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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION**

GILEAD SCIENCES, INC.,
Plaintiff,
v.
MERCK & CO, INC., et al.,
Defendants.

Case No. [13-cv-04057-BLF](#)

**ORDER REGARDING MOTIONS IN
LIMINE**

[Re: ECF 218, 219, 220, 221, 222, 223, 224,
225, 226, 227]

Plaintiff Gilead Sciences, Inc. (“Gilead”) brings this declaratory relief action, asking the Court to declare that the manufacture, sale, and use of its drug sofosbuvir does not infringe two patents owned by Defendants, Merck & Co., Merck Sharp and Dohme Corp., and Ionis Pharmaceuticals, Inc., formerly known as Isis Pharmaceuticals, Inc. (collectively “Merck”), U.S. Patent Nos. 7,105,499 (“the ’499 Patent”) and 8,481,712 (“the ’712 Patent”) (collectively, “the asserted patents”). This Order addresses the parties’ motions *in limine*. For the reasons explained below and on the record at the February 25, 2016 pretrial conference, the motions are decided as follows:

Plaintiff’s Motion *in Limine* No. 1: DENIED.

Plaintiff’s Motion *in Limine* No. 2: DENIED.

Plaintiff’s Motion *in Limine* No. 3: DEFERRED.

Plaintiff’s Motion *in Limine* No. 4: GRANTED IN PART AND DENIED IN PART.

Plaintiff’s Motion *in Limine* No. 5: GRANTED IN PART AND DENIED IN PART.

Defendant’s Motion *in Limine* No. 1: GRANTED IN PART AND DENIED IN PART.

Defendant’s Motion *in Limine* No. 2: MOOT.

Defendant’s Motion *in Limine* No. 3: DENIED.

Defendant’s Motion *in Limine* No. 4: DENIED.

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Defendant’s Motion *in Limine* No. 5: DEFERRED.

I. GILEAD’S MOTIONS *IN LIMINE*

Gilead brings five motions *in limine*, which the Court addresses in turn.

A. Gilead’s Motion *in Limine* No. 1 to Exclude Evidence Regarding Sofosbuvir’s Infringement. DENIED.

Gilead seeks to exclude all testimony and argument that its sofosbuvir products infringe the asserted claims pursuant to Federal Rules of Evidence 402 and 403. MIL No. 1, ECF 223. Gilead argues that sofosbuvir’s infringement is not relevant to any of its invalidity defenses under 35 U.S.C. § 112. *Id.* at 1. Gilead also claims that it would be unfairly prejudicial for the jury to learn that Gilead infringes the asserted patents before the jury decides whether those patents are invalid. *Id.* at 1-2. Merck responds that sofosbuvir’s infringement is relevant to several issues in this case. According to Merck, sofosbuvir’s infringement is relevant to (1) determining damages, (2) rebutting Gilead’s lack of utility defense under § 112, (3) rebutting Gilead’s derivation defense, (4) rebutting Gilead’s claims that Merck would never enforce the asserted patents against Gilead, and (5) challenging the credibility of Gilead’s witnesses. OPP. No. 1 at 1, ECF 235.

At the pretrial conference, the Court informed the parties that the trial would proceed in two phases, with the first phase involving Gilead’s invalidity defenses and the second phase involving damages. As a result, the relevance of sofosbuvir’s infringement to damages is not a reason to allow it into evidence during the first phase of the trial. Sofosbuvir’s infringement may be relevant to rebutting Gilead’s invalidity defenses during the first phase of the trial and challenging the credibility of Gilead’s witnesses. At this juncture, however, the Court cannot rule definitively on the relevance of sofosbuvir’s infringement without knowing how the evidence will be presented at trial. Sofosbuvir’s infringement appears to have marginal relevance to the issue of credibility and the Court is concerned that it could be used in a way where its prejudicial effect will substantially outweigh its probative value and tip the Rule 403 balancing in favor of exclusion. Accordingly, the Court DENIES Gilead’s motion without prejudice to further objections being raised during trial.

At the pretrial conference, the parties requested clarification on whether sofosbuvir’s

1 infringement may be referenced in the openings. The Court will allow the parties to use the word
2 “infringement” during openings but the parties may not indicate that the Court has made a finding
3 of infringement.

