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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

* * *

AMARIN PHARMA, INC., *et al.*,

Plaintiffs,

v.

WEST-WARD PHARMACEUTICALS
INTERNATIONAL LIMITED, *et al.*,

Defendants.

Case No. 2:16-cv-02525-MMD-NJK

ORDER

I. SUMMARY

This is a consolidated patent infringement case brought under the Hatch-Waxman Act where Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited seek to prevent Defendants West-Ward Pharmaceuticals International Limited (“West-Ward”), Hikma Pharmaceuticals USA Inc. (“Hikma”), and Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd. (collectively, “DRL”) from launching generic competitor drugs to Plaintiffs’ drug Vascepa. Before the Court are the parties’ consolidated motions in limine (ECF Nos. 291, 292),¹ and two motions to seal corresponding to responses to those motions (ECF Nos. 297, 300). As further explained below, the Court will grant in part, and deny in part, Defendants’ motions in limine, mostly deny Plaintiffs’ motions in limine, grant Defendants’ motion to seal (ECF No. 297), and deny Plaintiffs’ motion to seal (ECF No. 300)—but will also give Defendants an opportunity to show cause why the Court should not unseal the exhibits attached to Plaintiff’s response (ECF No. 299).

¹Both parties filed responses to the other party’s consolidated motion in limine. (ECF Nos. 296, 299.) The motions to seal are unopposed. This order does not address Defendants’ additional motion in limine (ECF No. 310), or that motion’s corresponding motion to seal (ECF No. 311).

1 **II. BACKGROUND**

2 The Court incorporates the background facts set forth in the Court's order on the
3 parties' motions for summary judgment. (ECF No. 278 at 1-4.)

4 **III. LEGAL STANDARD**

5 A motion in limine is a procedural mechanism to limit testimony or evidence in a
6 particular area in advance of trial. See *United States v. Heller*, 551 F.3d 1108, 1111-12
7 (9th Cir. 2009). It is a preliminary motion whose outcome lies entirely within the discretion
8 of the Court. See *Luce v. United States*, 469 U.S. 38, 41-42 (1984). To exclude evidence
9 on a motion in limine, "the evidence must be inadmissible on all potential grounds." See,
10 e.g., *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004). "Unless
11 evidence meets this high standard, evidentiary rulings should be deferred until trial so that
12 questions of foundation, relevancy and potential prejudice may be resolved in proper
13 context." *Hawthorne Partners v. AT & T Tech., Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill.
14 1993). This is because although rulings on motions in limine may save "time, cost, effort
15 and preparation, a court is almost always better situated during the actual trial to assess
16 the value and utility of evidence." *Wilkins v. Kmart Corp.*, 487 F. Supp. 2d 1216, 1218 (D.
17 Kan. 2007).

18 In limine rulings are provisional. Such "rulings are not binding on the trial judge . . .
19 [who] may always change h[er] mind during the course of a trial." *Ohler v. United States*,
20 529 U.S. 753, 758 n.3 (2000). "Denial of a motion in limine does not necessarily mean that
21 all evidence contemplated by the motion will be admitted at trial." *Ind. Ins. Co.*, 326 F.
22 Supp. 2d at 846. "Denial merely means that without the context of trial, the court is unable
23 to determine whether the evidence in question should be excluded." *Id.*

24 Evidence is relevant if "it has any tendency to make a fact more or less probable
25 than it would be without the evidence" and "the fact is of consequence in determining the
26 action." Fed. R. Evid. 401. Only relevant evidence is admissible. See Fed. R. Evid. 402.
27 Relevant evidence may still be inadmissible "if its probative value is substantially
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1 outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury,
2 undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid.
3 403. “Unfairly prejudicial” evidence is that which has “an undue tendency to suggest
4 decision on an improper basis, commonly, though not necessarily, an emotional one.”
5 *United States v. Gonzalez-Flores*, 418 F.3d 1093, 1098 (9th Cir. 2005) (quoting *Old Chief*
6 *v. United States*, 519 U.S. 172, 180 (1997)).

