IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 17-374-LPS (CONSOLIDATED)
AUROBINDO PHARMA USA INC. et al.,	:	
Defendants.	:	

MEMORANDUM ORDER

Having reviewed the proposed pretrial order (D.I. 672) ("PTO") submitted by the remaining parties in this consolidated Hatch-Waxman pharmaceutical patent litigation – Plaintiffs Bristol-Myers Squibb Company and Pfizer, Inc. (collectively "BMS" or "Plaintiffs") and Defendants Sigmapharm Laboratories, LLC ("Sigmapharm"); Sunshine Lake Pharma Co., Ltd. and HEC Pharm USA Inc. (together, "Sunshine Lake"); Unichem Laboratories Ltd. ("Unichem"); and Zydus Pharmaceuticals (USA) Inc. ("Zydus" and, collectively, "Defendants") – in relation to the bench trial scheduled to begin on October 31, 2019, IT IS HEREBY ORDERED that:

1. Plaintiffs' motion in limine ("MIL") number 1, to exclude Defendants' indefiniteness defense to the asserted claims (13, 104) of the '208 patent, is GRANTED. The Court cannot find anywhere in the report of Defendants' expert, Dr. Clayton Heathcock, any reference to indefiniteness of the asserted claims. Further, in his deposition, Dr. Heathcock testified that he did not know the legal standard for indefiniteness or even that such a standard exists. Under these circumstances, Plaintiffs – who took no discovery on indefiniteness and did

not ask their expert to opine on the issue – have been surprised by the untimely disclosed defense and would be unfairly prejudiced by having to address it at trial (or by the disruption to the trial or trial preparation schedule that would result if the motion were denied).

2. Plaintiffs' MIL number 2, to exclude SigmaPharm's non-infringement defenses based on a disavowal that occurred in prosecution of the '945 patent, is DENIED. While the Court will apply the "plain and ordinary meaning" to the claim term "crystalline apixaban particles," consistent with the parties' agreement and the Court's claim construction order, the evidence Plaintiffs seek to strike may be found to be relevant and probative of the proper understanding and application of that plain meaning. Moreover, as SigmaPharm points out, its expert (Dr. Zaworotko) filed his report with the "40% Crystalline Theory" many months ago, so Plaintiffs had opportunities to address this theory (for instance, by testing). Therefore, the Court is not persuaded by Plaintiffs' timing or prejudice arguments. Plaintiffs will have an opportunity at trial (and in post-trial briefing) to persuade the Court that there was no disavowal of claim scope (or that any such disavowal is irrelevant to the asserted claims) and that the plain and ordinary meaning of the claim term includes no numerical limitation.

The parties have collectively filed seven *Daubert* motions, requesting exclusion of all or part of certain proposed expert testimony. All of the *Daubert* motions are DENIED.

3. There are three distinct requirements for admissible expert testimony: (1) the expert must be qualified; (2) the opinion must be reliable; and (3) the opinion must relate to the facts. *See generally Elcock v. Kmart Corp.*, 233 F.3d 734, 741-46 (3d Cir. 2000). Hence, expert testimony is admissible if it "is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods

to the facts of the case." Fed. R. Evid. 702(b)-(d). Rule 702 embodies a "liberal policy of admissibility." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (internal citations omitted). Motions to exclude evidence are committed to the Court's discretion. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994).

4. All five of Plaintiffs' *Daubert* motions (D.I. 559, 560, 562, 563, 565) are DENIED.

a. The motion to preclude portions of the non-infringement testimony of Dr. Harry G. Brittain is denied because Dr. Brittain's reliance on Sunshine Lake testing – which was sufficiently reliable, in Sunshine Lake's view, to be included in its ANDA submission to the FDA – is proper, as an expert "may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703. Dr. Brittain may rely on the Sunshine Lake testing as potential corroborating evidence for opinions he formulated independently.

b. The motion to preclude a portion of Dr. Wayne Genck's testimony is denied because the Court is not persuaded by Plaintiffs' argument that the challenged testimony contradicts the Court's claim construction order. The Court's construction does not preclude the measurement of particle size with a light scattering method; it only provides that such technique is not the "one and only one way" of conducting the measurement. (D.I. 380 at 10)

c. The motion to preclude portions of Dr. Mark Sacchetti's non-infringement testimony is denied because the expert is sufficiently qualified to provide the intended opinions relating to solid-state nuclear magnetic resonance ("SSNMR"). Dr. Sacchetti testified that although he has not run SSNMR tests, he knows how to interpret them. Plaintiffs' criticisms of

Dr. Sacchetti's qualifications can be explored on cross-examination and may impact the weight accorded to his opinions, but they do not persuade the Court he is insufficiently qualified to provide his opinion.

d. The motion to preclude portions of Dr. Robert Schurko's and Dr. David Apperley's non-infringement testimony are denied. The Court believes Dr. Apperley's methodology is sufficiently reliable to make his opinion helpful to the Court as trier of fact; Plaintiffs' criticisms of that methodology go to the weight and not admissibility of the testimony. Dr. Schurko's opinion is not objectionable just because it is based, in part, on Dr. Apperley's analysis (although whatever success Plaintiffs have in undermining the value of Dr. Apperley's opinion will likely also impact the weight the Court will accord to Dr. Schurko's partially derivative opinions). Nor is there anything improper in Dr. Schurko having reached a more definitive opinion ("no crystalline apixaban [is] present" in Sigmapharm's product) than Dr. Apperley (opining merely that "the data did not indicate the presence of crystalline apixaban"), particularly given that Dr. Schurko conducted independent analysis as well.

e. The motion to preclude portions of Dr. Michael Zaworotko's non-infringement testimony is denied because the challenged opinions are sufficiently reliable to be helpful to the Court as trier of fact. Plaintiffs' criticisms of Dr. Zaworotko's use of XRPD tests go to the weight to be accorded to his opinions, not their admissibility. Nor do the expert's opinions contradict the Court's claim construction; to the contrary, they may be found to be relevant and probative of the proper understanding and application of the plain meaning of the "crystalline apixaban particles."

