

United States District Court
Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED FOOD AND COMMERCIAL
WORKERS LOCAL 1776 &
PARTICIPATING EMPLOYERS HEALTH
AND WELFARE FUND, et al.,

Plaintiffs,

v.

TEIKOKU PHARMA USA, et al.,

Defendants.

Case No. [14-md-02521-WHO](#)

ORDER ON PENDING MOTIONS

Currently before me are the parties’ motions for summary judgment and motions to exclude expert testimony. Defendants move for summary judgment as to all of plaintiffs’ claims, but as described below plaintiffs have significant evidence that Watson could have (if not would have) ultimately prevailed in the ’529 litigation and a cognizable (if not disputed) theory of alternate injury in a but-for world. Defendants’ motion is DENIED.¹ Plaintiffs more narrowly move for partial summary judgment that they have satisfied the “contract, combination, or conspiracy” element of their Section 1 and Section 2 claims (defendants do not oppose) and also to define the relevant antitrust market as the market for generic and brand 5% lidocaine patches. Rejecting defendants’ arguments in support of an essentially unlimited market for pain relief products, I agree that plaintiffs have shown on undisputed material facts that the relevant market is the market for 5% lidocaine patches and GRANT their motion.²

¹ Defendants’ alternate motion for partial summary judgment for a finding of fact under Rule 56(g) that Watson could not have launched its generic earlier than December 17, 2012 is not opposed by plaintiffs and is GRANTED.

² On October 31, 2017, I signed a stipulated dismissal, dismissing with prejudice the claims asserted by Retailer Plaintiffs Walgreen Co., Safeway Inc., Kroger Co., HEB Grocery Company L.P., Albertson’s LLC., CVS Pharmacy, Inc., Rite Aid Corp., and Rite Aid Hdqtrs Corp. against

1 The general background and history of this litigation is well known and laid out in my
2 prior orders. Dkt. Nos. 117, 670. The facts material to the determination of these motions, both
3 undisputed and disputed, will be addressed below.

4 LEGAL STANDARD

5 Summary judgment on a claim or defense is appropriate “if the movant shows that there is
6 no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of
7 law.” Fed. R. Civ. P. 56(a). In order to prevail, a party moving for summary judgment must show
8 the absence of a genuine issue of material fact with respect to an essential element of the non-
9 moving party’s claim, or to a defense on which the non-moving party will bear the burden of
10 persuasion at trial. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has
11 made this showing, the burden then shifts to the party opposing summary judgment to identify
12 “specific facts showing there is a genuine issue for trial.” *Id.* The party opposing summary
13 judgment must then present affirmative evidence from which a jury could return a verdict in that
14 party’s favor. *Anderson v. Liberty Lobby*, 477 U.S. 242, 257 (1986).

15 On summary judgment, the court draws all reasonable factual inferences in favor of the
16 non-movant. *Id.* at 255. In deciding a motion for summary judgment, “[c]redibility
17 determinations, the weighing of the evidence, and the drawing of legitimate inferences from the
18 facts are jury functions, not those of a judge.” *Id.* However, conclusory and speculative testimony
19 does not raise genuine issues of fact and is insufficient to defeat summary judgment. *See Thornhill*
20 *Publ’g Co., Inc. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir.1979).

21 DISCUSSION

22 I. DEFENDANTS’ MOTIONS FOR SUMMARY JUDGMENT

23 A. Defendants’ Motion for Summary Judgment on All Claims

24 Plaintiffs’ case rests on two theories of antitrust injury causation: (i) absent the large
25 reverse payment, Watson would have launched at-risk; and (ii) absent the large reverse payment
26

27 Defendant Endo Pharmaceuticals Inc. However, as the defense arguments are asserted by all three
28 defendants against all of the claims asserted by plaintiffs, nothing in this Order appears to be
impacted by the Stipulated Dismissal.

1 the parties would have reached an alternative “no payment settlement” giving Watson early entry
 2 into the market. Pls. Oppo. to MSJ [Dkt. No. 819] at 1. Defendants argue that summary judgment
 3 must be granted in their favor on plaintiffs’ first theory because Watson’s infringement of the ’529
 4 patent breaks the “chain of causation” as illegal activity and cannot support an antitrust claim.
 5 Plaintiffs counter that under Ninth Circuit case law, the chain cannot be broken by the ’529 patent,
 6 but even if it could, plaintiffs have ample evidence from which a reasonable juror could determine
 7 that Watson would have prevailed in the patent litigation. As to plaintiffs’ second theory,
 8 defendants argue that the “hypothetical” settlement proposed by plaintiffs is not legally cognizable
 9 and not supported by evidence in the record. Plaintiffs counter that numerous courts have
 10 recognized that hypothetical settlements are an acceptable basis for causation and that there is
 11 significant evidence in the record that a reasonable juror could rely on to find that, absent the
 12 reverse-payment settlement agreed-to in this case (hereafter Settlement), another settlement would
 13 have been reached to allow Watson early-entry to the market.

14 **1. At-Risk Launch Theory**

15 **a. Necessity to Address Watson’s Chances of Success in the ’529**
 16 **Patent Litigation**

17 Plaintiffs argue that they need not show that Watson would have likely won the ’529 patent
 18 litigation in order to prevail at trial in this case. They rely primarily on the Supreme Court’s
 19 decision in *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). There, the Court explained that “it is
 20 normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps,
 21 to determine whether the patent litigation is a sham An unexplained large reverse payment
 22 itself would normally suggest that the patentee has serious doubts about the patent’s survival.” *Id.*
 23 at 2236; *see also* 3 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2046d2 (Supp. 2016)
 24 (“The size of the payment operates as a surrogate for direct patent-law-based questions about
 25 patent quality. Indeed, payment size may actually be a more reliable indicator to the extent it
 26 reflects the settling parties’ market-based judgment about the patent’s prospects in a fully litigated
 27 infringement suit.”). According to plaintiffs, that is exactly the shape of this case; the reverse
 28 settlement payments are unexplained by legitimate factors (such as avoidance of litigation costs or

1 the provision of other services) and are indisputably large. Plaintiffs also rely on their expert,
 2 Professor Einer Elhauge, who opined that if Endo thought it had more than a 15.1% chance of
 3 winning, Endo would not have rationally agreed to the Settlement because its expected profits
 4 from continuing to litigate would have exceeded its profits from the settlement. Elhauge Report,
 5 Declaration of Dena Sharp [Dkt. No. 819] Ex. 1 [Dkt. No. 819-2] ¶¶ 6, 8, 147-48.

6 Recent decisions have limited the use of sole reliance on a large and unexplained reverse
 7 payment as a proxy for the weakness of the underlying patents to cases, like *Actavis*, that are
 8 brought by the FTC. In a detailed analysis, the district court in *In re Wellbutrin XL Antitrust*
 9 *Litig.*, 133 F. Supp. 3d 734 (E.D. Pa. 2015), as affirmed by the Third Circuit, concluded that the
 10 Supreme Court’s admonition in *Actavis* that “it is normally not necessary to litigate patent validity
 11 to answer the antitrust question” was limited to the context of an action brought by the FTC under
 12 the FTC Act’s “more relaxed” “likely to” causation standard. 133 F. Supp. 3d at 764. The court
 13 concluded that where private litigants are proceeding under the Clayton Act, that Act’s more
 14 stringent “proximate cause” standard requires showing that it was the settlement that precluded
 15 competition and not the patents. *Id.* If that could not be proved, the patent protection provided to
 16 the brand manufacturer (and that manufacturer’s right to exclude) cuts off the chain of causation.
 17 “In other words, if an agreement only replicates the effect of the underlying patent litigation, any
 18 exclusion resulting from that agreement must be caused by the underling patent.” *Id.* at 765; *see*
 19 *also In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 169 (3d Cir.
 20 2017) (recognizing what while the “size of a reverse payment may have some relevance in
 21 determining how confident a litigant is in the strength of its case” it could not standing along
 22 provide a “surrogate” for the weakness of the challenged patent).³

23 Similarly, the First Circuit in *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34
 24

25 ³ The district court considered whether plaintiffs had introduced evidence in the antitrust case
 26 showing that a “reasonable juror could find” that the generic defendant would have prevailed in
 27 the underlying patent litigations. *Id.* Because defendants’ expert presented unchallenged
 28 testimony that the generic had only a 20% chance of success in one of the cases “no reasonable
 juror” could have found that the generic would have succeeded. *Id.* at 767. The Third Circuit
 affirmed. 868 F.3d at 169 (“no reasonable jury could conclude that Anchen would have been
 more likely than not to prevail.”).

1 (1st Cir. 2016) rejected plaintiffs’ contention that they were impermissibly prevented from putting
 2 on evidence regarding multiple theories of causation, including a theory based on an assertion that
 3 the generic manufacturer would have won the Paragraph IV patent litigation, by the district court’s
 4 summary judgment ruling. In reaching that conclusion, the First Circuit accepted the proposition
 5 that “the plaintiffs did not present such evidence that the brand-name’s patents would have been
 6 declared invalid or that an at-risk launch would not have infringed the patents. And without such
 7 evidence, the ‘patent served as an independent regulatory bar to [a generic’s] launch.’” *Id.* at 63
 8 (*quoting In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d at 767); *see also id.* (“The district
 9 court thus did not err by requiring some evidence of the patents’ invalidity or noninfringement
 10 before allowing the plaintiffs to pursue an at-risk launch theory.”); *cf. Apotex, Inc. v. Cephalon,*
 11 *Inc.*, No. 2:06-CV-2768, 2017 WL 2473148, at *8 (E.D. Pa. June 8, 2017) (“The clear import of
 12 Nexium and Wellbutrin is that a plaintiff must offer some evidence of non-infringement or patent
 13 invalidity in order to proceed on an at-risk launch theory of causation. The fact that the patent in
 14 question has been found to be invalid and non-infringed is relevant evidence on that required
 15 proof. Against this backdrop, I agree with Plaintiffs that evidence of a patent’s subsequent
 16 invalidation is highly probative to the lawful launch question.”).⁴

17 Plaintiffs respond, first, that these cases are inapposite under binding Ninth Circuit case
 18 law and that the existence of the ’529 patent does not make the but-for at-risk sales of Watson
 19 illegal. Plaintiffs point out that under the Hatch-Waxman Act and Paragraph IV litigation scheme,
 20 generic entrants are allowed into the market prior to patent expiration or invalidity. They need
 21 only secure an ANDA approval and have made the Paragraph IV certification that the patent is
 22 invalid, unenforceable, or will not be infringed. *See Anesta AG v. Mylan Pharm., Inc.*, No. CV
 23 08-889-SLR, 2014 WL 3976456, at *2 (D. Del. Aug. 14, 2014) (“although their launch was at
 24

25 ⁴ As broader support for their argument that a valid patent cuts off plaintiffs’ antitrust claims,
 26 defendants rely on a line of cases holding that plaintiffs cannot prove antitrust injury where an
 27 existing law or regulation would have prevented the competition that was allegedly foreclosed by
 28 collusive conduct. *See* Defs. Mot. SJ at 7 & n.9. Plaintiffs persuasively distinguish those cases
 because here, Watson would have been expressly permitted by regulation to enter the market upon
 ANDA approval and because patent law does not require a competitor to obtain permission *before*
 entering the market, but instead allows the patentee to seek an injunction stopping that
 competition.

1 risk, it was not illegal when it took place”).

2 Plaintiffs then rely on *Memorex Corp. v. Int'l Bus. Machines Corp.*, 555 F.2d 1379 (9th
3 Cir. 1977). There, Memorex brought antitrust claims against IBM who in turn asserted as a
4 defense that Memorex’s own wrongful acts (theft of IBM’s trade secrets) barred Memorex’s
5 antitrust claims. The Ninth Circuit held “that illegality is not to be recognized as a defense to an
6 antitrust action when the illegal acts by the plaintiff are directed against the defendant. A
7 wrongful act committed against one who violates the antitrust laws must not become a shield in
8 the violator’s hands against operation of the antitrust laws.” *Id.* at 1382. That concept, however,
9 was “particularly true when the defendant has other remedies available,” namely a counterclaim
10 against Memorex for the alleged misappropriation. *Id.* Plaintiffs argue that the principle
11 recognized in *Memorex* is particularly relevant here because there is no allegation that plaintiffs
12 committed any wrong, only a thin allegation that one of the alleged antitrust violators may have (if
13 the patent was ultimately held to have been valid) been making sales that would expose it to
14 damages and an injunction. However, I do not find *Memorex* as persuasive as plaintiffs contend.
15 Here, it is not defendants’ attempting to use plaintiffs’ illegal conduct, or even Watson’s conduct,
16 as a shield against antitrust liability. Instead, the question is what amount of evidence (if any)
17 must plaintiffs present to substantiate their assertion that defendants’ reverse settlement was
18 motivated by Endo and Teikoku’s concerns that their patent rights were at serious risk in light of
19 Watson’s patent litigation.⁵

20 More persuasive are plaintiffs’ criticisms of the *Wellbutrin* and *Nexium* decisions, and also
21 their argument that they have, nevertheless, met the burdens imposed on plaintiffs in those cases.

22 _____
23 ⁵ Plaintiffs also rely on a series of cases that rejected the related but distinct concept that the
24 regulatory requirements of the Hatch/Waxman Act (the 30-month automatic stay and the
25 requirements of securing ANDAs) could be the cause of the plaintiffs’ antitrust injury instead of
26 the conduct of the defendants in engaging in inequitable conduct before the PTO and filing sham
27 patent litigation cases. *See, e.g., In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, No.
28 CIV.A. 06-52 (GMS), 2010 WL 1485328, at *7 (D. Del. Apr. 13, 2010); *In re K-Dur Antitrust
Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004) (rejecting Hatch/Waxman Act as creating
intervening cause of antitrust injuries defeating claims, but further recognizing that “conjecture”
that at-risk launch “may have been improvident given the risk that the generic manufacturer might
lose the patent suit and been liable for damages, is not this Court’s concern on a motion to
dismiss.”). Defendants point out that those cases have been superseded on the point relevant here
by the *Nexium* and *Wellbutrin* decisions.

1 I agree that those courts' reliance on the FTC being the plaintiff in *Actavis* to discount the "large
2 and unexplained" reverse payment proxy for patent weakness standard adopted by the *Actavis*
3 majority is not supported by anything said by the *Actavis* majority. So does the California
4 Supreme Court, which in a thorough analysis of the *Actavis* decision concluded that "nothing in
5 the United States Supreme Court's discussion of the legal rules at the boundary between antitrust
6 and patent law hinged on the happenstance that the case under review involved a public
7 prosecutor." *In re Cipro Cases I & II*, 61 Cal. 4th 116, 142 (2015), *reh'g denied* (July 8, 2015).

8 The *In re Cipro* court pointed out that the if a reverse payment settlement "only replicates
9 the likely average result of litigation, any exclusion is a function of the underlying patent strength;
10 if it extends exclusion beyond that point, this further exclusion from the marketplace—and the
11 attendant anticompetitive effect—is attributable to the agreement." 61 Cal.4th at 150. In
12 discussing a defendant's burden to demonstrate that a reverse payment settlement was
13 procompetitive, the court later explained that "consideration of whether the agreement is justified
14 as procompetitive will not turn on whether the patent would ultimately have been proved valid or
15 invalid" because "[a]greements must be assessed as of the time they are made . . . at which point
16 the patent's validity is unknown and unknowable." *Id.* at 158 (recognizing that "[j]ust as later
17 invalidation of a patent does not prove an agreement when made was anticompetitive . . . later
18 evidence of validity will not automatically demonstrate an agreement was procompetitive."). The
19 court then acknowledged the Court's explanation in *Actavis* that an unexplained large reserve
20 payment could provide a workable surrogate for a patent's weakness. *Id.* at 159. In sum, in
21 explaining how the rule of reason analysis should play out in a reverse-payment settlement
22 scenario under the Cartwright Act, the *Cipro* court recognized that evidence regarding the strength
23 of the patent – assessed as of the time of the settlement – was important and also recognized that
24 the existence of a large and unexplained reverse payment was, likewise, relevant evidence of a
25 patent's weakness.

26 The *In re Cipro* court's conclusion, that patent validity and potential enforceability (*e.g.*,
27 strength and potential infringement) needs to be considered but that it is not necessary for a
28 plaintiff to show that the patents would ultimately be declared invalid or the generic determined

1 not to infringe, is not inconsistent with *In re Nexium*. In *Nexium* the First Circuit concluded the
 2 district court did not err by requiring plaintiffs to put forth “some evidence of the patents’
 3 invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory.” *In*
 4 *re Nexium*, 842 F.3d at 63 (emphasis added). “Some evidence” is not the same as requiring
 5 plaintiffs to prove that the generic defendant *would have* won, only that it *could have*. See also
 6 *Wellbutrin*, 868 F.3d at 169 (“On this record, then, no reasonable jury could conclude that Anchen
 7 would have been more likely than not to prevail.”); *In re Opana ER Antitrust Litig.*, 162 F. Supp.
 8 3d 704, 720 (N.D. Ill. 2016) (rejecting contention on a motion to dismiss that plaintiffs “must
 9 plead that the Endo patents would ultimately have been invalidated or found un infringed” as
 10 contrary to *Actavis*); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 241 (D. Conn. 2015) (in a
 11 motion to dismiss, the “salient question” as “not whether the fully-litigated patent would
 12 ultimately be found valid or invalid—that may never be known—but whether the settlement
 13 included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid
 14 the risk of competition.”).⁶

15 Taken together, these cases stand for the proposition that a plaintiff must have “some
 16 evidence” that the generic could have won the patent litigation, a burden that plaintiffs have
 17 satisfied as discussed below. That showing will be weighed by the trier of fact, along with the
 18 other factors recognized as relevant by the Supreme Court in *Actavis*, such as the large and
 19 unexplained nature of the reverse payment itself.

20 In sum, I disagree that plaintiffs need to prove *in this case* that Watson *would have* won its
 21 patent litigations. That turducken is not only unappetizing as a matter of judicial efficiency, it is
 22 not required (or even suggested) by the *Actavis* opinion.⁷ Instead, to put their at-risk launch theory
 23 of antitrust causation to the jury, plaintiffs must show “some evidence” that Watson could have
 24

25 ⁶ The district court subsequently certified that question for interlocutory review. *In re Aggrenox*
 26 *Antitrust Litig*, No. 3:14-MD-2516 SRU, 2015 WL 4459607 (D. Conn. July 21, 2015).

27 ⁷ Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, Carl Shapiro, The *Actavis* Inference: Theory
 28 and Practice. 67 Rutgers U. L. Rev. 585, 617 (2015) (citing to *F.T.C. v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012), *rev'd and remanded sub nom. F.T.C. v. Actavis, Inc.* (2013) 133 S.Ct. 2223(2013)).

1 won at trial before Judge Sleet or on appeal at the Federal Circuit. As discussed below, they have
2 made that showing.

3 **b. Watson's Chance of Success in the '529 Patent Litigation**

4 Plaintiffs argue that significant evidence exists that a reasonable juror could rely on to find
5 that Watson was likely to succeed in the '529 litigation including: (i) the large reverse payments
6 themselves; (ii) Watson's positions in its Paragraph IV certification and during the '529 litigation;
7 (iii) defendants' contemporaneous assessments that the '529 patent was weak; (iv) the testimony
8 of the parties' respective experts that Watson would have won on appeal on invalidity defenses (as
9 well as defendants' own experts concession that Watson would have won in the district court on
10 infringement); and (v) the evidence of record in the '529 litigation.

11 No one disputes that the record in the '529 patent litigation was closed at the time of the
12 parties' settlement. There had been a six day bench trial and the parties had submitted post-trial
13 briefing. All that remained was for the Judge Sleet to issue his findings of fact and conclusions of
14 law. As discussed below, for purposes of ruling on this motion, I conclude that plaintiffs have put
15 forth significant evidence that Watson could have prevailed in the '529 litigation. While there is
16 "some evidence" that Watson could have won on invalidity with respect to anticipation and non-
17 infringement, I need not consider that evidence in-depth, because plaintiffs present stronger
18 evidence on invalidity due to obviousness and unenforceability due to inequitable conduct.

