IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In Re: OPANA ER ANTITRUST LITIGATION	**MDL No. 2580** **Case No 14 C 10150**
This Document Relates to All Cases	**Judge Harry D. Leinenweber**

MEMORANDUM OPINION AND ORDER

This is a case involving patents for prescription opioids and alleged violations antitrust law through intellectual property licenses and lawsuit settlements. Broadly speaking, three groups of plaintiffs bring this case: the "End Payor" Plaintiffs, who consist of health insurance companies and trust funds, the "Direct Purchaser" Plaintiffs, who consist of drug distribution companies, and the "Retailer" Plaintiffs, who sell medicines to the general populace. (Pl.'s Resp. to Def.'s Stmt. of Facts on Damages/Causation ("PSOF-DC") ¶¶ 1–3, Pl's Stmt. of Facts on Damages/Causation, Ex. 1, Dkt. No. 618-1.) Defendants are patent holders Endo Pharmaceuticals, Endo Health Solutions, Inc., and its acquired subsidiary Penwest Pharmaceuticals Co., (together, "Endo") as well as the patent licensee Impax Pharmaceuticals. (*Id.* ¶¶ 4–5.) Defendants argue that they are entitled to summary judgment because Plaintiffs have failed to show there was an

antitrust injury or that damages resulted from the putative injury. (Dkt. No. 539.) In the alternative, Defendants filed a second summary judgment motion to argue that they are, at a minimum, entitled to summary judgment on various patent issues. (Dkt. No. 532.) Integral to both summary judgment arguments and in anticipation of trial, the parties have also filed twenty-one *Daubert* motions. (Dkt. Nos. 510, 513, 516, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 537, 541, 545, 546, 550, 552, 556.) For the reasons set forth below, the Court first resolves the *Daubert* motions and then denies Defendants' motions for summary judgment in part.

I. BACKGROUND

Oxymorphone has been available as a prescription opioid in the U.S. market since the 1960s. ("Regulatory History of Opana ER" at 5, Mem. on Causation/Damages, Ex. 4, Dkt. No 558-19.) Starting in the early 2000s, Endo Pharmaceutical Holdings developed, patented, and sold an oxymorphone medication that allowed patients to take a single large dose of medication and relieve pain over a longer duration, in other words an "extended release" oxymorphone, referred to throughout this opinion as "Opana ER" or "oxymorphone ER." (*Id.* at 6–7.) Opana ER was officially approved by the U.S. Food & Drug Administration in 2006. (*Id.*)

Oxymorphone ER was originally protected with one patent which expired on February 29, 2008. *See* U.S. FOOD & DRUG ADMIN., APPROVED

DRUG PRODS. WITH THERAPEUTIC EQUIV. EVALS. 6-333 (41st ed. 2021) https://www.fda.gov/media/71474/download. To manage patented drugs and their approved substitutions, the FDA issues a yearly publication called the *Approved Drug Products with Therapeutic Equivalence Evaluations*, usually referred to as the "Orange Book." *Id.* at iv. As is pertinent to this litigation, the Orange Book identifies drug products approved by the FDA under the Federal Food, Drug and Cosmetic Act as well as patent and exclusivity information related to approved drug products. *Id.* at iv–vi.

In June 2007, Impax filed an Abbreviated New Drug Application ("ANDA") with the FDA. (Pretrial Stipulation ¶ 15, Mem. on Causation/Damages, Ex. 5, Dkt. No. 558-24.) The abbreviated application process was created by the Hatch-Waxman Act of 1984, enacted to encourage the entry of generic drugs into the U.S. market. KEVIN J. HICKEY, CONG. RSCH. SERV., R45666, DRUG PRICING AND INTELL. PROP. L. 20 (2019) *https://crsreports.congress.gov/product/pdf/R/R45666*. The Hatch-Waxman Act allows generic drug entrants to file a shorter application, relying on data and results from the original applicant, and gives temporary secondary exclusivity on the market to the first generic drug producer to file. *Id.* at 25. Specifically, the first successful applicant has exclusive right to sell the generic drug, apart from the patent holder, for up to 180 days after going on the market. *Id.* Once the FDA approves the

abbreviated application, the generic drug producer is required to notify the original patent holders of their intention to produce a generic drug. The patent holders must challenge this action in court to prevent production and sale. (PSOF-DC ¶ 15.)

In the October 2007 Orange Book, Endo asserted for the first time U.S. Patent No. 7,276,250 ("the '250 patent"), and recently acquired U.S. Patent Nos. 5,662,933 ("the '933 patent") and 5,958,456 ("the '456 patent") in connection with Opana ER. (Pretrial Stipulation ¶¶ 4,5,11,12.) These additional patents pertained to the controlled release mechanism of drug dosages, and the latest of these added patents expired in September 2013. (Pl.'s Resp. to Def.'s Stmt. of Facts on Patent Issues ("PSOF-PI") ¶ 6, Opp'n, Ex. 2, Dkt. No. 615-2.) In response to Endo's new patent claims, Impax amended its ANDA to certify that these new patents were "invalid, unenforceable, or will not be infringed upon by the manufacture, use or sale of Impax's generic Original Opana ER product." (*Id.* ¶ 9.) On November 15, 2007, Endo subsequently filed a suit for patent infringement based on the acquired '933 and '456 patents (the "underlying litigation patents"). (Joint Stipulation ¶ 18.)

Throughout the course of the 2007 patent litigation, Endo and Impax discussed resolving the case through settlement. Ultimately, Endo rejected each of Impax's proposals, including a July 2011 proposal. (Def.'s Resp. to Pl's Stmt. Of Facts on Damages/Causation

("DSOF-DC") ¶ 19, Dkt. No. 693. ("Impax's proposed July 2011 entry date 'was shut down very quickly.'") (citing Snowden Dep. 147:7-148:9, DSOF-DC, Ex. 66, Dkt. No. 676-10).) Meanwhile, Endo sued and subsequently settled its lawsuit with Actavis, Inc., another ANDA first filer, albeit on the less popular dosage strengths of Opana ER. (DSOF-DC ¶ 24.) The settlement between Actavis, Inc. and Endo resulted in a July 15, 2011, start date for Actavis' generic Opana ER sales. (*Id.*)

Approximately one month before trial, Impax received tentative approval from the FDA to produce its dosages of generic Opana ER. (PSOF-PI ¶14.) At that time, Endo reinitiated settlement talks with Impax, and the parties eventually settled five days into the patent trial on June 8, 2010. (DSOF-DC ¶ 1.) The parties signed two documents on that date. (*Id.*)

The parties first signed the official settlement between Endo and Impax on the patent infringement litigation, entitled the 2010 Settlement and License Agreement ("2010 SLA"). (2010 SLA at 22-24, Mem. on Patent Issues, Ex. 17, Dkt. No. 535-19.) The 2010 SLA contained five notable provisions. First, Impax agreed to delay the sales of generic Opana ER until, at the latest, January 1, 2013. (*Id.* at 2-3.) Second, Endo agreed to grant Impax a broad license to sell generic Opana ER against both current and future patents, referred to as the "Broad License" provision. (*Id.* at 10-12.) Third, Endo agreed it would not launch its own competing

generic version of Opana ER for at least six months after Impax's generic launch, meaning that Impax would be the only generic on the market during the secondary exclusivity period granted through the Hatch-Waxman Act. (*Id.* at 11.) This is referred to as the "No Authorized Generic" provision. The fourth and fifth important provisions constitute related compensation formulas based on the future 2013 market for generic Opana ER. (*Id.* at 13.) Essentially, if the market for generic Opana ER was still strong when Impax launched, then Impax would pay Endo a portion of its revenue. (*Id.*) This is the "Impax Royalty" provision. Conversely, if the market was weak, as might happen if Endo cannibalized the market with an upgraded Opana ER product in the intervening years, Endo would have to pay Impax. (*Id.*) This is referred to as the "Endo Credit" provision. The central dispute of this litigation is whether these provisions of the 2010 SLA violated antitrust law as an unreasonable restraint on trade.

The second agreement signed that day was a document forming a joint venture between Endo and Impax to develop a Parkinson's disease treatment. (DSOF-DC ¶ 5.) Endo was provided with future "profit-sharing rights," and Impax was provided with an upfront payment of ten million dollars. (*Id.* ¶ 2.) At summary judgment, the parties dispute whether the ten-million-dollar payment is an unrelated negotiation term or a sham venture created to provide an upfront payment to Impax. (*Id.*)

Approximately one month after the 2010 Settlement and License Agreement was signed, Endo submitted a New Drug Application with the FDA for a reformulated version of Opana ER. The "reformulated Opana ER" was crush-resistant and designed to curb the well-documented crushing and snorting abuse of opioid drugs. (PSOF-PI ¶4.) This information was made public when the reformulated Opana ER was approved by the FDA in December 2011. Reformulated Opana ER went on the market in March 2012. (*Id.*) During the next year, Endo filed multiple citizen petitions with the FDA asking the FDA to find the original Opana ER unsafe. (PSOF ¶ 55.) Had Endo been successful, the FDA would have revoked its approval of the generic versions of Opana ER. (*Id.*) The FDA declined to do so.

As a result, Impax launched its generic original Opana ER per the terms of the 2010 SLA between the parties in January 2013. (PSOF-DC ¶ 34.) Because the market for the original Opana ER had been drastically reduced through the launch of the reformulated Opana ER, Endo paid Impax the "Endo Credit," which was approximately $102 million. (DSOF-DC ¶ 4.)

Endo also worked to acquire additional patents to protect Opana ER from infringement. In late 2012, Endo acquired U.S. Patent No. 8,309,122 (the '122 patent) and 8,329,216 (the '216 patent). (PSOF-PI ¶ 34.)

Endo then aggressively enforced the '122 and '216 patents against the many generic drug producers who had filed either

original or reformulated Opana ER ANDAs with the FDA. (PSOF-PI ¶ 35.) One of these lawsuits ended with a settlement agreement where Endo became the exclusive licensee of U.S. Patent No. 8,871,779 (the '779 patent) (with the '122 and '216 patents, the "later acquired patents"). (*Id.* ¶¶ 34, 37 n.11.) As the last of the extended release oxymorphone patents, the '779 patent does not expire until 2029. (*Id.* ¶ 34.) Once Endo became licensee of the '779 patent, Endo also sued generic drug producers for infringement on this patent as well. (*Id.* ¶ 44.)

In sum, Endo sued eleven additional generic drug producers over original and reformulated Opana ER infringement on the later acquired patents. (*Id.* ¶ 35.) Following two separate district circuit court decisions and one federal circuit affirmation, all other generic Opana ER producers other than Impax were enjoined from selling generic Opana ER based on the later acquired patents. (PSOF ¶¶ 41-43, 49-51.)

Even though Impax had the Broad License, Endo also sued Impax in a separate contention regarding the later acquired patents. Compl. ¶ 1, Endo Pharmaceuticals Inc. v. Impax Laboratories, Inc., No. 16-CV-2526 (D.N.J. May 4, 2016). In its complaint, Endo alleged that the 2010 SLA's Broad License included a requirement by Impax to enter good faith negotiations to provide Endo with a percentage of the profits. *Id.* The parties settled their dispute with an agreement for Impax to pay Endo three million dollars immediately

and 50% of the profits thereafter. (2017 Settlement Agreement at 3, 15, App'x of Exs., Ex. 75, Dkt. No. 620-20.) In return, Endo authorized Impax to be the exclusive producer of generic Opana ER. (*Id.*)

In June 2017, the FDA requested that Endo withdraw reformulated Opana ER "based on its concern that the benefits of the drug may no longer outweigh its risks due to the public health consequences of abuse." Notice, 85 FED. REG. 247 (Dec. 23, 2020). As a result, Impax's generic Opana ER is the only extended release oxymorphone product currently on the market.

This multidistrict litigation began with the December 12, 2014, transfer order from the United States Judicial Panel on Multidistrict Litigation (Dkt. No. 1.) Upon Defendants' motion to dismiss, on February 10, 2015, the Court dismissed all state consumer protection and unjust enrichment claims and allowed the antitrust claims to proceed. (Dkt. No. 151.) On March 2, 2016, the End Payor Plaintiffs filed a Second Consolidated Amended Class Action Compliant. (Dkt. No. 164.) On August 11, 2016, the Court dismissed some, but not all, of the state unjust enrichment and consumer protection claims. (Dkt. No. 210.)

