

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS
IRELAND CO., LTD. and ASTELLAS
PHARMA GLOBAL DEVELOPMENT, INC.,

1:20CV1589

Plaintiffs,

vs.

Lupin Ltd., et al.,

Defendants.

MEMORANDUM AND ORDER

This matter is before the Court on Plaintiffs', Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc., Motions in Limine, D.I. 1006-17; and Defendants', Lupin and Zydus, Motions in Limine, D.I. 1006-18. The parties submitted their Motions in Limine with the Proposed Pretrial Order (D.I. 1006) on January 20, 2026. On January 26, 2026, the Court held an on-the-record pretrial conference and did not hear the parties' arguments. This order resolves the pending Motions in Limine.

I. LEGAL STANDARDS

“A district court is accorded a wide discretion in determining the admissibility of evidence under the Federal Rules.” *Toledo Mack Sales & Serv., Inc. v. Mack Trucks, Inc.*, 386 F. App’x 214, 218 (3d Cir. 2010) (quoting *United States v. Abel*, 469 U.S. 45, 54 (1984)). “A motion in limine is a vehicle to exclude inadmissible or prejudicial evidence before it is offered at trial.” *Novartis AG v. Actavis Elizabeth LLC*, No. CV 14-1487-LPS, 2017 WL 1398347, at *2 (D. Del. Apr. 17, 2017).

II. ANALYSIS

A. Astellas's First Motion in Limine

Astellas first moves to preclude Defendants from offering at trial any irrelevant and prejudicial evidence, testimony, or argument regarding the parties' prior litigation on unasserted patents and inflammatory characterizations of Astellas's patent enforcement actions against Defendants.

Astellas argues that Defendants intend to paint Astellas as a serial litigant against Defendants by emphasizing the volume of the parties' litigation. Additionally, Astellas states that Defendants plan to reference prior litigation concerning patents not asserted here to argue that the resulting settlement agreements granted Defendants permission "to launch and sell their ANDA Products." However, Astellas does state that evidence of prior settlement agreements may be relevant in the damages context, and that they are not seeking to wholly preclude Defendants from introducing limited evidence from the procedural history of this case in connection with willfulness arguments at trial.

Defendants argue that the parties' litigation history and settlement agreements are crucial for the jury to assess Astellas's willful-infringement allegations and to understand Defendants' decision to launch their ANDA products in 2024. Additionally, Defendants state they will adhere to the Court's bifurcation order and will not allege that Astellas's prior litigations are "shams."

The Court agrees the parties' litigation history and settlement agreements may be relevant for the jury to assess Astellas's willful-infringement allegations and Defendants' decision to launch their ANDA products. However, at this point in time, the nature of the supposed evidence identified by Astellas is too broad to warrant exclusion on a

prospective basis. Accordingly, this motion is denied as premature without prejudice, and Astellas should make objections to specific evidence as it is adduced at trial.

B. Astellas's Second Motion in Limine

Astellas's second motion in limine seeks to preclude Defendants from presenting argument, evidence, or testimony suggesting Astellas engaged in "evergreening" in connection with Myrbetriq®, or has somehow acted to improperly "delay generic entry" or to overextend Myrbetriq's patent protection and FDA-granted exclusivity. Astellas argues that this inflammatory subject matter has no bearing on any issue before the jury and serves no purpose beyond disparaging Astellas as a brand pharmaceutical company for enforcing its rights under both FDA and patent law. However, both parties have submitted a joint letter and resolved disputes as to "evergreening" or referencing a potential injunction. D.I. 1010. Thus, Astellas's remaining motion in limine is to preclude Defendants from presenting argument, evidence, or testimony suggesting Astellas has somehow acted to improperly "delay generic entry" or to overextend Myrbetriq's patent protection and FDA-granted exclusivity.

Astellas argues that the motion should be granted because Defendants' efforts are (1) an end-run around the Court's clear bifurcation order by suggesting Astellas has abused the patent system to unfairly extend exclusivity over Myrbetriq, and (2) they improperly incite negative sentiment toward Astellas as a brand. Defendants argue that Astellas never identifies what evidence and statements their motion entails but rather appear to seek a blanket prohibition of any mention of the Orange Book, which are central to Defendants' damages experts' apportionment arguments.