19 **i. Contemporaneous Evidence from Defendants**

20 Plaintiffs note that in filing its ANDA application, Watson was required to and did certify
21 that the '529 patent was invalid, unenforceable, and would not be infringed by Watson's planned
22 generic. Watson spent over two years actively litigating the issues, contrary to defendants' current
23 characterizations of Watson's chances of success.

24 The parties' contemporaneous statements, according to plaintiffs, also support a finding
25 that Watson would have prevailed, including:

26 (i) Watson CEO's November 2011 earning call statements about its "strong litigation
27 stance" and intent to start sales in 2012, Sharp Decl., Ex. 3 at 7. Defendants argue that these
28 statements – made before the patent trial started – are irrelevant because they ignore the key

1 question here, what would have happened at and after trial and on appeal;

2 (ii) A July 2012 Watson memorandum that “the patents covering Lidoderm are not valid,”
3 that “Watson’s legal assessment” was that the patents were weak, and that as such Watson had
4 been preparing for launch upon FDA approval in July or August of 2012. *Id.*, Ex. 4 at 1. The
5 same memorandum described “Watson’s legal assessment of the patent held by Endo as being
6 weak.” *Id.* at 3. Defendants note that the provenance of this “draft” disclosure statement is in
7 dispute, as the purported author, Joe DosSantos denied having knowledge of it;

8 (iii) A February 2012 email from Endo General Counsel Caroline Manogue characterizing
9 the patent as “very weak” and deposition testimony from Teikoku’s outside counsel characterizing
10 Endo’s “negative impression” of the strength of the patent. Sharp Decls., Exs. 5 (email) and 6
11 (Shimoda Depo. Tr.) at 267-269. Defendants again downplay the significance of these documents,
12 as they too were drafted before the patent trial, which they believe is the relevant point of focus;
13 and

14 (iv) Draft Endo accounting letters from July 2012 that, “[w]hile the settlement with
15 Watson was reached prior to the court’s ruling, it was the view of [Endo’s] management that there
16 was a significant probability that the courts may find one or more of the patents to be invalid” and
17 that “Watson and potentially other Companies may be able to launch a generic version of
18 Lidoderm.” *Id.*, Ex. 7 at 11. Endo also admitted that it “believed a ruling in favor of Watson was
19 very plausible, thus furthering our desire to settle.” *Id.* Ex. 8 at 15. Defendants characterize these
20 as having been written by individuals without knowledge of the ’529 patent litigation and were
21 prepared for review by others with actual knowledge “to fill in the gaps.”

22 This evidence is relevant. Although its implications and importance are clearly disputed, it
23 is significant enough – in combination with the expert opinions discussed below – to defeat
24 defendants’ motion for summary judgment.

25 **ii. Expert Analysis**

26 Plaintiffs rely most heavily – and defendants dispute most vigorously – on the testimony of
27 plaintiffs’ patent experts. After reviewing the trial record in the ’529 litigation, those experts
28 opine that Watson would have prevailed, if not in trial court then on appeal, on the issues of

1 invalidity due to anticipation and obviousness, as well as unenforceability due to inequitable
2 conduct before the PTO.

3 Anticipation

4 Plaintiffs argue that Watson would have won on anticipation, maybe at trial but definitely
5 on appeal, based on Watson's argument and evidence at trial that the '529 claims were anticipated
6 by the "Takeda reference" that disclosed a lidocaine hydrogel patch.⁸ Defendants challenge that
7 assertion, arguing – as they did in the underlying '529 trial – that because the Takeda reference did
8 not sufficiently disclose use of lidocaine in the patch, it did not "enable" a lidocaine patch.
9 Defendants also argue that because Takeda did not disclose a particular concentration of lidocaine
10 that could be used in the patch, the Takeda disclosure cannot support the "adequate description"
11 requirement of an anticipation defense. Plaintiffs, in turn, dispute those contentions, arguing that
12 the record below shows and arguments on appeal would have established that lidocaine was
13 sufficiently disclosed. More particularly, as the Takeda reference discusses various embodiments,
14 the teaching to use "expected clinical effect" was sufficient in conjunction with the fact that the
15 Takeda concentration ranges overlap with the 5% lidocaine concentration claimed in the '529
16 patent, even if a 5% concentration was not expressly identified within Takeda for lidocaine. *Id.*⁹

17 For support, plaintiffs rely on Professor Martin Adelman who opines that based on the
18 record before the trial court, Watson would have won on anticipation in light of the Takeda
19 reference. Adelman Report (Declaration of Dena Sharp [Dkt. No. 819-1], Ex. 12 [Dkt. No. 819-
20

21 ⁸ The Takeda reference is U.S. Patent No. 4,695,465, entitled "Soft Patch." Takeda Patent (Sharp
22 Decl., Ex. 16 [Dkt. No. 819-17]). The patent discloses 161 compounds that can be used in a
23 hydrogel patch in various concentrations where the "concentration of the drug need only be that
24 which exhibits the expected clinical effect, and in many instances ranges from about 0.01 to 14
25 weight percent, preferably 0.05 to 10 weight percent." *Id.* 3:30-34.

26 ⁹ Plaintiffs note that the burden to show non-enablement fell on Endo. *Amgen Inc. v. Hoechst*
27 *Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003) ("Thus, a court cannot ignore an
28 asserted prior art patent in evaluating a defense of invalidity for anticipation, just because the
accused infringer has not proven it enabled. Like the applicant in *ex parte* prosecution, however,
the patentee may argue that the relevant claimed or unclaimed disclosures of a prior art patent are
not enabled and therefore are not pertinent prior art. If a patentee presents evidence of
nonenablement that a trial court finds persuasive, the trial court must then exclude that particular
prior art patent in any anticipation inquiry, for then the presumption has been overcome.").

13) ¶¶ 22-37.¹⁰ Reviewing the evidence admitted at trial and the argument made by both Watson and Endo, Adelman opines that “a reasonable factfinder would conclude that Takeda discloses both lidocaine and discloses the use of lidocaine in a soft patch formulation in [the various disclosed ranges of concentration].” Adelman Report ¶ 37.¹¹

Defendants counter with patent litigator Robert S. Frank, Jr., who disputes Adelman’s conclusions and opines that Judge Sleet would have not found Takeda anticipating. Frank Report (Declaration of Daniel B. Asimow [Dkt. No. 786-1], Ex. [Dkt. No. 786-12], ¶¶ 48-49. Frank argues that in order for Watson to have won on anticipation, Judge Sleet would have had to credit Watson’s expert (Walters) over Endo’s expert (Lane), which he was unlikely do given Judge Sleet’s statements in closing argument suggesting that he found Lane credible over Walters. *Id.* ¶¶ 41-47;¹² *see also* Report of David L. Schwartz (Asimow Decl., Ex. 25 [Dkt. No. 786-13] ¶ 177 (no anticipation because Takeda disclosure does not contain a disclosure regarding the concentration of lidocaine, but merely disclosed ranges).

In their briefs, the parties spend significant time debating whether and how persuasively various arguments were made in the trial court, relying on transcripts as well as Judge Sleet’s

¹⁰ Defendants move to exclude Adelman’s testimony. The motion, as discussed below, is DENIED.

¹¹ Plaintiffs mention in passing that they also rely on Dr. Kishore Shah for anticipation. Shah Report (Sharp Decl., Ex. 14 [Dkt. No. 819-15]) ¶¶ 54-72. However, they do not discuss Shah’s opinions in their Opposition. Shah’s opinions are likewise the subject of a motion to exclude by defendants, which as discussed below is DENIED.

¹² In closing, Judge Sleet made the following comments:

. . . I am a jury of one, and in this case, it seems to be not inappropriate for me to take advantage of the opportunity to ask a few questions of counsel.
It may help me resolve this case.

So, as you both know, jurors are typically instructed that as the fact-finder, they are free to accept or reject all or any part of any witness’ testimony, including that of so-called opinion witnesses or expert witnesses.

My question is: What result should there be if I largely discount the testimony of Dr.

Walters either because of an absence of opinion . . . in critical areas, or because I simply don’t find him credible over Dr. Lane?

Asimow Decl., Ex. 5, Closing Arg. Tr. 44. Defendants place much support on these comments as indicating that Judge Sleet intended to find Lane credible over Walters, and given the standard of review on anticipation, the Federal Circuit would have been bound to follow Judge Sleet’s acceptance of Lane’s opinion there was no anticipation. Defendants read too much into these comments.

1 comments in closing argument about who he might find credible. However, Judge Sleet had not
 2 yet ruled and there was significant, if disputed, evidence in the record to support both sides.
 3 Reviewing the record and arguments as a whole, plaintiffs have produced “some” evidence that
 4 Watson would have won on anticipation, if not at the district court, then on appeal.

5 Obviousness

6 Plaintiffs rely again on Adelman, who opines that even if anticipation was not shown, “the
 7 Takeda reference presented a strong case for obviousness, especially when combined with the
 8 Teikoku Hydrogel Art and Topical Lidocaine Art.” Adelman Report ¶ 108; *see also id.* ¶¶ 39-
 9 81.¹³ Plaintiffs note that Endo’s expert in the ’529 trial admitted that the only distinction between
 10 the ’529 claims and Teikoku’s own prior-disclosed hydrogel art was lidocaine, and Watson
 11 showed through its expert that Takeda disclosed a lidocaine hydrogel patch that made the ’529
 12 claims obvious.¹⁴

13 Defendants argue that plaintiffs have failed to adduce evidence that Watson was likely to
 14 succeed on both prongs of the obviousness test: to show person of ordinary skill in the art had (a)
 15 the motivation to make the invention and (b) a reasonable expectation of success in doing so.
 16 Defendants point out at that at trial Endo spent much time arguing through its expert that the art
 17 was unpredictable and even Watson’s expert had not made a lidocaine hydrogel patch (although he
 18 had formulated other lidocaine patches). As to motivation, defendants acknowledge that there was
 19 “conflicting testimony” in the trial court, but again rely on Judge Sleet’s comments during closing
 20 that he would credit Endo’s expert over Watson’s, and that Endo’s expert (Lane) made an
 21 extensive argument that prior art “taught away” from putting lidocaine in a hydrogel patch because
 22

23 ¹³ Plaintiffs in passing note that they also rely on Shah, who opines that Watson would have won
 24 at trial and on appeal on obviousness because, even if not anticipating, the patent was invalid over
 25 prior art. Shah Report ¶¶ 73-97. Neither side addresses Shah’s opinions in their summary
 26 judgment briefing.

27 ¹⁴ Adelman ¶ 84 (“The only conceivable argument against a combination of the Teikoku Hydrogel
 28 Art with the Topical Lidocaine Art is that there was no apparent reason to combine lidocaine with
 a hydrogel patch formulation, but Dr. Lane, Endo’s own expert, foreclosed that argument when
 she admitted that Rowbotham suggests to those of ordinary skill in the art that a patch formulation
 should be created to better control the rate of administration of lidocaine. Trial Tr. at 996:21-
 25.”).

1 all prior lidocaine patches were water-free. Closing Argument Tr. at 44.¹⁵

2 Reviewing the evidence in *this* record as a whole, plaintiffs have made a strong showing
3 that Watson could have won on obviousness sufficient to defeat defendants' motion for summary
4 judgment.

5 Unenforceability

6 Plaintiffs also argue, again relying heavily on Adelman, that Watson was likely to prevail
7 at trial and on appeal because the '529 patent was unenforceable as a result of Teikoku's
8 inequitable conduct. Adelman Report ¶¶ 82-92.¹⁶ The inequitable conduct at issue is whether
9 Teikoku and the '529 inventor (Ono) affirmatively misled the PTO by failing to disclose specific
10 "Teikoku Hydrogel" prior art references. Adelman Report ¶¶ 83-88.

11 Defendants assert that this defense rises and falls to the same extent as the obviousness
12 defense above, as both rely on the Teikoku Hydrogel prior art. As to intent to deceive, defendants
13 point to Judge Sleet's questions and comments in closing, attempting to distinguish where intent
14 lies when an inventor simply signs whatever disclosures are given to him without review (as Ono
15 testified), and Judge Sleet's comments that he found Ono credible and believed him. Closing
16 Argument Tr. at 45, 108-09. Plaintiffs respond that Judge Sleet's inclinations cannot be
17 deciphered solely from the comments identified by defendants and point out that Judge Sleet also
18 referred to the importance of full disclosure to the PTO from a factual and policy perspective and
19 noted he was free to draw reasonable inferences based on Watson's attempt to show specific intent
20 to deceive. Closing Argument Tr. at 23 105-107.

21 Plaintiffs also argue that there was sufficient evidence and supporting argument in the
22 record so show that Teikoku engaged in an inequitable "failure to disclose" because the

23 _____
24 ¹⁵ As noted above, I do not interpret Judge Sleet's questions asking counsel to opine on the impact
of his crediting one expert over another as strongly and concretely as defendants do.

25 ¹⁶ As explained by the Federal Circuit, "as a general matter, the materiality required to establish
26 inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO,
that prior art is but-for material if the PTO would not have allowed a claim had it been aware of
27 the undisclosed prior art." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291
(Fed. Cir. 2011). There is an exception for but-for materiality, "[w]hen the patentee has engaged
28 in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit,
the misconduct is material." *Id.* at 1292.

1 declarations submitted to the PTO asserted only “fictional distinctions” over prior art and its
2 experts (and Watson’s at the ’529 trial) asserted that the non-disclosure was material and Ono’s
3 failure to disclose the prior art was egregious. Defendants respond that because Watson did not
4 assert affirmative misrepresentations (based on omissions) in the ’529 trial itself, plaintiffs cannot
5 rely on that theory to show Watson could have won on that ground in this case. However, the
6 evidence underlying this theory is *in* the ’529 record and even if not expressly argued at closing,
7 could have formed a basis of either the trial court or Federal Circuit’s decisions.

8 Plaintiffs have presented strong evidence that Watson could have succeeded on
9 unenforceability.

10 Other Grounds

11 Defendants argue that in light of an erroneous claim construction by Judge Sleet (as
12 subsequently confirmed by the Federal Circuit in *Multilayer Stretch Cling Film Holdings, Inc. v.*
13 *Berry Plastics Corp.*, 831 F.3d 1350 (Fed. Cir. 2016)), Watson would have lost its appeal on
14 infringement. Plaintiffs do not really dispute this position, although they rely on an expert for the
15 essentially-agreed-to position that Watson would have won on non-infringement at the trial court
16 level. Instead, plaintiffs argue in passing that Endo bears the burden to show infringement on
17 summary judgment *here* – because they bore that burden in the ’529 litigation – and they failed to
18 do so. Pls. Oppo. to Defs. MSJ at 22. Defendants dispute this, contending that because it is
19 plaintiffs’ burden here to show antitrust injury premised on non-infringement or invalidity, they
20 bear the burden to show non-infringement by Watson. Plaintiffs have *not* introduced “some
21 evidence” that a reasonable juror could rely on to find that Watson would have ultimately won on
22 non-infringement.

23 Similarly, defendants also move for “summary judgment” on the “derivation defense,”
24 arguing plaintiffs cannot establish a genuine issue of material fact that Watson could have proven
25 in the ’529 litigation that a third-party conceived of the ’529 invention. Defs. MSJ at 12.
26 Plaintiffs do not address this defense in their Opposition.

27 Accordingly, under Rule 56(g), the material facts that Watson could not have won on non-
28 infringement and derivation are established for trial.

iii. '529 Litigation Record

1 Plaintiffs also rely on three categories of evidence introduced by Watson in the '529
2 litigation that a reasonable juror could rely on to determine that Watson would have won at trial
3 and on appeal without regard to plaintiffs' experts' analyses. That evidence concerns: (i)
4 anticipation by Takeda; (ii) obviousness in light of the Teikoku Hydrogel prior art and teachings to
5 use lidocaine in those patches; and (iii) inequitable conduct before the PTO. Pls. Oppo. to Defs.
6 MSJ at 16-18. This evidence is the same as that relied upon by its experts above and, as noted,
7 helps plaintiffs meet the "some evidence" mark.¹⁷

8 Defendants' motion for summary judgment on the ground that the '529 patent broke the
9 chain of antitrust causation is DENIED.

2. Plaintiffs' Alternative Theory of Causation

10 Plaintiffs have a second theory of causation; that absent the reverse-payment Settlement,
11 the parties still would have agreed to an anticompetitive settlement, but one where no payment
12 was made and only early generic entry was allowed. Defendants argue that this theory is not
13 legally viable (and move to exclude the expert testimony submitted in support of it). Even if
14 legally viable, defendants argue that it is purely speculative as there is no evidence in the record to
15 support it.
16

a. Whether the Theory is Cognizable

17 Defendants argue this alternate theory is not cognizable as a matter of law and (at least
18 with respect to the Cartwright Claims) is barred by the California Supreme Court's decision in *In*
19 *re Cipro Cases I & II*, 61 Cal. 4th at 153. There, in determining the elements of a prima facie case
20 under the Cartwright Act and who bears the burdens, the court noted that: "Unless a challenged
21
22

23
24 ¹⁷ Plaintiffs also argue, as a fallback position, that defendants failed to produce evidence showing
25 that if Endo/Teikoku won the '529 patent litigation, Endo/Teikoku would have forced Watson off
26 the market. Plaintiffs contend that even if Endo/Teikoku had been successful at trial and on the
27 eventual appeal, an injunction forcing Watson off the market was uncertain as to timing (because
28 when that remedy would have been available depended on what grounds the Federal Circuit
decided on and whether judgment was entered by the Circuit or the case was remanded to Judge
Sleet) and as to certainty (because Endo/Teikoku could well have determined that Watson's
penetration into the market made it more profitable for Endo/Teikoku to allow Watson to continue
its sales with royalties). In light of the rulings made above, I need not reach this argument on
summary judgment.

1 settlement agreement includes *both* a restraint on generic competition and a reverse payment to the
2 generic in excess of both brand litigation costs and generic collateral products and services, there
3 is no reason to assume the settlement includes any element of purchased freedom from
4 competition, as opposed to a limit on competition flowing naturally, and lawfully, from the
5 perceived strength of the brand’s patent.” *Id.* at 153 (emphasis added). The court explained that
6 the relevant “baseline” is the “average period of competition that would have obtained in the
7 absence of settlement.” *Id.* at 158.

8 As plaintiffs point out, however, the *Cipro* court was not analyzing causation – the critical
9 issue here – but whether a Cartwright antitrust claim could be asserted in face of a patent defense,
10 essentially considering the same issue that was before the Supreme Court in *Actavis*. Moreover,
11 the *Cipro* court’s comments do not foreclose an argument that antitrust injury could have been
12 nonetheless *caused* in absence of a reverse-payment if there is evidence in the but-for world that
13 the parties would have reached an agreement to drop the patent litigation in exchange for early
14 generic entry into the market.

15 The district court in *Wellbutrin* recognized the viability of the “alternate settlement”
16 method of proving causation, *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 757 & n.2
17 (E.D. Pa. 2015), but rejected the theory on the facts of that case where there were “no facts in the
18 summary judgment record” to support it. *Id.* at 757. The evidence there was expressly to the
19 contrary; the record was replete with evidence that the generic manufacturer would not settle
20 absent a no authorized generic (AG) agreement. *Id.*¹⁸ On appeal, the Third Circuit agreed that
21 alternate settlement scenarios can support causation, but that evidence was required to support
22 such a theory and it could not rest on “pure speculation.” *Wellbutrin*, 868 F.3d at 167 & n.57.

23 Relatedly, defendants argue that plaintiffs’ alternate theory – that some other settlement
24 would have been reached – is an impermissible attempt to show cognizable harm by arguing “that
25

26 ¹⁸ In rejecting plaintiffs’ alternate settlement causation theory, the district court also noted that
27 plaintiffs’ expert Leitzinger (who is plaintiffs’ expert here) did not explain what the proposed
28 “alternate” settlement would have looked like and rested his testimony solely on fact that their
reverse payment was not “justified.” *Id.* at 757-58.