The parties then entered extensive, multi-year discovery. At the close of discovery, the parties filed 25 motions. Defendants filed two motions for summary judgment and eleven *Daubert* motions. The Direct Purchaser Plaintiffs and End Payor Plaintiffs each filed

motions for class certification and ten *Daubert* motions. The Court resolves the *Daubert* motions and the summary judgment motions in this opinion and order.

II. STANDARD

Summary judgement is proper "only where the moving party is entitled to judgment as a matter of law, where it is quite clear what the truth is, and where no genuine issue remains for trial." *Lupia v. Stella D'Oro Biscuit Co.*, 586 F.2d 1163, 1166 (7th Cir. 1978) (quoting *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 467 (1961)). There is a genuine issue of material fact when "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *See Harney v. Speedway SuperAmerica, LLC*, 526 F.3d 1099, 1104 (7th Cir. 2008) (citation omitted). The Court construes all facts and reasonable inferences in favor of the plaintiffs. *Id.* For the nonmoving party to prevail, it must show a genuine dispute of facts that might affect the outcome at trial; "[i]rrelevant or unnecessary facts do not deter summary judgment, even when in dispute." *Id.* (citation omitted).

"Any assessment of the admissibility of expert witness testimony begins with Federal Rule of Evidence 702 and the Supreme Court's opinion in *Daubert*, as together they govern the admissibility of expert witness testimony." *Krik v. Exxon Mobil*

Corp., 870 F.3d 669, 673 (7th Cir. 2017); *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). Under Rule 702:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. "In *Daubert*, the Supreme Court interpreted Rule 702 to require 'the district court to act as an evidentiary gatekeeper, ensuring that an expert's testimony rests on a reliable foundation and is relevant to the task at hand.'" *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 778 (7th Cir. 2017) (quoting *Krik*, 870 F.3d at 674).

To screen proposed expert testimony, a district court must answer three questions: "whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." *Id.* at 779 (citations omitted). To evaluate the reliability of an expert's scientific methodology, *Daubert* offers the following factors for case-by-case

consideration: whether the methodology can be tested, whether it has been subject to peer review, what the known or potential rate of error is and whether there are standards controlling the technique's operation, and whether there is general acceptance of the technique in the relevant scientific community. *Daubert*, 509 U.S. at 594. This list is neither exhaustive nor mandatory. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999).

The Court's "'gatekeeping' obligation . . . applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." *Kumho*, 526 U.S. at 141. The court must adjust the *Daubert* factors "to fit the facts of the particular case at issue, with the goal of testing the reliability of the expert opinion" because "the reliability of different kinds of expertise may be shown in different ways." *United States v. Brumley*, 217 F.3d 905, 911–12 (7th Cir. 2000). Where an expert's testimony is based on extensive experience, the court determines the extent and type of experience and may limit both the questioning and the testimony to reflect only those areas in which the expert has extensive experience and training. *Id.* at 911. Nevertheless, "[t]alking off the cuff — deploying neither data nor analysis — is not an acceptable methodology." *Lang v. Kohl's Food Stores, Inc.*, 217 F.3d 919, 924 (7th Cir. 2000). Ultimately, the court's gatekeeper role does not replace the role of the trier of fact, and the "jury must still be allowed to play

its essential role as the arbiter of the weight and credibility of expert testimony." *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 765 (7th Cir. 2013).

III. DISCUSSION

The Court notes at the outset that few experts were challenged on the basis of insufficient credentials or that the experts do not qualify as experts in their fields. As a result, the Court focuses on the second and third prongs, the methodology of the expert and the expert opinion's relevance for the trier of fact, unless specifically noted otherwise in the subsequent challenges to the proffered experts.

A. Defendants' *Daubert* Motions

1. Defendants move to exclude the testimony of John R. Tupman, Jr. (Dkt. No. 510)

Defendants first move to exclude fully the opinion of John R. Tupman Jr. Plaintiffs have retained Mr. Tupman, a former pharmaceutical executive from Eli Lilly and Co., to give the opinion that "no reasonable pharmaceutical company in Endo's position" would have entered the side agreement regarding Parkinson's Disease, which was executed by Endo and Impax on the same day as the Opana ER Settlement agreement. (Tupman Rep. ¶¶ 1–3, Mem., Ex. 2, Dkt. No. 512-3.) In support of his opinion, Mr. Tupman identifies the lack of due diligence and contract terms that favor Impax from a risk-sharing perspective. Plaintiffs hope

to use Mr. Tupman's testimony to argue that the Parkinson's Disease joint venture was a sham, and that the payment should be considered a reverse payment and part of the settlement between Impax and Endo's Opana ER patent lawsuit. As held in *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013), a reverse payment can indicate that a patent infringement lawsuit settlement was an unlawful restraint on trade.

Defendants argue the Mr. Tupman's expert opinion is deficient in two ways. The first argument is that, under *Actavis*, the trier of fact must determine whether the agreement represents a "fair value for services" rendered. *Id.* at 156. Because Mr. Tupman's opinion relates to the reasonableness of Endo's actions, it does not assist the trier of fact to determine whether the ten million dollars paid was a fair value for the promised development of the Parkinson's Disease research. Second, Defendants argue that there is no methodology employed by Mr. Tupman when making the determination that Endo was being atypical and unreasonable.

In response, Plaintiffs argue that Defendants, not Plaintiffs, have a burden to show the procompetitive rationale for the restraint. Under the rule of reason test, Plaintiffs have the burden to show that the agreements between the parties was an unreasonable restraint of trade, which Mr. Tupman provides through his testimony. In response to the second argument, Plaintiffs argue

that Mr. Tupman's expertise is one of experience, not scientific analysis.

The Court finds neither of Defendants' arguments persuasive. Plaintiffs have the burden to show that the putative reasons set forth in the joint agreement between Endo and Impax are less plausible than Plaintiffs' alternative theory of a sham contract and secret settlement. By opining that Endo acted in an unusual and financially detrimental manner, Mr. Tupman's evidence makes Plaintiffs' theory more plausible and thus relevant to the litigation. The Court's review of Mr. Tupman's testimony shows that Mr. Tupman first articulates a standard process for engaging in pharmaceutical partnerships and then analyzes how Endo deviated from this process. As a result, Mr. Tupman's methodology is reliable under *Daubert*. *See Walker v. Soo Line R. Co.*, 208 F.3d 581, 591 (7th Cir. 2000) ("Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience.") "Whether a payment was large and unjustified . . . requires viewing the payment in the context of the facts of the case, which may include business considerations that are less tangible or quantifiable." *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503, 2018 WL 734655, at *4 (D. Mass. Feb. 6, 2018). Here, Defendants' objections go to the weight of the evidence and not its admissibility, and the motion is denied. (Dkt. No. 510.)

2. Defendants move to exclude the testimony of Janet K. DeLeon (Dkt. No. 513)

Plaintiffs have retained Janet K. DeLeon, a pharmaceutical consultant, to provide an expert opinion on what the FDA would have done, absent the litigation, specifically (1) when it would have granted approval for Impax's generic Opana ER; (2) when it would have granted approval Actavis' generic Opana ER; (3) whether it would have allowed Endo to claim its reformulated version was an improvement over the original; and (4) other regulatory hurdles, if any, had Endo decided to launch an authorized generic. (DeLeon Rep. ¶ 3, Mem., Ex. 4, Dkt. No. 515-5.)

Defendants move to exclude partially this testimony on three grounds. First, Defendants argued that Ms. DeLeon does not have experience with the FDA on opioid products and lacks the expertise to evaluate the impact reformulated Opana ER had on opioid abuse. Second, Defendants argue that Ms. DeLeon does not employ any methodology, but simply repeats facts already in evidence. Finally, Defendants argue that Ms. DeLeon's opinion regarding Endo's promotion of reformulated Opana ER is a legal conclusion and not a proper subject matter of expert opinion.

Without reaching the question of Ms. DeLeon's expertise in the regulatory pharmaceutical industry, the Court agrees that Ms. DeLeon does not employ expert analysis in her proffered opinion. Instead, DeLeon's report highlights information that is already

available through documents and fact witnesses. First, as pointed out by Plaintiffs in their opposition brief, there is already substantial evidence in the record that the FDA declined to allow Endo to claim that the reformulated Opana ER was superior. (Opp'n to Mot. to Exclude DeLeon at 7, Dkt. No. 602.) Further, as stated in Ms. DeLeon's summary of the facts, the FDA had already tentatively approved generic Opana ER and would provide final approval after the required 30-month stay. (DeLeon Rep. ¶¶ 56–64.) Similarly, the FDA's approval of generic Opana ER necessarily means that Endo was free to produce a generic version as well. These facts are already in evidence, so it is unclear why Ms. DeLeon would provide any additional assistance to the jury.

Plaintiffs argue that courts routinely permit expert testimony to assist the jury in understanding complex regulatory issues, citing *Antrim Pharm. LLC v. Bio-Pharm, Inc.*, 950 F.3d 423, 430–31 (7th Cir. 2020). In *Antrim*, the Seventh Circuit held that the district court did not abuse its discretion in allowing the testimony of an FDA regulatory expert that testified about whether or not the FDA would infer ownership when receiving an ANDA application. *Id.* The Seventh Circuit, however, upheld the district court's decision because the jury needed to "determine a fact at issue" about this topic, noting that the fact witness "incorrectly stated there is 'no difference' between ownership of an ANDA and ownership of an underlying product." *Id.* at 431. Here, however,

both parties agree as to the underlying facts, and Plaintiffs have not brought any questionable testimony before the Court that might lead to confusion on the facts in question.

Plaintiffs' other cases are similarly inapposite. Plaintiffs' cited cases admitted expert testimony regarding general regulatory processes that would assist the jury. *See, e.g., Jones v. Novartis Pharms. Corp.*, 235 F.Supp. 3d 1244, 1255–56 (N.D. Ala. 2017) ("The court finds that Dr. Parisian is qualified, based on her experience at the FDA as a Medical Officer, to offer testimony about regulatory requirements for the testing, marketing, and development of prescription drugs."); *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011) ("Here, the Court finds that Dr. Kessler's testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it."). Ms. DeLeon has not submitted expert testimony about how the FDA ANDA approval process works generally. Instead, Ms. DeLeon's application of the FDA regulatory system to this case simply recited facts already present in the record. For this reason, the Court grants Defendants' motion to exclude Ms. DeLeon's testimony. (Dkt. No. 513.)

3. Defendants move to exclude the testimony of Luis A. Molina (Dkt. No. 516)

Luis A. Molina is an MBA-credited pharmaceutical consultant with more than twenty years of experience at a large pharmaceutical company. (Molina Rep. ¶¶ 5–6, Mem., Ex. 12, Dkt. No. 518-13.) Mr. Molina provides four opinions in his report: (1) absent the settlement agreement between Endo and Impax, Endo would have been ready and able to launch an authorized generic; (2) absent the agreement, a rational pharmaceutical company in Endo's position would have launched an AG version contemporaneously with Impax's launch; (3) Endo's actions were consistent with planning to launch an authorized generic; and (4) absent the agreement, a rational company in Endo's position would have continued its production of branded Opana ER and the authorized generic Opana ER, even with the launch of the reformulated version. (*Id.* ¶ 43.)

Defendants object to all of Mr. Molina's testimony, and the Court concurs. Mr. Molina's report does not engage in any analysis or method, but instead reiterates the facts of the case and then offers his opinion based entirely on his industry experience. (*See, e.g.*, *id.* ¶ 68 ("All of [the recited facts are] consistent with and confirms my opinions that absent the no-AG promise Endo made to Impax, Endo was ready, and, in similar circumstances a rational pharmaceutical company would have been willing and financially

incentivized to launch an AG version of Opana ER contemporaneously with an Impax generic launch."))

While experience can qualify a person to be an expert witness, the district court cannot simply take the witnesses' word at face value. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." FED. R. EVID. 702 advisory committee note to the 2000 amendment; *see also Lang*, 217 F.3d at 924 ("Many times we have emphasized that experts' work is admissible only to the extent it is reasoned, uses the methods of the discipline, and is founded on data."). Mr. Molina's expert report is devoid of method or analysis. For this reason, the Court grants the Defendants' motion to suppress Mr. Molina's testimony. (Dkt. No. 516.)

