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

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and AUSPECT PHARMACEUTICALS, INC., Plaintiffs, v. LUPIN LTD., and LUPIN PHARMACEUTICALS, INC. Defendants.	Civil Action No. 21-cv-13247-FLW-DEA **Scheduling Conference: October 19, 2021**
TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and AUSPECT PHARMACEUTICALS, INC., Plaintiffs, v. AUROBINDO PHARMA LTD., and AUROBINDO PHARMA USA, INC. Defendants.	Civil Action No. 21-cv-13240-FLW-DEA **Scheduling Conference: October 19, 2021**

JOINT PROPOSED DISCOVERY PLAN

Pursuant to Federal Rule of Civil Procedure 26(f), Local Civil Rules 16.1 and 26.1, and the Court's September 20, 2021 Order (ECF No. 26) (in 21-cv-13247, "the Lupin Case") and September 28, 2021 Order (ECF No. 24) (in 21-cv-13240, "the Aurobindo Case"), Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Auspex Pharmaceuticals, Inc. ("Auspex") (collectively, "Plaintiffs" or "Teva") and Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") and Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo") (together with Lupin, "Defendants"), submit the following proposed Joint Discovery Plan and proposed joint scheduling order in the above-captioned matters.

As a preliminary matter, the parties have proposed to coordinate these cases because they are both Hatch-Waxman patent litigations involving Teva's drug AUSTEDO® (deutetrabenazine). AUSTEDO® is indicated for use in treating chorea associated with Huntington's disease and tardive dyskinesia. Both Lupin and Aurobindo have filed Abbreviated New Drug Applications ("ANDAs") seeking approval from FDA to market and sell in the United States the products described therein.

The Aurobindo Case arises from its request to FDA to approve its ANDA prior to the expiry of six U.S. Patents (collectively, the "Asserted Patents"):

- U.S. Patent No. 8,524,733, which includes claims relating to the deutetrabenazine molecule (the "Drug Patent");
- U.S. Patent Nos. 9,233,959, 9,296,739, and 9,814,708, which include claims relating to the dosage form (the "Formulation Patents");
- U.S. Patent No. 9,550,780, which include claims relating to the deutetrabenazine crystal form (the "Polymorph Patent"); and
- U.S. Patent No. 10,959,996, which includes claims relating to the use of deutetrabenazine (the "Use Patent").

The Lupin Case overlaps in subject matter with the Aurobindo case because it arises from its request to FDA to approve its ANDA prior to the expiry of the Formulation Patents and the Polymorph Patent. Lupin has not asked FDA to approve its ANDA prior to the expiry of the Drug Patent.

1. Attorneys

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2. Statement of Facts and Legal Issues

The Lupin Case is an action for patent infringement arising out of the filing of an Abbreviated New Drug Application by Lupin seeking approval from FDA to market and sell in the United States the product described therein prior to the expiration of the Formulation and Polymorph Patents.

The Aurobindo Case is an action for patent infringement arising out of the filing of an Abbreviated New Drug Application by Aurobindo seeking approval from FDA to market and sell in the United States the product described therein prior to the expiration of the Drug, Formulation, Polymorph, and Use Patents

Plaintiff Auspex owns the Asserted Patents. Plaintiff Teva licenses the Asserted Patents and holds the New Drug Application ("NDA") pursuant to which it markets AUSTEDO® in the United States. The subject matter of the Asserted Patents are described above.

There is a statutory stay on FDA's approval of the Defendants' ANDAs that is in effect until April 3, 2025.

3. Settlement Discussions

The parties have not engaged in settlement discussions.

4. Rule 26(f) Conference

The parties met pursuant to Fed. R. Civ. P. 26(f) on September 30, 2021.

5. Fed. R. Civ. P. 26(a)(1) Disclosures

The parties have agreed to exchange their initial disclosures on October 19, 2021.

6. Problems with Fed. R. Civ. P. 26(a)(1) Disclosures

The parties do not anticipate any issues with Rule 26(a)(1) disclosures.

7. Third Party Funding

The parties have not filed disclosures of third-party litigation funding as they have nothing to disclose.

8. Status of Discovery

The parties have not conducted discovery, with the exception that pursuant to Local Patent Rule 3.6(a) on August 2, 2021, Lupin produced its ANDA No. 216065 to Teva, and on October 11, 2021, Aurobindo produced its ANDA No. 215971 to Teva.

9. Proposed Joint Discovery Plan

A. Discovery Needed on the Following Subjects

The parties expect to take discovery on issues raised in Plaintiffs' Complaints and in any Defendant's Answer, Affirmative Defenses and Counterclaims, which could include a need for physical samples and/or discovery from third parties who may be located abroad.

The Lupin case does not involve the Drug Patent or the Use Patent because Lupin has not sought FDA approval to market its product prior to the expiry of those patents. However, the Aurobindo Case does involve those patents and so the scope of discovery outlined below contemplates discovery concerning those patents.

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