4 **B. Gilead’s Motion *in Limine* No. 2 to Exclude Merck from Relying on Sofosbuvir as
5 Evidence that the Patents-in-Suit Disclose Practical Utility. DENIED.**

6 Gilead moves to exclude Merck from using sofosbuvir to establish the asserted patents
7 meet 35 U.S.C. § 112’s practical utility requirement. MIL No. 2, ECF 224. Gilead argues that
8 practical utility is determined as of the filing date of the application. *Id.* at 1-2. Since sofosbuvir
9 was not designed or synthesized until after the filing date of the asserted patents, Gilead claims
10 sofosbuvir cannot be used to prove the asserted patents disclose a practical utility. *Id.* Merck
11 counters that sofosbuvir’s infringement is relevant to damages and both relevant and dispositive as
12 to Gilead’s lack of utility defense. Opp. No. 2 at 1, ECF 236.

13 Information that post-dates the filing date of the patent application may be relevant to
14 utility. *In re Brana*, 51. F.3d 1560, 1567 (Fed. Cir. 1995) (finding that in some circumstances
15 post-filing evidence could satisfy applicants’ burden of proving utility); *see also Eli Lilly and Co.*
16 *v. Actavis Elizabeth LLC*, 435 Fed. App’x 917, 925 (Fed. Cir. 2011) (“[G]enerally the applicant
17 may provide data obtained either before or after the patent application was filed [to prove
18 utility].”). Accordingly, the Court DENIES Gilead’s motion. The Court addresses Merck’s
19 argument that evidence of infringement is dispositive to Gilead’s utility defense in the discussion
20 of Merck’s motion in *limine* No. 3.

21 **C. Gilead’s Motion *in Limine* No. 3 to Exclude Criticism of the Pricing of the Accused
22 Products. DEFERRED.**

23 Pursuant to Federal Rules of Evidence 402 and 403, Gilead moves to preclude all evidence
24 and argument relating to criticism of Gilead’s pricing of the accused pharmaceutical products, or
25 the pricing of Merck’s newly released drug, ZEPATIER. MIL No. 3, ECF 225. Specifically,
26 Gilead seeks to exclude four exhibits identified by Merck that criticize sofosbuvir’s pricing: (1) a
27 2015 Senate Finance Committee report entitled “The Price of Sovaldi and its Impact on the U.S.
28 Health System” and its appendices, (2) an article published by *The Motley Fool* entitled “Soaring
Hepatitis C Drug Prices Makes Cures Costly,” (3) an article published by *Bloomberg*

1 *Businessweek* entitled “How Much Should a Miracle Cost,” and (4) a letter from the
2 Massachusetts Attorney General threatening legal action against Gilead for its pricing of
3 Sovaldi®. *Id.* at 2. In addition to these four exhibits, Gilead moves to exclude “any other
4 evidence, testimony, or argument presented to elicit criticism of Gilead’s pricing of the accused
5 products” or the pricing of ZEPATIER. *Id.* Gilead argues that criticism of pricing is not relevant
6 to any issue in this case, and even if it were, its probative value would be substantially outweighed
7 by its inflammatory and unduly prejudicial nature. *Id.* at 1-5.

8 Merck responds that pricing is relevant to proving damages and challenging the bias of
9 Gilead’s witnesses. OPP No. 3, ECF 234-16. According to Merck, Gilead’s choice to set a higher
10 price for the accused products leads to lower unit sales. *Id.* at 2. Since Gilead argues damages
11 should be set per unit (per course of treatment), Merck claims accused product’s pricing, which
12 impacts the amount of units sold is relevant. *Id.* at 2-3. As for ZEPATIER’s pricing, Merck
13 argues that information is relevant to rebut Gilead’s argument that Merck’s demanded royalty rate
14 was prohibitive. *Id.* at 4-5.

15 Evidence regarding pricing criticism appears to be highly inflammatory and of little
16 relevance to the liability phase of the trial. At the pretrial conference, Merck clarified that it was
17 concerned Gilead would seek to portray itself as a company that has received unmitigated praise
18 for sofosbuvir and create the impression that Merck is a bad company seeking to take advantage of
19 Gilead’s work. Merck requested that the Court defer ruling on this motion to see if Gilead opens
20 the door to bring in pricing criticism evidence. Gilead did not object to this request. Accordingly,
21 the Court DEFERS its ruling on this motion, but Merck must inform the Court in advance if it
22 seeks to admit pricing criticism evidence. The Court cautions the parties the relevance of this
23 evidence during the first phase of the trial appears to be minimal, and appears to be more relevant
24 to the second phase of the trial.