4. Defendants move to exclude certain opinions of Dr. Jeffery J. Leitzinger (Dkt. No. 529.)

Dr. Jeffery J. Leitzinger holds a PhD and is an economist at a national research and consulting firm. (Leitzinger Rep. ¶ 1, Mem., Ex. 2, Dkt. No. 531-3.) Defendants dispute three opinions

provided by Dr. Leitzinger: (1) his 'Lerner index' analysis, from which he concludes there is proof of Endo's market power; (2) his analysis on the cross-price elasticity between Opana ER and other long-acting opioids which additionally purports to show Endo's market power; and (3) a damages model based on sales which were unlawful based on the subsequently-acquired patents in this case. (*Id.* ¶¶ 51–53, 79–85, 87–116.) The Court reviews each in turn.

First, Defendants object to Dr. Leitzinger's employment of an economic method of calculating excess profit called the 'Lerner index.' A first principle of economics is that, in a perfectly competitive market, firms will be making almost no economic profit because each firm sells their goods at the cost it takes to make the additional unit. The additional-unit cost is referred to as marginal cost. The Lerner index is employed by economists to calculate the economic profits beyond marginal cost. In theory, a firm that attempts to set its prices above marginal cost would be subject to plummeting demand as consumers switched to competing substitutes. As a result, any excess economic profits that a firm makes on a per-unit basis demonstrates imperfect competition, i.e., constitutes evidence that the firm has enough power in the relevant market to set its prices above the competitive level without consequence.

A firm's Lerner index is calculated using two inputs. Economists take the retail price of the good or service sold,

subtract out the marginal cost that it took to provide the good or service, and then divide the resulting number by the price sold. This is notated as (Price – Marginal Cost/Price) or P-MC/P = X. In practice, this number, noted as either a decimal or a percentage, will vary based on the type of product sold. For example, a product with low marginal cost, such as a software download to an end-user, could have a number closer to 1 (or closer to 100%). A company that provided extremely costly goods or services, such as a made-to-measure suit, would be expected to have a much lower ratio, or a number closer to 0 (or closer to 0%). Generally, a Lerner index score closer to 1 indicates strong market power. Dr. Leitzinger opines that Endo's Lerner index, estimated between 60.7 and 74.3 percent, is direct evidence of Endo's monopoly power. (*Id.* ¶¶ 51–53.) Defendants object, arguing the Lerner index is not a reliable method of calculating monopoly power in many industries with high initial costs, including the pharmaceutical industry.

In support of his assertion, Dr. Leitzinger cites to the textbook *Modern Industrial Organization* by Carlton and Perloff, as well as the Department of Justice Merger Guidelines. While the DOJ Guidelines are developed in a different context, the manual uses the same basic principles of economics outlined above. In the event of a proposed merger, the DOJ "employ[s] the hypothetical monopolist test to evaluate whether groups of products in candidate markets are sufficiently broad to constitute relevant antitrust

markets." Horizontal Merger Guidelines § 4.1.1, (U.S. Dep't of Justice & Fed. Trade Comm'n 2010). The DOJ evaluates whether products sold by the merging firms are (1) in the same market and (2) could, in the event of the merger, support a small but significant and non-transitory increase in price of at least 5% ("SSNIP"). *Id.* That small increase would have no effect on the cost it took to produce the good; it would be essentially profit, and thus show up as an .05 increase in a Learner index calculation.

Dr. Leitzinger admits in his report using the Merger Guidelines to suggest an absolute Lerner index score of .05 (or 5%) as a standard for monopoly power would be "prone to false indications of monopoly power." (*Id.* ¶52.) Unlike in a potential merger, Plaintiffs do not have a putative "before patent" oxymorphone ER market with which to compare their current economic profits, and thus Dr. Leitzinger's calculations cannot show increases. However, in principle, if a 5% increase in economic profit suggests market power, then a 60-70% calculation of absolute economic profit is an accurate indicator of general market power.

In their opposition, Defendants argue that many goods, including pharmaceutical drugs, have high fixed costs which do not show up on the Learner index because the equation only accounts for the marginal costs. Defendants' argument highlights the purpose of government-provided patents. A patent creates a monopoly to protect the company's investments in research in

development as an inducement to undertake those larger fixed costs. It does not fully explain, however, why there would be excess economic profits absent the patent.

Defendants also rely on *United States v. Eastman Kodak Co.*, 63 F.3d 95 (2d Cir. 1995), in support of their petition to exclude Dr. Leitzinger's calculations. In *Kodak*, the United States appealed a district court order granting a motion to terminate two antitrust consent decrees from 1921 and 1954. *Id.* at 97. Integral to the decision was the district court finding that the market for film was worldwide and thus encompassed both foreign and domestic film manufacturers. *Id.* at 102.

On appeal, the Government argued that the scope of the market should be domestic, citing the *Cellophane* case fallacy. *Id.* at 103. In the *Cellophane* case, the Supreme Court found that while the manufacturer "du Pont produced almost 75% of the cellophane sold in the United States," this "constituted less than 20% of all 'flexible packaging material' sales" and thus did not exercise market power. *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377, 379 (1956). Later academic literature criticized this decision because it failed to account for the fact that a monopolist "always faces a highly elastic demand; its products are so overpriced that even inferior substitutes begin to look good to consumers." *Kodak*, 63 F.3d at 103 (citing William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 HARV. L.

REV. 937, 960–61 (1981)). In *Kodak*, the district court rejected the Government's *Cellophane* fallacy argument and found that, unlike the inferior wrapping products that were compared to cellophane, "foreign film is an excellent substitute for Kodak film." 63 F.3d at 103.

The government appealed, arguing that because "the sales price of Kodak film is twice the short-run marginal cost," or .50 on the Lerner index, Kodak was earning monopoly profits and thus had significant market power. *Id.* at 108–09. The Second Circuit was unpersuaded, particularly because it had already affirmed the district court's determination on the scope of the market. *Id.* at 109. Noting the evidence in the record that "fixed costs in the film industry are huge," the Second Circuit affirmed the district court's termination of the antitrust decrees. *Id.* at 109–10.

Unlike *Kodak*, however, the Court has not made any determinations in this litigation regarding the scope of the market. Indeed, the Government in *Kodak* was clearly allowed to present the Lerner index as evidence of profit and thus evidence of market power throughout the district court proceedings. The Court finds that the Lerner index is a well-established method implemented in the field of economics to find evidence of market power, although not conclusive in and of itself. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *12 ("Plaintiffs' evidence of high margins is insufficient direct

evidence as a matter of law to demonstrate market power."); *c.f. Dial Corp. v. News Corp.*, 165 F.Supp. 3d 25, 41–42 (S.D.N.Y. 2016) (permitting an expert to use a Lerner index analysis to determine the margin variable in his critical loss analysis). For this reason, the Court denies Defendants' motion to exclude Dr. Leitzinger's Lerner index analysis.

Next, Defendants move to exclude Dr. Leitzinger's analysis regarding cross-price elasticity. To determine the relationship between wholesale drug prices and sales volume, Dr. Leitzinger provides an econometrics regression model. (Leitzinger Rep. ¶ 81.) Defendants argue that the model has the wrong inputs and thus reviews the wrong market — i.e., the model charts retailers' wholesale prices instead of the price paid by the patient, and as a result it cannot include rebates and coupons in the analysis. As a result, Dr. Leitzinger's model essentially assumes that coupons and rebates have no effect on price.

The lack of rebate and coupons in the analysis is a questionable assumption given the extent to which pharmacy companies participate and compete via these programs. The Court's review of the econometrics analysis, however, finds that, regardless of inputs, the analysis was not performed with a degree of rigor or reliability such that it would be "generally accepted within the specific scientific field" of economics. *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 810 (7th Cir. 2012). Specifically, Dr.

Leitzinger's model does not include a graph to show the variability in retail prices, and Dr. Leitzinger does not include a standard error rate or sample size of his data. This lack of information would make it impossible for another economist to replicate his analysis or determine whether the dummy variables he included smooths his data or are impermissibly selective.

Further, Dr. Leitzinger's evidence against the null hypothesis, noted in the model as the "p-value," is not particularly helpful. Here, the p-values in Dr. Leitzinger's table are higher than 0.05 and thus do not meet the standard for statistical significance. (*Id.* ¶ 82.) Because there is no significance, Dr. Leitzinger cannot rule out that retailer prices have low cross-price elasticity. (*Id.*) When a product has low-price elasticity as compared to another product, it indicates that the price of either one could increase significantly without the typical corresponding switch to the lower priced alternative product. As a result, it is proof that the products should be considered to be in separate antitrust markets.

Given so many unknowns in his data, however, it appears equally plausible that if Dr. Leitzinger changed his null hypothesis, he could not rule out its opposite, i.e., that prices have a high cross-price elasticity. "In a case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*." *Daubert*, 509 U.S. at 590 n.9. Because this analysis

lacks scientific validity and is equally likely to confuse the jury as to assist them, the Court grants Defendants' motion to exclude this testimony.

Defendants' final objection to Dr. Leitzinger's testimony is a legal one. Dr. Leitzinger's damages model includes the assumption that, had Endo and Impax not entered into the 2010 Settlement and License Agreement, then Impax would have been selling generic Opana ER on the market earlier. In Dr. Leitzinger's model, however, the entry of Impax's generic Opana ER pushes downward not only the price of Endo's branded Opana ER, but also Actavis' generic Opana ER, which was on the market with its limited settlement agreement from 2011 to 2012, and then sold from 2012 to 2016 'at risk' while the litigation was pending in federal court. Plaintiffs have included the difference between Actavis' generic actual price and the projected downward price of Actavis' generic Opana ER in their calculations for damages. Plaintiffs theorize that an antitrust injury affects the entire market, and thus even the marginal price differences in companies not currently involved this lawsuit constitutes part of their injury. Defendants point out, however, that a federal judge, later affirmed by the federal circuit, found that Actavis' generic was infringing on the later acquired patents. The district court then enjoined Actavis from selling its generic Opana ER until the later acquired patents' expirations. Defendants argue that by calculating damages that include Actavis' generic

Opana ER, Dr. Leitzinger's model incorporates 'illegal' conduct as part of its damages model and ask that the model be excluded, citing *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017) ("It is not enough for the Appellants to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal.")

Plaintiffs argue that Actavis' generic Opana ER was not illegal from 2012 to 2016 because it is not illegal to sell a generic drug 'at-risk' while the patent litigation is pending. *Anesta AG v. Mylan Pharms.*, Inc., No. CV 08-889-SLR, 2014 WL 3976456, at *2 (D. Del. Aug. 14, 2014) ("I agree with defendants that, although their launch was at risk, it was not illegal when it took place and, absent a directive from the Federal Circuit to recall their generic products, defendants had no legal obligation to do so."). Plaintiffs also submitted a recalculated damages model without Actavis' generic Opana ER price differences after 2012.

Although Plaintiffs are correct that Actavis was not acting in a criminal manner by using the Hatch-Waxman Act to launch at-risk, the fact indisputably remains that the later acquired patents' validity is now settled. As a result, the patents were also valid while Actavis was selling its product 'at-risk.' The Court will not permit Plaintiffs to benefit from generic entrants who infringed on Endo's patents for the purpose of damages. However, Dr. Leitzinger also submitted a revised model without

Actavis' projected price differences which the Court finds to be an acceptable alternative. To the extent that Dr. Leitzinger's revised model cures this deficiency, then, the Court denies Defendants' motion.

For the foregoing reasons, the Court grants in part and denies in part Defendants' motion to exclude certain portions of Dr. Leitzinger's testimony. (Dkt. No. 529.)

5. Defendants move to exclude partially the opinions of James R. Bruno (Dkt. No. 537)

James R. Bruno is the Managing Director of a pharmaceutical consulting company whose work includes assisting emerging companies develop and commercialize active pharmaceutical ingredients and finished drug products. (Bruno Rep. ¶ 5, Mot. to Exclude, Ex. 7, Dkt. No. 542-8.) Defendants move to exclude the entirety of Mr. Bruno's opinion and testimony, citing to two objections: first, that Mr. Bruno does not engage in expert analysis, but instead reads and summarizes the documents already in the record; second, that Mr. Bruno improperly speculates on Impax's state of mind.

The Court finds neither of these criticisms is persuasive. Upon review of Mr. Bruno's testimony, the closest that Mr. Bruno comes to reiterating a factual summary is his detailing of the progress Impax made prior to the 2010 Settlement Agreement. This information, however, is crucial to Mr. Bruno's expert opinion as

to whether an earlier commercial start date was feasible for Impax's commercial entry of generic Opana ER. Mr. Bruno's experience with the policies and procedures required for a mass production of a laboratory drug are clearly articulated and compared with Impax's progress in his testimony.

