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

# JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV,

Plaintiffs,

v.

MYLAN LABORATORIES LIMITED,

Defendant.

Civil Action No. 2:19-cv-16484-CCC-MF

#### CONFERENCE DATE: November 12, 2019 at 11 a.m.

Document Filed Electronically



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#### JOINT PROPOSED DISCOVERY PLAN

Pursuant to Federal Rules of Civil Procedure 16(b) and 26(f), Local Civil Rule 26.1(b), the Local Patent Rules, and the Court's October 7, 2019 Order (ECF No. 28), counsel for plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPN") (collectively "Janssen" or "Plaintiffs") and counsel for defendant Mylan Laboratories Limited ("Mylan" or "Defendant"), respectfully submit this Joint Discovery Plan.

#### I. NATURE OF CASE

This is a Hatch-Waxman case. Janssen alleges that Mylan has infringed one or more asserted claims of U.S. Patent No. 9,439,906 ("the '906 Patent") by submitting an Abbreviated New Drug Application ("ANDA") to market a generic version of JPI's Invega Sustenna® brand paliperidone palmitate extended release suspension products prior to the expiration of the '906 patent. Mylan denies the allegations of infringement and asserts affirmative defenses and counterclaims alleging that its proposed products do not infringe and/or that the asserted claims are invalid. Thus, the primary legal issues in this case include (1) whether Mylan's proposed generic products (including the uses thereof) infringe one or more asserted claims of the '906 patent, and (2) whether the asserted claims are invalid.

Janssen seeks to have this case declared exceptional under 35 U.S.C. §§ 285 and 271(e)(4).

#### II. DISCOVERY CONDUCTED TO DATE

1. The parties will exchange Initial Disclosures on November 14, 2019.

The parties will submit a proposed Stipulated Confidentiality Order pursuant to
L. Pat. R. 2.2.

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3. In accordance with L. Pat. R. 3.6(a), Mylan represents that it has produced its ANDA in its entirety.

#### III. DISCOVERY PROBLEMS ENCOUNTERED TO DATE

No discovery problems have been encountered to date.

#### IV. FURTHER DISCOVERY NEEDS

The parties anticipate seeking discovery on all the issues raised in the Complaint, the Answer and Counterclaims, and the Answer to Counterclaims in this case. The parties contemplate seeking written discovery, including requests for the production of documents and things, interrogatories, and requests for admission. The parties also anticipate taking depositions of both party and non-party witnesses. The parties propose that expert discovery will take place following the close of fact discovery. The parties do not believe that any phasing of discovery is appropriate.

Plaintiffs may request samples of Mylan's proposed generic paliperidone palmitate extended release suspension products and the active pharmaceutical ingredient for those products. Mylan does not concede that samples of its proposed generic paliperidone palmitate extended release suspension products and/or the active pharmaceutical ingredients for those products are relevant to the issues in the case or that the production of such samples is appropriate in the context of the instant litigation. The parties agree to discuss requests for samples in good faith and to bring any issues concerning the production of samples to the Court's attention when appropriate. The parties do not believe that the Court needs to enter a separate formal date at this time for production of samples.

#### V. PROPOSED DISCOVERY SCHEDULE

The parties propose the schedule set forth below. The parties have agreed to revisit

the schedule and approach the Court for an earlier trial date, subject to the Court's

availability, should the parties agree to forego dispositive motions at a later date.

Event	Proposed Date
Exchange of initial disclosures	November 14, 2019
Plaintiffs disclose asserted claims	November 19, 2019
Parties file proposed Stipulated Confidentiality Order	November 26, 2019
Defendant's Invalidity and Non-infringement Contentions and accompanying documents	December 20, 2019
Plaintiffs' Infringement Contentions and accompanying documents	February 7, 2020
Plaintiffs' response to Invalidity Contentions	February 7, 2020
Deadline for joining parties without leave of Court	February 10, 2020
Deadline for amending pleadings without leave of Court	October 16, 2020
Parties exchange list of claim terms in need of construction	February 21, 2020
Parties exchange preliminary proposed constructions and identify intrinsic and extrinsic evidence	March 13, 2020
Parties exchange intrinsic and extrinsic evidence that each party intends to rely on to oppose any other party's proposed construction	March 27, 2020
Joint Claim Construction and Prehearing Statement	April 10, 2020
Deadline to complete fact discovery relating to claim construction	June 12, 2020

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June 26, 2020
July 17, 2020
August 10, 2020
By August 24, 2020
September 11, 2020
November 13, 2020
November 18, 2020
January 8, 2021
January 22, 2021
February 19, 2021
February 26, 2021
TBD
TBD
June 2021 or at the Court's convenience
January 2, 2022

#### VI. EXPERT DISCOVERY

The parties expect that expert testimony will be required. The parties' proposed dates for expert reports and deposition discovery are set forth above.

#### VII. LIMITATIONS ON DISCOVERY

#### A. Written Discovery

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