The Court denies Astellas's motion. The motion is overly broad. Astellas may make relevance objections to specific evidence it believes is irrelevant as it is adduced at trial.

C. Astellas's Third Motion in Limine

Astellas's third motion in limine seeks to preclude Zydus from offering any expert testimony regarding the dissolution testing performed by Improved Pharma or Dr. Steven Little's commentary thereof ("Improved Pharma Testing") beyond its expert Dr. Fassih's narrow statement at his deposition (i.e. that Improved Pharma did not validate the method). Astellas argues that Zydus made the choice to not otherwise address such testing during expert discovery and explicitly declined Astellas's offer for Zydus to provide a sur-reply expert report in response to the Improved Pharma Testing.

A retained expert witness must provide a written report disclosing "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B). Accordingly, the expert witnesses will be permitted to testify about any expert opinion disclosed in their report relevant to the dissolution testing performed by Improved Pharma or Dr. Steven Little's commentary thereof. Expert witnesses will not be permitted to testify about the dissolution testing performed by Improved Pharma or Dr. Steven Little's commentary thereof if such opinion was not properly disclosed.

Therefore, the Court grants Astellas's motion in part. Zydus's experts are limited to what was disclosed during depositions and in their expert reports.

D. Astellas's Fourth Motion in Limine

Astellas's fourth motion in limine seeks to preclude Defendants from offering any evidence, testimony, argument, or questioning, through Dr. Walter Chambliss or otherwise, regarding Astellas's conduct during prosecution of the Asserted Patents, including any suggestion that Astellas engaged in any misconduct such as omitting or misrepresenting information to the Patent Office. Astellas argues that Defendants intend to introduce evidence to the jury that insinuates Astellas somehow acted improperly during prosecution of the Asserted Patents, which would circumvent the Court's bifurcation order and the strict legal standards for inequitable conduct by backdooring in allegations of misconduct to sway the jury.

Defendants argue that Astellas's motion is overbroad and seeks to exclude testimony relevant to the issues of obviousness, § 112 defenses, and for rebutting Astellas's invention story and infringement theories. Additionally, Defendants state that they will abide by the Court's decision to bifurcate inequitable conduct and patent misuse.

The Court finds that the evidence is relevant. However, the parties can make objections at trial. Therefore, Astellas's motion is denied.

E. Defendants' First Motion in Limine

Defendants first move to preclude Astellas's expert and fact witnesses from testifying regarding Defendants' purported intent, mental state, or knowledge. Defendants argue that neither Astellas's experts nor its fact witnesses have any personal knowledge regarding Defendants' intent, mental state, or knowledge. Additionally, Defendants argue that Astellas's experts do not have any scientific, technical, or

specialized knowledge that would help the jury determine Defendants' intent, mental state, or knowledge.

The Court grants Defendants' motion in part. Astellas's expert and fact witnesses may testify regarding the underlying facts that may show intent, mental state, or knowledge. As to expert opinion testimony concerning intent, mental state, or knowledge, the Court denies the motion without prejudice to reassertion during trial.

F. Defendants' Second Motion in Limine

Defendants' second motion in limine seeks to preclude Astellas from offering contentions that Defendants "copied" Astellas's patents or the Myrbetriq® product under the guise of such testimony being relevant to the issue of obviousness. Additionally, Defendants seek to preclude Astellas from referring to Defendants and their products with pejorative terms like "knock-off," "copy," "piggy-back," "steal," "duplicate," "pirate," or similar terms.

First, Defendants argue that the Federal Circuit and courts in this District have rejected giving any weight to evidence of "copying" in the Hatch-Waxman context. And Defendants argue that the prejudicial nature of the jury hearing these allegations of "copying" could unduly influence their consideration of infringement and validity, mandating exclusion under Rule 403. Second, Defendants argue that the use of pejorative language would prejudice Defendants and potentially confuse the jury.

