IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC. and BAUSCH & LOMB PHARMA HOLDINGS CORP. Plaintiffs, v. METRICS, INC., COASTAL PHARMACEUTICALS, INC., MAYNE PHARMA GROUP LIMITED, and MAYNE PHARMA (USA), INC., Defendants.	Civil Action No.: 1:14-cv-03962-JBS-KMW **PLAINTIFFS' BRIEF IN SUPPORT OF MOTION FOR ORDER ENJOINING DEFENDANTS FROM PROSECUTING PARALLEL *INTER PARTES* REVIEW PROCEEDINGS** **Return Date: August 4, 2014**

I. INTRODUCTION

Plaintiffs in the above-captioned patent infringement suit, which arises under the Hatch-Waxman Act, hereby move under the All Writs Act to enjoin pursuit of a subsequently-filed, parallel federal proceeding initiated by Defendants that (1) threatens to disrupt this proceeding, (2) threatens to disrupt the careful balance of competing interests embodied in the Hatch-Waxman statutory scheme, and (3) threatens the jurisdiction of this Court. Specifically, Defendants initially selected the federal district court as the forum to resolve this patent dispute by filing an Abbreviated New Drug Application ("ANDA") containing so-called "Paragraph IV" Certifications that the patents here in suit are invalid. Now Defendants are attempting an end run around the power of this Court to resolve the dispute they provoked by subsequently filing in the U.S. Patent and Trademark Office ("PTO") a request for Inter Partes Review ("IPR") under the recently enacted America Invents Act ("AIA") seeking to invalidate these patents on essentially the same grounds. Because the Hatch-Waxman Act provides a period of only 30 months to litigate this dispute before FDA approval may be granted, this action cannot be stayed to await the outcome of the IPR, which was a mechanism envisioned in the AIA

in non-Hatch-Waxman cases to avoid conflict with proceedings in federal district courts. For at least the reasons set forth below, an order from this Court enjoining Defendants from pursuing this subsequent proceeding is needed to avoid unintended and unforeseen conflict between these two statutory schemes and to protect the power of this Court to resolve this dispute.

II. BACKGROUND

Plaintiffs Senju Pharmaceutical Co., Ltd. ("Senju"), Bausch & Lomb Incorporated ("B+L") and Bausch & Lomb Pharma Holdings Corp. ("B+L Pharma Holdings") (collectively, "Plaintiffs") respectfully move this Court for an order enjoining Defendants Metrics, Inc. ("Metrics"), Coastal Pharmaceuticals, Inc. ("Coastal"), Mayne Pharma Group Limited ("Mayne Pharma"), and Mayne Pharma (USA), Inc. ("Mayne Pharma USA") (collectively, "Defendants") from prosecuting IPR Nos. 2014-01041 and 2014-01043 before the PTO Patent Trial and Appeal Board ("PTAB"). These IPR petitions challenge on alleged obviousness grounds all claims of U.S. Patent No. 8,129,431 ("the '431 patent") and U.S. Patent No. 8,669,290 ("the '290 patent"), which, along with U.S. Patent No. 8,754,131 ("the '131 patent"), are the patents-in-suit in this Hatch-Waxman case. Prior to Metrics' filing of these IPR petitions, Metrics filed an ANDA with Paragraph IV Certifications challenging the '431 and '290 patents on identical obviousness grounds, thereby provoking the present action.[1]

[1] While Metrics has filed IPR petitions challenging the '431 and '290 patents, which are both listed in the U.S. Food and Drug Administration's ("FDA's") Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), Plaintiffs' Complaint in this case also asserts infringement of the '131 patent. Plaintiffs have submitted the '131 patent for listing in the Orange Book and expect the FDA will soon do so. Plaintiffs expect that Metrics will then similarly submit a Paragraph IV Certification with the FDA challenging the validity of the '131 patent on obviousness grounds. To Plaintiffs' knowledge, Metrics has not yet filed an IPR petition challenging the '131 patent before the PTAB. To the extent Metrics submits an IPR petition challenging the '131 patent, Plaintiffs' instant request for injunctive relief would likewise be applicable to such a petition.

The '431, '290 and '131 patents disclose and claim novel formulations of bromfenac, the active pharmaceutical ingredient in the successful ophthalmic drug Prolensa®. (Ex. 1; Ex. 2; Ex. 3.) Prolensa® is approved by the FDA for treatment of post-operative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. (Ex. 4.) Prolensa® received FDA approval in April 2013 and immediately garnered acclaim in the medical community based on highly favorable clinical study data demonstrating "the benefits of the new formulation." (Ex. 5.)