1 the parties might have elected a different settlement agreement more favorable to competition and
2 consumers.” *In re Cipro Cases I & II*, 61 Cal. 4th at 150 n.10. But plaintiffs are not attempting
3 to require (or show) that defendants *should have* settled on terms that are the most favorable to
4 consumers. Instead, they are positing an alternative settlement scenario that shows but-for the
5 reverse-payment agreement, the parties would have reached a settlement that was still anti-
6 competitive and caused unjustified harm to consumers.¹⁹

7 In addition to *Cipro*, defendants rely on other cases (arising primarily in the legal
8 malpractice context, not in reverse-payment cases) to argue that “alternative settlement” scenarios
9 are generally not cognizable. *See* Defs. MSJ at 26-27. Those cases are inapposite. In the antitrust
10 context, where but-for worlds are considered and profit-maximizing goals assumed, there is by
11 necessity second-guessing involved, although that second-guessing has to be supported by
12 *evidence* as discussed below.²⁰ A similar concept has been adopted in patent litigation, where
13 reasonable royalties have to be constructed based on hypothetical negotiations. *See, e.g., Fujifilm*
14 *Corp. v. Motorola Mobility LLC*, No. 12-CV-03587-WHO, 2015 WL 1737951, at *2 (N.D. Cal.
15 Apr. 8, 2015) (“The hypothetical negotiation is a legal construct that ‘attempts to ascertain the
16 royalty upon which the parties would have agreed had they successfully negotiated an agreement
17 just before infringement began.’” (quoting *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d
18 1301, 1324 (Fed.Cir. 2009))).

19 **b. Whether There is Sufficient Evidence to Survive Summary**
20 **Judgment**

21 Plaintiffs’ experts identify various “no payment” settlements providing Watson with early
22 access at different dates that would still have been in defendants’ favor and still have caused

23 _____
24 ¹⁹ Plaintiffs spend significant time arguing that no-payment settlements of Hatch Waxman Act
25 (HWA) patent litigation are common (if not predominant) and arguing that HWA settlements that
26 restrict generic access, even in absence of payments, still have anticompetitive effects. Those
27 points are not in dispute.

28 ²⁰ As explained by the Ninth Circuit, “[i]n a hypothetical economic construction, such as the one
underlying Murphy’s theory on lost past profits, economic rationality must be assumed for all
competitors, absent the strongest evidence of chronic irrationality. Otherwise it will be impossible
to keep speculation in check.” *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir.
1981).

1 plaintiffs injury (*i.e.*, could not be justified by procompetitive reasons); the Retailer Plaintiffs rely
2 on the economic analysis of Dr. Keith B. Leffler and the remaining plaintiffs rely on Professor
3 Einer Elhauge. Elhauge concludes that the hypothetical licensed entry date would have been
4 October 26, 2012. Elhauge Report [Dkt. No. 783-2] ¶ 139. Leffler concludes that January 3, 2013
5 is the hypothetical early-entry date to which defendants would have agreed. Leffler Report [Dkt.
6 No. 278-2] ¶ 37.

7 Defendants argue that Elhauge’s opinions – based on estimated bargaining strength (tied to
8 the actual Settlement terms) that is then applied to the hypothetical negotiation – are based on
9 unreasonable assumptions about finances and risk. In particular, defendants challenge Elhauge’s
10 use of the actual Settlement to estimate bargaining power in a “very different” hypothetical
11 settlement.

12 Defendants challenge Leffler’s different approach – calculating entry dates by valuing the
13 parties’ expectation of profits from an early-entry only settlement as opposed to continued
14 litigation – as based only on an inference that otherwise unjustified delay exists from the existence
15 of the unjustified large reverse payment. Such an inference was found to be insufficient in
16 *Wellbutrin*, 133 F. Supp.3d at 757-58.

17 Finally, defendants challenge both Elhauge’s and Leffler’s lack of experience with real
18 world negotiations in general and HWA settlement negotiations in particular as grounds to find
19 their testimony speculative and insufficient to support summary judgment.

20 Plaintiffs respond that Elhauge’s analyses are based on the accepted-in-antitrust law
21 proposition that parties are profit-maximizing, meaning that no party would agree to a settlement
22 unless the settlement payoff exceeded its litigation payoff. Starting from this proposition, and
23 using the terms of the Settlement agreed to and the companies’ own profit projections, Elhauge
24 calculated that if Endo thought it had more than a 15.1% chance of winning, it would not have
25 rationally agreed to the actual Settlement. Elhauge Report ¶¶ 6, 147. Then he considered the
26 various possible strengths each party could have rationally had with respect to the litigation, to
27 produce a range of feasible no-reverse-payment-settlement early entry dates that still would have
28 provided each party with a payoff exceeding its litigation payoff. Plaintiffs explain that Leffler’s

1 analyses, while different, are also firmly rooted in economic theory and tied to the facts in this
 2 case. Leffler used economic literature analyzing settlements, but then also calculated Endo's
 3 profits from winning versus losing the patent litigation and weighted those expectations based on
 4 the objective expectations provided by Adelman.

5 Both of these case-based analyses – applying accepted principles in antitrust law and
 6 settlement analysis to evidence in this case – are different than what happened in *Wellbutrin*.
 7 There, the expert provided no testimony that an alternate settlement would have been reached nor
 8 described what that settlement would have looked like. 133 F. Supp. 3d at 757-58. Here, as
 9 noted above, both experts' approaches are fully consistent with the principles applied in but-for
 10 damage calculations. *See, e.g., Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d
 11 1506, 1511 (9th Cir. 1985) (plaintiffs “must presume the existence of rational economic behavior
 12 in the hypothetical free market.”); *see also Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262
 13 (9th Cir. 1981) (“economic rationality must be assumed for all competitors, absent the strongest
 14 evidence of chronic irrationality”).²¹

15 Defendants do not point to any specific evidence considered or assumptions made by the
 16 experts that are contrary to evidence in the record. *See, e.g., In re Online DVD-Rental Antitrust*
 17 *Litig.*, 779 F.3d 914, 924 (9th Cir. 2015) (“Subscribers' experts' testimony is contrary to the
 18 undisputed market facts.”); *Pennsylvania Dental Ass'n v. Med. Serv. Ass'n of Pennsylvania*, 745
 19 F.2d 248, 261 (3d Cir. 1984) (expert affidavit that expressed opinion based on specific factual
 20 assertions for which no support was provided, could not defeat summary judgment). At most
 21 defendants criticize plaintiffs' experts for failing to consider or adequately consider certain points
 22 they believe are significant (*e.g.*, risk adversity); those sorts of disagreements are the subject for
 23

24
 25 ²¹ The cases that defendants rely on to argue that economic rationality and profit-maximizing are
 26 not appropriate (much less required) assumptions stand at most as criticisms of expert testimony
 27 that ignored established facts and market structures and attempted to rely *only* on theories of
 28 rationality/profit-maximization. *See, e.g., Am. Booksellers Ass'n, Inc. v. Barnes & Noble, Inc.*,
 135 F. Supp. 2d 1031, 1040 (N.D. Cal. 2001); *The Iams Co. v. Nutro Prod., Inc.*, No. 3:00-CV-
 566, 2004 WL 5496244, at *3 (S.D. Ohio June 30, 2004) (expert could not rely on logical
 economic rationality assumptions to argue “perfect cross-elasticity of demand” between two
 brands of dog food where it was “untested by the evidence in this case.”).

1 cross-examination.²²

2 Plaintiffs, through their experts, have applied evidence from the record in this case to posit
3 alternative early entry settlement dates in support of their second causation theory. While
4 defendants challenge their methodologies, defendants have not shown that their conclusions are
5 contradicted by undisputed evidence in the record. Defendants' motion for summary judgment on
6 the second causation theory is DENIED.

7 **II. DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT RE**
8 **CAUSATION/MANUFACTURING**

9 In the alternative, defendants move for partial summary judgment arguing that undisputed
10 evidence demonstrates that Watson could not have launched its generic earlier than December 17,
11 2012, and defendants' conduct (if anticompetitive) could not have caused plaintiffs any alleged
12 injury before that date. Defs. Mot. for PSJ [Dkt. No. 794].

13 Plaintiffs do not oppose and do not intend to argue or show that they suffered any injury
14 prior to December 17, 2012. Pls. Oppo. to Mot. for PSJ at 1 [Dkt. No. 814]. Accordingly, I
15 GRANT defendants' partial motion under Rule 56(g) finding that: (i) Watson could not have
16 launched generic Lidoderm any earlier than December 17, 2012, and (ii) defendants' alleged
17 conduct could not have caused plaintiffs injury prior to that date. Dkt. No. 794-21.

18 Plaintiffs ask me to go further to find that there is no genuine dispute under Rule 56(a) or
19 (g) that: (i) Watson had 23 million patches manufactured by March 26, 2013 in the actual world
20 (*i.e.*, the world with the reverse payments), and thus it would have had at least that many patches
21 by that date in the but-for world (*i.e.*, the hypothetical world absent the delay caused by the reverse
22 payments), and (ii) 23 million patches is what Watson contemporaneously considered to be the
23 number with which it would launch its generic Lidoderm patches. *Id.*

24 Defendants oppose plaintiffs' request as procedurally improper and also argue that disputes
25 of material fact preclude the findings plaintiffs seek. Defs. Reply ISO MPSJ at 2 [Dkt. No. 850].

26
27 ²² Defendants' argument that Elhauge's and Leffler's opinions should be discounted (or excluded)
28 because they are not experts in legal negotiations or negotiations more generally (like defense
expert Moffitt), is also unpersuasive, particularly given the profit-maximizing assumption that
runs throughout the legal and factual issues to be resolved in this case.

1 First, defendants argue that there are disputes of fact whether Watson would have
2 manufactured generic Lidoderm in the but-for world at the same rate as it did in the actual world.
3 According to defendants, Watson’s manufacturing difficulties required Watson to pause its
4 production of generic Lidoderm in June 2012; after technical and operational fixes, it resumed
5 production in September 2012. Plaintiffs’ position is that absent the Settlement, Watson would
6 not have paused to make those fixes and continued production. Defendants respond that even if
7 that is correct, the level of production would have continued to be slow (much slower than it was
8 in the actual world after the fix) and Watson would not have had 23 million patches until July 21,
9 2013. Amended Expert Report of Benoit Cossart [Dkt. No.794-10] ¶¶ 95-97; *see also* Depo. Tr.
10 of John Spigiel [Dkt. No. 850-4] at 242-243 (production of 23 million patches by March 2013 was
11 due in part to the ability to fix technical issues). The Cossart and Spigiel testimony raise a dispute
12 of material fact precluding a finding under Rule 56(g).

13 As to the amount of patches Watson wanted to have at launch, 23 million patches (launch
14 quantities plus 4 weeks of inventory) or 35 million patches (launch quantities plus 12 weeks
15 inventory), plaintiffs rely on testimony from Watson’s plant General Manager Spigiel that
16 “sufficient quantities” for launch, 23 million patches, were not achieved until March 2013 and that
17 Watson documents show that 23 million patches was the forecasted launch quantity. Pls. Oppo. to
18 Defs. MSJ re Causation at 4-6. Defendants respond that a “typical” launch would have required
19 12 weeks of supply, relying on the testimony of then-Assistant Director of Materials Lee
20 Lamborn, who also testified that he could not recall a launch where Watson had less product on
21 hand. The documents plaintiffs rely on, according to defendants, address a reduced launch supply
22 and show that the launch target for Lidoderm was a moving target. Again, the differing
23 interpretations of the documents at issue and related testimony raise a material dispute of fact for
24 the jury precluding a finding under Rule 56(g).

25 Defendants’ motion for partial summary judgment on this limited issue is GRANTED and
26 plaintiffs’ attempted-cross motion is DENIED.

27 **III. PLAINTIFFS’ MOTION FOR PARTIAL SUMMARY JUDGMENT**

28 Plaintiffs move for partial summary judgment seeking to establish: (i) the “contract,

1 combination, or conspiracy” elements of their Section 1, Section 2, and state law conspiracy to
 2 monopolize claims is satisfied by the Agreement; and (ii) the composition of the relevant antitrust
 3 product and geographic markets is lidocaine 5% patches (both in branded and generic forms) sold
 4 in the United States. In the alternative, plaintiffs move under Rule 56(g) to establish the same
 5 facts for trial.

6 **A. Agreement, Conspiracy, or Combination Element**

7 Plaintiffs argue that the Settlement Agreement, signed by all three defendants, satisfies the
 8 “contract, combination, or conspiracy” elements of their Section 1, Section 2, and state law
 9 conspiracy to monopolize claims. Defendants do not dispute this, although they do dispute the
 10 significance, lawfulness, and effect of the various provisions in that Agreement. Def. Oppo. to
 11 MSJ [Dkt. No. 812] at 25. Plaintiffs’ motion is GRANTED on this issue.

12 **B. Antitrust Product Market²³**

13 Plaintiffs seek summary judgment defining the relevant antitrust product market as limited
 14 to lidocaine 5% patches; in other words, Lidoderm and its generics. Defendants oppose and
 15 contend that the market should include a host of other pain medications that come in various forms
 16 including nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and Celebrex,
 17 anticonvulsants like Lyrica, antidepressants like Cymbalta, muscle relaxers like Flexeril, opioids
 18 like tramadol, and topical anesthetic creams and gels like Qutenza.

19 Plaintiffs argue that there is no cross-elasticity of demand between Lidoderm and *any* other
 20 product (other than generic Lidoderm), and that therefore as a matter of law the relevant market is
 21 limited to Lidoderm and its generics. They contend that defendants’ experts did not consider the
 22 key and necessary legal issue of cross-elasticity of demand at all. Defendants counter that cross-
 23 elasticity of demand is relevant but not *required* to determine the relevant product market, and that
 24 other considerations – including evidence that other products are therapeutically similar and
 25 evidence about non-price competition in the pharmaceutical industry – are relevant to the
 26

27 _____
 28 ²³ The relevant antitrust market includes a geographic market and a product market. *Tanaka v. Univ. of S. California*, 252 F.3d 1059, 1063 (9th Cir. 2001). There is no dispute that the geographic market is the United States.

1 determination of the product market to be decided by the jury. Even if cross-elasticity is a
 2 required element, defendants argue their expert made evidence-based inferences about cross-
 3 elasticity that likewise raise material issues of fact precluding summary judgment on the product
 4 market definition.

5 1. In General

6 “The elements of a cause of action for an unreasonable restraint of trade under the rule of
 7 reason analysis” are: “(1) An agreement among two or more persons or distinct business entities;
 8 (2) Which is intended to harm or unreasonably restrain competition; (3) And which actually causes
 9 injury to competition.” *Kaplan v. Burroughs Corp.*, 611 F.2d 286, 290–91 (9th Cir. 1979) (citing
 10 *Times-Picayune Publishing Co. v. United States*, 345 U.S. 594, 615 (1953)). “Proof that the
 11 defendant’s activities had an impact upon competition in a relevant market is an absolutely
 12 essential element of the rule of reason case.” *Id.* at 291. Defining the appropriate market is key
 13 because “[i]t is the impact upon competitive conditions in a definable product market which
 14 distinguishes the antitrust violation from the ordinary business tort.” *Id.*

15 Determination of the relevant market is typically a fact-intensive inquiry, involving
 16 “identification of the field of competition: the group or groups of sellers or producers who have
 17 actual or potential ability to deprive each other of significant levels of business. . . . This
 18 definitional process is a factual inquiry for the jury; the court may not weigh evidence or judge
 19 witness credibility.” *Thurman Indus., Inc. v. Pay 'N Pak Stores, Inc.*, 875 F.2d 1369, 1374 (9th
 20 Cir. 1989).²⁴ Here, however, plaintiffs contend summary judgment is warranted because
 21 defendants cannot show that a material dispute of fact exists on a necessary element; cross-

22
 23 ²⁴ “In limited settings [] the relevant product market may be narrowed beyond the boundaries of
 24 physical interchangeability and cross-price elasticity to account for identifiable submarkets or
 25 product clusters.” *Thurman Indus.* 875 F.2d at 1374. As the Ninth Circuit has explained, “[t]he
 26 concept of identifying submarkets for antitrust purposes had its first exposition in *Brown Shoe* . . .
 27 . There, the Supreme Court delineated several factors for consideration in the conduct of a
 28 submarket inquiry: whether industry or the public recognizes the proposed submarket as a separate
 economic entity; whether the products involved have peculiar characteristics or uses; whether
 unique production facilities are involved; and whether distinct customers, distinct prices, price
 change sensitivity, or specialized vendors highlight the proposed submarket.” *Id.* at 1375. The
Brown Shoe “indicia are practical aids for identifying the areas of actual or potential competition
 and that their presence or absence does not decide automatically the submarket issue.” *Id.*

1 elasticity of demand between 5% lidocaine patches and the products defendants contend should be
2 included in the relevant market.

3 2. Cross-Elasticity of Demand

4 Plaintiffs' motion hinges on the position that cross-elasticity of demand *must* be present
5 between a defendant's product and other products for those other products to be "reasonably
6 interchangeable" and included in the antitrust product market. Cross-elasticity of demand occurs
7 where "an increase in the price of one product leads to an increase in demand for another, both
8 products should be included in the relevant product market." *Olin Corp. v. F.T.C.*, 986 F.2d 1295,
9 1298 (9th Cir. 1993). "The determination of what constitutes the relevant product market hinges,
10 therefore, on a determination of those products to which consumers will turn, given reasonable
11 variations in price." *Lucas Automotive Engineering, Inc. v. Bridgestone/Firestone, Inc.* (9th Cir.
12 2001) 275 F.3d 762, 767 (9th Cir. 1997); *see also Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1483
13 (9th Cir. 1997), *aff'd*, 525 U.S. 299 (1999), *overruled on other grounds by Lacey v. Maricopa Cty.*,
14 693 F.3d 896 (9th Cir. 2012) ("A high cross elasticity of demand indicates that products are close
15 substitutes, and should probably be treated as part of the same market. A low or zero cross
16 elasticity of demand is evidence that products do not compete in the same relevant market.").

17 Numerous cases have recognized the importance of cross-elasticity to determining what
18 products should be included in or excluded from the relevant antitrust market. *See, e.g., Gorlick*
19 *Distribution Centers, LLC v. Car Sound Exhaust Sys., Inc.*, 723 F.3d 1019, 1025 (9th Cir. 2013)
20 ("Instead, products must be reasonably interchangeable, such that there is cross-elasticity of
21 demand." (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962))²⁵; *Spindler v.*
22 *Johnson & Johnson Corp.*, No. C 10-01414 JSW, 2011 WL 12557884, at *2 (N.D. Cal. Aug. 1,
23 2011) ("Using these factors, products may be considered 'reasonably interchangeable,' where
24 there is cross-elasticity of demand, *i.e.* if customers would switch to alternatives in response to a
25 price increase in the alleged monopolist's product." (citing *Rebel Oil, Co. v. Atlantic Richfield*
26 *Co.*, 51 F.3d 1421, 1436 (9th Cir. 1995)); *Pinnacle Sys., Inc. v. XOS Techs., Inc.*, No. C-02-03804-

27 _____
28 ²⁵ *Gorlick* also recognized, however, that products only need to be reasonably interchangeable, not
"perfectly fungible" or physically identical. *Id.* at 1025.

1 RMW, 2003 WL 21397845, at *7 (N.D. Cal. May 19, 2003) (“‘alleged product market must (1)
 2 include all products reasonably interchangeable, determination of which requires consideration of
 3 cross-elasticity of demand’”) (quoting *Intellective, Inc. v. Massachusetts Mut. Life Ins. Co.*, 190
 4 F.Supp.2d 600, 609 (S.D.N.Y. 2000)); *see also Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*,
 5 375 F.3d 1341, 1364 (Fed. Cir. 2004), *rev'd on other grounds by* 546 U.S. 394 (2006) (“Nothing
 6 in the record addresses whether potential customers of the patented process faced with a price
 7 increase would shift to other processes offering different combinations of benefits. [] This
 8 determination, however, lies at the heart of market definition in antitrust analysis.”); *Telecor*
 9 *Commc'ns, Inc. v. Sw. Bell Tel. Co.*, 305 F.3d 1124, 1131 (10th Cir. 2002) (“The basic relevant
 10 product market test is ‘reasonable interchangeability.’ Interchangeability may be measured
 11 by, and is substantially synonymous with, cross-elasticity.”); *United States v. Microsoft Corp.*, 253
 12 F.3d 34, 53–54 (D.C. Cir. 2001) (“The test of reasonable interchangeability, however, required the
 13 District Court to consider only substitutes that constrain pricing in the reasonably foreseeable
 14 future, and only products that can enter the market in a relatively short time can perform this
 15 function.”); *Brookins v. Int'l Motor Contest Ass'n*, 219 F.3d 849, 854 (8th Cir. 2000) (“But that
 16 assertion requires proof there is no cross-elasticity of demand between this game and other games
 17 that modified car racers might choose to play.”); *Thurman Indus.*, 875 F.2d at 1374 (“a product
 18 market is typically defined to include the pool of goods or services that qualify as economic
 19 substitutes because they enjoy reasonable interchangeability of use and cross-elasticity of
 20 demand.”); *Oltz v. St. Peter's Cmty. Hosp.*, 861 F.2d 1440, 1446 (9th Cir. 1988) (“The product
 21 market includes the pool of goods or services that enjoy reasonable interchangeability of use and
 22 cross-elasticity of demand.”); *Hayden Pub. Co. v. Cox Broad. Corp.*, 730 F.2d 64, 70-71 (2d Cir.
 23 1984) (“There is persuasive authority for interpreting *du Pont* as requiring consideration of cross-
 24 elasticity of demand in determining an appropriate market definition. . . . We are persuaded that,
 25 as a general rule, the process of defining the relevant product market requires consideration of
 26 cross-elasticity of demand.”).