Astellas argues that Defendants' motion is a late partial summary judgment motion that at best raises points for cross examination. Astellas states that the evidence of "copying" is probative of not only secondary considerations but also infringement, including that Defendants' products (1) reduce food effects as claimed in the '451 and

'189 Patents and (2) exhibit the dissolution profile of the '780 and '409 Patents. Astellas also argues that the copying evidence is directly responsive to Defendants' theory that their labels do not mean their products act like Myrbetriq®, which embodies the claims. Astellas further argues that Defendants' copying is probative of willfulness.

Moreover, Astellas agrees to not use the terms "steal," "knock-off," "piggy-back," or "pirate." But Astellas argues that "copy" and "duplicate" are not pejoratives.

"[E]vidence should not be excluded pursuant to a motion in limine, unless it is clearly inadmissible on all potential grounds." *Leonard v. Stemtech Health Scis., Inc.*, 981 F. Supp. 2d 273, 276 (D. Del. 2013).

In light of Astellas's agreement, the Court finds that the evidence is relevant and should not be excluded. Therefore, the Court denies Defendants' motion.

G. Defendants' Third Motion in Limine

Defendants' third motion in limine seeks to preclude Astellas's expert, Teresa Rea ("Ms. Rea"), from testifying regarding the subject matter of paragraphs 28-82 of her Amended Expert Rebuttal Report ("Rebuttal Report") (Ex. 1) and paragraphs 7-17 of her Expert Reply Report ("Reply Report") (Ex. 2) because Ms. Rea's opinions are not offered from the appropriate perspective, and are therefore not relevant to the issues of infringement, validity, or damages. Defendants argue that Ms. Rea is testifying from the perspective of a patent attorney.

Astellas argues that only five paragraphs of Ms. Rea's opinions are offered in rebuttal to Mr. Shimer's opinions and withdraws those paragraphs. Astellas states that the bulk of Ms. Rea's remaining opinions rebut opinions offered by Dr. Chambliss about

the meaning of Astellas's Orange Book submissions for Myrbetriq, in the context of Astellas's prosecution conduct.

In light of Astellas's concession, the Court agrees that Ms. Rea's opinions are relevant to rebutting Dr. Chambliss's testimony. The Court agrees that Ms. Rea is not a POSA but her testimony otherwise is not precluded. Therefore, the Court denies Defendants' motion.

H. Defendants' Fourth Motion in Limine

Defendants' fourth motion in limine seeks to preclude all parties from presenting argument, testimony, or evidence regarding prior settlements or litigation with other generic manufacturers and their generic mirabegron products because it would be unfairly prejudicial, confusing, and misleading to the jury. Astellas argues that the evidence is relevant because the contested settlement agreements with other generic manufacturers granted licenses to the Asserted Patents in this case.

The Court denies Defendants' motion. The settlement agreements to the Asserted Patents are relevant to the issues to be decided by the jury and the probative value outweighs the risk of prejudice, jury confusion, or waste of time. Any objections for relevance can be made at trial.

III. CONCLUSION

For the foregoing reasons, IT IS ORDERED:

1. Plaintiffs' Motion in Limine No. 1, D.I. 1006-17 at 2, is denied as set forth herein.
2. Plaintiffs' Motion in Limine No. 2, D.I. 1006-17 at 179, is denied as set forth herein.
3. Plaintiffs' Motion in Limine No. 3, D.I. 1006-17 at 251, is granted in part and denied in part as set forth herein.

4. Plaintiffs' Motion in Limine No. 4, D.I. 1006-17 at 326, is denied as set forth herein.
5. Defendants' Motion in Limine No. 1, D.I. 1006-18 at 2, is granted in part and denied in part as set forth herein.
6. Defendants' Motion in Limine No. 2, D.I. 1006-18 at 127, is denied as set forth herein.
7. Defendants' Motion in Limine No. 3, D.I. 1006-18 at 321, is denied as set forth herein.
8. Defendants' Motion in Limine No. 4, D.I. 1006-18 at 410, is denied as set forth herein.

Dated this 30th day of January, 2026.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge