

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

Bayer Schering Pharma AG and Bayer
HealthCare Pharmaceuticals, Inc.,

Plaintiffs and Counterdefendants,

v.

Case No. 1:10-cv-05423-PGG

Lupin Ltd. and Lupin Pharmaceuticals, Inc.,

Defendants and Counterclaimants.

**STIPULATION AND ~~PROPOSED~~ ORDER AND FINAL JUDGMENT REGARDING
DISMISSAL OF CLAIMS AND COUNTERCLAIMS**

Plaintiffs and Counterdefendants Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer"), and Defendants and Counterclaimants Lupin Ltd. and Lupin Pharmaceuticals (collectively, "Lupin"), hereby enter into the following stipulation:

BACKGROUND

This is a patent infringement case arising under the Hatch-Waxman Act concerning Bayer's New Drug Application ("NDA") No. 21-098 on Yasmin® tablets, an Abbreviated New Drug Application ("ANDA") No. 20-1663 filed by Lupin Limited, and patents relating thereto. The Bayer NDA, Yasmin® tablets, the patents, and ANDAs filed by Sandoz, Inc. and Watson Pharmaceuticals, Inc. et al. are the subject of this Court's September 28, 2010 Memorandum Opinion and Order entered in *Bayer Schering Pharma AG et al. v. Sandoz, Inc. et al.*, No. 1:08-cv-03710-PGG-JCF ("the Sandoz/Watson Case"). The parties agree that the decision of this

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Court, embodied in the September 28, 2010, Memorandum and Opinion, provides the legal basis for entry of a final judgment in this case, as will be more fully explained herein.

Earlier this year, Lupin Limited submitted ANDA No. 20-1663 ("Lupin's ANDA") under 35 U.S.C. § 355(j) seeking approval for what Bayer describes as "a generic version of Bayer's Yasmin® tablets" for oral contraception. (Doc. 1, ¶¶ 31, 32.) In connection with the filing of its ANDA, Lupin Limited, on June 2, 2010, sent a statutorily-required ANDA notice letter to Bayer. (Doc. 10, ¶ 62.) This letter, which included an Offer of Confidential Access to the Lupin ANDA, advised Bayer, *inter alia*, that the Lupin ANDA included Paragraph IV certifications relative to three patents listed in the U.S. Food and Drug Administration's ("FDA") "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") for Yasmin®: U.S. Patents 5,569,652 ("the '652 patent"); 6,787,531 ("the '531 patent"); and 6,933,395 ("the '395 patent"). (Doc. 1, ¶ 33; Doc. 10, ¶¶ 33, 70, 71.) These certifications asserted that each patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the products described in the Lupin ANDA. (Doc. 10, ¶ 62.)

On July 15, 2010, and in response to its receipt of Lupin's ANDA notice letter, Bayer filed the instant patent infringement suit against Lupin. (Doc. 1.) In its Complaint, Bayer alleges that Lupin's ANDA seeks permission from the FDA to market a generic version of Bayer's oral contraceptive tablet product, Yasmin®. (Doc. 1, ¶ 31) More specifically, Bayer alleges that Lupin's filing of its ANDA constituted an act of infringement of the '652 patent, and that Lupin's manufacture, use, importation, offer for sale and/or sale, or inducement thereof, of the products described in Lupin's ANDA will infringe or induce infringement of the '652 patent. (Doc. 1, ¶¶ 35, 37, 39.) Bayer has not, and has agreed that it will not, assert the '395 patent against Lupin. (Doc. 1; Doc. 10, ¶¶ 50, 68, 69; Statement of Nonliability and Covenant Not to

Sue Regarding U.S. Patent No. 6,933,395 (filed concurrently with this Stipulation).) Bayer has not asserted against Lupin any action or claim related to the '531 patent.

Lupin answered Bayer's Complaint on September 27, 2010, denying Bayer's infringement allegations. In addition, Lupin Limited asserted counterclaims seeking, *inter alia*, a judgment of invalidity and noninfringement relative to the '652 patent as well as to another Bayer patent, the '395 patent. (Doc. 10, ¶¶ 37, 49, 52 and 54-86.)

Bayer previously filed suit against other companies regarding generic Yasmin® and the '652 patent. Specifically, on April 18, 2008, Bayer filed the Sandoz/Watson Case in this Court. (Docket No. 1:08-cv-03710-PGG-JCF.) The Sandoz/Watson case is a Hatch-Waxman Act patent infringement suit against Sandoz, Inc. ("Sandoz"), as well as Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. (collectively, "Watson"), alleging that Sandoz and Watson had filed ANDAs seeking permission from the FDA to market generic versions of Yasmin®. (Doc. 10, ¶ 73; Doc. 1, Sandoz/Watson Case.) Bayer alleged in the Sandoz/Watson Case that Watson's and Sandoz's conduct infringed or would induce infringement of the '652 patent. (*Id.*)

On September 28, 2010, and in response to a motion brought by Sandoz and Watson under FED. R. CIV. P. 12(c), this Court issued a Memorandum Opinion and Order dismissing Bayer's Complaint in the Sandoz/Watson Case with prejudice. (Docs. 78, 161, Sandoz/Watson Case.) In dismissing the Complaint, the Court considered, *inter alia*, the '652 patent (attached as an exhibit to the Sandoz/Watson Complaint, Doc. 1, Exh. 1); the FDA-approved labeling for Yasmin® (Exhibit B to Doc. 78 in the Sandoz/Watson Case; Doc. 1, ¶¶ 29, 30); the FDA Approval Letter for the NDA Bayer submitted in connection with Yasmin® (Exhibit C to Doc. 78, Sandoz/Watson Case; Doc. 1, ¶ 29); the parties' briefs and attached exhibits; and the proposed

labels submitted to the FDA by Watson and Sandoz in connection with their ANDA filings (Exhibit D to Doc. 78, Sandoz/Watson Case; Doc. 10, ¶ 73).

Bayer disagrees with the Court's opinion and intends to seek review before the United States Court of Appeals for the Federal Circuit and, if necessary, the United States Supreme Court.

STIPULATIONS

The parties recognize that the factual and legal bases of Bayer's claim for patent infringement in the Sandoz/Watson Case are substantially the same as those present in the instant action and seek to avoid unnecessary motion practice and discovery. As a result, the parties stipulate as follows:

1. The parties stipulate that the alleged basis for infringement in this matter is the same as the alleged basis for infringement asserted by Bayer in the Sandoz/Watson Case, with the exception that, in this action, it is Lupin that has filed an ANDA, which ANDA includes a proposed label for the drug product submitted for FDA approval (as well as a comparison of Lupin's proposed label with the Yasmin® label), submitted hereto as Exhibits A and B, respectively. Based on the Court's ruling dismissing Bayer's Complaint in the Sandoz/Watson Case, all briefing and orders related to that ruling, the Complaint and Answer and Counterclaims filed in this action, and the Lupin ANDA's proposed label (attached hereto as Exhibit A), the parties further agree the holdings in the Court's previous ruling require dismissal of Bayer's Complaint in the instant action, and entry of final judgment. Bayer makes this stipulation while expressly disagreeing with the content of the Court's ruling and does so simply to expedite the disposition of this case so that an appeal may be immediately taken. Lupin enters this stipulation

with the understanding that Bayer is not waiving any appellate rights in this matter or in the Sandoz/Watson Case.

2. The parties further stipulate that all documents referenced herein and in the Court's September 28, 2010, Memorandum Opinion and Order are incorporated by reference and constitute part of the record in this action, and further stipulate and request that the final judgment entered in this matter should expressly enter into the record of this action, for all purposes, all briefing, declarations, exhibits, orders, memoranda and other documents filed or otherwise submitted to the Court in the Sandoz/Watson Case.

3. Lupin further agrees that the First and Second Counts included as part of its Counterclaims in this action, which relate solely to the '652 patent, shall be dismissed without prejudice. In the event that the Federal Circuit or Supreme Court reverses or vacates all or part of this Court's final judgment in favor of Lupin in this matter, or a final or partial judgment in favor of Watson or Sandoz in the Sandoz/Watson Case, the parties expressly agree that Lupin shall be permitted to re-plead and re-assert the First and Second Counts included as part of its Counterclaims, as well as its Affirmative Defenses and any other defenses or counterclaims Lupin may have relative to the '652 patent.

4. Bayer has issued a statement of non-liability and covenant not-to-sue Lupin for infringement of the '395 patent relative to Lupin's ANDA No. 20-1663, a copy of which is filed concurrently with this stipulation. Based on this covenant not-to-sue, Lupin stipulates that the Third and Fourth Counts included as part of its Counterclaims in this action shall be dismissed without prejudice relative to Lupin's ANDA No. 20-1663.

5 The foregoing stipulations dispose of all claims and counterclaims in this case, and it is respectfully requested that the Court enter a final judgment in this action. A [Proposed] Final Judgment accompanies this stipulation.

IT IS SO STIPULATED:

Dated: December 8, 2010



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~~PROPOSED~~ ORDER OF DISMISSAL

In view of the parties' stipulation, and based on the legal reasoning set forth in the Memorandum Opinion and Order dated September 28, 2010, dismissing the Complaint in Civil Action No. 1:08-cv-03710-PGG-JCF ("the Sandoz/Watson Case"),

IT IS HEREBY ORDERED that:

1. Bayer's complaint against Lupin is dismissed WITH PREJUDICE. In dismissing Bayer's Complaint, the Court expressly incorporates and makes part of the record of this case all documents referenced in the foregoing stipulation and in this Court's September 28, 2010, Memorandum Opinion and Order, as well as all briefing, declarations, exhibits, memoranda, rulings and other documents filed, submitted or otherwise considered by this Court in the Sandoz/Watson Case. This dismissal is made without any prejudice to Bayer's right to appeal a final judgment entered in this matter or any final or partial judgment in the Sandoz/Watson Case.
2. Lupin Limited's First and Second Counts included in its Counterclaims are dismissed WITHOUT PREJUDICE. In the event that the Federal Circuit or Supreme Court reverses or vacates all or part of this Court's final judgment in favor of Lupin in this matter or this Court's final or partial judgment in favor of Watson or Sandoz in the Sandoz/Watson Case, Lupin shall be permitted to re-plead and re-assert its First and Second Counts included as part of its Counterclaims, as well as its Affirmative Defenses and any other defenses or counterclaims Lupin may have relative to the '652 patent.
3. Lupin's Third and Fourth Counts included as part of its Counterclaims are dismissed WITHOUT PREJUDICE.
4. Each party shall bear its own costs and attorneys' fees.

Date: Dec. 8, 2010

Paul G. Gardephe
Paul G. Gardephe, U.S.D.J.

~~PROPOSED~~ FINAL JUDGMENT

In view of the parties' stipulation of dismissal, this Court's Order of dismissal, and based on the legal reasoning set forth in the Memorandum Opinion and Order dated September 28, 2010, dismissing the Complaint in Civil Action No. 1:08-cv-03710-PGG-JCF ("the Sandoz/Watson Case"),

IT IS ORDERED, ADJUDGED, AND DECREED that:

1. Final judgment in this matter shall be entered in favor of Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. and against Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. as described in the parties' Stipulations and the Order of Dismissal.

2. This final judgment is entered without prejudice to any party's right to pursue an appeal before the United States Court of Appeals for the Federal Circuit. This judgment is entered with the express understanding that Bayer is preserving all rights to appeal the Court's decision in the Sandoz/Watson Case.

The Clerk of the Court is directed to close this case

Date: Dec. 8, 2010

Paul G. Gardephe
Paul G. Gardephe, U.S.D.J.