7 **IV. DEFENDANTS’ CONSOLIDATED MOTION IN LIMINE (ECF NO. 291)**

8 Defendants filed two motions in limine. (ECF No. 291.) The Court addresses each,
9 in turn, below.

10 **A. Rat and Mice Studies**

11 Defendants first move in limine to preclude Plaintiffs from relying on the preclinical
12 carcinogenicity rat and mice studies included in the product labelling to support Plaintiffs’
13 induced infringement theory because Plaintiffs did not preserve this argument in its
14 contentions, or alternatively because Plaintiffs’ experts did not rely on these animal studies
15 to support their infringement opinions. (ECF No. 291 at 2, 2-5.) Plaintiffs counter that they
16 were never required to disclose the precise evidence they intended to rely on to support
17 their infringement theory, but were merely required to disclose the theory itself. (ECF No.
18 299 at 2-9.) Plaintiffs further argue they have always been consistent in asserting their
19 theory that the labeling read in its entirety induces infringement, so they have not waived
20 reliance on the rat and mice studies. (*Id.*)

21 The Court mostly agrees with Plaintiffs, but also agrees with Defendants that
22 Plaintiffs’ experts will not be allowed to express opinions at trial that were not included in
23 their expert reports. The Court will therefore grant in part, and deny in part, the motion.
24 Plaintiffs’ experts are prohibited from testifying about the rat and mice studies at trial to
25 the extent they did not rely on those studies in their expert reports. See Fed. R. Civ. P.
26 26(a)(2)(B)(i) (providing that opening expert reports are normally expected to include a
27 complete statement of all opinions the witness will express at trial and their bases); see
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1 also *Aidini v. Costco Wholesale Corp.*, Case No. 2:15-cv-00505-APG-GWF, 2017 WL
2 10774824, at *1 (D. Nev. Apr. 24, 2017) (declining to reconsider decision to limit an expert
3 witness to the opinions expressed in his report).

4 But the Court denies Defendants' motion in all other respects. The Court is
5 persuaded by Plaintiffs' argument they were only required to disclose their infringement
6 theory, not every piece of evidence they intend to rely on in support of that theory at trial.
7 Local Patent Rule 1-6(d) provides in pertinent part, "For each claim that is alleged to have
8 been indirectly infringed, an identification of any direct infringement and a description of
9 the acts of the alleged indirect infringer that contribute to or are inducing that direct
10 infringement." The Court is satisfied that Plaintiffs have complied with this rule in insisting
11 throughout the litigation that Defendants' labels as a whole will induce infringement. (ECF
12 No. 299 at 4-7.) And that view appears to reflect the proper analysis. See *Bayer Schering*
13 *Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1324 (Fed. Cir. 2012) ("taken in its entirety"). In
14 addition, Plaintiffs may cross-examine Defendants' experts by relying on the rat and mice
15 studies detailed in the labeling to the extent Defendants' experts express opinions on the
16 content of the labeling as a whole.² See Fed. R. Evid. 705 (providing that an expert may
17 be required to disclose the facts or data supporting her opinion on cross-examination).

18 **B. Dr. Peck**

19 Defendants next move in limine to bar Plaintiffs from calling their rebuttal FDA
20 expert, Dr. Peck, to rebut the testimony of Defendants' clinical non-infringement expert Dr.
21 Sheinberg, because his opinions were limited to rebutting those of Defendants' expert
22 FDA expert Peter Mathers. (ECF No. 291 at 5-8.) Plaintiffs counter they should still be
23 allowed to call Dr. Peck because the relevant inquiry under Fed. R. Civ. P. 26(a)(2)(D)(ii)
24 is whether the rebuttal expert is testifying to the same subject matter as the other expert,
25 not who the other expert is. (ECF No. 299 at 9-13.) Thus, Plaintiffs argue, Dr. Peck should
26 be allowed to testify in rebuttal to opinions that Dr. Sheinberg expresses to the extent they