Defendants also object to Mr. Bruno statements indicating that Impax would have launched 'at-risk,' claiming that Mr. Bruno is thus ascribing intent to Impax's actions. As stated in his testimony, Mr. Bruno only opines that Impax would be capable of launching at a certain time period, and that it was up to the jury to determine when Impax would have launched in a but-for world without the 2010 Settlement Agreement. (Bruno Rep. ¶ 26.) The Court holds that capacity and capability are within the purview of acceptable expert testimony and are not related to Impax's state of mind. Defendants' motion to exclude the testimony of Mr. Bruno is denied. (Dkt. No. 537.)

6. Defendants move to exclude certain opinions of Glen P. Belvis. (Dkt. No. 541.)

Glen P. Belvis is an intellectual property attorney who worked for over 20 years at a nationally recognized intellectually property firm. (Belvis Rep. ¶ 4, Mem., Ex. 1, Dkt. No. 542-2.) He currently serves as intellectual property counsel for multiple companies while maintaining his own law practice. (*Id.*) Among other topics, Mr. Belvis offers testimony regarding the technical

aspects of the patents in dispute and their likelihood of success on the merits. Defendants object to one sentence of Mr. Belvis' report. As part of his analysis, Mr. Belvis reports that Impax had a "greater than 85% overall chance of ultimately prevailing at trial and through appeal." (*Id.* ¶ 431.) Defendants do not challenge Mr. Belvis' qualitative opinion that Impax "very likely" would have won the litigation. (*Id.* ¶ 104–05.) Instead, Defendants contend that the "85% chance" determination falsely denotes a level of mathematical precision does not present in Mr. Belvis' opinion and incorrectly relied upon by a later-discussed expert, Dr. McGuire, in his stock market analysis model.

Calculating a percentage chance of a but-for reality, such as Mr. Belvis' hypothetical jury verdict, requires uncertain estimates about human decisions and interactions. The Court is skeptical that Defendants' desired veneer of mathematical certainty on such an inherently dubious enterprise would be more helpful to the jury than what Dr. Belvis' estimate already provides. As Dr. McGuire cannot enter "very likely" into his mathematical model, it is reasonable for Mr. Belvis to draw upon his expertise to provide an estimate in mathematical terms. To the extent that Defendants wish to argue that "very likely" should be a different percentage, they will have the opportunity to do so on cross-examination before the jury.

Defendants also present a second argument, claiming that Mr. Belvis is wrong on the merits. The disagreements on the accuracy of Mr. Belvis' expert opinion goes to the weight of the evidence. For these reasons, Defendants' motion to exclude Mr. Belvis' testimony is denied. (Dkt. 541.)

7. Defendants move to exclude certain opinions of Dr. Meredith Rosenthal (Dkt. No. 545)

Dr. Meredith Rosenthal is a Health Economics and Policy Professor at Harvard University. (Rosenthal Rep. ¶ 1, Mem., Ex. 1, Dkt. No. 560-2.) Dr. Rosenthal opines that generic prices would have been lower without the 2010 Settlement and License Agreement and calculates Plaintiffs' damages based on those lower prices. Defendants object to Dr. Rosenthal's damages model on two grounds. First, Dr. Rosenthal includes sales of Actavis in her damages model, even after Endo's later acquired patents. Next, approximately 37% of Dr. Rosenthal's damages are attributed to "Medicare Part D" patients, who are not part of the proposed class.

The Court grants the motion. Plaintiffs argue that they are entitled to assume that Actavis would have begun selling at-risk in the hypothetical world, like Actavis' actual actions. Like the analysis above, however, the question at issue is not about the assumptions that Plaintiffs are permitted to incorporate into their models. Now that two district courts and the federal circuit have determined the later acquired patents are valid, there cannot

be damages that Plaintiffs "should" have received from Actavis being in the market past the acquisition of the '216 and '122 patents. This fact prohibits any recovery after the patents' issuances, and any model incorporating this for the purpose of calculating damages is stricken. For this reason, the Court grants the Defendants' motion to exclude Dr. Rosenthal's flawed damages model. (Dkt. No. 545.)

8. Defendants move to exclude the opinions of Dr. Stephen R. Byrn (Dkt. No. 546)

Dr. Stephen R. Byrn is a Professor of Medical Chemistry at Purdue University. (Byrn Rep. ¶ 3, Mem., Ex. 3, Dkt. 549-4.) He offers the opinion that the underlying patents Endo asserted and then settled in the 2010 Settlement and License Agreement are invalid. (*Id.* ¶¶ 12–16.) Defendants argue that Dr. Byrn's testimony is irrelevant and thus will not assist a trier of fact to understand the evidence or determine a fact in issue. Defendants argue that Dr. Byrn does not limit himself to the admissible and entered evidence present at the time of the 2010 litigation, and thus he will be unable to assist the upcoming jury in determining whether or not a 2010 jury would have found the patents infringed upon, and thus whether Impax or Endo would have prevailed in the underlying litigation. Plaintiffs disagree vehemently, stating that Dr. Byrn reached his conclusions based on the evidence Impax advanced in its materials filed in the 2010 patent litigation. In

response, Plaintiffs reviewed each allegation made by Defendants and then pointed to where it was used in the underlying litigation.

Defendants also object to Dr. Byrn's responses to Drs. Lowman and Fassihi's expert opinions, claiming that they contain novel arguments. Plaintiffs counter that it is Defendants' experts who advance the novel arguments, and Plaintiffs are thus required to counter these arguments with their own expert.

Upon review of the disputed evidence, Court finds that Defendants have failed "to identify a particular reference or piece of information that was verifiably outside the scope" of the prior record Dr. Byrn "*relied upon* to form his opinion on validity and enforceability." *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F.Supp. 3d 1142, 1186 (N.D. Cal. 2017). Ultimately, however, both of Defendants' arguments misunderstand the purpose of this antitrust litigation. The purpose of the jury is to find whether the actual patents in the underlying litigation were invalid, and thus the 2010 SLA an unreasonable restraint on trade, and not whether the patents would have been found valid in the but-for world where the 2010 litigation continued without settlement. Under Defendants' framework of slavish devotion to the recreation of the 2010 litigation, the Court would not be able to correct clear errors in the prior litigation, and be forced to allow the appellate court to review as would have after the 2010 litigation,

or, to Defendants' detriment, Defendants could not benefit from the knowledge that the 2012 lawsuit against Actavis would be successful on the merits. Defendants cannot insist on benefiting from later knowledge when it is convenient to Defendants and otherwise argue the Court and Plaintiffs are handicapped from bringing fresh analysis to the case. For these reasons, the Court denies the motion. (Dkt. No. 546.)

9. Defendants move to exclude the opinions of Patricia Zettler and Martin Lessem (Dkt. No. 550)

Plaintiffs have retained Patricia Zettler and Martin Lessem, both attorneys, to opine on any additional regulatory impediments, if any, Impax would have faced after receiving approval from the FDA. Defendants move to exclude these opinions on the basis that they are legal arguments, not expert opinions, and that Ms. Zettler and Mr. Lessem are advancing opinions as to Impax's intent and state of mind, both of which are prohibited under *Daubert*.

The Court's review of Ms. Zettler's expert report found that Ms. Zettler limited her opinions to (1) observations about the FDA's methods and processes regarding opioid launches generally, and (2) her professional opinion that the FDA's processes would not have impeded a generic Opana ER product launch. (Zettler Rep. ¶¶ 19–68, Mem., Ex. 8, Dkt. No. 554-9.) The Court did not review any initial report from Mr. Lessem, as no report was attached to any of the fillings associated with this motion, however, a review

of Mr. Lessem's rebuttal report and testimony appear to be similarly unrelated to Defendants' concerns. Mr. Lessem's rebuttal report opposed Dr. Patel's opinion regarding a "reasonable company in Impax's situation" would have faced regulatory hurdles to an earlier generic Opana ER launch. (Lessem Rebuttal Rep. ¶ 19, Mem., Ex. 12, Dkt. No. 554-11.) Mr. Lessem instead opines that there is no reason to think FDA's final approval letter would have been rescinded due to regulatory hurdles. (*Id.* ¶ 23.)

These opinions appear entirely unrelated to legal arguments or Impax's state of mind. In complex regulatory cases, opinions regarding government regulations are permitted "to testify on complex statutory or regulatory frameworks when that testimony assists the jury in understanding a party's actions within that broader framework." *Antrim Pharm. LLC*, 950 F.3d at 430-31. The Court finds that the testimony of Ms. Zettler and Mr. Lessem will be helpful to assist the trier of fact and denies Defendants' motion. (Dkt. No. 550.)

10. Defendants' motion to exclude partially the opinions of Dr. Keith Leffler (Dkt. No. 552.)

Dr. Keith Leffler is a Professor of Economics at the University of Washington, specializing in antitrust and industrial organization. He opines as to Endo's market share, the effect of Impax's generic Opana ER on the market, and presents a model for damages. (Leffler Rep. ¶ 11, Mem., Ex. 2, Dkt. No. 555-3.)

Defendants allege Dr. Leffler's opinions on (1) an alternative settlement, (2) damages, and (3) Endo's market power are all endemically flawed and do not pass the 'reliability test' in the second prong of *Daubert*'s analysis. Defendants move to exclude all aspects of these topics from Dr. Leffler's testimony.

Like Dr. Leitzinger, Dr. Leffler also performs a Lerner index analysis using Endo's public SEC filings. Dr. Leffler similarly admits that no firm would "engage in a research and development project absent an anticipation of being able to sell at a price" that would create a 'high' Lerner index number, which would allow it to recoup its fixed costs, such as research and development costs. (June 2019 Leffler Dep. 182:25-183:9). As stated in Section III.A.4, this statement explains why drug manufacturers seek patent protections on newly developed drugs. Absent the patent, however, a company in a perfectly competitive market would nonetheless be forced to sell at lower-than-recoupable costs to compete with those manufacturers who did not shoulder the initial drug development outlays, as long as the company could charge enough on a per-item basis to cover the products' marginal cost. As a result, this admission does not fully explain Endo's high economic profits beyond marginal costs.

Dr. Leffler also acknowledges that "third party insurers, managed care entities, and pharmacies play a role in constraining price increases," but considers these considerations to be

constraining the already-monopolized market of generic Opana ER, similar to the marginal price sensitivity of cellophane in the *Cellophane* case. (Leffler Rep. ¶ 50.) Despite these deposition concessions pointed out by Defendants, the Court reaches the same conclusion as it did with Dr. Leitzinger: a high Lerner index can be indicative of monopoly power. As such, it is permissible evidence to provide to the jury. Defendants' disagreement over the extent that insurance negotiations affect economic profits can be made before the jury. As such, Dr. Leffler is similarly permitted to present his expert opinion. The motion to exclude this opinion is denied.

Dr. Leffler also offers testimony regarding a hypothetical and more procompetitive agreement between Endo and Impax. Defendant first argues that Dr. Leffler impermissibly opines that an alternative agreement would have included the Broad License. Plaintiffs explain, however, that Dr. Leffler assumes the Broad License would have been included based on testimony by other fact witnesses. "The fact that an expert's testimony contains some vulnerable assumptions does not make the testimony irrelevant or inadmissible." *Stollings*, 725 F.3d at 768. The Court therefore declines to exclude Dr. Leffler's testimony on this basis.

Defendants also object to Dr. Leffler's hypothetical agreement between Endo and Impax because Dr. Leffler picked his entrance date based on a settlement offer letter from Impax.

Defendants argue that Dr. Leffler's model works for numerous dates, and thus it is not rational to pick one date instead of a range of dates. The Court finds that Dr. Leffler is similarly assuming a date based on the factual record which does not cause his testimony to be suddenly inadmissible. As such, Defendants' objections go to the weight of the evidence to be submitted to the jury.

Finally, Defendants challenge Dr. Leffler's damages models. Dr. Leffler presents models on both a 'continued litigation' theory as well as a 'alternative settlement' theory. First, the Court notes that Defendants' objection to the 'alternative settlement' is identical to their objection to the hypothetical procompetitive agreement. In both cases, Defendants find fault with Dr. Leffler's inclusion of the Broad License. For the same reasons set forth above, Dr. Leffler's assumption that a Broad License would be included in the Plaintiffs' alternative settlement scenario is a permissible part of Dr. Leffler's damages model. The Court denies the Defendants' motion to exclude this model.

Second, Dr. Leffler's presents multiple 'continued litigation' damages models depending on various dates that Opana ER could have come onto the market. The complication to any continued litigation model, however, is that Endo acquired additional patents in 2012 which Endo immediately enforced against all generic producers. To avoid this complication, Dr. Leffler stops his damages model prior to the acquisition of the later

acquired patents. Rather magnanimously, Plaintiffs state that they do not intend to seek damages after 2012.