27 The Ninth Circuit has specifically acknowledged that “[t]he principle most fundamental to
 28 product market definition is ‘cross-elasticity of demand’ for certain products or services.

1 Commodities which are ‘reasonably interchangeable’ for the same or similar uses normally should
 2 be included in the same product market for antitrust purposes.” *Kaplan*, 611 F.2d at 291. The
 3 ABA’s Model Jury Instruction in Civil Antitrust Cases (2016) uses the same concept:

4 To determine whether products are reasonable substitutes for each
 5 other, you must consider whether a small but significant and non-
 6 transitory increase in the price of one product would result in
 7 enough customers switching from that product to another product
 8 such that the price increase would not be profitable. In other words,
 9 will customers accept the price increase or will so many switch to
 10 alternative products that the price increase will be withdrawn?
 11 Generally speaking, a small but significant and non-transitory
 12 increase in price is approximately a 5 percent increase in price not
 due to cost factors [but you may conclude in this case that some
 other percentage is more applicable to the product at issue]. If you
 find that customers would switch and that the price increase would
 not be profitable, then you must conclude that the products are in the
 product market. If, on the other hand, you find that customers would
 not switch, then you must conclude that the products are not in the
 product market.

13 Instruction 4: Relevant Product Market, Model Jury Instructions in Civil Antitrust Cases ABA
 14 (2016) at 108.²⁶

15 Defendants respond that given the unique characteristics of the pharmaceutical market –
 16 primarily the prevalence of non-price methods of competition as well as that prescribing
 17 physicians do not typically consider price when prescribing drugs – cross-elasticity of demand is
 18 not required. Instead, they argue that evidence of reasonable interchangeability (therapeutic
 19 equivalency) with other pharmaceutical products used to treat the conditions Lidoderm was
 20 prescribed to treat is the more relevant factor that should determine the antitrust product market
 21 here.²⁷

22 ²⁶ *Id.* pg. 109 at n.2 (“In assessing whether products are within the relevant market, the jury must
 23 consider not only whether the products are functionally similar but also whether the products are
 24 economically interchangeable. That is, there *must* be cross-price elasticity of demand.”) (emphasis
 added).

25 ²⁷ Defendants do not argue about a submarket, but they rely for support in considering these other
 26 factors on the *Brown Shoe* decision, where the Supreme Court recognized that “within this broad
 27 market, well-defined submarkets may exist which, in themselves, constitute product markets for
 28 antitrust purposes. . . . [citation omitted]. The boundaries of such a submarket may be determined
 by examining such practical indicia as industry or public recognition of the submarket as a
 separate economic entity, the product’s peculiar characteristics and uses, unique production
 facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.”
 370 U.S. at 325.

1 In support, defendants rely on two experts: Dr. Gregory K. Bell and Dr. Christopher J.
2 Gilligan. Gilligan, a pain medicine specialist, provided a report identifying the clinical uses of
3 Lidoderm and products that could be substituted for those clinical uses in place of Lidoderm.
4 Gilligan Report [Dkt. No. 776-32]. Gilligan admits that Lidoderm was approved by the FDA to
5 treat postherpetic neuralgia (PHN), but contends it is also “frequently prescribed” to treat other
6 neuropathic, musculoskeletal and myofascial pain conditions, as well as pain associated with
7 arthritis and other miscellaneous pain conditions. *Id.* ¶ 18. When using Lidoderm to treat
8 musculoskeletal/myofascial pain, Gilligan opines that “physicians will often consider Lidoderm to
9 be interchangeable with the following prescription and over-the-counter (‘OTC’) medications:
10 lidocaine gel/ointment/cream, topical and systemic non-steroidal anti-inflammatory drugs
11 (‘NSAIDs’), acetaminophen, certain opioids and muscle relaxants. *Id.* ¶ 20.²⁸ When treating pain
12 associated with “arthritis, especially osteoarthritis, physicians consider Lidoderm to be
13 interchangeable with lidocaine gel/ointment/cream, topical NSAIDs, such as Voltaren Gel or
14 Flector Patch, and systemic NSAIDs such as Aleve, Advil or Motrin, Celebrex, and Tylenol.” *Id.*
15 ¶ 21. When treating “PHN and other neuropathic pain conditions, physicians may consider
16 Lidoderm to be interchangeable with topical lidocaine gel/ointment/cream, capsaicin creams and
17 patches, systemic nerve pain medications including anticonvulsants (such as Neurontin and
18 Lyrica), antidepressants (such as Nortriptyline, Amitriptyline, and Cymbalta), acetaminophen, and
19 as well as opioids (particularly tramadol).” *Id.* ¶ 22.²⁹

20 Using the information from Gilligan, actual prescription data, and additional other sources
21 showing Lidoderm could be interchanged with other treatments – including clinical guidelines and
22 formulary placements – Bell agreed that Lidoderm was not only used to treat PHN but also used
23

24 ²⁸ Gilligan believes that Lidoderm is most often prescribed to treat musculoskeletal/myofascial
25 pain. *Id.* ¶ 25. Bell concurs. Bell Report ¶ 46 (finding 57% of Lidoderm prescriptions were for
26 musculoskeletal pain).

27 ²⁹ Gilligan defines “interchangeable” as “that a treating clinician considers these treatments to be
28 therapeutically equivalent: their relative risks and benefits are such that they are frequently
substituted for each other depending on the patient’s specific circumstances. This does not mean
that the treatments are identical in other respects, such as their formulation, mechanism of action,
method of application, or risks and benefits for particular patients.” *Id.* ¶ 17.

1 “extensively” to treat other forms of neuropathic pain, pain from arthritis, and musculoskeletal
 2 pain. Bell Report [Dkt. No. 776-8] ¶ 6.³⁰ As a result, according to Bell and defendants, the
 3 relevant antitrust product market includes “the primary competitors from each of these four
 4 categories of significant Lidoderm use.” *Id.* Those “primary competitors” include, “at least the
 5 following: the opioid Ultram (tramadol); the anticonvulsants Neurontin (gabapentin) and Lyrica
 6 (pregabalin); the antidepressant Cymbalta (duloxetine); the muscle relaxant Flexeril
 7 (cyclobenzaprine); the nonsteroidal anti-inflammatory drugs (“NSAIDs”) Celebrex (celecoxib),
 8 diclofenac (including Voltaren Gel), ibuprofen, Mobic (meloxicam), and naproxen; and the topical
 9 anesthetics capsaicin (Qutenza and Zostrix) and lidocaine (including cream, gel, and ointment
 10 formulations).” *Id.* Based on his review of evidence, Bell concluded that “Lidoderm’s share of
 11 prescriptions among these products from 2011 through 2014 is 13 percent for PHN and no more
 12 than two percent otherwise.” *Id.* ¶ 83.³¹

13 In support of this broad market definition, defendants also rely on Endo documents
 14 showing how Lidoderm was marketed and promoted with managed care organizations (MCOs)
 15 and healthcare organizations as well as doctors. Those documents show that Endo made efforts to
 16 convince physicians to prescribe Lidoderm over other the other drugs, including Neurontin,
 17 Lyrica, capsaicin, topical aspirin formulations, lidocaine gel, and Qutenza. Asimow Decl. [Dkt.
 18 No. 812-1] Ex. 6, at ENDO-LID-AT-000967095 (identifying the competitive marketplace for
 19 PHN treatments). Finally, defendants also note that Endo monitored Lidoderm prescriptions and
 20 market share compared to Lyrica, branded and generic Neurontin, and Qutenza Asimow Decl. Ex.
 21 3, at slides 9-14.

22
 23 ³⁰ As part of his analysis, Bell opined that “off label” use of Lidoderm accounts for 92% of
 24 prescriptions. *Id.* ¶¶ 46, 64. As discussed below, if plaintiffs’ motion for partial summary
 25 judgment as to the market definition is not granted, plaintiffs’ move to exclude the testimony of
 Dr. Bell.

26 ³¹ In defining the market, Bell also examined evidence regarding the prevalence of non-price
 27 competition in the pharmaceutical market, concluding that “competitive constraints on Endo”
 28 required Endo to give significant rebates and other price concessions to MCOs and used free
 samples and other marketing efforts to encourage health care organizations and doctors to
 prescribe Lidoderm. *Id.* ¶¶ 70-76.

1 Defendants’ analysis – essentially ignoring cross-elasticity – creates a vastly overbroad
2 market that includes a host of different classes and types of drugs that are different from the
3 “unique” 5% lidocaine patches. As the Supreme Court has cautioned: “For every product,
4 substitutes exist. But a relevant market cannot meaningfully encompass that infinite range. The
5 circle must be drawn narrowly to exclude any other product to which, within reasonable variations
6 in price, only a limited number of buyers will turn; in technical terms, products whose ‘cross-
7 elasticities of demand’ are small.”³² *Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612
8 (1953).

9 Indeed, even where products are essentially identical, that alone is insufficient to require
10 their inclusion in the relevant market. *See, e.g., U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d
11 986, 996 (11th Cir. 1993) (excluding from the market functionally similar products where the
12 “record provides no support for finding significant cross-elasticity of demand or supply between
13 Danforths and generic anchors”); *United States v. Archer–Daniels–Midland Comp.*, 866 F.2d 242,
14 248 (8th Cir.1988) (functionally interchangeable sweeteners were separate product markets
15 because “a small change in the price of [one] would have little or no effect on the demand for [the
16 other]”);³³ *cf. In re Loestrin 24 Fe Antitrust Litig.*, No. 1:13-MD-2472-S-PAS, 2017 WL
17 3600938, at *12 (D.R.I. Aug. 8, 2017) (“Products are not reasonably interchangeable merely
18 because they share similar forms or functions, but rather ‘[s]uch limits are drawn according to the
19 cross-elasticity of demand for the product in question—the extent to which purchasers will accept
20 substitute products in instances of price fluctuation and other changes.” (quoting *In re Nexium*

21
22 _____
23 ³² The Court went onto note also that “[u]seful to that determination is, among other things, the
24 trade’s own characterization of the products involved.” *Id.*

25 ³³ Defendants argue that the Eighth Circuit’s emphasis on lack of cross-elasticity in *Archer*
26 *Daniels Midland (ADM)* was limited by *HDC Med., Inc. v. Minntech Corp.*, 474 F.3d 543, 548
27 (8th Cir. 2007). But any limitation was on a different proposition. *HDC* simply recognized that
28 *ADM* itself recognized a “narrow exception to the general prohibition against placing great weight
on *only* price differentials” in determining whether products reside in the same market, in
situations where government price support props up one product’s price. *Id.* at 548 (emphasis
added). Plaintiffs here are not arguing that mere price differentials between Lidoderm and the
generics ultimately introduced is evidence of *the market definition*. Defendants’ reliance on *In re*
Remeron Direct Purchaser Antitrust Litig., 367 F. Supp. 2d 675, 681 (D.N.J. 2005), where
plaintiffs did exactly that, is similarly misplaced.

1 (*Esomeprazole*) *Antitrust Litig.*, 968 F. Supp. 2d 367, 387–88 (D. Mass. 2013)); *F.T.C. v. Swedish*
 2 *Match*, 131 F. Supp. 2d 151, 158 (D.D.C. 2000) (“while loose leaf and moist snuff tobacco are not
 3 identical, in light of substantial similarities between them and in light of the rising trend in dual
 4 usage by consumers, the Court ultimately finds the products to be functionally interchangeable for
 5 the purpose of outlining the relevant product market. Finding two products to be functionally
 6 interchangeable, however, does not end the analysis” and rejecting inclusion in same market
 7 where no evidence of cross-elasticity of demand).

8 Defendants point to no cases arising in the pharmaceutical context where courts (or juries)
 9 have defined the relevant product market as broadly as they seek here. Indeed, in the
 10 pharmaceutical context courts have limited the market to similar classes of drugs or even more
 11 narrowly, down to the brand product itself in absence of cross-elasticity evidence. *See, e.g.*,
 12 *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064 (3d Cir. 1978) (despite a certain degree
 13 of functional interchangeability among antibiotics, specific class of antibiotics was separate
 14 product market based on court’s finding that there was a lack of price sensitivity and cross-
 15 elasticity of demand); *see also F.T.C. v. Lundbeck, Inc.*, 650 F.3d 1236, 1240 (8th Cir. 2011)
 16 (affirming decision to exclude from relevant market two functionally similar drugs because of lack
 17 of cross-elasticity of demand; “When the case was tried, Indocin IV and NeoProfen were the two
 18 drug treatments available for PDA. Aware of the drug options—the ‘practicable alternatives’—the
 19 neonatologists preferred one treatment or the other (without regard for cost), which the court
 20 credited as persuasive evidence of low cross-elasticity.”);³⁴ *Geneva Pharm. Tech. Corp. v. Barr*
 21 *Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (bioequivalent, functionally-interchangeable branded
 22 and generic drugs were in separate product markets); *see also In re Lorazepam & Clorazepate*
 23

24 ³⁴ Defendants point out that in a concurrence Judge Kopf found it odd “to define a product market
 25 based upon the actions of actors who eschew rational economic considerations” because doctors
 26 paid no mind to price, and that “oddity seems especially strange where, as here, there is no real
 27 dispute that (1) both drugs are effective when used to treat the illness about which the doctors
 28 testified and (2) internal records from the defendant raise an odor of predation.” *F.T.C. v.*
Lundbeck, Inc., 650 F.3d at 1243. The facts are different here where no one is contending there is
 a drug that was identical to Lidoderm (delivering lidocaine in a topical patch) on the market during
 the relevant time (although topical lidocaine cream was on the market).

1 *Antitrust Litig.*, 467 F. Supp. 2d 74, 82 (D.D.C. 2006) (reasonable jury could conclude that the
2 relevant antitrust market was comprised of only generic manufacturers where trial testimony was
3 that generic manufacturers did not consider brand price in setting their own prices, both sides'
4 experts testified that generics competed in a different market than the branded manufacturers, and
5 where evidence was that brand and generic drugs had different consumer bases and were promoted
6 and marketed differently).

7 Defendants' heavy reliance on *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838
8 F.3d 421, 436 (3d Cir. 2016) is misplaced. There, the Third Circuit approved the district court's
9 extensive focus on product interchangeability and refusal to limit the at issue market to just one
10 oral tetracycline and its generic and instead approved a much broader market consisting of "all
11 oral tetracyclines prescribed to treat acne." *Id.* at 436.³⁵ But the court's analysis did not end there.
12 It noted that "[i]nterchangeability is only one aspect of establishing a relevant antitrust market
13 through indirect evidence," and that the evidence of cross-elasticity of demand between Doryx and
14 other tetracyclines supported the broader adopted market definition. *Id.* at 437.³⁶

15 Consistent with the bulk of the case law, something *more* than mere therapeutic
16 equivalency is required to define the relevant antitrust product market. There must be some
17 showing of cross-elasticity. This conclusion is supported by the undisputed facts in this case:

18
19 _____
20 ³⁵ Part of that analysis included reliance on the FDA's approval of "virtually identical" labeling for
21 the products that treat the same condition, as well as evidence that managed care providers
encouraged the widespread substitution of numerous other oral tetracyclines for Doryx; showings
that are absent here. *Mylan*, 838 F.3d at 436.

22 ³⁶ Defendants also rely on *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569
23 (S.D.N.Y. 2011). There, however, the court rejected the proposed narrowly limited market (two
24 brand and two generic drugs that were a combined oral contraceptive and medication to treat
premenstrual dysphoric disorder) as implausible given the multitude of other functionally and
25 chemically similar drugs on the market designed to treat the same symptoms. That the court
26 recognized in those circumstances that the application of cross-elasticity of demand was
"complicated given that (1) patient choice is constrained by the physician's prescribing authority,
27 and (2) the impact of price variation may be blunted by the effect of health insurance," is not
surprising. *Id.* at 578. Similarly, defendants' reliance on *Kaiser Found. v. Abbott Labs.*, No.
28 CV02-2443-JFWFMOX, 2009 WL 3877513, at *8 (C.D. Cal. Oct. 8, 2009) is misplaced. There,
essentially identical drugs (alpha-blockers) were reasonably interchangeable, yet plaintiff's expert
excluded them from the market for the sole and erroneous reason that those drugs were not
"comparable therapeutic substitutes."

1 Endo and Teikoku have repeatedly characterized Lidoderm as a unique product with unique
 2 advantages. *See, e.g.*, Asimow Decl., Ex. 6, at ENDO-LID-AT-000967095 (“LIDODERM is the
 3 first and only lidocaine-based topical medication with FDA approved indication for the treatment
 4 of PHN pain. Furthermore by minimizing systemic exposure topical lidocaine reduces the risk of
 5 systemic side effects.”). In the underlying ’529 Patent litigation Edgar Ross, M.D. opined on
 6 behalf of Endo and Teikoku that Lidoderm was unique: “[Lidoderm] was a unique drug and
 7 delivery system combination. . . .” Kohn Decl. [Dkt. No. 776], Ex. DD at ¶¶ 2-4; *see also id.* at ¶ 9
 8 (“there are no satisfactory substitutes for Lidoderm as a highly safe, effective, and convenient
 9 topical treatment for neuropathic pain. . . . [T]he unique benefits of LIDODERM’s patch
 10 formulation have made it highly successful in the treatment of PHN and other types of pain.”).
 11 Brian Lortie, Endo’s President of Branded Pharmaceuticals Business, testified to the FTC that
 12 “Lidoderm was unique in the attributes that it presents to a physician and to a patient as they’re
 13 seeking a therapy for which they are considering products. It’s the only topical patch, for example.
 14 . . . So there really is not another product that is exactly like Lidoderm. . . . Lidoderm is really a
 15 unique product.” Kohn Decl., Ex. EE at ENDO-LID-AT-000005144-46; *see also id.* at ENDO-
 16 LID-AT-000005148 (“Lidoderm really had a distinct positioning in [physicians’] minds.”).³⁷

17 The market for determining monopoly power cannot be stretched as far as defendants seek.
 18 This is why numerous courts *have* required some showing of cross-elasticity of demand between
 19 products before including them in the same market. Defendants’ argument loses focus on the
 20 question at hand, which is defining the appropriate market to determine defendants’ power to
 21 engage in monopolistic behavior.

22 Defendants argue that instead of cross-elasticity (following a showing of therapeutic
 23 equivalency), the jury is entitled to rely on the practical indicia the Supreme Court identified in
 24 *Brown Shoe* for identifying submarkets. Def. Oppo. to Pls. MPSJ at 7.³⁸ Putting aside the fact

25 _____
 26 ³⁷ The differences between Lidoderm and some of the other drugs that Gilligan and Bell assume
 are equivalent (*e.g.*, ibuprofen) is obvious even without expert testimony.

