IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

KB PARTNERS I, L.P., Individually and on Behalf of All Others Similarly Situated,
Plaintiff,

-vs-

Case No. A-11-CA-1034-SS

PAIN THERAPEUTICS, INC., REMI BARBIER, NADAV FRIEDMANN, and PETER RODDY,
Defendants.

ORDER

BE IT REMEMBERED on this day the Court reviewed the file in the above-styled cause, and specifically Defendants Pain Therapeutics, Inc., Remi Barbier, Nadav Friedmann, and Peter Roddy's[1] Motion for Summary Judgment [#160-4] (sealed), Lead Plaintiff KB Partners I, L.P., Individually and on Behalf of All Others Similarly Situated (Plaintiff)'s Response [#163-2] (sealed) thereto, Defendants' Reply [#165-2] (sealed) thereto,[2] Defendants' Opposed Motions to File Pleadings Under Seal [##160, 165],[3] Plaintiff's Response [#161] thereto, Defendants' Reply [#164] thereto, and Plaintiff's Motion to File Pleadings Under Seal [#163]. Having reviewed the documents, the governing law, and the file as a whole, the Court now enters the following opinion and orders.

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[1] As the Court noted in its order denying Defendants' third motion to dismiss, Grant L. Schoenhard, previously named as a defendant, was not named in the second amended complaint, and has been removed as a party. *See* Order of Nov. 19, 2012 [#75] at 1 n.1; Second Am. Compl. [#70] at 1.

[2] As the parties are embroiled not only in a merits dispute, but also in a sealing dispute, there are currently two versions of Defendants' summary judgment pleadings before the Court: unredacted versions, which are those cited in this paragraph and presently filed under seal, and redacted versions, which are not. Redacted versions of Defendants' pleadings are filed under docket numbers 158 and 166.

[3] Plaintiff's position concerning both motions to seal is the same. *See* Pl.'s Mot. Seal [#165] at 2.

Background

This is a class action securities fraud suit. Defendant Pain Therapeutics, Inc. (PTI) is a biopharmaceutical company based in Austin, Texas which develops novel pharmaceutical products for commercial sale. The individual defendants—Remi Barbier, Nadav Friedmann, and Peter Roddy—are, respectively, the Chief Executive Officer, Chief Operating Officer, and Chief Financial Officer of PTI. The Lead Plaintiff, KB Partners I, L.P., is an investment firm which purchased PTI securities between December 27, 2010, and June 26, 2011, the class period. *See* Order of June 3, 2013 [#112] at 26 (certifying the class).

While PTI currently has no U.S. Food and Drug Administration (FDA)-approved drugs on the market, its leading candidate for FDA approval—and the subject of this lawsuit—is REMOXY, a controlled-release and purportedly abuse-resistant form of the opioid painkiller oxycodone. PTI began developing REMOXY in late 2004 in partnership with King Pharmaceuticals (King), which was later acquired by Pfizer, Inc. Things have not gone well for either REMOXY or PTI; following the FDA's second rejection of REMOXY, PTI's share price tumbled, and this litigation followed.

Plaintiff alleges that PTI and the individual defendants caused shares in PTI to trade at an artificially high price by concealing certain information from the public regarding the REMOXY FDA-approval process. Specifically, Plaintiff claims although Defendants knew they had failed to resolve problems with REMOXY's stability that caused the FDA to reject the first REMOXY New Drug Application (NDA), Defendants led the public to believe those problems had been resolved while reapplying for FDA approval. Plaintiff further alleges despite knowing the second NDA would also be rejected, PTI rewarded the individual defendants with unjustifiable compensation packages it asked the shareholders to approve. A summary of relevant events follows.

A. The First REMOXY NDA

Following several years of clinical testing, in mid-2008, PTI and King submitted the first REMOXY NDA to the FDA. An NDA contains data from clinical trials, pre-clinical studies, and manufacturing information which supports the applicant drug's safety and efficacy. Every NDA contains a section on "[c]hemistry, manufacturing, and controls," also called the "CMC" section. *See* Second Am. Compl. [#70] ¶ 25 (citing 21 C.F.R. § 314.50(d)(1)). The CMC section must include detailed data on the applicant drug's stability, or performance over its proposed shelf life. *Id.* ¶ 26. One important component of stability analysis is dissolution testing, which tests the rate at which the active ingredient is released from the capsule or tablet over time and is meant to simulate what will happen in the human body when a person takes the drug in question.