Seeking to capitalize on Prolensa®'s success, at least two different generic drug companies have submitted ANDAs requesting FDA approval for the commercial marketing of generic copies of Prolensa® before the patents-in-suit expire. By letters dated December 19, 2013, and May 13, 2014, Lupin Limited ("Lupin") stated that it had filed an ANDA for a generic version of Prolensa® with Paragraph IV Certifications challenging the '431 and '290 patents, respectively, primarily on validity grounds. (Ex. 6 at ¶ 16; Ex. 7 at ¶ 16.) By filing these Paragraph IV Certifications challenging the '431 and '290 patents, Lupin provoked Hatch-Waxman lawsuits before this Court for infringement of these patents.[2] (Ex. 6; Ex. 7.) These suits remain pending, with fact discovery having begun and contentions and claim construction proceedings pursuant to the New Jersey Local Patent Rules scheduled to proceed shortly. (Ex. 8.)

Nearly four months after the date of Lupin's first Paragraph IV Notice Letter, Metrics sent a letter to Plaintiffs dated March 13, 2014, in which Metrics stated that it also had submitted an ANDA for a generic version of Prolensa® with a Paragraph IV Certification challenging the '431 patent. (Ex. 9.) That letter was an unambiguous admission that Metrics had infringed

[2] Plaintiffs expect that Lupin will also challenge the '131 patent once it is listed in the FDA's Orange Book.

Plaintiffs' patent under 35 U.S.C. § 271(e)(2). Metrics subsequently filed an additional Paragraph IV Certification challenging the '290 patent, with the main thrust of the challenge to both patents centering on validity. (Ex. 10.) By filing these Paragraph IV Certifications challenging the '431 and '290 patents, Metrics, as Lupin had before it, provoked the present Hatch-Waxman lawsuit before this Court for infringement of these patents. (D.I. 1.)

Given that Lupin was the first filer of an ANDA for a generic version of Prolensa® with a Paragraph IV Certification challenging the '431 patent, Metrics—as a later filer—is statutorily blocked by the Hatch-Waxman Act from receiving FDA approval of its ANDA for at least 180 days after Lupin obtains FDA approval, unless Lupin forfeits its 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv). Accordingly, Metrics, knowing that its delay in filing its ANDA would subordinate it to Lupin's 180-day exclusivity period, attempted to circumvent the very provisions of the Hatch-Waxman Act that it had invoked through its Paragraph IV Certification. In its March 13 letter, Metrics stated that it had prepared but not yet filed an IPR petition seeking cancellation of all the claims in the '431 patent. (Ex. 9.) Metrics' letter made clear Metrics' intent to circumvent the judicial framework of the Hatch-Waxman Act and threatened the disruptive filing of the draft IPR petition to extract a commercially favorable agreement from Plaintiffs. (*Id.*) In subsequent non-confidential discussions, Metrics confirmed its intention to procure from Plaintiffs early market entry, either with its ANDA product or with an authorized generic, in derogation of Lupin's 180-day exclusivity period.

Metrics ultimately filed IPR petitions on June 26, 2014—after the present case was filed—challenging all claims of the '431 and '290 patents on alleged obviousness grounds. (Ex. 11; Ex. 12.) By letter dated the same day as Metrics' IPR petitions, Metrics purported to notify Plaintiffs of its Paragraph IV Certifications against the '431 and '290 patents and purported to

provide statements of the factual and legal bases for its obviousness allegations in the present district court litigation. (Ex. 10.) Notably, Metrics' Paragraph IV Notice Letter and its IPR petitions raise identical obviousness allegations. (*Compare* Ex. 10 *with* Ex. 11 and Ex. 12.)

III. LEGAL STANDARDS

While this motion raises a question of first impression relating to the interplay between Hatch-Waxman Act litigation in federal court and IPR proceedings in the PTO, the existing law relating to pursuit of parallel legal proceedings provides useful guidance. In this regard, the All Writs Act gives this Court the power to issue all orders necessary in aid of its jurisdiction, including the power to enjoin a party from pursuing parallel litigation in another forum. 28 U.S.C. § 1651 (1980); *see, e.g., Phillips Beverage Co. v. Belvedere, S.A.*, 204 F.3d 805, 806 (8th Cir. 2000) (affirming district court's authority under the All Writs Act to order defendant to withdraw from a later-filed action before the United States Customs Service); *Carlough v. Amchem Products, Inc.*, 10 F.3d 189, 204 (3d Cir. 1993) (affirming district court's authority under the All Writs Act to order class action plaintiffs to refrain from further prosecution of state court action). A decision to enjoin concurrent proceedings in another forum is predicated on "the proceedings involv[ing] the same parties and issues." *Katz v. Lear Siegler, Inc.*, 909 F.2d 1459, 1463 (Fed. Cir. 1990).

The "first-to-file" rule is also relevant. That rule, which was originally articulated by the Supreme Court in 1824, states that "in all cases of concurrent jurisdiction, the Court which first has possession of the subject must decide it." *Smith v. M'Iver,* 22 U.S. 532, 535 (1824). The Third Circuit formally adopted this rule in *Crosley Corp. v. Hazeltine Corp.,* 122 F.2d 925, 929 (3d Cir. 1941), adding that "the party who first brings a controversy into a court of competent jurisdiction for adjudication should, so far as our dual system permits, be free from the vexation of subsequent litigation over the same subject matter." *Id.* at 930. It is well settled that courts

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