27 ³⁸ Defendants cite one case where cross-elasticity was explicitly not required, primarily because
 28 that analysis was not feasible. *See Nobody in Particular Presents, Inc. v. Clear Channel
 Commc’ns, Inc.*, 311 F. Supp. 2d 1048, 1082 (D. Colo. 2004) (“whether reasonable

1 that defendants have not identified a submarket, but instead argue for a broad initial market, these
 2 practical indicia do not support defendants. The “fact-intensive” practical indicia recognized by
 3 *Brown Shoe* (and subsequent Ninth Circuit cases) – the product’s peculiar characteristics and uses,
 4 unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and
 5 specialized vendors – support limiting the relevant antitrust market here to Lidoderm and its
 6 generics. *Brown Shoe Co.*, 370 U.S. at 325. There is no dispute that during the relevant time,
 7 Lidoderm was the only hydrogel 5% lidocaine patch on the market, and the evidence readily
 8 shows (without dispute) that Lidoderm required distinct production facilities and capabilities, had
 9 distinct prices that were not set with respect to any other drug, and employed specialized sales
 10 channels.³⁹

11 The only “practical indicia” relied on by defendants is the evidence that *generally* in the
 12 pharmaceutical market, competition occurs on non-price fronts in order to get physicians to
 13 prescribe and MCOs and pharmacy benefit managers (PBMs) to cover and include specific drugs
 14 in their formularies. As a result, Endo heavily marketed its products to physicians (including
 15 extensive use of free samples) and used rebates and other price concessions with MCOs and PBMs
 16 to encourage adoption and inclusion of Lidoderm. Defendants cite evidence that Endo
 17 consistently tracked its sales/prescriptions of Lidoderm in comparison with therapeutically similar
 18 products, primarily anticonvulsants (like Lyrica) and the Qutenza (capsaicin) patch. But
 19 defendants do not show that the availability of those other products *forced* Endo to limit its
 20 Lidoderm price or otherwise constrained Endo’s pricing. That Endo has evidence that physicians

21
 22 interchangeability can be determined for antitrust purposes without economic analysis of cross-
 23 elasticity of demand. Although the Tenth Circuit has not addressed this specific issue, . . . the
 24 court finds that a plaintiff may, through sufficient evidence of other indicia of market definition,
 25 define a relevant market without economic study of cross-elasticity of demand, especially when
 26 economic analysis of cross-elasticity of demand is infeasible based on pricing data.”). As
 27 discussed below, there is no evidence that an economic analysis of cross-elasticity of demand was
 28 infeasible, but only that defendants did not seek the data to do it.

³⁹ Plaintiffs rely on these “practical indicia” to support their argument that the market should
 include only Lidoderm and its generics, focusing on Endo and Teikoku’s representations to the
 market and to the FTC about the “uniqueness” of Lidoderm as the only lidocaine hydrogel patch
 on the market. *See supra*.

1 and MCOs were concerned about the “high” price of Lidoderm and prescribed more or made more
2 available where prices were lower or significant rebates were provided does not mean that the
3 *other* products on the market for treatment of PHN and other pain conditions constrained the price
4 of Lidoderm. It simply shows that, in order to grow the market for what defendants repeatedly
5 characterize as a unique product, price concessions and rebates for Lidoderm were necessary.

6 3. Evidence of Lack of Cross-Elasticity

7 Plaintiffs rely on their experts’ analyses that conclude that there is no evidence of any
8 significant cross-elasticity of demand between Lidoderm and other pharmaceuticals. For example,
9 Dr. Jeffrey J. Leitzinger opines, based on Endo and Teikoku’s own documents and testimony, that
10 there is little cross-elasticity between Lidoderm and other pain treatments, with the exception of
11 generic Lidoderm. Kohn Decl., Ex. C, Leitzinger Report [Dkt. No. 776-3] at ¶¶ 44-51. He also
12 relies on an analysis of the price differential between brand Lidoderm (when no generic was on the
13 market) and brand Lidoderm (when generics entered). *Id.* ¶¶ 57-67 (no product other than generic
14 Lidoderm exhibited substantial cross-elasticity of demand with Lidoderm). Dr. Hal J. Singer
15 reviewed price data of Lidoderm, as compared to that of seven PHN treatment drugs that Endo
16 identified as “competitors,” and concluded that sales of the competitor drugs were unfazed by
17 changes in the relative price of Lidoderm. Kohn Decl., Ex. D, Singer Report [Dkt. No. 776-4] at
18 ¶¶ 47-51.

19 Dr. Keith Leffler opines, based again on Endo’s own internal documents and projections as
20 well as on his review of sales and price data, that other products used to treat PHN do not have
21 high cross elasticities of demand with Lidoderm. Kohn Decl., Ex. E, Leffler Report [Dkt. No.
22 776-5] at ¶¶ 27-46. Dr. Glenn Melnick opines that the unique method of administration
23 (transdermal patch) distinguishes Lidoderm from other PHN treatments and that Endo’s ability to
24 maintain “inflated” prices demonstrates that there are no constraints on the price of Lidoderm from
25 other products. Kohn Decl., Ex. F, Melnick Report [Dkt. No. 776-6] at ¶¶ 88-91. Finally,
26 plaintiffs also rely on Endo’s own evidence and testimony that Endo did not forecast or expect that
27 wholesale acquisition cost (WAC) price increases would result in Endo losing sales to other drugs.
28 *See, e.g.*, Kohn Decl., Ex. I, Depo. Tr. Brian Lortie [Dkt. No. 776-9] at 254; Kohn Decl., Ex. N,

1 Depo. Tr. Andrew Gesek [Dkt. No. 776-14] at 194.

2 If evidence on price competition is required, defendants argue that they have it. Bell
 3 analyzed Lidoderm’s “own price elasticities” to show that when rebates to MCOs/PBMs
 4 decreased, utilization decreased and vice-versa. Bell Report ¶¶ 71-74. Plaintiffs respond that
 5 evidence of one’s “own price elasticities” is not sufficient to allow inclusion of *other*,
 6 uncomparing on-price products in the relevant antitrust product market. For example, that Endo
 7 increased its price concessions to MCO’s from 2008 through 2013 (before generic entry) does not
 8 necessarily show that Endo was in price competition with other drugs. It could equally reflect that
 9 Endo decided to provide rebates in order to encourage MCOs to continue to provide access (or
 10 preferred access) to Lidoderm in their formularies and to increase profits by taking measures to
 11 increase the ultimate number of prescriptions by providing larger rebates to MCOs.⁴⁰

12 Defendants then challenge plaintiffs’ experts’ evidence on lack of cross-elasticity as
 13 deficient and argue that it cannot support summary judgment. The primary deficiency identified
 14 by defendants is that plaintiffs’ experts – particularly Singer – relied on wholesale acquisition cost
 15 (WAC or list price) as opposed to net price (after rebates or other incentives). Defs. Oppo. to Pls.
 16 MPSJ at 21-24. Defendants contend that net prices are what matters, given the significant level of
 17 rebates and other incentives provided to MCOs. Bell Report ¶¶ 88, 98. Plaintiffs respond that
 18 Singer testified that at least for Lidoderm, increases in the WAC closely correlated with changes in
 19 net price. As a result, his use of WAC does not undermine his analysis. Asimow Decl., Ex. 8
 20 (Singer Depo. Tr.) at 675:20-676:10.⁴¹ In contrast, defendants’ expert Bell asserted only “that
 21

22 ⁴⁰ Defendants appear to argue that Bell did not need to conduct an economic analysis of cross-
 23 elasticity of demand because Bell did not have access to the data to do so. Def. Oppo to Pl. MSJ
 24 at 19-20. However, defendants do not argue or show that the data to enable Bell to perform a net
 25 price comparison between Lidoderm and other drugs they contend should be in the same market
 26 was unavailable. They contend only that Bell did not have access to it. Plaintiffs respond that the
 27 relevant data could have been secured through discovery subpoenas if defendants had wanted to
 28 counter plaintiffs’ showing. Reply at 9 n.4.

⁴¹ Defendants do not point any evidence, by Bell or otherwise, that increases in the WAC did not
 generally correlate to increases in the net prices for Lidoderm. Instead, defendants note that Bell,
 when using net prices, concluded that the price increases for Lidoderm between May 2012 and
 September 2013 were not *as high* percentage-wise as plaintiffs contended. Defs. Oppo. to Pls.
 MPSJ at 22 n.10. They do not dispute net percentage increases occurred.

1 growth in gross sales of Lidoderm outpaced the growth in net sales, indicating that gross prices
 2 grew faster than net price.” Bell Report ¶ 88. While Bell criticized Singer’s (and plaintiffs’ other
 3 experts’) reliance on WAC, Bell did not indicate or offer an analysis on how large the purported
 4 gap between those two was or address in substance Singer’s analysis that changes in the gross and
 5 net prices were largely correlated. Bell Report ¶ 88.

6 In sum, plaintiffs present evidence that price data and sales data show that during the
 7 relevant time there was no significant cross-elasticity of demand between Lidoderm and any
 8 product other than generic Lidoderm. Those analyses are generally supported by defendants own
 9 documents and analyses. Defendants show, at most, an issue regarding Lidoderm’s *market share*
 10 for PHN and pain treatment with respect to only a few of the drugs defendants believe should be
 11 included in the relevant antitrust market (and at most a limited concern over the price of Lidoderm
 12 with respect to the 2010 entry of one drug, Qutenza), but those discrete references are insufficient
 13 to raise a material question of fact on whether the availability of those drugs *constrained* the price
 14 charged for Lidoderm.

15 4. The Relevant Market

16 For the foregoing reasons, based on undisputed facts and total lack of evidence to show
 17 that Lidoderm’s prices were constrained by therapeutically equivalent products, I conclude as a
 18 matter of law that the market is limited to 5% lidocaine patches, Lidoderm and its generic
 19 equivalents. Plaintiffs’ motion for partial summary judgment in this issue is GRANTED.

20 IV. MOTIONS IN LIMINE

21 A. Legal Standard

22 Federal Rule of Evidence 702 allows a qualified expert to testify “in the form of an opinion
 23 or otherwise” where:

- 24 (a) the expert’s scientific, technical, or other specialized knowledge
 25 will help the trier of fact to understand the evidence or to determine
 a fact in issue;
- 26 (b) the testimony is based on sufficient facts or data;
- 27 (c) the testimony is the product of reliable principles and methods;
 28 and

1 (d) the expert has reliably applied the principles and methods to the
facts of the case.

2 Fed. R. Evid. 702.

3 Expert testimony is admissible under Rule 702 if it is both relevant and reliable. *See*
4 *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). “[R]elevance means that the
5 evidence will assist the trier of fact to understand or determine a fact in issue.” *Cooper v. Brown*,
6 510 F.3d 870, 942 (9th Cir. 2007); *see also Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010)
7 (“The requirement that the opinion testimony assist the trier of fact goes primarily to relevance.”)
8 (internal quotation marks omitted).

9 Under the reliability requirement, the expert testimony must “ha[ve] a reliable basis in the
10 knowledge and experience of the relevant discipline.” *Primiano*, 598 F.3d at 565. To ensure
11 reliability, the court must “assess the [expert’s] reasoning or methodology, using as appropriate
12 such criteria as testability, publication in peer reviewed literature, and general acceptance.” *Id.* at
13 564. These factors are “helpful, not definitive,” and a court has discretion to decide how to test
14 reliability “based on the particular circumstances of the particular case.” *Id.* (internal quotation
15 marks and footnotes omitted). “When evaluating specialized or technical expert opinion
16 testimony, the relevant reliability concerns may focus upon personal knowledge or experience.”
17 *United States v. Sandoval-Mendoza*, 472 F.3d 645, 655 (9th Cir. 2006).

18 The inquiry into the admissibility of expert testimony is “a flexible one” where “[s]haky
19 but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to
20 the burden of proof, not exclusion.” *Primiano*, 598 F.3d at 564. “When the methodology is
21 sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the
22 degree of relevance or accuracy (above this minimum threshold) may go to the testimony’s
23 weight, but not its admissibility.” *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir.
24 2010). The burden is on the proponent of the expert testimony to show, by a preponderance of the
25 evidence, that the admissibility requirements are satisfied. *Lust By & Through Lust v. Merrell*
26 *Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996); *see also* Fed. R. Evid. 702 Advisory Cttee.
27 Notes.

B. Plaintiffs' Motions**1. Motion to Exclude in Part Bell**

If plaintiffs' motion for partial summary judgment as to the definition of the relevant antitrust product market is denied, plaintiffs move to exclude the testimony regarding that market by defendants' expert Dr. Gregory K. Bell. Dkt. No. 778. However, as noted above, plaintiffs' motion is granted, thereby making moot Bell's testimony regarding the market definition and his criticisms of plaintiffs' experts' testimony relevant to price-elasticity and market definition. Other portions of Bell's testimony may still be relevant to issues to be decided at trial. What, if any, remaining issues Bell may address at trial can be determined on a motion in limine prior to trial.

2. Motion to Exclude in Part Carlton

Plaintiffs move to exclude in the testimony of Dr. Dennis Carlton, to the extent of his testimony regarding: (a) the possibility that after losing the patent trial against Watson, Endo might be able to obtain an injunction against Watson before any appellate ruling; and (b) whether and/or how *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) should be applied to the facts of this case. As to the first issue, plaintiffs argue that Carlton, as an economist, is not qualified to opine on whether had Watson won at trial (which both sides agree was the likely outcome), Endo/Teikoku could nevertheless have secured an injunction preventing Watson from entering the market. As to the second issue, plaintiffs argue that Carlton's opinion – that the inferences and burdens created by the Supreme Court in *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) should not apply in this case because in his view a cash payment (like the one in *Actavis*) is competitively different than the \$96 million worth of free branded Lidoderm that Endo gave to Watson – should be excluded because that is an impermissible legal conclusion and outside the realm of his expertise in economics.

Defendants respond that the "testimony" plaintiffs seek to exclude are not Carlton's central opinions. Carlton's central opinions are that: (i) accounting for the projected royalties associated with the no-AG clause, the clause is more rationally viewed as a payment from Watson, rather than a payment to Watson; (2) the settlement inventory had procompetitive features ignored by plaintiffs' experts because it "allowed Watson to compete in those situations where it would not

1 have been able to otherwise” due to lack of FDA approval; and, in any event, (3) the settlement
 2 did not delay generic entry or otherwise harm competition relative to expected outcomes from
 3 continued patent litigation. Carlton Report, Asimow Decl., Ex. 4 [Dkt. No. 807-4] ¶¶ 46, 77, 94.
 4 As to the first issue identified by plaintiffs, defendants argue that the testimony plaintiffs are
 5 concerned with arose in Carlton’s deposition where he described his opinions as “conservative”
 6 because they did not rely on Endo seeking and securing an injunction and because Carlton did
 7 nothing more than identify an injunction pending appeal as one possible factor but one he did not
 8 rely on in reaching his “conservative” opinion. As to the second issue, defendants characterize
 9 plaintiffs’ concern as being one over deposition testimony they elicited but not part of Carlton’s
 10 opinions. That said, defendants argue that because plaintiffs’ experts testify that it is of no
 11 consequence as an economic matter that the free products and no-AG-competition provisions
 12 provided were “not payments,” Carlton should be able to dispute that by arguing that the non-cash
 13 “payments” here were “competitively different” from an exchange of cash. Carlton Oppo. at 6.

14 The issue of an injunction is not central to Carlton’s opinions and so plaintiffs’ motion is
 15 DENIED, subject to renewal at trial if Carlton’s testimony ventures into whether an injunction was
 16 possible or expected. On the purported significance between cash payments and other types of
 17 payments, the motion is GRANTED in part. *No expert* may opine that there is a legal significance
 18 to cash versus non-cash payments in reverse payment settlements. However, the expert
 19 economists can discuss any differences that various types of payments had or have on competition.

20 3. EPPs’ Motion to Exclude Fritz

21 The EPPs renew their motion from class certification to exclude the opinion of John Fritz
 22 that health insurer members of the EPP class have not suffered any economic harm due to delayed-
 23 entry of a generic alternative for brand Lidoderm because any overcharges were passed on. Dkt.
 24 No. 769. The EPPs argue, again, that Fritz is not qualified to offer that opinion based on his
 25 general actuarial experience (a) because he lacks knowledge of how insurers set premiums or
 26 actual practices with respect to Lidoderm and (b) his opinion is based on the experience of one
 27 opt-out plaintiff (GEHA) and were not validated to any of the actual class members. The EPPs
 28 point out that I denied premium-related pass on discovery in April 2016, because there was, at that

1 juncture, no evidence that any plaintiff insurer had been able to “recoup” amounts spent in the past
2 on prescription drugs when setting employer contribution rates for the future. April 5, 2016
3 Minutes.

4 However, in ruling on the motions for class certification, I denied the motion to exclude
5 Fritz, concluding:

6 The weight to be given Fritz’s opinion (based on his experience, or
7 lack thereof, and based on the information he did or did not review)
8 is more appropriately challenged at summary judgment or trial.
9 Moreover, while the relevance of Fritz’s opinion has not been fully
10 briefed or finally determined (although I have expressed skepticism
11 that the “pass-on” defense will be allowed in this case at least with
12 respect to the federal claims), as explained above the opinion is not
13 persuasive in my determination of the EPPs’ certification motion.

14 February 2017 Class Certification Order at 51-52.

15 Defendants rely on the fact that I did not exclude Fritz at the class certification stage and
16 contend no new challenges to his testimony have been adduced by plaintiffs. Defendants also
17 argue, again, that pass-on is a defense to many of the EPPs’ state law claims. Fritz Oppo. [Dkt.
18 No. 804].

19 I DENY the motion to exclude. Fritz has actuarial experience and understanding of how,
20 at least in some instances, insurers negotiate and set premiums. Any deficiencies or weaknesses in
21 his testimony based on a lack of facts or experience pertaining to how the EPPs in this case
22 actually set premiums can be fully explored at trial. I will, however, accept a jury instruction to
23 expressly limit any pass-on defense to the applicable state law claims. Plaintiffs are correct that
24 defendants have not, at this juncture, shown that any type of pass-on defense is applicable to the
25 direct purchaser federal claims.

26 **4. Motion to Exclude in Part Moffitt**

27 Plaintiffs move to exclude the testimony of Professor Michael Moffitt to the extent Moffitt
28 proffers testimony to the effect that in the “but-for world,” defendants might behave economically
irrationally in negotiating a patent settlement without a large reverse payment. Moffitt Mot. [Dkt.
No. 771]. Plaintiffs contend that Moffitt’s testimony about negotiator irrationality (*e.g.*, that
sometimes negotiators act irrationally and against their economic interests) creates a danger of
unfair prejudice and is contrary to antitrust law’s presumption that firms act rationally. Plaintiffs

1 point to Moffitt’s opinion that economically rational settlements might not be reached where:
2 parties might hold unrealistic views of the strengths of their case (Moffitt Report [Dkt. 771-8] at
3 ¶¶ 66(a), (b)); “might fear to signal agreement” out of reputational concerns (*id.* ¶ 66(c)); might
4 adopt a stubborn, “take-it-or-leave-it” approach (*id.* ¶ 66(d)); or might reject reasonable offers for
5 a variety of other “psychological reasons.” *Id.* ¶ 10. Plaintiffs assert that testimony about these
6 “human factors” are improper in a trial where participants must be assumed to be rational profit-
7 maximizers.

8 Defendants counter that since plaintiffs are contending (under their disputed second
9 causation theory) that defendants would have negotiated a hypothetical settlement that bears little
10 resemblance to the actual Settlement, they are entitled to rely on Moffitt. Defendants also
11 challenge plaintiffs’ characterization of Moffitt’s testimony, arguing that he does not in fact testify
12 that the parties would have acted in an economically irrational manner but that there are several
13 evidentiary-based reasons why parties may never reach an agreement.

14 A few initial points bear emphasis. As plaintiffs clarified at the hearing, they only seek to
15 exclude testimony from Moffitt that the parties might have acted in an economically irrational
16 way, as that runs against the presumption in antitrust cases – including those underlying but-for
17 analyses – that economic actors act in economically rational and profit maximizing ways. Hearing
18 Tr. at 96:2-6. Moffitt’s testimony concerns two broad areas: first, what factors would have gone
19 into determining whether there was a “zone of possible agreement” (ZOPA) between
20 Endo/Teikoku and Watson and if the negotiation history and other facts show a ZOPA existed
21 does that “necessarily demonstrate that real-world negotiators” could have reached a settlement;
22 and, second, if the settlement negotiations were restricted to entry date only (plaintiffs’ alternative
23 but-for scenario), would a settlement have occurred and (if so) could an alternate start date be
24 reasonably determined. Moffitt Report ¶ 2.

