

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG and TAKEDA PHARMACEUTICALS AMERICA, INC.,

Plaintiffs,

v.

APOTEX INC., et al.,

Defendants.

C.A. No. 18-88-LPS CONSOLIDATED

MEMORANDUM ORDER

At Wilmington this 7th day of January, 2021:

Having reviewed the proposed pretrial order ("PTO") submitted by Plaintiffs and Defendants (D.I. 985, 985-1, 986-1, 987-1, 988-1), IT IS HEREBY ORDERED that:

1. Plaintiffs' motion in limine ("MIL") No. 1, to exclude obviousness theories (from Defendants Zydus and Sigmapharm, relating to claims of the '884 and '279 patents) based on undisclosed lead compounds, is DENIED. Plaintiffs have not met their burden to show that this evidence and opinion should be excluded. While Defendants' expert, Dr. Lepore, will not be permitted to identify lead compounds "for the first time at trial," as that would be substantially and unfairly prejudicial to Plaintiffs, he will be permitted to opine on any lead compound and "lead motif" he identified as a lead compound in his expert reports and/or deposition. To the

extent there is a dispute as to the legal sufficiency of a theory based on a “lead motif,” the Court will evaluate that issue post-trial based on a full record.

2. Plaintiffs’ MIL No. 2, to exclude “a new argument” that asserted claims of some of the patents-in-suit would have been obvious over PCT Publication No. WO 2003/029232 A1 (“WO ’232”) “because a POSA would have screened all 24 preferred compounds listed in WO ’232,” is DENIED. By Plaintiffs’ own telling, they have not been recently surprised by the “new” argument. Instead, Plaintiffs acknowledge “Defendants planted the seeds of this new theory in the Reply Report of their expert” and later “during depositions, multiple Defendant experts offered this new theory of how WO ’232 purportedly renders the claims of Plaintiffs’ patents obvious.” (D.I. 988-1 at p. 196 of 857)<sup>1</sup> Plaintiffs have failed to show that the *Pennypack* factors favor exclusion. In particular, Plaintiffs have not persuaded the Court that its decision today will unfairly prejudice Plaintiffs in the manner or to the degree that concerned the Court when it granted an earlier defense motion (a decision which was supported by the *Pennypack* factors). (See D.I. 801)

3. The parties shall be prepared to discuss at tomorrow’s pretrial conference (“PTC”) the following issues raised in the PTO:

A. whether the Court should compel any party to include more “disputed facts” as “undisputed facts” (see PTO ¶¶ 15-16);

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<sup>1</sup> Defendants’ contentions that these theories were adequately disclosed in opening reports, and that Dr. Myerson’s responsive report proves this point (see D.I. 988-1 at p. 709 of 857), are unpersuasive. While disclosure of a truly “new” theory of invalidity in a reply report and/or a deposition will not always be acceptable, in the context of this case the applicable *Pennypack* factors considered in combination do not warrant exclusion of the challenged evidence and opinion.

- B. whether there is a dispute as to whether fact witnesses should be sequestered prior to their testimony (PTO ¶ 24);
- C. the parties' positions on how they will make motions for judgment on partial findings under Rule 52(c) (PTO ¶ 103);
- D. the procedure for closing the virtual courtroom for testimony that contains Competitively Sensitive Confidential evidence (PTO ¶ 105); and
- E. whether the Court should require Defendants to provide "clarity regarding which invalidity defenses Defendants actually plan to pursue at trial" and whether Plaintiffs will be reducing the number of asserted claims and/or patents (PTO ¶ 106).

4. With respect to Defendants' objection in PTO ¶ 39, the parties are directed that should they be unable to resolve objections with respect to any intended use of any deposition testimony, that objection shall be raised and argued consistent with the procedures set out in the PTO for resolution of deposition objections (*see id.* ¶¶ 40-44).

5. With respect to the dispute in PTO ¶ 55, the Court adopts Defendants' proposal, meaning that exhibits may be used on cross-examination (even for non-impeachment purposes) without necessarily having been listed in the pretrial order.

6. All objections to admissibility of exhibits and expected use of demonstrative exhibits that the parties are unable to resolve without judicial intervention must be raised with the Court at the beginning of the trial day on which it is anticipated that the exhibit is to be used. Failure to comply with this Order will result in waiver of the objection. A party will be charged for all time it spends arguing for or against such objections and for half of the time the Court requires to resolve such objections.

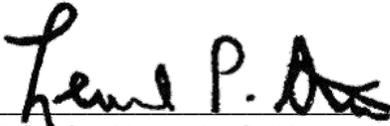
7. The Court will confer with the parties at the conclusion of trial to determine an appropriate schedule and all necessary page limits for post-trial briefing and other submissions.

8. The parties shall submit to the Court, no later than January 13, 2021 at 12 p.m., (i) two sets of binders containing hard copies of all trial exhibits organized in numerical order, separated into PTX, DTX, and JTX; and (ii) a single bookmarked PDF document containing all trial exhibits, via FTP. Credentials may be directly emailed to Chambers. The PDF containing the trial exhibits must include both a linked index and a bookmark for each exhibit, and the exhibits should be organized in numerical order, separated by PTX, DTX, or JTX. Each party shall submit to the Court via e-mail full color copies of any demonstrative exhibits that each intends to use at trial by 8 a.m. on the calendar day such demonstrative exhibit is expected to be used. At the end of trial, the parties shall submit to the Court two sets of hard copies of all demonstrative exhibits, organized in an easily identifiable manner.

9. Based on the Court's understanding of the number and scope of the parties' disputes – which include allegations of infringement of at least 23 claims of at least eight patents against seven sets of Defendants as well as invalidity based on at least obviousness, anticipation, and lack of adequate written description – and considering the parties' requests for time (Plaintiffs seek 63 hours for trial and Defendants request 70) (*see* PTO ¶ 95), the Court will allocate ***between 22 and 25 hours per side***, with the final amount to be determined at the PTC. The Court recognizes this is a large case even among ANDA cases over which it has presided. Nevertheless, the requested amount of hours is significantly greater than the amounts the Court has permitted in recent years. In the Court's view, this case can be effectively litigated, with both sides having the opportunity to make full and fair presentations, in the hours being allocated by the Court.

10. Trial will be held at some or all of the following times, subject to the parties' time limits and the Court's other commitments:

Friday, January 15:	9 a.m. to 5:30 p.m.
Tuesday, January 19:	9 a.m. to 5:30 p.m.
Wednesday, January 20:	8:30 a.m. to 11:30 a.m. and 2 p.m. to 4 p.m.
Thursday, January 21:	9:00 a.m. to 5:30 p.m.
Friday, January 22:	8:30 a.m. to 1:30 p.m. and 4 p.m. to 6 p.m.
Monday, January 25:	12:30 p.m. to 5:30 p.m.
Tuesday, January 26:	9 a.m. to 5:30 p.m.
Wednesday, January 27:	8:30 a.m. to 4 p.m.
Thursday, January 28:	8:30 a.m. to 5:30 p.m.
Friday, January 29:	8:30 a.m. to 5:30 p.m.

  
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HONORABLE LEONARD P. STARK  
UNITED STATES DISTRICT JUDGE