The FDA rejected the first REMOXY NDA in December 2008, explaining its reasoning for the rejection in a "Complete Response Letter" (the First CRL) sent to PTI. Among the FDA's reasons for rejecting the NDA were problems with the stability data supplied in the CMC section. *See* Defs.' Mot. Seal [#160-18] (sealed) Ex. 13 pp. 4–15 (First CRL) at 7. Specifically, the FDA stated REMOXY's dissolution specifications exceeded "the maximum allowable difference between the upper and lower specifications," ±10% from the mean of all batches. *Id.* at 9. In other words, the dissolution data showed the rate of release of REMOXY's active ingredient was too inconsistent from batch to batch to ensure REMOXY would perform as expected when administered. The FDA directed PTI to revise its stability protocols and provide additional data. *Id.* at 9.

On December 11, 2008, PTI issued a press release informing its shareholders the First CRL had been rejected; in explaining why, PTI stated the FDA did not need any further clinical efficacy

studies prior to approval, but was requesting "additional non-clinical data." Pl.'s Mot. Seal [#163-8] (sealed) Ex. 5 (Dec. 8, 2011 Press Release) at 1. PTI provided no further details in the press release.

Following the rejection, King took charge of the REMOXY FDA-approval process and assumed sole responsibility for resubmission of the NDA. While a "Collaboration Agreement" executed by King and PTI required King to provide PTI with periodic updates on the resubmission process, *see* Pl.'s Mot. Seal [#163-4] (sealed) Ex. 1 (Collaboration Agreement) § 4.1.2 ("[E]ach Party shall . . . provide periodic reports in reasonable detail" concerning drugs in development), the parties hotly dispute the precise extent to which King and PTI actually collaborated as the resubmission process was ongoing. At minimum, the evidence shows several committees comprised of King and PTI employees, including a "Joint Oversight Committee" (JOC), a "CMC Response Working Group," and a "Dissolution Working Group," met and discussed aspects of the REMOXY resubmission process. *See id.* [#163-29] (sealed) Ex. 26 (Apr. 6, 2010 JOC Minutes) at 1–3 (noting JOC discussed in detail numerous aspects of the REMOXY resubmission, including dissolution and stability testing); Defs.' Mot. Seal [#160-25] (sealed) Ex. 19B (Seto Dep.) at 48:1–49:16 (explaining CMC Response Working Group was responsible for determining what needed to be done to address deficiencies outlined in the First CRL and allocating those tasks); Pl.'s Mot. Seal [##163-11, -12] (sealed) Exs. 8, 9 (indicating Dissolution Working Group would be meeting to discuss the development of a new dissolution method for REMOXY). Additionally, Michael Zamloot, PTI's Senior Vice President of Technical Operations, testified "[t]here were a number of sub-teams established within PTI to target the different questions within the [First CRL.]" Defs.' Mot. Seal [#160-28] (sealed) Ex. 21B (Zamloot Dep.) at 74:2–15.

On July 2, 2009, King met with the FDA concerning the REMOXY NDA resubmission. During the meeting, in response to the FDA's concerns regarding REMOXY's unacceptable dissolution specifications, King proposed "the development of a new dissolution method" which would "more closely mimic[] the *in-vivo* [in the body] release characteristics of Remoxy capsules." Pl.'s Mot. Seal [#163-9] (sealed) Ex. 6 (King-FDA Meeting Minutes) at 11. The FDA told King its "approach to develop a new dissolution method [wa]s reasonable" but indicated its ultimate assessment of the new method would depend upon the data contained in the resubmitted NDA. *Id.* Additionally, the FDA directed King to "[i]nclude a minimum of 6 months of long term and accelerated stability data" using the newly-developed dissolution method, and following clarifying questions from King, "reiterated that a minimum of 6 months" of stability data generated on new batches of REMOXY was "required." *Id.* at 11–12.