Absent the 2010 SLA, Endo's acquisition of additional patents would have resulted in some change in the alleged oxymorphone ER market based on Endo's subsequent business decisions. On a general level, Endo could have decided (1) to sell a generic Opana ER either through its own production or a license agreement with another company, (2) to restart operations to sell branded Opana ER, or (3) to stop selling Opana ER entirely. Because some of these post-2012 continued litigation alternative histories would have decreased the competitiveness of the market or the price that Opana ER was sold to consumers, the 2010 SLA contained potentially procompetitive effects.

For this reason, Defendants argue that models that stop calculating damages after 2012 are inherently inaccurate as they do not consider the time periods where Plaintiffs received a procompetitive effect. Defendants argues that it is solely because of the 2010 SLA's Broad License that Plaintiffs can purchase any Opana ER product to this day. Defendants acknowledge that, in a continued litigation alternative history, Plaintiffs may have been able to purchase generic Opana ER earlier (either August 17, 2010 or July 14, 2011, as predicted Dr. Leffler's various models) but that ability would have stopped in 2012, and no Opana ER would have been available at that point forward.

The Court agrees in part. "[A]ny model supporting a 'plaintiff's damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation.'" *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013) (citing ABA Section of Antitrust Law, Proving Antitrust Damages: Legal and Economic Issues 57, 62 (2d ed. 2010)). Absent the 2010 SLA and particularly after the FDA's request for Endo to remove the reformulated Opana ER, it is possible that Endo may have decided to exit the extend release oxymorphone market entirely. However, this is not the only potential outcome: Endo may have made other, more financially lucrative decisions such as continuing in the market as either a branded or generic product. To succeed on the merits in a continued litigation scenario, Plaintiffs must put forth evidence to support the likely outcome of generic or branded Opana ER market without the 2010 SLA. What Plaintiffs cannot do, however, is avoid the post-2012 market in its entirety. For that reason, Dr. Leffler also cannot cut off his damages model as to only some of the effects of the settlement. For these reasons, the Court grants the motion to exclude the challenged 'continued litigation' models and denies the motion on all other grounds. (Dkt. No. 552.)

11. Defendants' motion to exclude partially the opinions of Dr. Thomas G. McGuire (Dkt. No. 556)

Dr. Thomas G. McGuire is Professor of Health Economics at Harvard University. (McGuire Rep. ¶ 5, Mem., Ex. B, Dkt. No. 559-3.) He has been retained by Plaintiffs to conduct an economic analysis of the 2010 SLA and the accompanying joint-venture agreement to determine whether the agreements are anticompetitive. (*Id.* ¶ 2.) Defendants challenge two portions of Dr. McGuire's testimony. First, Defendants challenge Dr. McGuire's assumption that the Broad License would be part of any alternative settlement. As determined in Section III.A.10 *supra*, the inclusion of an assumption based on the testimony of fact witnesses is admissible, and the Court similarly denies this part of the motion.

Second, Defendants challenge Dr. McGuire's testimony regarding his stock price analysis. As part of his opinion, Dr. McGuire makes the following assumption about the real-world financial markets:

> If the announcement of a pay-for-delay settlement was not anticipated by financial markets, new profits kept by the brand will be capitalized by traders in financial markets and reflected in the brand's stock price (i.e., the market will reward the brand for keeping its monopoly and associated profits beyond the expected expiration).

(*Id.* ¶ 151.) According to Defendants, Dr. McGuire's resulting opinion on Endo's stock prices is methodologically unsound. Defendants first object to Dr. McGuire relying on Mr. Belvis' opinion that Impax had a "greater than 85% likelihood of success"

in the underlying patent litigation. (*Id.* ¶ 184.) "[A]s a general matter, there is nothing objectionable about an expert relying upon the work a colleague." *Gopalratnam*, 877 F.3d at 789. Dr. McGuire is permitted to assume that the jury will accept the testimony of another witness, and the Court will not prohibit the jury's access to Dr. McGuire's model on that basis.

Defendants also argue that the stock price increase following the announcement of the 2010 Settlement and License Agreement could have been due to any number of factors beyond the settlement announcement, and Dr. McGuire failed to properly consider the myriad of other reasons a stock price fluctuates in his analysis. Plaintiffs oppose the motion on the basis that Dr. McGuire's work has been published in prominent peer-reviewed economic journals. *See, e.g., Do "Reverse Payment" Settlements Constitute an Anticompetitive Pay-for-Delay?,* 22 Int'l J. Econ. Bus. 173 (2015). The Court finds no issue with Dr. McGuire's methodology, and any theories that Defendants have on confounding variables properly go to the weight of Mr. McGuire's testimony and should be argued before the jury. For these reasons, the Court denies the motion. (Dkt. No. 556.)

B. Plaintiffs' *Daubert* Motions

Plaintiffs filed ten motions to Exclude various experts presented by Defendants. The Court reviews whether the witness is "qualified as an expert by knowledge, skill, experience, training,

or education;" whether "the expert's reasoning or methodology underlying the testimony [is] scientifically reliable;" and whether "the testimony [assists] the trier of fact to understand the evidence or to determine a fact in issue." *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007) (citation omitted).

1. Plaintiffs' motion to exclude the opinions of Dr. Nina Patel (Dkt. No. 519)

Dr. Nina Patel is Vice President of a consulting group that specializes in advising pharmaceutical, biotech, and medical device companies. (Patel Rep. ¶ 1, Curley Aff., Ex. 67, Dkt. No. 534-71.) Dr. Patel opines that it "would not have been reasonable for a company in Impax's position to have launched or sold its generic Opana ER product without an FDA-approved risk management program in place." (*Id.* ¶ 14.)

The Hatch-Waxman Act "allows generic manufacturers to rely on FDA's prior approval of another drug with the same active ingredient — the reference listed drug (RLD) — to establish that the generic drug is safe and effective." KEVIN J. HICKEY, CONG. RSCH. SERV., R45666, DRUG PRICING AND INTELL. PROP. L. at 20. Dr. Patel acknowledges that Impax received a "final approval" letter regarding Impax's generic Opana ER from the FDA on this basis. (Patel Rep. ¶ 39.) While Dr. Patel appears to walk back her specific claim that additional approvals were required to launch

a pharmaceutical drug in her deposition, Dr. Patel's testimony suggests that additional money, time, and research was required before Impax could launch generic Opana ER. (*See* Patel Dep. at 416:14-22, Curley Aff., Ex. 70, Dkt. No. 534-74. ("I have no opinion on [whether Impax had a statutory right to launch its generic Opana product after final approval].") While this may be true for initial drugs coming onto the market, it is without dispute that the FDA subsequently approved Impax's application based on Endo's research and safety analyses without the additional concern, cost or time highlighted by Dr. Patel.

An expert witness "ha[s] the responsibility to apply his [or her] analysis to the facts of the case." *Deimer v. Cincinnati Sub-Zero Prod., Inc.*, 58 F.3d 341, 345 (7th Cir. 1995). The Court finds that Dr. Patel's testimony did not do so here, and as such it would be unhelpful to jurors during trial. The Court grants the motion to exclude Dr. Patel's testimony. (Dkt. No. 519.)

2. Plaintiffs' motion to exclude partially the opinions of Mr. Jonathan Singer (Dkt. No. 520)

Mr. Jonathan Singer is a patent law attorney who has been hired by Defendants to rebut Plaintiffs' patent expert, Mr. Glen Belvis. Plaintiffs move to exclude portions of Mr. Singer's opinions and testimony, arguing that that it fails *Daubert's* relevancy requirement and Federal Rule of Evidence 702's reliability requirement.

The majority of Mr. Singer's report is a review of Endo's current and pending patents at the time of the 2010 Settlement and License Agreement. (Singer Rep. ¶¶ 118–261, Resp., Ex. 1, Dkt. No. 601-2.) Plaintiffs ask the Court to exclude the concluding paragraph of Mr. Singer's report where Mr. Singer states that, for the technical reasons described above, "one cannot simply assume that Endo would have entered into an alternative settlement agreement that provided (1) an earlier entry date for Impax; and (2) broad freedom to operate, including a broad license to all future patents covering Opana ER." (Singer Rep. ¶ 262.) Plaintiffs argue that this statement goes beyond the scope of Mr. Singer's expertise. Mr. Singer is a patent law attorney, not an economist, and Mr. Singer opined on the settlement and license agreement terms based off knowledge only provided by counsel instead of experts.

The Court declines to strike this portion of the opinion. While Plaintiffs attempt to frame this as an economic opinion, the discussion is in the context of Endo's bargaining position for settlement and licensing of its patents, a subject well within Mr. Singer's expertise.

Plaintiffs also move to exclude an earlier portion of Mr. Singer's report, where Mr. Singer notes that the "average cost of bringing a new drug to market in the United States was $1.32 billion in 2010," and that "new drugs can take at least ten years to reach profitability, if at all." (*Id.* ¶¶ 53–54.) Plaintiffs

argue that this statement is not relevant to the case at hand and in no way relates to the costs of developing Opana ER or Opana ER's profitability profile. The Court agrees. The average cost of drug development is not relevant here and, if provided, could create an anchoring bias as to the cost Endo had in developing Opana ER. The Court grants the motion to exclude this portion of the testimony.

For the reasons stated above, the Court grants in part and denies in part the motion to exclude portions of Dr. Singer's testimony. (Dkt. No. 520.)

3. Plaintiffs' motion to exclude the opinions of E. Anthony Figg (Dkt. No. 521)

E. Anthony Figg is an intellectual property attorney and co-founder of his present patent law firm who was hired by Impax to assess whether it was reasonable for Impax to settle with Endo. (Figg Rep. ¶¶ 1-3, Curley Aff., Ex. 17, Dkt. No. 534-17.) Plaintiffs move to exclude two of Mr. Figg's opinions regarding the 2010 Settlement and License Agreement. First, Plaintiffs object to Mr. Figg's opinion that it was "reasonable" or "prudent" for Impax to settle. Second, Plaintiffs move to exclude Mr. Figg's opinion that the agreement "likely provided Impax the earliest

opportunity to sell generic Opana ER to the benefit of consumers." (*Id.* ¶ 3.)

Plaintiffs argue that they do not challenge Impax's right to settle, or even Impax's right to settle reasonably. Generally, private parties may contract with each other in any way not prohibited by law. Here, however, Plaintiffs challenge the reverse payments between Endo and Impax as proof of Endo and Impax's collusive behavior. According to Mr. Figg's deposition testimony, however, he did not consider the reverse payments when making his determination about reasonableness. Mr. Figg also took pains to state that he does not "intend[] to comment on the rule of reason analysis in the antitrust sense" but rather offers an opinion on the "reasonable outcome of the patent litigation." (Figg Dep. 196:8–11, Curley Aff., Ex. 18, Dkt. No. 534-18.) Because the reasonableness of the patent litigation is not in dispute, the Court agrees with Plaintiffs that Mr. Figg's testimony is not relevant and thus unhelpful to the jury. The Court grants Plaintiffs' motion to exclude this portion of Mr. Figg's testimony.

The Court finds Mr. Figg's second opinion to be equally problematic. Mr. Figg's expert report does not describe or implement any scientific method for reaching his conclusions regarding what the "likely" earliest opportunity Impax had to sell generic Opana ER. "An expert scientific opinion must be grounded in the 'methods and procedures of science,' and must consist of

more than simply 'subjective belief or unsupported speculation.'" *Cummins v. Lyle Indus.*, 93 F.3d 362, 368 (7th Cir. 1996) (quoting *Deimer*, 58 F.3d at 344). As Mr. Figg fails to offer a method for reaching his conclusion, the Court grants the Plaintiffs' motion to exclude Mr. Figg's opinion in this matter. (Dkt. No. 521.)

4. Plaintiffs' motion to exclude opinions of Dr. Anthony Lowman (Dkt. No. 522)

Dr. Anthony Lowman is a Professor of Chemical Engineering at Drexel University. (Lowman Rep. ¶¶ 1–2, Resp., Ex. 1, Dkt. No. 595-2.) He was hired by Defendants to provide an expert opinion on the patent infringement claim in Impax's ANDA that gave rise to the lawsuit between Endo and Impax. (*See id.* ¶¶ 11–13.) Plaintiffs move to exclude Dr. Lowman's testimony because Dr. Lowman allegedly applies the wrong standard in the patent infringement claims. Specifically, Plaintiffs claim that Dr. Lowman impermissibly interchanges the material description from "that which is effective to slow the hydration of the gelling agent without disrupting the hydrophilic matrix" with the "hydration rates of the tablets" generally. (Mot. at 1–2, Dkt. No. 522.) Defendants disagree and argue that Dr. Lowman only used the term "tablets" as a shorthand for measuring the gelling agent.