25 I agree with plaintiffs that in the experts’ competing testimony about the but-for world,
26 only opinions that are economically rational may be provided.⁴² Factors that are economically

27 _____
28 ⁴² As noted above, in construction but-for world scenarios, there is a presumption of economical
rationality. *See, e.g., Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511

1 rational (*e.g.*, consideration of the impact of a potential settlement on other or future litigation) are
 2 admissible. So is testimony that access to imperfect information or overconfidence based on that
 3 imperfect information (as opposed to irrationality) can impact settlements or willingness to enter
 4 settlements. *See, e.g.*, Moffitt Rep. ¶¶ 66a. I am not aware of cases showing that these well-
 5 known imperfections and hurdles in the settlement process suffered by economically rational
 6 actors are impermissible considerations in constructing but-for worlds; therefore, that testimony is
 7 permissible. But to the extent that Moffitt or any expert intends to opine that even though other
 8 economically rational settlements could have been reached, economically irrational factors (*e.g.*, a
 9 general but irrational reticence to settle) would have foundered any settlement, that testimony will
 10 not be admissible.

11 I recognize that this ruling does not lead to a clean segregation of what is impermissible
 12 and excludable in Moffitt’s report and testimony. Plaintiffs themselves, although moving to
 13 exclude in part, have not identified which specific portions of the Moffitt Report that they seek to
 14 exclude by line or paragraph number. *See* Dkt. No. 771-10 (Proposed Order). In advance of the
 15 pretrial conference, the parties should attempt to agree on the topics to which experts will not be
 16 allowed to testify with respect to the theoretical but-for settlement proposed by plaintiffs
 17 consistent with this Order, and submit any disputed issues for my determination.

18 **5. Motion to Exclude Murthy**

19 Plaintiffs seek to exclude the opinion of Mr. Harsha Murthy, offered by defendants as an
 20 expert on pharmaceutical company decision-making relating to “at-risk” and authorized generic
 21 launches – that “it is very unlikely that a company in Watson’s position would have launched a
 22 generic version” of Lidoderm at-risk because Murthy made “no effort to examine the facts in this
 23 case specifically or in the generic drug industry generally to determine what a reasonable company
 24 would do here, rendering his opinion wholly speculative and thus unreliable.” Murthy Mot. at 1
 25

26
 27 (9th Cir. 1985) (plaintiffs “must presume the existence of rational economic behavior in the
 28 hypothetical free market.”); *see also* *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th
 Cir. 1981) (“economic rationality must be assumed for all competitors, absent the strongest
 evidence of chronic irrationality”).

1 [Dkt. No. 773].⁴³ Plaintiffs criticize Murthy’s opinions as “speculative” and not based on any
2 specifically cited evidence in the record of this case or “industry related data.”

3 Defendants oppose, arguing that in accordance with my prior ruling regarding objective
4 expert testimony, Murthy draws on his experiences to explain: (i) what factors a reasonable
5 pharmaceutical executive considers when deciding whether to launch a product “at-risk,” (ii) why
6 a reasonable pharmaceutical executive considers those factors in particular, and (iii) how applying
7 those factors to the objective facts here would have made a reasonable pharmaceutical executive
8 less likely to launch generic Lidoderm at-risk as of the time defendants settled their Lidoderm-
9 related patent litigation. Murthy Oppo. [Dkt. No. 809] at 1. Defendants also point out that,
10 contrary to plaintiffs’ assertion, Murthy reviewed and relied on documents produced in this case,
11 depositions taken in this case, as well as publicly available documents. Ex. 2 to Murthy Report.

12 The motion to exclude is DENIED. Murthy’s opinions on what pharmaceutical executives
13 consider with respect to at-risk launch fall reasonably within Murthy’s experience in the industry,
14 and his opinions about whether a reasonable company in Watson’s position would have launched
15 at-risk (based on his understanding of the disputed facts, in light of the record evidence he
16 reviewed), are also permissible.⁴⁴

17 **6. EPPs’ Motion to Exclude Navarro**

18 The EPPs move to exclude the September 2, 2016 Report of Dr. Robert Navarro that
19

20 _____
21 ⁴³ Specifically, plaintiffs seek to exclude paragraphs 13(a), 23-28, 37-50 and 52-57 of the Murthy
22 Report. In 13(a), as an example, Murthy opines, “A generic company will consider many factors when
23 evaluating whether to launch a product ‘at risk,’ including without limitations:
24 (i) the likelihood and timing of obtaining all regulatory approvals;
25 (ii) the likelihood of an adverse litigation outcome (including potential damages based on the
26 magnitude of sales of the branded product—which could be trebled—and how an adverse ruling could
27 affect “first to file” opportunities);
28 (iii) the company’s manufacturing capabilities and ability to meet demand; and
(iv) the likelihood and timing of entry of additional generic manufacturers.
When evaluating the record relating to these factors, it is my opinion that it is very unlikely that a
company in Watson’s position would have launched a generic version of Endo’s Lidoderm patch ‘at
risk.’” Murthy Report [Dkt. No. 809-2].

⁴⁴ In accordance with my prior Orders, defense experts will only be able to testify as to what “a
reasonable” company would have done when faced with the (disputed) facts in this case, and not
what Watson actually knew or was motivated by. *See, e.g.*, June 6, 2016 Minute Order [Dkt. No.
746] at 1.

1 discusses how payments flow for prescription drugs in managed care systems and responds to the
2 opinions of plaintiffs' expert W. Paul DeBree on the same. As explained in the briefing on the
3 motions for class certification, Navarro opined that: (1) "As a result of the individualized and
4 complex nature" of contractual relationships in the "market for prescription drug benefits,"
5 individualized inquiry" is necessary to evaluate the "harm, if any" to class members from the
6 conduct at issue and to "ascertain proposed class members"; (2) claims data, even if available,
7 fails to properly reflect rebate data and thus the price paid by class members; and (3) Pharmacy
8 Benefit Managers ("PBMs") may pay or reimburse for Lidoderm or generic lidocaine through
9 "spread pricing" or guaranteed rebates. Navarro Report [Dkt. No. 550-35] ¶¶ 9-15. The EPPs
10 argue, first, that Navarro's opinions were elicited to defeat class certification (on ascertainability)
11 and, therefore, are irrelevant at this juncture. Second, they argue his opinions are unreliable and
12 based on pure speculation that because PBM might bear theoretical risk from their spread pricing
13 and rebate strategies, there is no evidence that any PBM in the class period actually suffered injury
14 (as opposed to the EPPs) with respect to Lidoderm. Third, as a result, his testimony is unduly
15 prejudicial and likely to confuse the jury.

16 Defendants respond that Navarro's opinions are based on his extensive experience in the
17 industry and critical to injury and state law damages issues to show that some of the overcharges
18 were either not passed onto the EPPs or absorbed in whole or in part by other parties. Defendants
19 are correct that Navarro's testimony is not irrelevant. That said, plaintiffs are correct that the same
20 defect in Navarro's testimony that existed at class certification continues; while Navarro
21 identified a risk that PBMs could suffer all or some of the harm on a particular transaction for a
22 particular drug because of their spread-pricing and rebate practices, he did not identify any
23 instance of that happening with respect to Lidoderm (and plaintiffs' witnesses testified that there
24 was no harm to PBMs in the relevant timeframe). Therefore, at trial, his testimony will be limited
25 to the fact that PBMs could have borne the risk of injury, but he cannot opine that PBMs suffered
26 harm on their Lidoderm transactions.

27 Defendants are also correct that in the class certification Order I recognized that Navarro's
28 opinions could be relevant to apportionment of damages. February 21, 2017 Class Certification

1 Order [Dkt. No. 670] at 39 n.33. However, damages was not a focus of Navarro’s expert report
2 (as noted above, its primary if not sole purpose was to undermine ascertainability) and is
3 mentioned only twice in passing. Narvarro also admitted at his deposition that he was not retained
4 as a “damages expert.” Navarro Depo. Tr. [Dkt. No. 834-2] at 131:10-14. That does not mean his
5 testimony is wholly irrelevant to damages. As this juncture, I will not preclude limited testimony
6 by Navarro – given his background and experience – into the relationships between PBMs and
7 plan sponsors, as well as pharmacies and manufacturers, and how rebates play into the payment
8 flows for prescription drugs.

9 **7. Motion to Exclude Schaede**

10 Plaintiffs seek to exclude the testimony proffered by the Teikoku entities of Professor
11 Ulrike Schaede concerning Japanese business practices and how Teikoku’s role and agreement
12 with respect to the Settlement reflected typical Japanese business practices. Specifically, plaintiffs
13 object to Schaede’s opinions that: (i) Japanese business culture differs from Western business
14 culture, in that Japanese business culture emphasizes long-term trade relationships built on trust
15 and behavioral norms such as incremental commitment, obligation, loyalty, and intertemporal
16 exchange of favors, and (ii) Teikoku’s decisions—engaging Endo as a U.S. distributor, amending
17 a supply agreement with Endo, giving Endo “substantial control” over patent infringement
18 litigation, and entering the settlement agreement with Watson—are “entirely consistent with
19 Japanese business practices, and understandable in light of what a typical Japanese company
20 would perceive and do in this situation. Schaede Report [Dkt. No. 772-2].

21 Plaintiffs argue that these opinions have no relevance to the antitrust issues and that
22 admission of the testimony would be unduly prejudicial and risk jury confusion under Rule 403.
23 Plaintiffs surmise that Teikoku wants to introduce this testimony to show its “good motives” and
24 reluctance to join the agreement but that it did so out of obligation. Plaintiffs contend that good
25 motives are irrelevant, as is Teikoku’s purported reluctance.

26 Teikoku responds that the purpose of Schaede’s opinions is two-fold: to show that Teikoku
27 did not have the “intent” to monopolize when it entered the agreement, relevant to the Section 2
28 Sherman Act claim; and to explain why Teikoku contributed to the Settlement (to preserve its

1 good relationship with Endo), which in its view is a traditional and legitimate settlement
 2 consideration under *Actavis* and a “justification” defense that cannot be precluded through a
 3 motion in limine. Teikoku Sur-Reply re Schaede [Dkt. No. 885].⁴⁵

4 Both sides agree “intent” is an element of a Section 2 conspiracy to monopolize claim.⁴⁶
 5 However, Schaede specifically admitted that her testimony was not relevant to Teikoku’s *intent*:

6 Q . . . Is the point of your testimony to infer Teikoku’s intent in
 7 entering the settlement agreement?

8 A No, it is not.

9 Q What is the point of your testimony?

10 A I am evaluating Teikoku's decision-making over time, in light of
 11 Japanese business practices, to assess whether those decisions can
 12 be explained by way of the norms and values of Japanese business
 13 practices.

14 Depo. Tr. of Ulrike Schaede [Dkt. No. 772-3] at 105:15-23. Therefore, Schaede’s testimony is not
 15 admissible for that limited purpose.

16 As to justification, I disagree with Teikoku that plaintiffs should have moved for summary
 17 judgment to attempt to preclude Teikoku from putting on its “justification” defense and cannot do
 18 so by trying to exclude the Schaede opinion. Teikoku Sur-Reply re Schaede at 2-3. Plaintiffs, by
 19 moving to exclude Schaede’s testimony as not relevant under the law, are not raising a
 20 “dispositive” issue that should have been raised in a summary judgment motion. Instead,
 21 exclusion of opinions that are irrelevant as a matter of law or contrary to the law is appropriate
 22 through the *Daubert* process. *See, e.g., Apple, Inc. v. Samsung Elecs. Co.*, No. 11-CV-01846-
 23 LHK, 2012 WL 2571332, at *7 (N.D. Cal. June 30, 2012) (excluding expert opinions that are
 24 “contrary to the law” and therefore not helpful to the jury).⁴⁷

25 ⁴⁵ Teikoku’s motion for leave to file a sur-reply in opposition to plaintiffs’ motion to exclude the
 26 Schaede testimony [Dkt. No. 885] is GRANTED. I have considered the arguments made by
 27 Teikoku in that Sur-Reply, as well as the responses made by plaintiffs’ in their Opposition to the
 28 Motion for Leave. Dkt. No. 887.

⁴⁶ *See, e.g., Paladin Assocs., Inc. v. Montana Power Co.*, 328 F.3d 1145, 1158 (9th Cir. 2003)
 (elements of a Section two claim are: “(1) the existence of a combination or conspiracy to
 monopolize; (2) an overt act in furtherance of the conspiracy; (3) the specific intent to
 monopolize; and (4) causal antitrust injury.”).

⁴⁷ Plaintiffs are not, as in many of the cases cited by Teikoku, attempting a second “bite at the
 apple” after losing on an issue at summary judgment. *See, e.g., Venture Corp. v. Barrett*, No.
 5:13-cv-03384-PSG, 2015 U.S. Dist. LEXIS 59477, at *11 (N.D. Cal. May 5, 2015); *cf. Guzik*

1 Finally, Teikoku’s “maintain good relations with Endo” motivation for entering the
 2 Settlement Agreement is not a defense under *Actavis*. Teikoku points to no authority that
 3 recognizes anything other than pro-competitive justifications as defenses for otherwise anti-
 4 competitive agreements under *Actavis*. While the Supreme Court in *Actavis* expressly recognized
 5 at least two “traditional settlement considerations” that may account for a reverse payment – *e.g.*,
 6 “a rough approximation of the litigation expenses saved” or “compensation for other services that
 7 the generic has promised to perform” – and noted that “[t]here may be other justifications,” those
 8 justification must be *relevant* to the “rule of reason” analysis. *F.T.C. v. Actavis, Inc.*, 133 S. Ct.
 9 2223, 2236 (2013); *see, e.g., Anderson v. Am. Auto. Ass’n*, 454 F.2d 1240, 1246 (9th Cir. 1972)
 10 (“The promotion of self-interest alone does not invoke the rule of reason to immunize otherwise
 11 illegal conduct. It is only if the conduct is not unlawful in its impact in the market place or if the
 12 self-interest coincides with the statutory concern with the preservation and promotion of
 13 competition that protection is achieved.” (quoting *United States v. Arnold, Schwinn & Co.*, 388
 14 U.S. 365, 375 (1967) *overruled on other grounds by Cont’l T. V., Inc. v. GTE Sylvania Inc.*, 433
 15 U.S. 36 (1977)); *see also In re Lipitor Antitrust Litig.*, 868 F.3d 231, 263 (3d Cir. 2017) (“intent is
 16 not an element of an antitrust claim, and benign intent does not shield anticompetitive conduct
 17 from liability.”); *Levine v. Cent. Florida Med. Affiliates, Inc.*, 72 F.3d 1538, 1552 (11th Cir. 1996)
 18 (“The rule of reason analysis is concerned with the actual or likely effects of defendants’ behavior,
 19 not with the intent behind that behavior.”).⁴⁸

21 *Tech. Enters. v. W. Digital Corp.*, No. 5:11-cv-03786-PSG, 2013 U.S. Dist. LEXIS 171327, at
 22 *28 (N.D. Cal. Nov. 22, 2013). (denying motion in limine seeking to preclude claim of
 23 infringement by importation as “thinly-veiled” dispositive motion, but granting motion in limine
 24 to preclude evidence regarding willfulness, despite failure to seek summary judgment on that
 25 issue, where willfulness was irrelevant as a matter of law). Nor are they seeking to exclude
 26 testimony on the ground that it was inadequately disclosed where there were other more
 27 appropriate remedies (*e.g.*, motions to compel). *See, e.g., Nortek Air Sols., LLC v. Energy Lab*
 28 *Corp.*, No. 14-cv-02919-BLF, 2016 U.S. Dist. LEXIS 92468, at *6 (N.D. Cal. July 15, 2016).

⁴⁸ Given the apparent lack of case law supporting Teikoku’s position (that its benign intent is a
 defense under the rule of reason), Teikoku takes a different tack, arguing that *judicial estoppel*
 prevents plaintiffs from arguing intent is not relevant. Teikoku Opp. to Schaeede at 7-9. However,
 that pro-competitive justifications are relevant (*e.g.*, where a generic manufacturer provides
 distribution services) and anti-competitive justifications are relevant (*e.g.*, defendants were paying
 for delay of generic entry) does not mean that other justifications that have nothing to do with
 competition are relevant. Plaintiffs’ repeated efforts to force Teikoku (or have me force Teikoku)

1 While maintaining good business relations with Endo might have been a key goal of
 2 Teikoku, Teikoku does not show how that goal has any pro-competitive impact on consumers or
 3 on the industry in general, or on any other consideration relevant to a rule of reason analysis. That
 4 justification, if true, does nothing to negate the inference (or according to plaintiffs, the actuality)
 5 that the payments agreed to by Endo and Teikoku were to delay competition.

6 Plaintiffs' motion to exclude the testimony of Ulrike Schaede is GRANTED, as that
 7 testimony is irrelevant and will not assist the trier of fact.⁴⁹

8 **C. Defendants' Motions**

9 **1. Motion to Exclude Adelman & Shah**

10 Defendants move to exclude in part the opinions of plaintiffs' experts Professor Martin
 11 Adelman [Dkt. No. 819-13] and Dr. Kishore Shah [Dkt. No. 819-15], who offer expert testimony
 12 on what would have been the likely outcome of the '529 patent litigation, on the grounds that
 13 those experts' opinions are divorced from the record evidence in the '529 trial. Dkt. No. 780.

14 Adelman. Defendants move to exclude Adelman's opinions on validity and enforceability.
 15 Defendants argue that because he did not opine on how Judge Sleet or the Federal Circuit would
 16 have decided validity and enforceability, but instead analyzed validity and enforceability as a
 17 "reasonable factfinder," his opinions are based on the wrong legal standard. Defendants posit that
 18 Adelman used the "reasonable factfinder" construct to avoid statements made by Judge Sleet on
 19 the credibility of witnesses that would, if considered, undermine Adelman's opinions. Adelman &
 20 Shah Mot. at 4. Defendants also complain that Adelman makes an argument on enforceability
 21 (regarding misleading statements made by Teikoku in declarations and responses to the PTO) that
 22 was not made at trial.

23 In his deposition, Adelman explains that "reasonable factfinder" was short hand for how
 24

25 to produce attorney-client information in discovery to uncover Teikoku's true purposes for
 26 entering the Agreement does not estop plaintiffs from arguing that the Schaede testimony is
 27 irrelevant.

28 ⁴⁹ For similar reasons, even though the plaintiffs did not move to exclude it, testimony from
 Moffitt about "maintaining a good business relationship" as a "traditional settlement
 consideration" will not be allowed. Moffitt Rep. ¶¶ 72-73.

1 the factfinder in the first instance (as anticipation is a question of fact) should have and then the
 2 Federal Circuit on appeal (under a clearly erroneous standard of review) would have decided the
 3 validity question. Adelman Depo. Tr. [Dkt. No. 817-2] at 70:12-16; 101:15-21. When discussing
 4 questions of law, like obviousness and inequitable conduct, Adelman referred to “the court”
 5 (including the Federal Circuit on review).⁵⁰ Adelman Report ¶ 39.

6 As to Judge Sleet’s comments that Adelman supposedly ignored, I do not find them as
 7 certain or persuasive as defendants assert. While Judge Sleet asked a question about the
 8 significance and impact of a decision to credit Endo’s witness (Lane) over Watson’s (Walters) on
 9 some undisclosed bases and issues, it was phrased as a question and by no means indicates how
 10 Judge Sleet was going to credit the testimony, let alone how he would rule. As to the credibility
 11 that Judge Sleet found (much more affirmatively and specifically) concerning the ’529 inventor
 12 (Ono), even though Judge Sleet found Ono credible, that does not answer the question of how he
 13 would have ruled on the intent to deceive issue with respect to Ono’s representations made to the
 14 PTO. Indeed, as plaintiffs point out, Judge Sleet also expressly acknowledged that he could *infer*
 15 intent and recognized the important policy considerations at play that encourage full disclosure of
 16 prior art to the PTO. Closing Argument Tr. 105. While all experts agree that Judge Sleet was
 17 going to find infringement in light of his comments and claim construction order, defendants point
 18 to no testimony or other indication how he was going to decide validity or enforceability other
 19

20
 21 ⁵⁰ Defendants are correct that Adelman was not emphatic about what a reasonable factfinder/Judge
 22 Sleet/the Federal Circuit would have done on anticipation, but he *was* clear about what “the
 23 courts” should have (in the case of Judge Sleet) or would have (in the case of the Federal Circuit)
 done with respect to obviousness *based on the record in the underlying case*. See *id.* at 155
 (responding to the question of whether “court” included reasonable factfinder or Judge Sleet:

24 A. I did not make that distinction. So I was talking about the -- really the courts, including
 25 the Federal Circuit. And in that, I’m assuming that the Federal Circuit would look at it as
 -- the same as KSR. And I would have expected Judge Sleet to do the same. But that
 doesn’t always happen.