25 **D. Gilead’s Motion *in Limine* No. 4 to Prohibit Merck’s Use of Late-Identified**
26 **Witnesses. GRANTED IN PART AND DENIED IN PART.**

27 Gilead seeks to exclude William Krovatin and Douglas Pon from testifying at trial. MIL
28 No. 4, ECF 226. Gilead argues that Mr. Krovatin and Mr. Pon were not identified in Merck’s

1 initial disclosures, neither witness was identified as knowledgeable about the topics they are now
2 being disclosed to testify about, and neither witness was deposed. *Id.* at 1-5. In response, Merck
3 has withdrawn Mr. Pon as a witness. OPP. No. 4 at 1 n.1, ECF 237. As to Mr. Krovatin, Merck
4 claims his testimony will be used to impeach Gilead’s equitable defenses. *Id.* at 1-3. According
5 to Merck, Rule 26 does not require the disclosure of impeachment witnesses. *Id.* at 3-4. Merck
6 also notes that Gilead has not sought a deposition of Mr. Krovatin, which would have been
7 accommodated by Merck. *Id.* at 4.

8 Rule 26(a)(1)(A)(i) provides that “a party must . . . provide to the other parties: (i) the
9 name and, if known, the address and telephone number of each individual likely to have
10 discoverable information – along with the subjects of that information – that the disclosing party
11 may use to support its claims or defenses, unless the use would be solely for impeachment.” Since
12 Merck is calling Mr. Krovatin solely for impeachment purposes, he did not need to be disclosed
13 pursuant to Rule 26. Accordingly, the Court DENIES Gilead’s motion to exclude Mr. Krovatin.
14 This is without prejudice to Gilead reasserting its objection upon the presentation of Mr.
15 Krovatin’s testimony if it is not used solely for impeachment. Merck shall make Mr. Krovatin
16 available for a deposition of no more than three hours and produce any documents relating to his
17 anticipated impeachment testimony. Since Merck has withdrawn the testimony of Mr. Pon, the
18 Court GRANTS Gilead’s motion with respect to Mr. Pon.

19 **E. Gilead’s Motion *in Limine* No. 5 to Exclude Certain Deposition Testimony.**
20 **GRANTED IN PART AND DENIED IN PART.**

21 Gilead moves to exclude the deposition testimony designated by Merck from the 2010
22 deposition of Dr. Ray Schinazi, the 2010 deposition of Dr. Michael Otto, and a deposition of
23 Ronald Renaud pursuant to Federal Rules of Evidence 402, 403, 611, 804 and Federal Rules of
24 Civil Procedure 30 and 31. MIL No. 5, ECF 227. Gilead argues that the depositions of Dr.
25 Schinazi and Dr. Otto were taken in a 2010 arbitration proceeding involving Pharmasset and
26 Emory University. Since Pharmasset, a predecessor-in-interest to Gilead, did not have a similar
27 motive as Gilead in this action to develop Dr. Schinazi’s and Dr. Otto’s deposition testimony,
28 Gilead claims they should be excluded. *Id.* at 1-2. As to Mr. Renaud, Gilead argues his testimony

1 consists of inadmissible hearsay, is irrelevant, and even if it was relevant, its probative value is
2 substantially outweighed by the risk of unfair prejudice, confusion, and waste of time. *Id.* at 2-3.

3 With respect to Dr. Schinazi’s testimony, under Federal Rule of Evidence 804(b)(1), the
4 former testimony of an unavailable witness is not admissible unless it is “offered against a party
5 who had—or, in a civil case, whose predecessor-in-interest had—an opportunity and similar
6 motive to develop it by direct, cross-, or redirect examination.” Fed. R. Evid. 804(b)(1). Neither
7 party disputes that Dr. Schinazi is unavailable nor that Gilead’s predecessor-in-interest,
8 Pharmasset, questioned Dr. Schinazi. The Court agrees with Merck and finds that Pharmasset had
9 a similar motive to develop Dr. Schinazi’s testimony. In the prior dispute, Pharmasset’s motive
10 was to commercialize sofosbuvir without making payments to others, which parallels Gilead’s
11 motive in this action. *See Murray v. Toyota Motor Distributors, Inc.*, 664 F.2d 1377, 1379 (9th
12 Cir. 1982) (For testimony to be admissible under Rule 804(b)(1), “the motive need only be
13 ‘similar,’ not identical.”). Accordingly, the Court DENIES Gilead’s motion with respect to Dr.
14 Schinazi’s testimony.

15 As to Dr. Otto’s testimony, at the pretrial conference, Gilead indicated Dr. Otto would be
16 testifying live at trial. Merck wanted to preserve its ability to use Dr. Otto’s deposition testimony
17 even if he is called as a witness. The Court will allow the parties to use deposition designations
18 even if a witness is called live, with the caution that all deposition designations will count against
19 their trial time. Accordingly, the Court DENIES Gilead’s motion to exclude Dr. Otto’s deposition
20 testimony.