27 ²Such as, 'there is nothing in the labeling that suggests a duration of treatment.'
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1 reflect the subject matter that Peter Mathers covered in his report, especially because
2 here, Dr. Sheinberg’s testimony on FDA approval is based on Mathers’ report. (*Id.*)
3 Plaintiffs alternatively request that, “the Court should not preclude Dr. Peck from testifying
4 until it hears the testimony of Dr. Sheinberg and can determine whether Dr. Peck’s
5 testimony would be responsive and useful to the Court.” (*Id.* at 13 n. 7.)

6 The Court will take Plaintiffs’ alternative approach. The Court will defer a ruling on
7 this issue until trial, and will determine whether Dr. Peck’s testimony will be responsive to
8 Dr. Sheinberg’s testimony, and useful, after it hears from Dr. Sheinberg. The Court agrees
9 with Plaintiffs that the relevant inquiry goes to the subject matter of the testimony, not the
10 expert’s identity. See *Smith v. Wal-Mart Stores, Inc.*, Case No. 2:11-CV-01520-MMD,
11 2012 WL 4051925, at *2 (D. Nev. Sept. 13, 2012) (“rebuttal expert testimony must address
12 the ‘same subject matter’ identified by the initial expert and that a rebuttal expert may only
13 testify after the opposing party’s initial expert witness testifies.”). Thus, the Court will let
14 Dr. Peck testify in rebuttal to Dr. Sheinberg if Dr. Sheinberg opines about “the scope of
15 FDA approval reflected in the Vascepa label[.]” (ECF No. 299 at 13.) Defendants’ motion
16 in limine on this issue is therefore denied.

17 **V. PLAINTIFFS’ CONSOLIDATED MOTION IN LIMINE (ECF NO. 292)**

18 Plaintiffs also filed two motions in limine. (ECF No. 292.) The Court addresses both
19 below.

20 **A. Lavin Declarations**

21 Plaintiffs first seek to exclude any evidence or testimony regarding the prosecution
22 of the patents-in-suit, focusing specifically on declarations submitted to the patent office
23 by Dr. Philip Lavin (the “Lavin Declarations”), as irrelevant under Fed. R. Evid. 402 and a
24 waste of time under Fed. R. Evid. 403. (ECF No. 292 at 2-6.) Defendants counter that
25 evidence regarding the Lavin Declarations is relevant because it tends to show the
26 patents-in-suit should not have issued—effectively lowering the bar for Defendants to
27 establish obviousness—and will not waste time because both parties have already agreed
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1 to limit their trial time, and Defendants will further agree to limit the time they spend on this
2 issue if Plaintiffs will. (ECF No. 298 at 3-8.) Defendants specifically state that they do not
3 oppose Plaintiffs' motion "to the extent it seeks to 'bar the testimony of Plaintiffs' expert,
4 Stephen Kunin, and Defendants' expert, Nicholas Godici.'" (*Id.* at 8.) The Court both
5 agrees with Defendants and will accept their proposal to bar the testimony of Mr. Kunin
6 and Mr. Godici as uncontested.

7 "Generally, a motion in limine based solely on relevance or unfair prejudice is
8 improper when the matter is set for a bench trial." *Shaw v. Citimortgage, Inc.*, Case No.
9 3:13-CV-0445-LRH-VPC, 2016 WL 1659973, at *3 (D. Nev. Apr. 26, 2016) (citation
10 omitted). That general rule applies here because this case is set for bench trial. More
11 substantively, the Court agrees with Defendants that while Defendants bear the burden of
12 establishing obviousness by clear and convincing evidence, and that burden never
13 changes, it is easier to carry if Defendants rely on evidence of obviousness that was not
14 presented to the patent office—such as evidence that Dr. Lavin later backed away from
15 key factual assertions he made in the Lavin Declarations. *See Microsoft Corp. v. I4I Ltd.*
16 *P'ship*, 564 U.S. 91, 111 (2011) ("if the PTO did not have all material facts before it, its
17 considered judgment may lose significant force."); *see also Syntex (U.S.A.) LLC v. Apotex,*
18 *Inc.*, 407 F.3d 1371, 1379 (Fed. Cir. 2005) ("In addition, we think the district court failed to
19 appreciate that the prosecution history of the relevant patents, while not establishing
20 inequitable conduct, casts some doubt on the final examiner's conclusion that the claimed
21 surfactant produces unexpected results sufficient to overcome a prima facie case of
22 obviousness."). Thus, the evidence that Defendants seek to present regarding the Lavin
23 Declarations is relevant to Defendants' obviousness defense.

24 The Court will therefore mostly deny Plaintiffs' motion on this issue. However, it will
25 grant as uncontested Plaintiffs' motion to the extent it seeks to bar the testimony of Mr.
26 Kunin and Mr. Godici. Precluding them from testifying will streamline the bench trial, and
27 the parties appear to agree that testimony from those two witnesses is unnecessary.

1 **B. Priority Date**

2 Plaintiffs next seek to preclude Defendants from presenting testimony, evidence,
3 or argument about a priority date for the patents-in-suit other than March 2008, which is
4 the priority date the parties have used throughout this litigation, including in their expert
5 reports. (ECF No. 292 at 6-9.) Defendants counter that they should be allowed to argue
6 the patents-in-suit are merely entitled to a priority date corresponding to their filing date
7 (February 2009) because Plaintiffs have failed to meet their initial burden of showing the
8 named inventor of the patent invented anything in March 2008, Defendants never
9 stipulated to a March 2008 priority date, and Plaintiffs have been on notice throughout this
10 litigation that the priority date may be an issue at trial. (ECF No. 298 at 8-14.) The Court
11 again agrees with Defendants.

12 While the Court does not rule today on the proper priority date for the patents in
13 suit, Defendants may make a priority date argument at trial—because the Court sees no
14 good reason to rule to the contrary. To start, it appears both parties hedged as to priority
15 date throughout the litigation, merely assuming a March 2008 priority date for various
16 purposes. (ECF No. 298 at 8-9.) Further, Defendants attack the evidence Plaintiffs have
17 put forth in support of the March 2008 priority date, arguing Plaintiffs have not carried their
18 initial burden to show the patents-in-suit are entitled to a priority date other than their filing
19 date. (*Id.* at 9-14.) This argument is reasonable under governing law. *See, e.g., Purdue*
20 *Pharma L.P. v. Iancu*, 767 F. App'x 918, 924-25 (Fed. Cir. 2019) (stating that a patent
21 challenger does not need to present any evidence as to priority date when the plaintiff has
22 not met its burden to establish a particular priority date). And Plaintiffs have not pointed to
23 any stipulation with Defendants as to priority date. Thus, the Court will allow the parties to
24 litigate the priority date issue at trial if they choose to do so.

25 The Court will therefore deny Plaintiffs' motion in limine as to this issue.

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1 **VI. MOTIONS TO SEAL (ECF NOS. 297, 300)**

2 The parties filed redacted versions of their responses to the other party's motion in
3 limine and seek to seal certain exhibits attached to those responses—so both responses
4 were accompanied by a motion to seal in accordance with LR IA 10-5.

5 In the Ninth Circuit there is “a strong presumption in favor of access to court
6 records.” *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003). To
7 overcome this presumption, a party must articulate “compelling reasons” justifying
8 nondisclosure, such as use of the record to gratify spite, permit public scandal, circulate
9 libelous statements, or release trade secrets. *Kamakana v. City of Honolulu*, 447 F.3d
10 1172, 1179 (9th Cir. 2006). “The mere fact that the production of records may lead to a
11 litigant’s embarrassment, incrimination, or exposure to further litigation will not, without
12 more, compel the court to seal its records.” *Id.* (citation omitted).

13 In general, the parties seek to maintain under seal evidence designated as
14 confidential by the parties during discovery, which they contend contains proprietary and
15 confidential information that could subject them to commercial disadvantage were it to be
16 made public. The Court addresses both motions to seal below.

17 **1. ECF NO. 297**

18 In this motion to seal, Defendants seek to seal exhibits falling within the following
19 four categories, and redact material pulled from those exhibits in their response to
20 Plaintiffs’ consolidated motion in limine: (1) expert deposition testimony in which the expert
21 discusses trade secret information; (2) expert reports in which the expert discusses trade
22 secret information; (3) Plaintiffs’ internal emails regarding the development of Vascepa;
23 and (4) Plaintiffs’ internal meeting notes regarding the development of Vascepa. (*Id.* at 2.)
24 Having reviewed the exhibits in question, the Court agrees Defendants have shown
25 compelling reasons to seal them. *See, e.g., Phase II Chin, LLC v. Forum Shops, LLC*,
26 Case No. 2:08-cv-00162-JCM, 2010 WL 2695659, at *2 (D. Nev. July 2, 2010) (granting
27 motion to seal and noting that “Fed. R. Civ. P. 26(c)(1)(G) anticipates that the Court may
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1 require that ‘a trade secret or other confidential research, development, or commercial
2 information not be revealed or be revealed only in a specified way.’”). The Court will thus
3 grant Defendants’ motion to seal.

4 **2. ECF No. 300**

5 However, the Court does not find that Plaintiffs have presented compelling reasons
6 to grant their motion to seal. In their motion to seal, Plaintiffs seek “to file under seal four
7 excerpts from Amarin’s Preliminary Infringement Contentions and claims charts.” (ECF
8 No. 300 at 3.) The reason Plaintiffs seek to file these exhibits under seal is because they
9 cite to discovery materials marked as confidential by Defendants. (*Id.*) However, having
10 reviewed the exhibits, the citations are to documents identified merely by bates number—
11 they do not appear include any content that Defendants marked as confidential. (ECF Nos.
12 301, 302, 303, 304.) The Court thus sees no reason to seal these exhibits, and will deny
13 Plaintiffs’ motion to seal.

14 However, because the unsealing of these exhibits could prejudice Defendants—
15 and that is the risk Plaintiffs seem to seek to avoid—the Court will grant Defendants leave
16 to show cause in writing within five days why the Court should not unseal the documents
17 referenced in Plaintiffs’ motion to seal. If Defendants do not respond within five days, or
18 indicate in writing they do not object to these documents being unsealed within that time,
19 the Court will direct that the exhibits in question (ECF Nos. 301, 302, 303, 304) be
20 unsealed.

21 **VII. CONCLUSION**

22 The Court notes that the parties made several arguments and cited to several cases
23 not discussed above. The Court has reviewed these arguments and cases and determines
24 that they do not warrant discussion as they do not affect the outcome of the motions before
25 the Court.

26 It is therefore ordered that Defendants’ consolidated motion in limine (ECF No. 291)
27 is granted in part, and denied in part, as specified herein.

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It is further ordered that Plaintiffs' consolidated motion in limine (ECF No. 292) is denied except to the extent it seeks to bar the testimony of Mr. Kunin and Mr. Godici.

It is further ordered that Defendants' motion to seal (ECF No. 297) is granted.

It is further ordered that Plaintiffs' motion to seal (ECF No. 300) is denied.

It is further ordered that Defendants must show cause in writing within five days why the Court should not unseal the exhibits referenced in Plaintiffs' motion to seal (ECF Nos. 301, 302, 303, 304). If Defendants do not respond within five days, the Court will direct the Clerk of Court to unseal the documents.

DATED THIS 2nd day of January 2020.



MIRANDA M. DU
CHIEF UNITED STATES DISTRICT JUDGE