26 A. I’m offering the opinion that he should have, and the combination of Judge Sleet and
 27 the Federal Circuit would have, under these facts, these -- and every one of these cases is
 different -- that, as I said before, the evidence is overwhelming on obviousness, and I
 28 believe it is on inequitable conduct.

Adelman Depo. Tr. at 154-55.

1 than the two statements identified above, which do not bear the weight defendants put on them.⁵¹

2 Finally, as to the “new” argument Adelman makes that was, according to defendants, not
3 argued by Watson – that Teikoku knowingly submitted materially misleading declarations to the
4 PTO – plaintiffs point out that Watson argued in closing that the declarations submitted to the
5 PTO focused on the “unique” nature of the patches claimed in the patent application and how that
6 was indisputably not true in light of Ono’s own prior art, even if Watson did not use the term
7 “misleading.” Closing Argument Tr. at 94-96; *see also* Adelman Depo. Tr. at 253:8 – 254:19.
8 That is sufficient to support Adelman’s testimony.

9 The motion regarding Adelman is DENIED.

10 Shah. Defendants argue that Shah reached outside the closed record of the ’529 patent
11 litigation to form his opinions on whether the ’529 patent was valid and enforceable. Shah
12 testified that his opinions were based on the trial court record as well as his own “technical
13 assessment of the case.” Shaw Depo. Tr. [Dkt. No. 817-7]. As Shah explained in his deposition,
14 because he was applying his scientific background and knowledge to his review of the trial record,
15 his opinions were informed by scientific literature. *Id.* at 21. Shah also explained that he relied on
16 specific references (outside of the ’529 record), but only to explain the “technology” background
17 (and not as prior art references to the ’529 patent) and those references did not impact his decision
18 as to the ’529 patent’s validity or enforceability. *Id.* at 95-96 (as background); 103 (book cited in
19 report for background but did not “impact my opinion about the validity or invalidity”). Shah’s
20 reliance on his general knowledge and on specific references outside of the ’529 record to explain
21 the context for the technology at issue was not impermissible, especially given his clear statement
22 that these additional references did not impact his opinions as to the ’529 patent’s validity or
23 enforceability.

24 Defendants also argue that Shah’s refusal in his deposition to say whether his opinions
25 would change if he were limited to the “trial testimony” was an admission that he relied on

26 _____
27 ⁵¹ Even if Judge Sleet’s credibility comments were as strong and set in stone as defendants
28 contend, defendants do not explain how they would impact obviousness (which is determined as a
matter of law).

1 materials outside the trial record for his opinions. Adelman & Shah Mot. at 7. But this
 2 “concession” is not as strong as defendants would hope. On its face, “trial testimony” doesn’t
 3 necessarily include all of the *evidence* before the ’529 trial court (and available for the Federal
 4 Circuit’s review on appeal). Shah also repeatedly clarified that he was asked to look at “all the
 5 information” and “all of the references” to give his opinions. Shah Depo. Tr. at 129, 130. But
 6 nowhere in his deposition were defendants able to identify a particular reference or piece of
 7 information that was verifiably outside the scope of the ’529 record that Shah *relied upon* to form
 8 his opinion on validity and enforceability as to the ’529 patent.⁵²

9 The motion to exclude is DENIED as to Shah.

10 2. Motion to Exclude Elhauge

11 Defendants move to exclude the opinions of Professor Einer Elhauge, a law professor who
 12 opines in support of plaintiffs’ alternate causation theory that in the hypothetical but-for world,
 13 even without a reverse payment the defendants would have agreed to a settlement allowing
 14 Watson into the market nearly a year earlier than the date on which the parties agreed in the real
 15 world. Elhauge Mot. [Dkt. No. 783].

16 Elhauge first estimated the parties’ bargaining strength using the actual Settlement. He
 17 then used that estimation of strength, and the companies’ own profit projections, to opine that if
 18 Endo thought it had more than a 15.1% chance of winning, it would not have rationally agreed to
 19 the actual Settlement. Elhauge Report [Dkt. No. 819-2] ¶¶ 6, 147. Then he considered the various
 20 possible strengths each party could have rationally had with respect to the litigation to produce a
 21 range of feasible no-reverse-payment settlement early entry dates that still would have provided
 22 each party with a payoff exceeding its litigation payoff. *Id.* ¶¶ 8, 149-153.

23 Defendants argue that this “model” of Elhauge’s own invention was described by the
 24 Retailer Plaintiffs’ expert (Leffler) as “not transparent” and “difficult to understand.” Because of
 25 its complexity and lack of transparency, defendants argue it should be excluded. *See Oracle Am.*,

26
 27 _____
 28 ⁵² Plaintiffs also argue that the “background” references included in Shah’s Report were not
 limited to the ’529 technology but were also relevant to Shah’s opinions on the Rolf patents.
 Adelman & Shah Oppo. at 9. Defendants do not address or contest this position in their Reply.

1 *Inc. v. Google Inc.*, 798 F. Supp. 2d 1111, 1119–20 (N.D. Cal. 2011) (adopting “the normal
2 *Georgia–Pacific* factors” and rejecting adoption of a mathematical model for juror use to
3 determine reasonably royalties where the model “has never been approved by a judge to calculate
4 reasonable royalties in litigation, at least in the face of objection. This is despite the fact that for
5 decades it has been lurking in the field of economics. The [] solution involves complex
6 mathematical formulas and equations that would surely be incomprehensible to the average
7 juror.”).

8 Defendants also argue that the model should be excluded because it has not been tested or
9 peer reviewed. Elhauge admitted that the model he used in this case was a combination of
10 principles published in at least three different articles (according to defendants, two of which were
11 student-run, not peer reviewed, and did not address bargaining strength, and the third addressed
12 “patent holdup” and “royalty stacking,” not bargaining strength). Elhauge also conceded that he
13 was unaware of any study that “validated” the idea that bargaining strength derived from one
14 settlement can be used to predict the outcome of an alternative negotiation. Elhauge Depo. Tr.
15 114:23-115:23. Defendants rely on *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 52
16 (1st Cir. 2016), where the court concluded it was not an abuse of discretion to exclude a
17 methodology, purporting to use stock market data to estimate a but-for entry date, where the data
18 and model “did not fit the conclusions for which it was offered” and where no one else had ever
19 used the method to predict settlement terms, except in “an unpublished, non-peer-reviewed
20 working paper” that the expert had co-authored during the course of the litigation.” *Id.* at 52.

21 In general, I note that numerous courts have admitted testimony from Elhauge as an expert
22 in antitrust economics generally, although some have excluded his testimony where it was based
23 on unreliable assumptions as to market definitions or because of problems in his regression
24 analysis. *See, e.g., In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2015 WL
25 5767415, at *4 (E.D. Pa. July 29, 2015) (admitting Elhauge’s testimony and noting, “[t]here is no
26 dispute that setting aside the issue of regression analysis in particular, courts have admitted Prof.
27 Elhauge as an expert in antitrust economics generally.”); *It’s My Party, Inc. v. Live Nat., Inc.*, 88 F.
28 Supp. 3d 475, 488 (D. Md. 2015), *aff’d sub nom. It’s My Party, Inc. v. Live Nation, Inc.*, 811 F.3d

1 676 (4th Cir. 2016) (excluding Elhaug’s definition of market power because “the methods
2 utilized by Elhaug to create a category of artists who ‘prefer amphitheatres’ is unreliable”).

3 While defendants are correct that Elhaug could point to no other case where an expert has
4 employed the exact model he employs here, both the components of his model (estimating parties’
5 bargaining strengths and expectations of patent strength) and the assumptions that go with it (the
6 parties’ own pre-settlement forecasts) are consistent with accepted economic theory and well-
7 established principles. As to Elhaug’s use of the “event study” based on an analysis of stock
8 market gains, while a similar study was excluded in *In re Nexium*, 842 F.3d at 52, Elhaug uses
9 the study here as only a “back stop” to corroborate his bargaining strength conclusions. Elhaug
10 Report ¶¶ 89, 141. Standing alone, it is not the basis for his model and opinions.

11 Defendants do not point to any irrational outcomes (or outcomes that are contrary to profit
12 maximizing assumptions in a but-for world) that flow from Elhaug’s analysis. Defendants will
13 be free to mount attacks on Elhaug’s approach – deriving the bargaining strengths in his
14 suggested but-for early entry settlement based on his analysis of the parties’ actual bargaining
15 strengths as represented by the Settlement they actually reached – in their cross-examination.

16 Elhaug may opine that in his view the parties would have been rationally motivated to
17 agree to settlement allowing Watson early entry by specific dates. However, Elhaug cannot
18 testify that the parties *would have* agreed to entry on a date certain, as that impinges on a
19 determination left up to the jury. Defendants’ motion is otherwise DENIED.

20 **3. Motion to Exclude Hardigan**

21 Defendants move to exclude the opinions of Peter J. Hardigan, plaintiffs’ designated expert
22 to opine on the amount of litigation expenses (including trial and appellate expenses) that
23 defendants saved by settling the two pending patent infringement cases relating to Lidoderm, the
24 ’529 litigation and the “Rolf litigation” *Endo Pharmaceuticals Inc. v. Watson Laboratories, Inc.*,
25 No. 1:11-cv-00575 (D. Del.). Hardigan Mot. [Dkt. No. 785] at 1.

26 Defendants attack the qualifications of Hardigan, as he is neither a lawyer nor an expert in
27
28

1 patent law but instead works in patent and patent litigation investing.⁵³ Defendants complain that
 2 Hardigan did not examine the patents or the record involved in either the '529 or the Rolf patent
 3 litigations. Accordingly, they argue that his opinions – about projected appellate costs based on a
 4 belief that Endo/Teikoku would have lost at the trial court in the '529 case and that the Rolf case
 5 would have been less expensive to litigate given that it was related to the '529 litigation (which
 6 defendants contest) – are examples of why his analysis is unreliable and excludable.

7 As an initial matter, plaintiffs confirm that Hardigan will not be opining on whether
 8 Watson *would* have won at the trial court; his analyses are based on that assumption. With respect
 9 to the Rolf litigation, Hardigan did not simply rest on his understanding that the two lawsuits were
 10 closely related and could generate cost efficiencies. He started with the '529 litigation costs as a
 11 “significant input” for his analysis of the Rolf costs, but also looked to defendants’ documents and
 12 deposition testimony regarding costs budgeted and (where data was provided) actually incurred at
 13 specific rates and stages of the two cases in order to help him reach his ultimate conclusions. For
 14 example, he noted that Watson budgeted (and at various stages incurred) less costs for the Rolf
 15 case than the '529 case. Hardigan Report ¶¶ 3.1, 5.1 – 5.4. He also “back stopped” his analyses
 16 by comparing them to the American Intellectual Property Associations publication on median
 17 ANDA litigations costs. Hardigan Report ¶ 6.1. Defendants do not point to any of Hardigan’s
 18 calculations as misstating the evidence or argue that he came up with unreasonable estimates (*e.g.*,
 19 Hardigan’s estimate that the Rolf litigation would have cost Endo \$7.9 million, less that the
 20 estimated costs for the '529 patent but still more than the median costs to try an ANDA case). *Id.*
 21 ¶ 6.1. Hardigan did use the expenses occurred through trial in the '529 patent as a benchmark for
 22 his Rolf patent estimates, but did not rely exclusively on the “relatedness” between the two.
 23 Defendants may use that issue – and their belief that Hardigan relied too heavily on it – as a basis
 24

25
 26 _____
 27 ⁵³ Hardigan describes himself as “an independent consultant” who is an executive and advisor to
 28 companies that engage in IP litigation with over 15 years of experience. He has been personally
 responsible for investment in and management of over 50 U.S. patent cases and has provide a
 range of IP advisory services to attorneys, Fortune 500 companies, and institutional investors
 engaged in patent licensing, patent transactions, and patent litigation. Hardigan Report [Dkt. No.
 785-2] ¶ 1.1.

1 for cross-examination.⁵⁴

2 As to his ability to predict and experience in predicting costs made on those types of
3 assumptions, defendants complain that Hardigan's only prior experience on cases that went to trial
4 were two cases that did not involve pharmaceuticals. Plaintiffs counter that Hardigan has
5 estimated litigation costs for hundreds of projects. More specifically, for the (at least) 50 patent
6 litigation cases he managed, even where a contingency or flat fee arrangement was adopted,
7 Hardigan estimated what the legal fees would be by each stage of the case on a "full fee" basis.
8 Hardigan Depo. Tr. [801-2] at 156-57. Defendants do not explain why his limited direct
9 experience with pharmaceutical patent litigations undermines his ability to estimate costs here.
10 Given the record evidence he considered as well as relevant publications, he has sufficient
11 expertise and knowledge to estimate legal fees for this type of litigation.

12 The motion to exclude is DENIED, except (as noted above and agreed-to by plaintiffs)
13 Hardigan will not be allowed to testify on the likely outcome of the '529 litigation.

14 4. Motion to Exclude Leffler

15 Defendants move to exclude the opinions of Dr. Keith B. Leffler in support of plaintiffs'
16 alternate causation theory that in the hypothetical but-for world, but-for the reverse payment, the
17 defendants nonetheless would have agreed to a settlement allowing Watson into the market on a
18 date before its actual September 15, 2013 entry. Dkt. No. 782; Dkt. No. 782-2 (Leffler Report).

19 Leffler started his analysis by evaluating the expected profits from litigation as opposed to
20 an alternative settlement, an analysis approved by a large amount of economic literature. He
21 calculated Endo's profits from winning or losing the patent litigation and "weighted" the
22 alternatives by the objective expectations (from Adelman's opinion) that Endo would win or lose.
23 Leffler Report ¶ 80. He initially concluded that Watson would have accepted a no-payment
24 settlement allowing it early entry in October 2012. *Id.* ¶ 82. When considering the testimony of
25 plaintiffs' manufacturing witness (Miller) that Watson would not have had sufficient launch

26
27 ⁵⁴ Defendants do not argue that *no* efficiencies would flow from the '529 litigation to the Rolf
28 litigation, but because that the same product (5% lidocaine patches) was involved, the same
counsel were involved, and the same court was involved certainly there would be some. How
many and how significant those efficiencies may have been can be tested at trial.

1 quantities by that date, Leffler revised his estimate to a later date. *Id.* ¶ 83.

2 Defendants argue that Leffler’s analyses must be excluded because there is no peer-review
 3 published article that teaches taking standard and accepted economic analyses of settlements and
 4 applying them in a way to predict early entry in this sort of case. Leffler Mot. at 5-6. However, as
 5 with the challenge to Elhauge, that prior experts or academics have not combined different but
 6 *accepted* economic theories and modes of analysis for patent settlements and then applied them to
 7 this specific set of facts – which are unique in the relatedness between the actual Settlement and
 8 consideration that the identical parties are essentially identically situated – is not surprising and
 9 does not require exclusion. *See* Leffler Depo. Tr. [Dkt. No. 782-4] at 184 (the “details” of this
 10 model are specific to the facts of this case, although the conceptual underpinnings are from
 11 economic literature).⁵⁵

12 Defendants also argue that Leffler’s opinions are somehow based on an impermissible
 13 inference that an anticompetitive effect can be inferred from simply the large reverse payment,
 14 which in defendants’ view is impermissible under *Wellbutrin*. Leffler Mot. at 6. As noted earlier,
 15 I have concluded that the large and unexplained nature of the reverse-settlement payment (if
 16 established) is particularly relevant evidence even if not sufficient on its own. Moreover, Leffler
 17 explained that he did not rest solely on the inference, but also considered the terms of the actual
 18 settlement and the parties’ expectations of the outcome of the litigation. Leffler Depo. Tr. 128-29.

19 Defendants criticize Leffler’s reliance on Adelman’s estimate of the low likelihood that
 20 Endo would win the patent litigation because he did not test that figure/assumption himself and
 21 only received that figure the day before his report was due. As explained above, Adelman’s
 22 opinions have not been excluded and are subject to testing at trial. As to the timing, Leffler

23 _____
 24 ⁵⁵ The full exchange at issue reads:

25 Q. From any of this literature, did you, for lack of a better term, “pluck off” the shelf a
 26 model and implement it here in this report?

26 THE WITNESS: No. The details of these would be very, very specific to the situation so
 27 the answer is no in the sense I think you’re asking the question. If you mean just in a more
 28 conceptual sense of considering the gains from litigation and then considering the gains
 from settlement, then the answer is yes, but not specifically grabbing an existing set of
 analyses and changing a number here or there.

Leffler Depo. Tr. at 184:3-18.

1 explained in his deposition that he created his model and used a placeholder for the Adelman
2 figure and was able to test different inputs in his model, but inserted the final figure when he
3 received it shortly before his report was due. Leffler Depo. Tr. 211 – 213. There is nothing
4 improper about this approach.

5 Finally, defendants argue Leffler's opinions must be excluded because they are not based
6 on sufficient facts in the record. This is the same argument made above. Because this case is set
7 in a but-for world, it is not surprising that no evidence shows that defendants were contemplating
8 anything other than the actual Settlement. Leffler's failure to address (or adequately address)
9 various factors that defendants believed would impact Watson's actual ability to launch (status of
10 Endo's Citizen Petition, Watson's manufacturing capacity, Teikoku's willingness to enter into a
11 settlement) can be addressed on cross-examination.

12 Leffler may opine that the parties would have been economically motivated to enter into a
13 no-payment settlement as of a particular date or within a range of dates. He cannot testify that the
14 parties would have entered on a date certain, as that impinges on a determination left up to the
15 jury. Defendants' motion is otherwise DENIED.

16 **5. Motion to Exclude Miller**

17 Defendants move to exclude the opinions of Dr. Kenneth Miller, who opines that in the
18 but-for world, Watson would have manufactured the 23 million patches earlier than it actually did.
19 Dkt. No. 793; Miller Report [Dkt. No. 793-2]. Miller's opinions rest on two assumptions: (i)
20 Watson could and would have manufactured sufficient launch quantities by December 17, 2012
21 had it continued production and not stopped in June 2012; and (ii) even if Watson stopped in June
22 2012 and restarted in November 2012 after correcting manufacturing issues (what actually
23 happened), Watson would have had sufficient launch quantities by January 2013, as long as it
24 employed profit-maximizing strategies, including delaying a plant closure and working through
25 the holidays.

26 Defendants first argue that Miller's failure to fully explain his experience in patch
27 manufacturing in his deposition prevented defendants from fully testing the reliability of his
28 opinions. Defendants point out that Miller testified that he was involved with the development of

1 a hydrogel patch, but he would not provide specifics because of confidentiality concerns and only
 2 responded that “he had never been involved in the development of a hydrogel that has become a
 3 commercial product.” Miller Depo. Tr. [Dkt. No. 793-4] at 62. The exchange continued:

4 Q. So in providing your testimony on behalf of plaintiffs in this
 5 case, should we assume that you are not drawing upon your
 6 experience with respect to this hydrogel patch product?

7 A. I am drawing upon my experience. My experience of
 8 understanding the chemistry that is at play here. My understanding
 9 of the mixing processes, and the coating processes, and the
 10 packaging processes. Because those unit operations are all the same.
 11 They operate on the same principles, using the same types of
 12 equipment for a matrix patch or for the case at hand, this Lidocaine
 13 patch.

14 Q. Okay. So I'm going to ask again. In what prospect have you been
 15 involved in the development of a hydrogel patch product?

16 □

17 THE WITNESS: I am uncomfortable answering a question about
 18 products that I may or may not have worked on in the past because
 19 that is all confidential information.

20 Miller Depo. Tr. at 63. Defendants also complain that Miller failed to answer specific questions as
 21 to the exact mix, mix process, and application to a patch for a patch he worked on at Mylan,
 22 although Miller did respond with general answers about those processes. *Id.* at 36-37. Miller also
 23 refused to identify the date that Mylan started working on a lidocaine patch. *Id.* at 45-46. Finally,
 24 defendants complain that while Miller opined based on his experience that pharmaceutical
 25 companies would cancel vacations, holidays, and plant shut downs, he refused to disclose with
 26 which companies he had experiences with on those topics. *Id.* at 184-85.