21 Finally, with respect to Mr. Renaud, Merck seeks to offer testimony about a conversation
22 between Mr. Renaud and Dr. Schinazi about inventorship of Gilead’s patents. If Mr. Renaud’s
23 deposition testimony was allowed, it would create a trial within a trial as the parties fight about
24 accuracy of his testimony. Given that Mr. Renaud’s testimony is of marginal relevance and a
25 significant waste of time would result, the Court GRANTS Gilead’s motion and exclude Mr.
26 Renaud’s testimony under Rule 403.

27 **II. MERCK’S MOTIONS *IN LIMINE***

28 Merck brings five motions *in limine*, which the Court addresses in turn.

1 **A. Merck’s Motion in *Limine* No. 1 to Preclude Gilead from Presenting Evidence or**
2 **Argument Concerning its Equitable Defenses of Laches, Estoppel, Waiver or**
3 **Unclean Hands to the Jury. GRANTED IN PART AND DENIED IN PART.**

4 Merck seeks to preclude Gilead from presenting evidence or argument about its equitable
5 defenses of laches, estoppel, waiver and unclean hands to the jury pursuant to Federal Rules of
6 Evidence 402 and 403. MIL No. 1, ECF 218. Merck broadly argues that Gilead’s equitable
7 defenses are within the discretion of the court and would be confusing and a waste of time if
8 presented to the jury. *Id.* at 2. More specifically, Merck takes issue with potential evidence that
9 Gilead might present in support of its unclean hands defense. *Id.* According to Merck, Gilead
10 relies on a 2004 disclosure Pharmasset made to Merck to argue that Merck derived the asserted
11 claims from that disclosure. *Id.* Merck claims this 2004 disclosure is not relevant to Gilead’s
12 written description, enablement, and derivation defenses because the 2004 disclosure happened
13 after the January 18, 2002 filing date of the asserted patents. *Id.* at 2-4.

14 Gilead responds that Pharmasset’s 2004 disclosure to Merck is not only relevant to its
15 unclean hands defense but also to its written description and derivation defenses. OPP. No. 1,
16 ECF 238. According to Gilead, the asserted claims were added by Merck by amendment to the
17 asserted patents after 2004. *Id.* at 4-5. Gilead believes that the originally filed application did not
18 have support for Merck’s amended claims. *Id.* at 5. As a result, Gilead argues that it is not
19 prohibited from using evidence from after the 2002 filing date of the asserted patents in support of
20 its written description and derivation defenses. *Id.* at 2-5.

21 Since the equitable defenses will be tried separately outside the presence of the jury, the
22 Court GRANTS Merck’s motion to exclude legal argument concerning Gilead’s equitable
23 defenses. With respect to evidence, Merck’s motion is extremely broad about what evidence it
24 seeks to exclude. At the pretrial conference, Merck clarified that it was seeking to exclude
25 evidence that Dr. Philippe Durette used confidential information to guide his prosecution of the
26 claims in the ’499 patent. However, this information is also highly relevant to Gilead’s derivation
27 defense. Since its probative value is not outweighed by its prejudicial effect, the Court DENIES
28 Merck’s motion to exclude evidence regarding confidential information obtained by Dr. Durette.

1 **B. Merck’s Motion in *Limine* No. 2 to Preclude Evidence or Argument to the Jury**
2 **Concerning Certain Work Performed by Dr. Jean-Francois Griffon. MOOT.**

3 On February 25, 2016, the parties reached a stipulation where (1) Gilead will not present
4 evidence at trial concerning the work of Dr. Jean-Francois Griffon, (2) Merck will not call Dr.
5 Anthony Barrett or Dr. Alexander Clemens at trial, will not otherwise present evidence related to
6 work done at AMRI, and will not present and will not present testimony or opinions of Dr. Mark
7 Wentland concerning Dr. Griffon’s work, including but not limited to the opinions expressed in
8 Section IV.D of Dr. Wentland’s expert report, and (3) this motion is moot. ECF 253.
9 Accordingly, the Court GRANTS the parties’ stipulation and MOOTS this motion.