Plaintiffs' objection to Dr. Lowman's testimony appears to this Court to be a distinction without a difference, as the hydration of the tablet will necessarily be a hydration of the

gelling agent that resides within the tablet. To the extent that Plaintiffs disagree, however, it is with the "soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis" and not with Dr. Lowman's credentials, methods, or relevance to this case. *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). As such, the disagreement must be left to the trier of fact. The Court denies Plaintiffs' motion to exclude Dr. Lowman's testimony. (Dkt. No. 522.)

5. Plaintiffs' motion to exclude the opinions of Dr. Reza Fassihi (Dkt. No. 524)

Dr. Reza Fassihi is a Professor in Biopharmaceutics and Industrial Pharmacy at Temple University. (Fassihi Rep. ¶ 2, Resp., Ex. 1, Dkt. No. 596-2.) Dr. Fassihi was initially hired by Endo in the underlying 2010 litigation and was rehired in the current litigation to provide similar testimony on the disputed patents. Plaintiffs move to exclude Dr. Fassihi's opinions, arguing she used the incorrect standard of law when determining whether the underlying patents were valid.

Dr. Fassihi's testimony centers around the "anticipation reference" defense to a patent infringement suit. A patent cannot be granted if the invention was "described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C.

§ 102(b)(2002)(amended 2011). An anticipatory reference discloses "each and every element of the claimed invention, whether it does so explicitly or inherently." *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (citing *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006)). "Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure." *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003).

According to Plaintiffs, Dr. Fassihi incorrectly discounts several disclosures that potentially qualify as "anticipatory disclosures" of the sustained release component of the underlying litigation patents. Dr. Fassihi's testimony states that there isn't enough data attached to these disclosures to prove the idea works correctly, and thus the disclosures fail to meet the standard for anticipatory disclosures under federal law. Plaintiffs argue that proof is not legally necessary, and Dr. Fassihi's incorrect espousal of law would mislead jurors if presented at trial.

In response, Defendants first argue that it would be unfair to limit Dr. Fassihi's testimony in any manner because Impax did not move to limit Dr. Fassihi's testimony prior to the 2010 Settlement and License Agreement. As pointed out by Plaintiffs, however, the 2010 trial was intended before a judge, as opposed to a jury, which necessarily changes Plaintiffs' trial strategy.

Further, as previously stated, the Court is unconvinced by Defendants arguments that an exact replica of 2010 is required to meet Defendants' exacting sense of fairness. The Court's hands are not so tied such that it cannot correct mistakes of law that might have occurred had the original trial happened as scheduled; to preserve potentially incorrect proceedings in the name of "fairness" would compound only the original mistake instead of fixing it. The Court freely considers whether Dr. Fassihi's opinion incorrectly states the legal requirements for anticipatory disclosure.

Defendants' second argument is that Plaintiffs have presented only inherent anticipatory disclosures, as opposed to explicit ones. Defendants argue that, because there are only inherent disclosures, Plaintiffs have a somewhat higher standard, as articulated in *Continental Can Co. USA, Inc. v. Monsanto Co.*:

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

948 F.2d 1264, 1269 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)). According to Defendants, the fact that the prior disclosures stated "sustained-release over any desired period and, in particular, over a twelve-hour period" (Mot.

at 7, Dkt. No. 524.) does not show that "the disclosure of the required 'sustained release' as construed by the court (release out of a tablet over 12 hours does not equate to maintaining therapeutically beneficial levels of the active in a patient's bloodstream for 12 hours)." (Resp. at 16., Dkt. No. 596).

Even using Defendants' inherency standard, the natural and expected result of having a sustained-release drug over a twelve-hour period would be to have the drug be present in the patient's bloodstream over that same period. Defendants may argue on the factual record that the prior anticipatory patents did not, for some reason not mentioned in the briefing, intend for the drug to enter the bloodstream. The Court was not provided with any evidence to suggest that this patent intended something other than the natural result of a sustained drug release. For this reason, the Court holds that Defendants cannot use an expert testimony to require more than the "inherency" standard required by law. The Court grants Plaintiffs' request that Dr. Fassihi's testimony be excluded to the extent that it suggests additional proof as required by law. (Dkt. No. 524.)

6. Plaintiffs' motion to exclude the opinions of Dr. Christopher J. Gilligan (Dkt. No. 525)

Dr. Christopher J. Gilligan is Chief Physician at Brigham and Women's Hospital and Assistant Professor at Harvard Medical School. (Gilligan Rep. ¶ 2, Resp., Ex. 1, Dkt. No. 599-2.) Dr.

Gilligan has been asked to offer his opinions on the interchangeability of long-lasting opioids and the benefits of the tamper resistant reformulated Opana ER. (*Id.* ¶ 1.) Plaintiffs object to Dr. Gilligan's characterizations about what clinicians generally believed, beyond his own experience, claiming it lacks reliable methodology or evidence. Plaintiffs also move to exclude opinions espoused by Dr. Gilligan that suggest that the reformulated Opana ER deterred abuse or was safer than original Opana ER in any capacity. Plaintiffs argue such an opinion is contrary to the facts in the case, as reformulated Opana ER was, in fact, more dangerous as determined by the FDA.

In response, Defendants argue that doctors are permitted to testify about uses beyond the recommendations of the FDA. Defendants also argue that Dr. Gilligan is a leader in his field, and thus qualified to testify generally about what physicians do or don't do, without an explicit methodology or scientifically measured component. The Court agrees. Plaintiffs objections go to the weight of the testimony and may be brought up at cross-examination. The motion is denied. (Dkt. No. 525.)

7. Plaintiffs' motion to exclude the opinions of Dr. Sumanth Addanki (Dkt. No. 526)

Dr. Sumanth Addanki is an economist and managing director of an economist research company. (Addanki Rep. ¶ 1, Attachment, Ex. 3, Dkt. No. 531-4.) Dr. Addanki primarily testifies regarding

Endo's lack of market power, which Plaintiffs do not challenge on this motion. Plaintiffs do, however, move to exclude some of Dr. Addanki's ancillary opinions.

First, Plaintiffs argue to exclude Dr. Addanki's opinion that "economics provides no standard to evaluate the size of the reverse payments." (Mot. at 4, Dkt. No. 526.) The Court was unable to find where in Dr. Addanki's expert report he purported to make such a statement, and Plaintiffs unhelpfully did not cite to the record in their briefing. Defendants, perhaps similarly confused, do not address the point directly in their response. Since it is unclear to the Court whether Dr. Addanki holds this position in dispute, and, if so, the exact context for the statement, the Court denies the motion.

Plaintiffs' second contention also relates to another of Dr. Addanki's opinions on reverse payments. Under *F.T.C v. Actavis*, reverse payment settlements (i.e., payments from patent holder plaintiff to patent infringer defendant) are subject to the rule of reason test because the reverse payment could either be an innocuous "rough approximation of the litigation expenses saved through the settlement" or a problematic transfer of "'large sums' to induce 'others to stay out of its market.'" 570 U.S. at 156 (citing P. Areeda & H. Hovenkamp, Antitrust Law ¶ 2046, p. 351 (3d ed. 2012)). According to Dr. Addanki, it is impossible for Plaintiffs in this case to establish the size of the reverse

payment associated with the 2010 Settlement and License Agreement. The terms of the 2010 SLA were conditioned on real-world events — specifically, the sale numbers of branded Opana ER prior to the launch date — so there was no exact payment calculated at the time of the agreement. (Addanki Rep. ¶¶ 112–127.) Without a specific number in the agreement, Dr. Addanki opines that the settlement agreement could not have contained a problematic reverse payment. Plaintiffs argue this standard is incorrect as a matter of law and ask the Court to find that the standard for a reverse transfer is met if the parties could estimate the worth of the contract at the time of the agreement, and that estimation was greater than the estimated attorneys' fees.

In support, Plaintiffs cite to language in *Actavis* and *Brown Shoe Co. v. United States*. *Actavis*, 570 U.S. at 158 ("[A] court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent."); *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962) ("Congress used the words 'may be substantially to lessen competition,' to indicate that its concern was with probabilities, not certainties. Statutes existed for dealing with clear-cut menaces to competition; no statute was sought for dealing with ephemeral possibilities.")

Defendants object, claiming that "[i]t is necessary . . . to show" that an agreement produces "actual harm to competition," citing *Bunker Ramo Corp. v. United Bus. Forms, Inc.*, 713 F.2d 1272, 1283 (7th Cir. 1983). According to Defendants, Plaintiffs must prove actual harm as reviewed at the time the agreement. Because the payment amount was not known at the time of the agreement, and the estimated payment not "actual harm," Defendants are in effect arguing that any contract containing a contingency would escape review under the Sherman Act and other antitrust laws. Defendants go on to argue that it is only after Plaintiffs have shown actual harm that Defendants need to show a procompetitive reason for the agreement's terms.

The logic of this argument is flawed. Plaintiffs must prove both an actual antitrust injury and an unreasonable restraint on trade to succeed on an antitrust claim. *In re Humira (Adalimumab) Antitrust Litig.*, 465 F.Supp. 3d 811, 835 (N.D. Ill. 2020). To prove the injury, Plaintiffs may rely on the actual amount paid from Endo to Impax. To show the parties engaged in an unreasonable restraint on trade, Plaintiffs may present the parties' expected outcome at the time the contract was signed. Unexpected market forces are a part of all negotiations, and that alone cannot prohibit a contract from being in violation of antitrust laws. By separately requiring both components, an attempted unreasonable

restraint of trade that did not result in an actual injury would properly fail to state a claim.

Importantly, the provision at issue here gave Endo full control over whether to continue to sell branded Opana ER or whether to take it off the market, which in turn controlled how much money would be provided to Impax under the contingent provisions. This control aligns with the traditional concerns of reverse payments. *See Actavis*, 570 U.S. at 157 ([W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice."). To the extent that Dr. Addanki's opinion relies on Defendants unsound articulation of law, the Court grants Plaintiffs' motion to exclude Dr. Addanki's opinion regarding the contract's uncertainty.

Plaintiffs next object to Dr. Addanki's opinions regarding the alternative settlements presented by Plaintiffs. According to Dr. Addanki, unless Plaintiffs show "the parties would have agreed on an alternative settlement [without a reverse payment,] the provisions giving rise to the payment cannot be deemed 'unjustified' as a matter of economics." (Addanki Rep. ¶ 129.) Similar to Dr. Figg, Section III.B.3 *supra,* Dr. Addanki proposes to testify as to whether it is economically reasonable to enter into this contract between two private actors. The Court notes that many contracts that are prohibited by antitrust law would be

'economically reasonable' to enter, e.g., a cartel agreement is usually wildly profitable, and it would be economically rational to enter such agreement. However, the question that will be before the jury in this matter is not whether the contract was economically reasonable or even advantageous for both parties. Instead, the jury will determine whether the 2010 SLA was an unreasonable restraint on trade. Presenting the jury with an unrelated reasonability standard is unhelpful and potentially misleading. For this reason, the Court grants the motion to exclude this section of Dr. Addanki's testimony.

In addition to the above concerns, Plaintiffs object to Dr. Addanki's opinions regarding the economic feasibility of an alternative settlement absent the FDA's approval of reformulated Opana ER and Dr. Addanki's characterization of the 2010 Settlement and License Agreement as procompetitive. In these cases, Plaintiffs' objections are disputes with factual evidence and conclusions based on those facts, and thus should be presented to the jury. The Court denies the motion to exclude these opinions. (Dkt. No. 526.)

8. Plaintiffs' motion to exclude the opinions of Dr. Jody L. Green (Dkt. No. 527)

Dr. Jody L. Green is currently the Chief Scientific Officer at Inflexxion, a health analytics company. (Green Rep. ¶ 9, Resp., Ex. 1, Dkt. 597-2.) Dr. Green testifies that the new reformulated

Opana ER "was associated with a reduction in the overall rate of abuse for Opana ER." (*Id.* ¶ 14.) Plaintiff seeks to exclude Dr. Green's testimony in its entirety as it is (1) irrelevant, (2) rejected by the FDA, and (3) based on unreliable data.

