 2011 the prevailing party at trial, Valeant, filed a Rule 59(e) motion to amend the final judgment to include specific language on two issues: (1) to set June 27, 2026, the expiration date of Valeant's patents, as the earliest date on which Watson could seek FDA approval of its generic drug product (declaratory relief); and (2) to permanently enjoin Watson from the commercial manufacture or sale of its generic drug before June 27, 2026 (injunctive relief). This Court denied Valeant's motion to amend the final judgment on the grounds that it had been divested of jurisdiction based on Watson's filing of its appeal to the Federal Circuit on December 7, 2011.

On February 23, 2012, the Court issued a Second Amended Final Judgment to include the declaratory judgment, finding there was jurisdiction because the motion to amend the final judgment predated the notice of appeal. The remaining issue is whether the Court should amend the judgment further to include a claim for injunctive relief.

II. Injunctive Relief

35 U.S.C. § 271(e)(4)(B) says that "injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States. . . of an approved drug. . .." Injunctive relief is permissive under this statute. Valeant also seeks injunctive relief under 35 U.S.C. § 283, which applies generally to all patents.

The parties do not dispute that the legal standard set forth in *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006) applies. At issue is whether Valeant's evidence at trial meets the standard to issue an injunction and whether an injunction is necessary in light of the Court's rulings in this case. In its 2006 *eBay* decision, the Supreme Court held that an award of injunctive relief in

a patent case is subject to the same four-prong analysis as in other cases.

> According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1)that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

Id. Both sides agree that *eBay* eliminated the automatic grant of injuctive relief based solely upon a finding of patent infringement, without more.

Before deciding whether Valeant sufficiently met the traditional test for injunctive relief, Defendant Watson raises the issue of whether injunctive relief is necessary in light of the Court's November 8, 2011 ruling and the subsequent award of declaratory relief. In that order, the Court found that Defendant Watson failed to prove by clear and convincing evidence that Valeant's asserted patent claims were invalid. By virtue of that ruling, Watson will not be able to obtain approval to market its proposed bupropion hydrobromide products until all the patents-in-suit expire. Defendant Watson argues the Court's order prevents it from directly competing with Valeant or usurping Valeant's market share during the patent terms.

Watson argues that ordering a further injunction along the lines of the November 8, 2011 Order would additionally expose Watson to the threat of contempt proceedings. Relying primarily on *Alcon, Inc. v. TEVA Pharmaceuticals USA, Inc.*, 2010 WL 3081327 (D. Del. Aug. 5, 2010), Watson argues the Court should deny the motion to amend to include an award of injunctive relief – a ruling that would mirror that in *Alcon*. In *Alcon, Inc.*, the district court found that the patent was valid and that the defendant had infringed the patent. Like in this case, the plaintiff, Alcon, Inc., moved to amend the judgment to include a declaration of the effective date of the ANDA and for

injunctive relief under 35 U.S.C. § 271(e)(4)(B). The *Alcon, Inc.* court granted the declaratory relief, but denied injunctive relief finding that the plaintiff had not made the necessary showing of irreparable harm under *eBay*. The court reasoned that an injunction was unnecessary in light of the court's granting declaratory relief.

By contrast, Plaintiff Valeant relies on a line of cases granting injunctive relief to patentees in Hatch-Waxman cases. *See Eli Lilly & Co. v. Sicor Pharms., Inc.*, 705 F. Supp. 2d 971, 1011 (S.D. In. 2010), *aff'd,* 426 Fed. Appx. 892 (Fed. Cir. 2011); *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, No. 07-1000, 2010 WL 4596324, at *36 (D.N.J. Nov. 15, 2010). Plaintiff argues that all Hatch-Waxman cases involve a direct competitor attempting to take market share by selling a cheaper generic version of the patented drug product, which would create irreparable harm to the prevailing patentee were an injunction not to issue. While this may be true, given the procedural posture of this case, the Court agrees with the analysis of the *Alcon, Inc.* court. After the *eBay* decision, the Federal Circuit and district courts repeatedly have required that such evidence must be presented before an injunction may issue in cases, including pharmaceutical cases, involving generic competition. *See, e.g., Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1347-48 (Fed. Cir. 2006) (vacating district court's decision granting a preliminary injunction, stating that "[W]e do not doubt that generic competition will impact Abbott's sales of Biaxin XL, but that alone does not establish that Abbott's harm will be irreparable.") Under *Abbott*, it is unclear that Plaintiff's showing of generic competition, without more, would establish irreparable harm.

Even if the Court were to find that the evidence of competition establishes irreparable harm, Plaintiff Valeant still does not meet the *eBay* standard for injunctive relief. The Court agrees that its findings of fact, rulings, and declaratory judgment under 35 U.S.C. § 271(e)(4)(A) render injunctive relief unnecessary in this case. The Court's February 22, 2012 Second Amended Final Judgment prohibits Watson from marketing its proposed bupropion hydrobromide products prior to the

expiration of Valeant's Orange Book patents, which currently are set to expire on the same day as Valeant's 992 patent, or June 27, 2026. This prevents Watson from directly competing with Valeant or usurping any market share from Valeant's Aplenzin® products until Valeant's patents expire. In the event there is a violation of the Court's February 22, 2012 Declaratory Judgment, Valeant may file another case in the Southern District of Florida and note this related case.

DONE AND ORDERED in Chambers at Miami, Florida, this 6th day of July, 2012.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Counsel of Record