10 **C. Merck’s Motion in *Limine* No. 3 to Preclude Evidence or Argument Concerning**
11 **a Purported Lack of Utility. DENIED.**

12 Merck seeks to preclude Gilead from presenting evidence or argument to the jury that the
13 specification for the asserted patents fail to disclose a practical utility. MIL No. 3, ECF 220.
14 Merck argues that the Gilead’s concession that its sofosbuvir products infringe the asserted patents
15 prevents it from challenging utility under 35 U.S.C. § 112. *Id.* at 1-3. Gilead responds that
16 Merck’s motion is an inappropriate attempt to seek summary judgment on Gilead’s utility defense.
17 OPP. No. 3 at 1-2, ECF 240. Gilead further argues that a finding of infringement does not prevent
18 it from challenging utility. *Id.* at 2-5.

19 The Court agrees with Gilead and finds that it may assert a lack of utility defense. Merck’s
20 argument primarily relies upon the Federal Circuit’s holding in *Raytheon Co. v. Roper Corp.*, 724
21 F.2d 951, 959 (Fed. Cir. 1983) and related cases. In *Raytheon*, the Federal Circuit held that a
22 finding of infringement precludes a lack of utility defense. *Id.* However, in *Raytheon*, the
23 question was not whether patent’s specification disclosed practical utility under § 112 but rather
24 whether the claimed invention lacked utility because it was inoperative. *Id.* at 956. Contrary to
25 the situation in *Raytheon*, Gilead is not contesting that the claimed invention is operable but rather
26 arguing that Merck did not discover or disclose that utility. As a result, *Raytheon* is inapposite to
27 this case and the Court DENIES Merck’s motion.

28 **D. Merck’s Motion in *Limine* No. 4 to Preclude Evidence and Argument Regarding**
 Anticipation, Improper Derivation, and Prior Invention. DENIED.

 Merck seeks to exclude any evidence or argument regarding anticipation, improper

1 derivation, and prior invention pursuant to Federal Rules of Evidence 402 and 402. MIL No. 4,
2 ECF 221. Merck argues that Gilead bases the preceding defenses on events that occurred after
3 what Merck contends is the priority date of the asserted patents. *Id.* at 2-5. As a result, Merck
4 claims that Gilead's post-priority date evidence is not relevant. *Id.* at 3-5. Gilead argues that
5 Merck's motion is yet again an improper motion for summary judgment. OPP. No. 4 at 1-2.
6 Gilead also disagrees with Merck on the asserted claims' priority date. *Id.* at 2-4. According to
7 Gilead, Merck's asserted claims were filed after January 18, 2002 and Gilead believes those later-
8 filed claims are not entitled to an earlier priority date. Finally, Gilead argues that a derivation
9 defense does not focus on the dates of the references.

10 Contrary to Merck's briefing, the priority date of the asserted patents is disputed. As a
11 result, it is unclear at this time whether Gilead's evidence of anticipation, improper derivation, and
12 prior invention post-date the priority date of the asserted patents. Accordingly, the Court DENIES
13 Merck's motion.

14 **E. Merck's Motion in *Limine* No. 5 to Preclude Evidence or Argument Concerning**
15 **Examinations of Patent Applications, Interferences and Foreign Litigations, and**
16 **Arbitrations Concerning Patents Other than the Patents-in-Suit. DEFERRED.**

17 Merck moves to preclude Gilead from presenting evidence or argument to the jury
18 concerning the examination of patent applications other than those that issued as the asserted
19 patents, interferences and foreign litigations regarding patents other than the asserted patents, and
20 arbitrations concerning patents other than the asserted patents. MIL No. 5, ECF 222. In response,
21 Gilead argues that Merck's motion is vague has Merck not specifically identified what it seeks to
22 exclude. OPP. No. 5 at 1, ECF 242.

23 The Court agrees with Gilead and finds it difficult to resolve this motion absent knowing
24 the specific evidence Merck seeks to exclude and the context in which this evidence might be
25 presented. Accordingly, the Court DEFERS its ruling on this motion. Should Gilead wish to
26 introduce any of this evidence, it must give advance notice to the Court.

27 **III. OTHER ORDERS**

- 28 1. To the extent the courtroom needs to be closed to the public, the party requesting closure
must submit a written request by 5:00 p.m. on the day before the presentation of evidence


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sought to be sealed.

2. All fact witnesses, with the exception of corporate designees sitting at counsel table, will be excluded from the courtroom and may not discuss their testimony with anyone else.
3. The bench trial on equitable defenses is tentatively set for March 28, 2016. This may be adjusted depending on how the jury trial progresses. The parties' briefing on equitable defenses is due on or before March 18, 2016. The Court's Bench Pretrial Standing Order has further information for the parties.

IT IS SO ORDERED.

Dated: February 26, 2016


BETH LABSON FREEMAN
United States District Judge