Defendants object, claiming that it would be prejudicial to Endo if Plaintiffs could characterize the FDA's actions without an opportunity for Endo to rebut Plaintiffs' interpretations. The Court disagrees. The reformulation of Opana ER is only marginally relevant to the underlying patent litigation at the heart of this case. Whether or not the reformulation was successful is arguably even less relevant. Moreover, the facts surrounding the FDA's 2013 and 2017 decisions regarding the reformulated Opana ER are public and straightforward. *See Oxymorphone (marketed as Opana ER) Information*, U.S. Food & Drug Admin., (Feb. 6, 2018) *https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/oxymorphone-marketed-opana-er-information.* Both parties may characterize the public statements through their attorneys at argument, but Defendants cannot produce an expert whose testimony directly contradicts the FDA and the facts of the case. The Court grants Plaintiffs' motion to exclude Dr. Green's testimony. (Dkt. No. 527.)

9. Plaintiffs' motion to exclude the opinions of Dr. Louis P. Berneman (Dkt. No. 528)

Dr. Louis P. Berneman holds a doctorate in Education and is currently managing director of a technology transfer consulting company. (Berneman Rep. ¶ 76, Curley Aff., Ex. 13, Dkt. No. 534-13.) Dr. Berneman assesses the commercial reasonableness of the Parkinson's Disease joint venture between Impax and Endo, entered into by the parties at the same time as the 2010 SLA. (*Id.* ¶ 11.) Plaintiffs challenge Dr. Berneman's 'fair value' analysis, arguing that Dr. Berneman does not employ any methodology when making this determination. Plaintiffs point to Dr. Berneman's testimony where he acknowledges that he did not use any of the industry standards, nor did he identify any comparable contracts, or do any "independent evaluation." (Berneman Dep. 173:11–12, Curley Decl., Ex. 16, Dkt. No. 534-16.) As a result, Plaintiffs move to exclude his testimony based on his lack of methodology.

Defendants object, stating that Dr. Berneman relies entirely on Endo's contemporaneous valuation for his opinion. Defendants further argue that it is necessary for Dr. Berneman to explain Endo's contemporaneous valuation despite those facts already being in the record for the jury to consider. The Court disagrees. Because Dr. Berneman does no valuation or other independent analysis, the Court grants Plaintiffs' motion to exclude Dr. Berneman's testimony. (Dkt. No. 528.)

10. Plaintiffs' motion to exclude experts that post-date the challenged reverse payment agreement. (Dkt. No. 523.)

Finally, Plaintiffs move to exclude certain portions of the opinions of Dr. Fassihi, Mr. Singer, Mr. Figg, and Dr. Addanki, each of whom has already been discussed in this opinion. All four experts opine in some way on the patents acquired by Endo after the 2010 Settlement License and Agreement. Plaintiffs argue that these patents are not relevant to any issue in the case, and thus these experts' opinions should be discarded. In support, Plaintiffs cite to *Valley Drug Co. v. Geneva Pharmacy, Inc.*, 344 F.3d 1294, 1306 (11th Cir.), *cert. denied* 543 U.S. 939 (2004) ("[T]he reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.") Because these patents did not exist at the time of the agreement, Plaintiffs argue that any mention of them is inappropriate in the trial.

The Court denies the motion. (Dkt. No. 523.) When deciding as to whether there was an unreasonable restraint on trade, the jury takes into consideration "a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). As a result, the later acquired patents are relevant to the determination as to whether the overall effect of the agreement

was an unreasonable restraint on trade and whether an actual antitrust injury resulted from the restraint on trade.

C. Motions for Summary Judgment

Having reviewed all *Daubert* motions, the Court turns to Defendants' two motions regarding summary judgment. The first motion contends that Plaintiffs have failed to show that the 2010 Settlement and License Agreement between Endo and Impax caused an injury, and that Plaintiffs cannot show damages from the 2010 SLA's restraint on trade because Plaintiffs would be financially worse off absent the agreement. The second motion argues that there should be summary judgment as to the underlying patent issues in this case. For the reasons below, the Court denies all parts except Defendants' motion on the state claims.

1. Motion for Summary Judgment on Causation and Damages

Section 1 of the Sherman Act declares illegal "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce." 15 U.S.C. § 1. To state a claim, Plaintiffs must plead "(1) a contract, combination, or conspiracy; (2) a resultant unreasonable restraint of trade in a relevant market; (3) and an accompanying injury." *In re Humira (Adalimumab) Antitrust Litig.*, 465 F.Supp. 3d at 835 (citation omitted). In this case, Plaintiffs, all of whom purchased Opana ER either wholesale or individually, argue that the 2010 Settlement and License Agreement between Endo Pharmaceuticals and Impax

Laboratories, Inc. was an unreasonable restraint on trade in the extended release oxymorphone market which caused financial loss. Defendants argue that Plaintiffs have not proven an antitrust injury, however, the arguments employed by Defendants primarily hinge on whether the restraint is unreasonable. The Court reviews the best arguments presented by Defendants in both cases. Finally, the Court addresses Defendants argument that Plaintiffs have been unable to prove damages in this action.

a. Unreasonable Restraint on Trade

Under *Actavis,* courts reviewing reverse payment agreements apply the rule of reason test. 570 U.S. at 156. The test directs courts to determine "whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition." *Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 343 (1982). Judges consider the following factors: "(1) whether the alleged agreement involved the exercise of power in a relevant economic market, (2) whether this exercise had anti-competitive consequences, and (3) whether those detriments outweighed efficiencies or other economic benefits." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F.Supp. 2d 367, 387 (D. Mass. 2013) (citations omitted). The parties also engage in a "three-step, burden-shifting framework." *Ohio v. Am. Express Co.*, 138 S.Ct. 2274, 2284 (2018). The plaintiff "has the initial burden to prove that the challenged restraint has a substantial

anticompetitive effect that harms consumers in the relevant market." *Id.* If successful, the defendant must show a procompetitive reason for the restraint. *Id.* If the defendant can make this showing, then the burden "shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Id.*

First, a reasonable juror could conclude that Opana ER constituted its own market, and thus an agreement regarding Opana ER was an exercise of market power. Patent ownership of a good or manufacturing process is not dispositive of market power. *See Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45 (2006) ("Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee.") In this case, however, it is undisputed that Endo was selling Opana ER at a large profit. Dr. Leffler and Dr. Leitzinger estimate between 60% to 93% profit beyond marginal cost. (*See* Leitzinger Rep. ¶ 53 ("Endo's reported contribution margins for 2011 and 2012 were 74.3 percent and 60.7 percent, respectively."); Leffler Rep. ¶ 48 ("The evidence in this case shows that Endo achieved Lerner Indices as high as .93 from 2008 through 2011.") In contrast, the DOJ scrutinizes mergers with a 5% increase in price over marginal cost. Horizontal Merger Guidelines §§ 4, 4.1.1, 4.2, 4.2.1.

Taken alone, of course, there are other explanations for the high profit margin, including the research and other fixed costs associated with drug development. Here, Impax has presented enough supporting evidence that a reasonable juror could find Endo's actions regarding Opana ER on the underlying litigation patents to be evidence of shoring up supracompetitive pricing practices. For example, Endo imitated lawsuits and then settled with ANDA filers Actavis and Impax, both of whom allegedly infringed on the underlying litigation patents. Part of the reason the Court is faced with the question of whether the underlying patents are valid in this litigation is because Endo did not allow the jury to make a determination about the underlying patent lawsuits, preferring instead to settle that first round of patent disputes. In contrast, once Endo had the later acquired patents, Endo relied on their protections to twice reach trial and win.

Further, as repeatedly emphasized by the Defendants, Endo negotiated a settlement agreement with Impax that potentially negated the need for a reverse payment based on Endo's future conduct. For example, if Endo had continued to sell Opana ER at a similar volume up until Impax's launch, a small or non-existent reverse payment might have been instituted. Endo instead chose to transition the market over to the more profitable reformulated Opana ER and pay Impax $102 million. A reasonable juror could find this behavior evidence of protecting monopoly profits to the

detriment of the consumer. For this reason, there is sufficient evidence such that a juror could find there to be evidence of market power.

Plaintiffs have the initial burden of proof to show this exercise of market power had a detrimental effect on competition. Assuming the underlying litigation patents to be invalid, the primary harm to the consumer in a Hatch-Waxman Act related lawsuit is the late start date of the generic entrant, which increases the amount of time that customers pay artificially inflated prices. In the 2010 Settlement and License Agreement, there was also a No Authorized Generic clause, where Endo agreed to forbear selling generic oxymorphone ER while Impax was the exclusive generic market entrant, again allowing higher prices to the detriment of the consumer.

These anticompetitive practices, however, are only anticompetitive to the extent the underling litigation patents are invalid. *Actavis* instructs that "it is normally not necessary to litigate patent validity to answer the antitrust question." 570 U.S. at 157. Instead, "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id.* The combination of a delayed release and a large payment to the generic drug producer, such as in this case, "suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the

challenger rather than face what might have been a competitive market." *Id.*

Once Plaintiffs meet their initial burden, it is Defendants' burden to show the procompetitive benefits of the anticompetitive restraint. "An allegedly anticompetitive restraint survives a rule of reason analysis if it achieves legitimate, procompetitive justifications and is reasonably necessary to achieve those justifications." *In re Wellbutrin XL Antitrust Litig.*, 133 F.Supp. 3d 734, 760 (E.D. Pa. 2015), *aff'd sub nom. In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017).

According to Defendants, "the undisputed evidence demonstrates that the 2010 SLA benefitted [Plaintiffs]." (Mem. at 20, Dkt. No. 558.) Because of the Broad License provision, Impax was licensed to sell generic Opana ER even if Endo acquired additional patents. Defendants argue this procompetitive license outweighs any anticompetitive effects from the other provisions in the contract. Without the Broad License, Defendants would be entitled to either reintroduce branded Opana ER, which would be more expensive, or take oxymorphone ER entirely off the market until the expiration of the last acquired patent. Defendants state that Plaintiffs cannot prove that Defendants would have agreed to Impax starting production any earlier than January 2013. As a

result, Defendants argue that Plaintiffs are worse-off without the 2010 SLA.

A reverse payment settlement has three components. First, the plaintiff agrees to stop pursuing the patent infringement case. Second, and theoretically in return, the defendant stops the production and sale of the generic version of the drug until a later time. In theory, if the parties feel the patent is likely to be found valid by the Court, the start date for the generic entrant would be closer to the patent's expiration, and in a weak patent case, earlier and closer to the FDA's ANDA approval date. The problem identified in *Actavis*, however, is the third element: a payment from the plaintiff, the allegedly injured party in need of relief, to the defendant. Under the rule of reason test, *Actavis* contemplated that the payment could be explained quite unobjectionably as saved litigation costs or the "compensation for other services that the generic [defendant] has promised to perform—such as distributing the patented item or helping to develop a market for that item [for the plaintiff]." 570 U.S. at 156. If it cannot be explained, however, there is a risk that "a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.*

In addition to the three elements outlined above, Endo and Impax also agreed to the Broad License provision. Defendants would like to use the Broad License as a counterbalance to the reverse

payment, but the Broad License is a concession in the same direction as the reverse payment—from Endo to Impax. As a result, while the Broad License has potentially beneficial effects to consumers, it does not counterbalance the $102 million reverse payment from Endo to Impax. Instead, the Broad License concession serves only to highlight how much Endo valued Impax's delayed start, suggesting monopolistic effects instead of procompetitive ones.

Defendants also argue that the reverse payment was an unfortunate $102-million accident, as mathematically Defendants could have engineered the sales to be between the Impax Royalty provision (paid from Impax to Endo if sales remained strong) and the Endo Credit (from Endo to Impax if sales faltered) such that no money would have exchanged hands. While this is one interpretation of the facts, the Court finds it equally compelling to interpret these facts mean that Endo was making so much money by delaying the production of the generic drug and switching patients from original Opana ER to reformulated Opana ER that the $102 million cost was worth the benefit of cannibalizing Opana ER sales. And even if the jury discounts the later payment due to market uncertainty, the jury could consider either the ten million dollar payment purportedly made in furtherance of the Parkinson's Disease joint venture or the Broad License itself as items of value not fully explained under *Actavis*' reverse payment rubric.

Assuming that there are sufficient procompetitive justifications for the restraint, Plaintiffs may also present evidence that the procompetitive reason for the anticompetitive restraints — in this case, the January 2013 start date provision and the No Authorized Generic provision in the 2010 SLA – are "not reasonably necessary to achieve the stated objective." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d at 753 (citation omitted). Here, there is additional evidence in the record that the Broad License was not a reasonably necessary part of the 2010 Settlement and License Agreement.