5. Unichem's motion to exclude Dr. Cory J. Berkland's expert testimony (D.I. 567)

is DENIED. The Court is not persuaded by Unichem's characterization of Dr. Berkland's methodology as so novel and speculative as to be too unreliable to be admitted into evidence. To the contrary, the Court believes Dr. Berkland's analysis is sufficiently reliable and fits the facts of the case and, thus, will be helpful to it as the trier of fact. Unichem's criticisms go to the weight and not admissibility of the evidence.

6. Sigmapharm's motion to exclude certain experts (D.I. 570) is DENIED. The Court is not persuaded that Dr. Jerry Atwood's or Dr. Eric Munson's tests relating to the '945 patent are so unreliable that they must be excluded, particularly given the support cited by Plaintiffs in the United States Pharmacopoeia for these experts' methods. Instead, these analyses will be helpful to the Court as trier of fact. Nor does the Court believe that any of Dr. Atwood's or Dr. Munson's opinions contradict the Court's claim construction opinion.

The Court is also not persuaded that it should exclude Dr. David MacMillan's and Dr. Peter Kowey's testimony on the validity of the '208 patent. Dr. MacMillan did not conclude that certain salts were pharmaceutically acceptable merely because they were "explicitly described in the '208 Patent's specification;" rather, he relied on, among other things, his own analysis and Dr. Jacobsen's report (something an expert is permitted to do). Nor does Dr. Kowey's reliance on a fact he was asked to assume render his opinion excludable as unreliable.

Having reviewed the PTO, the Court holds as follows:

7. Any objections to the admissibility of exhibits, to demonstratives, and to designated and counter-designated deposition testimony (*see, e.g.*, PTO ¶¶ 18, 36, 47) shall be presented to the Court at the start of the trial day, or such objections will be deemed untimely and waived.

8. The parties' proposed schedule and format for post-trial briefing (PTO ¶¶ 55-59) will likely be acceptable, but the parties shall raise this issue (as well as the page lengths of their proposed submissions) at the conclusion of the trial, at which point the Court will be in a better position to determine what it needs in order to prepare its post-trial Opinion.

9. Each Defendant will be permitted to cross-examine Plaintiffs' witnesses. (*See* PTO at 15 n.5)

10. The parties jointly request a total of twenty-five (25) hours per side for trial. (*See* PTO ¶ 62) This case involves two related Plaintiffs, two asserted patents, 14 asserted claims, four Defendants, four separate non-infringement defenses, and numerous invalidity defenses. Thus, some substantial increase in the number of hours typically accorded by this Court to an ANDA trial (i.e., approximately 10-12 hours per side) is warranted. However, having reviewed the extensive PTO submissions, as well as the parties' multiple *Daubert* motions (addressed above), the Court believes the parties can fully and appropriately present their cases in a more efficient manner than they propose. Accordingly, each side will be allocated between 20 and 22 hours for its trial presentation, with the precise number to be the subject of discussion at tomorrow's pretrial conference.

11. Further, given the Court's other commitments, this bench trial will be held at some or all of the following times, subject to the parties' time limits:

a. Wednesday, October 23: 5:00 - 6:45 pm

b. Thursday, October 31: 8:30 am - 5:00 pm

c. Friday, November 1: 11:00 am - 2:00 pm

d. Monday, November 4: 8:30 am - 6:00 pm

e. Tuesday, November 5: 8:30 am - 4:00 pm

f. Thursday, November 7: 12:30 pm - 6:00 pm

g. Friday, November 8: 8:30 am - 6:00 pm

h. Tuesday, November 12: 8:30 am - 6:30 pm

i. Wednesday, November 13: 8:30 am - 6:30 pm

12. Plaintiffs' proposal that the parties be required to disclose in advance the exhibits they intend to use on cross-examination (PTO ¶ 65) is DENIED.

13. The parties shall be prepared to address the following issues identified in the PTO at the PTC tomorrow:

a. Defendants' objections (including authenticity objections) to 1,335 of Plaintiffs' exhibits (PTO ¶¶ 64, 66)

b. Whether Drs. Zusman's and Kowey's testimony are relevant to any issue remaining for trial (PTO ¶¶ 67, 71)

c. Whether Defendants should be required to reduce the number of invalidity defenses they present at trial (PTO ¶ 68)

d. The procedure (if any) for temporarily closing the courtroom and/or precluding any Defendant from learning the highly confidential information of any other Defendant (PTO ¶ 69)

e. Any concerns with accommodating the conflicts in Dr. Chambliss's schedule (PTO ¶ 72).

October 21, 2019
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT COURT