27 Plaintiffs respond that Miller testified extensively about his experiences with matrix
 28 patches, including the Mylan patches that Miller initially expressed confidentiality concerns about
 before going on to testify fully about the general process of manufacturing them. Miller Depo. Tr.
 at 36:6 – 37:13. According to plaintiffs, Miller’s experience with matrix patches is transferrable to
 hydrogel patches, so that his few limited confidentiality assertions on his experience with hydrogel
 patches is not a problem. Miller Oppo. at 2. As to his experience with plant operations (in order
 to rush product production), plaintiffs argue that because Miller identified the two companies he
 had worked at full-time (Mylan and Noven), and also went onto disclose that Mylan had one
 plantwide shutdown during his time and that he knew of instances where Mylan cancelled

1 vacations due to production demands, the bases for his opinions have been disclosed. 184-86, 188-
2 89, 192-93.

3 Generally, reviewing his testimony as a whole, I find that Miller disclosed enough about
4 his experience with matrix and hydrogel patches to allow defendants to test his level of
5 experience.⁵⁶

6 Defendants also move to exclude Miller's opinions on what Watson "would have done"
7 because Miller has no relevant expertise on those subjects, including his purported profit-
8 maximizing strategies. While Miller admitted that he had not been responsive for "pulling the
9 switch and manufacturing a first commercial batch that I signed off on, I will grant you that. No, I
10 haven't done that[]", Miller Depo. Tr. at 60, he went onto explain, that "there are a lot of processes
11 that occurred before that that are at that level of responsibility." Miller Depo. Tr. at 60; *see also* at
12 61 (testifying to his "extensive involvement in" pre-commercial production and that he "had many
13 responsibilities throughout the organization and they did involve whether or not products were
14 commercially manufactured and how that was done."). As to employee schedules, he testified that
15 he did not set company calendars, but he did have employees work through holidays "for him" and
16 had knowledge of companies' practice in the area. *Id.* at 62.⁵⁷ Again, read in full, Miller's
17 experiences are sufficient to allow him to opine on these subjects, but defendants will be free to
18 challenge Miller's lack of experience on particular decision-making points during cross-
19 examination.

20 On the related point of Miller's interpretation of Watson's documents and his reliance on
21 those documents in support of his but-for theories, I conclude that Miller's testimony synthesizing
22 the various technical and non-technical documents is appropriate.

23
24 _____
25 ⁵⁶ This ruling does not preclude defendants from objecting to and moving to strike particular
26 testimony if Miller asserts confidentiality concerns as a basis to refuse to answer questions at trial
27 or if Miller testifies on matters at trial that he refused to testify on during his deposition.

28 ⁵⁷ Miller testified that he had never been involved in setting the amount of product required for
product launch. Miller Depo. Tr. at 59. But in this case, Miller's opinion is based on Watson's
own documents indicating various launch date quantity scenarios. His lack of direct experience in
this area is not problematic.

1 With respect to Miller’s alternate January 28, 2013 launch scenario, defendants argue that
 2 Miller admitted in his deposition (contrary to his Report) that his maximizing-theory (*e.g.*,
 3 working through holidays and cancelling plant shutdowns) would not have allowed Watson to
 4 manufacture enough quantity by January 28, 2013, so his opinion is without basis. But as Miller
 5 explained, his theory is based on Watson’s own projections of two batches a week and having staff
 6 “work every day” (not just over the holidays) to meet those projections. Miller Depo. Tr. 197-98.
 7 The justification in his deposition is consistent with his theory of maximizing strategies from his
 8 Report.⁵⁸

9 Finally, defendants move to exclude Miller’s opinions about claim construction and
 10 infringement, as he is a chemical engineer with no relevant experience. They contend that
 11 testimony by Miller as to claim construction and literal or doctrine of equivalents (DOE)
 12 infringement would be outside of the record of the actual ’529 litigation because: (1) Watson did
 13 not present a technical expert on claim construction; (2) Miller’s opinion on literal infringement is
 14 based on an undisputed fact; and (3) Miller cannot make doctrine of equivalents arguments that
 15 were not made by Watson. Plaintiffs initially note Miller’s qualifications and argue that his
 16 testimony is admissible (and appropriate) because he is simply responding to the arguments
 17 presented by defendants *in this case* by their expert (Majella Lane, who was Endo/Teikoku’s
 18 expert in the ’529 litigation). In doing so, Miller relies on evidence and arguments (as to claim
 19 construction) actually made by Watson in the ’529 litigation (even if not presented through a
 20 “technical expert”) and disputed in that case between Miller and Lane (as to literal infringement).
 21 *See, e.g.*, Miller Reply Report [Dkt. No. 816-8] ¶¶ 15-20. This testimony is admissible.

22 Miller’s testimony regarding the doctrine of equivalents purports to answer questions of
 23 law (no infringement under the DOE due to vitiation, disclosure-dedication, or prosecution history
 24 estoppel). It falls outside of his area of expertise and he cannot opine on the ultimate legal
 25 conclusions that may have been reached in the ’529 litigation. He can, however, dispute the
 26

27 ⁵⁸ In his Report, Miller gives examples of how Watson could have “squeezed” extra “man-hours”
 28 out of its manufacturing process. Miller Report ¶¶ 41, 300-301. As to the two-batches-a-week
 projection, defendants can attack Miller’s basis for believing that projection was realistic or
 actually viable.

1 factual issues (for example, he can contest Lane’s analysis based on “principles of pharmaceutical
2 formulation”) and opine on what a person of ordinary skill in the art would have known or how
3 she would have viewed the Teikoku file history (as relevant to legal questions arising under the
4 DOE).

5 Other than the objection to Miller’s testimony on questions of law under the doctrine of
6 equivalents, defendants’ motion is DENIED.

7 **6. Motion to Exclude Molina**

8 Defendants move to exclude the opinions of Luis Molina that in absence of the Settlement,
9 Watson would have launched at-risk and Endo would have launched its Authorized Generic (AG)
10 immediately after Watson’s launch. Defendants argue that Molina lacks the background and
11 experience to opine on these subjects because while he provided input on these sorts of decisions,
12 he was not the final decision-maker or included in the senior management’s decision-making.
13 Defendants also object to Molina’s testimony about the “intent” of Watson and Endo regarding
14 their launch plans, arguing that intent and state of mind are not appropriate areas for expert
15 testimony. Finally, defendants object to Molina’s “interpretation” of disputed facts, contending
16 Molina is attempting to usurp the factfinder’s role at trial.

17 On experience, defendants make much of the fact that Molina was never involved in
18 deciding whether to launch a generic at-risk, was never the ultimate decision-maker on whether to
19 launch an AG, never had specific responsibility concerning patent litigation, and had never
20 presented his financial information directly to a Board or investors. Molina Mot. at 3-6.
21 However, Molina bases his opinion on Watson’s likelihood of launching at-risk on statements
22 made by Watson employees and executives and also on evidence regarding the steps Watson took
23 towards manufacturing their generic patch before and after the Settlement, evidence that in his
24 view was consistent with the actions of a company preparing to launch at-risk. Molina Report
25 [Dkt. No. 777-5] ¶ 17.⁵⁹ While Molina admitted that he had no first-hand experience with at-risk

26
27 ⁵⁹ Defendants also complain about Molina’s testimony regarding defense-expert Murthy’s
28 treatment of the patent-litigation risk in Murthy’s Report. *See* Molina Reply Rep. ¶¶ 96-102. It is
unclear whether Molina or Murthy have experience sufficient to testify as to how reasonable
companies would weigh patent-risk in deciding to launch, but those objections can be made at trial

1 launch and while defendants contend that Molina ignores the possibility Watson’s public
 2 statements were “posturing,” his background in analyzing the likelihood of potential generic
 3 competition and his own efforts in launching authorized generics gives him the experience to
 4 opine on the indicators that show a company was preparing to launch a product and whether they
 5 existed here. *See, e.g.*, Molina Rep. ¶ 54. Defendants agree that Molina has direct experience
 6 with AG launches, but note that Molina never operated at the “senior executive” level and never
 7 made high-level presentations (to the Board or to investors) regarding AG launch, although
 8 information prepared by Molina was presented at these levels. Molina Mot. at 5-7. But given
 9 Molina’s experience in the industry, he is qualified to opine on this subject based on his review of
 10 the evidence.

11 Molina’s testimony concerning Watson and Endo’s “intent” is about what he believed
 12 Watson and Endo were prepared to do prior to the Settlement based on his review of the record
 13 evidence. It is not the type of “motivation” or “state of mind” testimony that courts have
 14 excluded.⁶⁰ As made clear in his reply, Molina relied on his industry experience and the evidence
 15 he reviewed that Watson was preparing for an expeditious launch, but did not opine on what
 16 Watson executives subjectively decided, thought, believed, or intended. Molina Reply Rep. ¶ 69.
 17 If Molina veers into purely speculative opinions on the subjective motivations or beliefs of
 18 employees or executives at Watson or Endo at trial, objections may be made and sustained. In
 19 light of his experience in the industry, Molina is allowed to opine that Watson and Endo had
 20 decided to launch generics, given the steps those companies had taken and the public and non-

21
 22 if that sort of testimony is elicited and an appropriate foundation is not laid.

23 ⁶⁰ *See, e.g., Stanley v. Novartis Pharmaceuticals Corp.*, 2014 WL 12573393, at *6 (C.D.Cal.,
 24 2014), quoting *In re Rezulin Products Liability Litigation*, 309 F.Supp.2d 531, 547 (S.D.N.Y.
 25 2004) (excluding “speculative inferences” about defendants’ motivations); *In re Flonase Antitrust*
 26 *Litigation*, 884 F.Supp.2d 184, 193 (E.D.P.A. 2012 (experts not permitted to testify as to “state of
 27 mind” as to why a company filed its citizen petition); *In re Fosamax Products Liability Litigation*,
 28 645 F.Supp.2d 164, 192 (S.D.N.Y. 2009) (“To the extent Merck’s motion seeks to preclude Dr.
 Parisian from testifying as to the knowledge, motivations, intent, state of mind, or purposes of
 Merck, its employees, the FDA, or FDA officials, it is GRANTED. Dr. Parisian conceded at the
 hearing that her regulatory expertise does not give her the ability to read minds. Nevertheless, her
 report is replete with such conjecture.”); *see also Siring v. Oregon State Bd. of Higher Educ. ex*
rel. Eastern Oregon University, 927 F.Supp.2d 1069, 1077 (D. Or. 2013) (collecting cases).

1 public comments that were made.

2 Finally, plaintiffs will not be allowed to elicit testimony from Molina for the sole purpose
3 of entering a factual narrative in the record. He will, of course, be allowed to identify the facts
4 (documents, testimony) that support his otherwise permissible opinions. Defendants are free to
5 challenge Molina on the stand regarding his interpretations of those documents and testimony.

6 Defendants' motion to exclude Molina is DENIED.

7 **7. Motion to Exclude Read**

8 Defendants move to exclude the opinions of David T. Read, a lawyer at the U.S. Food and
9 Drug Administration (FDA) until 2015. Dkt. No. 779. Defendants argue that because Read
10 participated in FDA ANDA discussions, including discussion about Watson's ANDA and because
11 Read signed off on the FDA's eventual approval of Watson's ANDA, Read's personal knowledge
12 and participation blurs the line between expert and lay testimony and risks misleading the jury or
13 elevating him in their estimations. Defendants also complain that Read refused to disclose in his
14 deposition specifics of certain internal FDA discussions (at counsel's advice, based on concerns
15 that to do so would violate confidentiality obligations) and, therefore, defendants were unable to
16 adequately test Read's experiential qualifications and fully test his opinions.

17 Plaintiffs respond that Read is testifying only as to one, limited issue: whether the non-
18 interference provision in the Settlement (where Endo agreed to not further amend or otherwise
19 pursue its Citizen Petition with the FDA) sped up the denial of the Citizen Petition, and relatedly
20 that the Citizen Petition was not acting as a barrier to Watson's ANDA.⁶¹ Plaintiffs argue that in
21 order to manufacture a conflict (and this motion), defense counsel attempted to ask Read questions
22 about his work on ANDAs generally and Watson's ANDA specifically. Read objected to some
23 questions on the basis of the deliberate process privilege but provided limited testimony about his

24 _____
25 ⁶¹ Read Report [Dkt. No. 779-2] ¶ 15 ("I have been asked by counsel to review the facts and
26 circumstances concerning the disposition of Endo's citizen petition and related amendments, and
27 to render an opinion on whether the purported notification to FDA by Watson of the existence of
28 the so-called non-interference provision in the settlement agreement between Endo and Watson
accelerated FDA's denial of Endo's citizen petition."). Plaintiffs argue this testimony may not be
necessary because defendants have no admissible evidence that the FDA knew about the non-
interference provision.

1 ministerial role in signing off on the Watson ANDA approval letter.⁶² Those few instances of
 2 assertions of privilege, according to plaintiffs, were to information that was irrelevant to Read’s
 3 opinion on the non-interference provision.

4 Read asserted in his deposition that he had no involvement in the resolution of the Endo
 5 Citizen Petition. Depo Tr. [Dkt. No. 818-21] at 104. His involvement with Watson’s ANDA was
 6 limited to reviewing and signing off on the approval letter, with his focus directed to the language
 7 regarding the patent and regulatory exclusivity language. *Id.* at 50-55. He agreed generally that
 8 the FDA’s treatment of and timing of work on Citizen Petitions and ANDA were interrelated. *Id.*
 9 at 125 (“Q These two issues, the Lidoderm ANDA that Watson filed and the Lidoderm citizen
 10 petition, those two issues in that sense are interrelated, correct? That’s why they get decided
 11 “simultaneously,” in your words, correct? A That’s correct. Q They’re interrelated, correct? A
 12 Yes.”).

13 Read declined to answer questions about how competing ANDAs were handled with
 14 respect to Lovenox (while asserting that his testimony and knowledge were not relevant to how
 15 the Lovenox Citizen Petition was determined), *id.* at 92-98, as well as questions concerning
 16 whether the FDA had discussed or made a decision on whether and how exceptions to *forfeiture of*
 17 *exclusivity* might apply to the Watson ANDA. *Id.* at 225-226. He also indicated that he would not
 18 disclose the “conversations” he had with colleagues at the FDA about Citizen Petitions.” *Id.* at
 19 98-99; *see also id.* at 94 (expressing reticence to disclose nonpublic information). That said,
 20 defendants point to no questions relevant to the subjects Read is opining on – the impact of the
 21 non-inference Settlement provision on the FDA’s determination of Endo’s Citizen Petition and
 22 (according to his Report) more generally whether the Endo Citizen Petition acted as a barrier to
 23 Watson’s ANDA – that he refused to answer based on his concern over the confidentiality or
 24 privilege covering internal FDA deliberations.

25
 26 _____
 27 ⁶² As part of the background, Read does explain the FDA’s internal review process for Citizen
 28 Petitions. *See generally* Read Report. Read’s discussions about the timing of ANDA approvals is
 largely contextual and confined to his testimony that Citizen Petitions will usually be given a low
 priority unless there is a pending ANDA and if so, then the resolution of the Citizen Petition will
 typically be hinged to timing for the resolution of the ANDA. Read Report ¶¶ 38, 50.

1 While defendants are correct that plaintiffs' counsel repeatedly "cautioned" and reminded
 2 Read about confidentiality, in all but the two instances identified above, Read actually answered
 3 the questions asked. Defendants have not shown that Read refused to explain the bases for his
 4 opinions in this case based on confidentiality concerns. *See Sanchez v. Boston Scientific Corp.*,
 5 2014 WL 4851989 *12 (S.D.W.Va. 2014) (excluding expert testimony because expert's
 6 confidentiality obligations prevented him from explaining the bases for his opinions and,
 7 therefore, precluded testing the reliability of those opinions); *Gray v. Cottrell, Inc.*, 2007 WL
 8 4864393 *2 (E.D. Mo. 2007) (same). If at trial it becomes clear that Read's opinions *in this case*
 9 are based in part on his substantive review of the Watson's ANDA (which does not appear to be
 10 the case based on the current record) or are otherwise informed by *relevant* information over
 11 which Read asserts confidentiality, I will revisit the motion to exclude and or address specific
 12 objections and motions to strike. *See, e.g., In re Mirena IUD Products Liability Litigation*, 169
 13 F.Supp.3d 396, 472 (S.D.N.Y. 2016) (excluding testimony of former agency employee who
 14 "personally participated" in agency actions at issue in the subsequent litigation, but only testimony
 15 concerning the time period where expert worked at agency).⁶³

16 Defendants' motion is DENIED. However, defendants may re-raise this motion at the
 17 pretrial conference in light of the recently produced FOIA responses.⁶⁴

18 **V. PENDING ADMINISTRATIVE MOTIONS TO SEAL**

19 There are numerous pending administrative motions to file under seal, filed in connection
 20 with Teikoku's Proffer [Dkt. Nos. 562]; plaintiffs' Motion to Strike [Dkt. Nos. 680, 681, 690,

21 _____
 22 ⁶³ Read's position in a publicly run agency and the limited nature of his testimony distinguishes
 23 him from the expert excluded in *Gill v. Arab Bank, PLC*, 893 F.Supp.2d 523, 541-42 (E.D.C.A.
 24 2012) (excluding testimony from employee of Israeli Security Agency as "[m]uch, if not all, of
 25 Mr. Shmilovitch's testimony is based on facts developed through confidential ISA investigations
 and investigatory methods. Any weight to Mr. Shmilovitch's testimony would be excessive in
 light of plaintiff's inability to adequately cross-examine Mr. Shmilovitch as to the basis of his
 conclusions.").

26 ⁶⁴ In their Reply, defendants cite to FDA documents that were produced pursuant to a FOIA
 27 request but only received by defendants after they filed their initial motion. Defendants argue
 28 those documents show that Read was involved in the Endo Citizen Petition and had a more active
 role in shaping the Watson ANDA responses than he recalled in deposition. Read Reply [Dkt. No.
 840] at 2-5. Plaintiffs have not had an opportunity to respond to the significance (if any) of those
 documents and arguments made by defendants.

1 692]; and the parties’ motions for summary judgment and to exclude. [Dkt. Nos. 769-780, 782-
2 783, 785-786, 793-794, 801-802, 804-807, 809-819, 833-835, 837-838, 840, 843-844, 846-854].

3 The parties are directed to meet and confer to prepare a joint chart showing what specific
4 information – by ECF Dkt. No. (*e.g.*, 837, 837-1, 837-4) and page/line number therein for each
5 docket entry – a party or third-party believes should continue to remain under seal. The chart shall
6 cite, for each piece of information to remain sealed, to the docket number, paragraphs and/or line
7 numbers from the declaration where a party, third-party, or other person with personal knowledge
8 provides the justification for sealing.

9 The joint chart shall also identify – again by ECF Dkt. No. and sub-number (*e.g.*, 837-1,
10 837-4) – docket numbers that can be wholly unsealed because no party currently believes the
11 information should remain under seal.

12 The joint chart shall be filed within 20 days of the date of this Order.

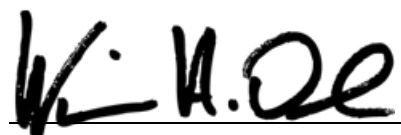
13 In reviewing the chart and declarations in support of continued sealing, I will apply the
14 “compelling justification” standard, because the motions themselves (and the information
15 discussed therein and sought to be sealed) have a significant connection to the merits of this
16 litigation. Only specifically identified compelling justifications based on narrowly-tailored sealing
17 requests will meet that high standard.

18 **CONCLUSION**

19 Defendants’ motion for summary judgment as to all the claims is DENIED. Defendants’
20 motion for partial summary judgment for findings of fact under Rule 56(g) as to causation is
21 GRANTED. Plaintiffs’ motion for partial summary judgment is GRANTED. The motions to
22 exclude are resolved as indicated above.

23 **IT IS SO ORDERED.**

24 Dated: November 3, 2017

25
26 

27 William H. Orrick
28 United States District Judge