After Endo successfully defended Opana ER on the basis of its later acquired patents, Endo also filed a lawsuit regarding the Broad License between itself and Impax. According to Endo's filings, inherent in the Broad License provision was the understanding that Endo would receive royalties from Impax's use of any future patents. The parties eventually settled the suit without a determination on the merits, and Impax currently pays half its profits to Endo, likely raising the current price of generic Opana ER on the market. This is significant because it is unclear how the other provisions of the agreement were a necessary or even related to the Broad License, as Endo both settled a multitude of other lawsuits without this provision and later negotiated 50% of all proceeds from Broad License from Impax to this day. It is at least equally plausible that procompetitive

conduct was sufficiently unrelated to the anticompetitive conduct at issue and therefore not necessary to induce the procompetitive conduct.

Ultimately, while it is "true that granting an exclusive licensing agreement is procompetitive relative to not granting it," the question here is "whether a large and unjustifiable reverse payment was made in order to avoid the risk of patent invalidation." *In re Aggrenox Antitrust Litig.*, 94 F.Supp. 3d 224, 245 (D. Conn. 2015). "If a settlement that grants an exclusive license violates the rule of *Actavis*, it is not saved by . . . the licensing arrangement being more competitive than a settlement agreement that lacked one." *Id.*

Because a jury could find that the anticompetitive portions were not necessary to receive the procompetitive benefit of Impax's licensing agreement, the Court declines to enter summary judgment for Defendants on this basis.

b. Anti-Trust Injury

To succeed on an antitrust claim, "a plaintiff must prove the existence of "antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990) (citation omitted). This analysis is generally done in two parts: the type of injury and the but-for cause of the injury.

The alleged injury at issue here, "the improper use of a patent monopoly, is invalid under the antitrust laws." *Actavis*, 570 U.S. at 148 (citation omitted). As a result, assuming the jury first finds the patent to be invalid, the reverse payment agreement constitutes an injury that the antitrust laws were meant to prevent.

Second, Plaintiffs must show that the injury is one "that flows from that which makes the defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). Endo and Impax entered into an agreement that delayed production and sale of generic Opana ER. As a result, there is a direct causal line between the agreement and the injury.

Defendants argue the later acquired patents are an independent barrier which breaks the causal chain. In support, Defendants cite to *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d at 152 (3d Cir. 2017) (holding that it would be difficult to show an antitrust injury because "generic entry would have been blocked by the '708 patent owned by Andrx.") However, the Third Circuit's decision *In re Wellbutrin XL Antitrust Litigation* contemplates a patent present at the time of the alleged antitrust injury. Because Endo did not acquire its additional patents until years after the agreement was signed, the additional patents do not break the causal chain. The Court cannot grant summary judgment on this ground.

c. Damages

Defendants argue that, under either of Plaintiffs' theories, Plaintiffs have failed to prove that they are financially worse off from the 2010 Settlement and License Agreement. First, Defendants argue that Plaintiffs cannot prove that Endo would have signed an alternative agreement that still included the Broad License. As a result, in either the theories of alternative agreements or in Plaintiffs' theory of continued litigation, Plaintiffs would not have had access to generic Opana ER after 2016.

As discussed earlier in this opinion, the Court has permitted Plaintiffs' experts to pursue a theory of alternative settlement based on factual evidence in the record that Impax would not have agreed to a settlement without the Broad License provision. Assuming the jury is convinced by this evidence, Plaintiffs theory of damages based on an "alternative settlement" survives summary judgment.

However, even under a continued litigation or alternative agreement without the Broad License provision, the Court finds that it is possible there would still be damages available to Plaintiffs. Because there is evidence in the record disputing that the procompetitive effect of the Broad License is reasonably necessary to the anticompetitive conduct, Defendants' theory of damages on summary judgment also fails. As previously discussed,

both the reverse payment and the Broad License benefited Impax, making it unlikely that they were interdependent on each other.

Nevertheless, Defendants claim without evidence in the record that, absent the 2010 SLA, there would be no Opana ER on the market, generic or otherwise. While technically possible, the Court is skeptical that Defendants or any other rational economic actor would have sued eleven generic drug companies to cease and desist production of Opana ER and then forgo profits on seventeen years of patent-protected pain medication.

There are other reasons to think that, had the parties continued the underlying patent litigation, Defendants and Plaintiffs would have ended up in a similar financial situation. It is undisputed that Endo made a strategic decision to distance itself from the original Opana ER in order to promote the reformulated version, including a stop on its own production and petitions to the FDA to remove original Opana ER from the market prior to the entrance of Impax and other generic drug producers. Despite Endo's best efforts, generic Opana ER did enter the market for several years before Endo was able to secure the later acquired patents and enforce them against them against infringers. Unfortunately for Endo, the FDA also subsequently asked Endo to remove the reformulated Opana ER from the market, which meant that consumers had already purchased oxymorphone ER at generic prices

and there was no oxymorphone ER alternative in the market sold by Endo.

Having, in effect, backed the wrong horse, Endo could have decided to stop selling any extended release oxymorphone pain medication as intimated by Defendants. Endo could have also attempted to reintroduce the branded Opana ER at its original price, although there could have been a risk of consumer pushback against that decision. A reasonable juror, however, could also find that Endo would have either produced an authorized generic version or entered a very similar license agreement with any number of generic drug companies after enforcing the later acquired patents, at which point the later acquired patents would have little to no effect on the damages claimed by Plaintiffs.

Because it is at least possible that Plaintiffs could prove damages under either theory, the Court denies summary judgement on this ground.

d. State Law Claims

Finally, Defendants move to narrow the scope of the unjust enrichment claims under Arizona, Massachusetts, and Mississippi law. According to Defendants, all three state laws contain a three-year statute of limitations for torts. The first End Payor Plaintiff complaint was filed on June 4, 2014. As a result, all recovery is limited to the three years prior to the filing date of the Complaint. Under one of End Payor Plaintiffs' theories,

however, Impax would have launched its generic Opana ER as early as April 2011, which is approximately two months beyond the statute of limitations.

End Payor Plaintiffs concede that Mississippi law prevents relief beyond three years but argue that unjust enrichment claims in Massachusetts and Arizona are governed by alternative statutes which have longer statute of limitations. Antitrust claims have traditionally sounded in tort. *See, e.g., Supreme Auto Transp., LLC v. Arcelor Mittal USA, Inc.*, 902 F.3d 735, 743 (7th Cir. 2018) (analyzing state unjust enrichment claims as a tort). A review of Arizona and Massachusetts tort law shows it is governed by the three-year statute of limitations. *See Costanzo v. Stewart*, 453 P.2d 526, 528 (Ariz. Ct. App. 1969) (applying Ariz. Rev. Stat. Ann. § 12-543(1)); Mass. Gen. Laws ch. 260, § 2A. For this reason, the Court grants the motion to limit summary judgment to damages within three years of the first filed complaint as to the state law claims in Mississippi, Arizona, and Massachusetts.

2. Patent Issues

In the alternative to their first motion, Defendants have also filed a motion for partial summary judgment as to some of the patent issues within the litigation. First, Defendants note that Opana ER's later acquired patents have already been determined to be valid and upheld by the Federal Circuit. As a result, Defendants move to limit any recovery by Plaintiffs to the point of

acquisition of the earliest valid patent, as opposed to point of injunction from the district court or the subsequent affirmation from the appellate court. Second, Defendants' motion to limit Plaintiffs from presenting any defense Impax had not prepared to provide at the beginning of the underlying patent litigation which ended shortly before trial with the 2010 Settlement and License Agreement.

a. Subsequently Acquired Patents

Endo received approval from the FDA on the '122 and '216 patents in late 2012 and prevailed in federal court against numerous generic drug manufacturers in defense of these patents. (PSOF-PI ¶¶ 35–36, 41–47.) As a result, Endo argues that the Court should grant summary judgment as to this material fact and prevent Plaintiffs from recouping potential damages after the issuance of these two patents.

Plaintiffs object on the theory that the later acquired patents are not a material fact. Because the patents did not exist at the time the 2010 Settlement and License Agreement was entered, Plaintiffs argue that it is irrelevant too for the Court to grant summary judgment as to this fact. Plaintiffs also note that they do not seek damages after November 2012, obliviating the need to consider the patents. A restraint on trade is "viewed at the time it was adopted." *Polk Bros. v. Forest City Enterprises, Inc.*, 776 F.2d 185, 189 (7th Cir. 1985). As a result, this fact is not

material in determining whether was an antitrust injury. However, as discussed above, if successful, the fact is potentially salient to show the extent of Plaintiffs' damages. Defendants may argue that the Broad License's benefit to consumers over 2012 to present outweighs the prior injury, and Plaintiffs must convince the jury that the benefit of the Broad License either do not outweigh was sufficiently unrelated to the harm as to merit damages. As such, the Court denies the motion for summary judgment as to this marginal fact.

b. Underlying Patent Litigation Defenses

Defendants also argue that Plaintiffs are limited in their patent defenses to those that Impax would have prepared at trial and asks the Court to grant Endo summary judgment with respect to two of Endo's infringement claims. According to Defendants, this will "streamline any trial" and "pare away any patent defenses asserted by Plaintiffs that the trial court in the underlying litigation would have found deficient as a matter of law." (Mem. on Patent Issues at 10–11, Dkt. No 535.)

Both parties vigorously dispute the specifics as to what Impax would or would not have done in the original underlying litigation, however, the Court does not find this to be an appropriate matter to resolve on summary judgment. It is not usually necessary to litigate patent's validity to determine whether or not antitrust laws were violated. *Actavis*, 570 U.S. at 157. Defendants' focus on

forcing summary judgment on patent issues is not helpful for the trier of fact. If Endo believed that the patent was strong at the time the contract was signed, Defendants can show that by providing a justification for the reverse payment. Otherwise, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 158.

Further, the jury must evaluate the contested restraint on the market, here the 2010 Settlement and License Agreement, at the time the restraint was adopted. The Court notes there was no summary judgment motion pending when the agreement was reached five days after the start of trial, and to resolve patent issues now would confuse rather than aid the jury.

While discussion of the underlying patent at issue is inevitable, the Court will not prematurely foreclose the jury's determination in this matter through summary judgment on the hypothetical patent defenses that might have been made at trial. As stated throughout this opinion, the purpose of this litigation is not to recreate the decision the 2010 jury would have made a determination about the validity of the patent, but rather whether Endo had, or likely had, a valid patent at the time of the 2010 Settlement and License Agreement. For these reasons, the Court denies the motion.

III. CONCLUSION

For the reasons stated herein, the Court rules as follows:

1. Defendants' *Daubert* motions to exclude Ms. DeLeon (Dkt. No. 513), Mr. Molina (Dkt. No. 516), and Dr. Rosenthal (Dkt. No. 545) are granted.

2. Defendants' *Daubert* motions to exclude Dr. Leitzinger (Dkt. No. 529) and Dr. Leffler (Dkt. No. 552) are granted in part and denied in part.

3. All of Defendants' other *Daubert* motions (Dkt. No. 510, Dkt. No. 537, Dkt. No. 541, Dkt. No. 546, Dkt. No. 550, Dkt. No. 556) are denied.

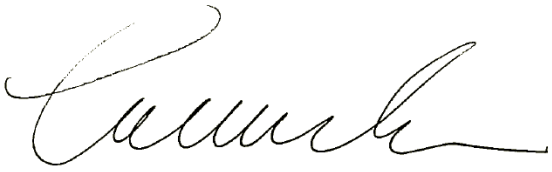
4. Plaintiffs' motions to exclude Dr. Patel (Dkt. No. 519), Mr. Figg (Dkt. No. 521), Dr. Fassihi (Dkt. No. 524), Dr. Green (Dkt. No. 527), and Dr. Berneman (Dkt. No. 528) are granted.

5. Defendants' *Daubert* motions to exclude Dr. Addanki (Dkt. No. 526) and Mr. Singer (Dkt. No. 520) are granted in part and denied in part.

6. All of Plaintiffs' other *Daubert* motions (Dkt. No. 522, Dkt. No. 525, Dkt. No. 523) are denied.

7. Defendants' motion for summary judgment as to the state claims is granted but denied as to all other claims in Defendants' summary judgment motions. (Dkt. No. 532, Dkt. No. 539).

IT IS SO ORDERED.



Harry D. Leinenweber, Judge
United States District Court

Dated: 6/4/2021