Following that meeting, on July 7, 2009, PTI issued a press release informing its shareholders about the meeting and stating in relevant part:

> King now anticipates the resubmission of the NDA could occur mid-year 2010. [PTI] believes the rate-limiting step is the generation of six-month stability data, and no new clinical trials are required. King remains committed to the development and commercialization of REMOXY, and looks forward to working closely with the FDA toward approval of the product.

Defs.' Mot. Seal [#160-19] (sealed) Ex. 14 (July 7, 2009 Press Release) at 1.

By March 2010, King and PTI became aware that even when employing the new dissolution method, testing showed REMOXY's dissolution variability remained greater than ±10% from the mean of all batches, the range the First CRL had described as the "maximum allowable." Pl.'s Mot. Seal [#163-18] (sealed) Ex. 15 (Mar. 11, 2010 Remoxy Update) at 5; *see id.* at 2. Given the test results, King decided to add a three-month "curing" step to the REMOXY manufacturing process,

meaning after creation and bottling, the drug product would be held for three months before stability testing would begin. *See id.* at 7; Defs.' Mot. Seal [#160-33] (sealed) Ex. 24 (Touw Dep.) at 55:10–23 ("Something was happening to the product . . . over that first one-month period [after manufacture] that caused a large change in the way it dissolved in vitro. And to account for that we had added this curing step[.]"). Because a three-month curing period meant it would take a minimum of nine months to generate six months of stability data on new batches of REMOXY, King informed PTI the NDA could be resubmitted no earlier than December 2010. Touw Dep. at 70:23–72:9; Apr. 6, 2010 JOC Minutes at 4.

At some point prior to resubmission of the REMOXY NDA and for reasons that are not clear to the Court, a decision was made to cure certain batches of REMOXY for an additional three months, for a total curing period of six months.[4] While six months of stability data *was* included in the resubmitted NDA for those batches cured for three months, six months of stability data *was not* included in the resubmitted NDA for those batches cured for six months. *See* Defs.' Mot. Seal Reply [#165-9] (sealed) Ex. 6 pp. 4–8 (Second CRL) at 5 ("[T]he variable 3- or 6-month holding period has resulted in your submission of a limited amount of stability data (3 or 6 months) for drug product tested with your new dissolution method.").

B. The Second REMOXY NDA

King resubmitted the NDA in December 2010. PTI thereafter issued the following statement:

> King Pharmaceuticals, Inc. and Pain Therapeutics, Inc. today announced that King has resubmitted a New Drug Application for REMOXY to the U.S. Food and Drug

[4] In its response, Plaintiff represents the additional three months of curing were added to those batches that failed stability testing after the first three months. Resp. Mot. Summ. J. [#163-2] (sealed) at 6. Plaintiff provides no citation to the record for this proposition, and the Court's review of the surrounding citations revealed no support. It is not the Court's responsibility to "sift through the record in search of evidence" to support Plaintiff's claim. *See Adams v. Travelers Indem. Co. of Conn.*, 465 F.3d 156, 164 (5th Cir. 2006).

Administration in response to a Complete Response letter received by Pain Therapeutics in December 2008.

Defs.' Mot. Seal [#160-20] (sealed) Ex. 15 (Dec. 27, 2010 Press Release) at 1. On February 3, 2011, PTI filed its 2010 Form 10-K with the Securities and Exchange Commission (SEC), which generally described the REMOXY FDA-approval process to date and stated the FDA had requested, prior to the resubmission, "additional non-clinical data" on REMOXY. *See id.* [#160-15] (sealed) Ex. 10 (2010 Form 10-K) at 5.

On March 4, 2011, the FDA sent a "Discipline Review Letter" to King concerning the CMC section of the resubmitted REMOXY NDA. A discipline review letter conveys the FDA's preliminary thoughts on possible deficiencies in a section of the NDA under review.[5] In the Discipline Review Letter sent to King, the FDA expressed doubt concerning REMOXY's new stability data, directing King to "[r]emove the variable 'curing' period" and indicating that although a curing period could properly be part of a drug manufacturing process, "the fact that your proposed 'curing' period may be either 3 or 6 months is not an indication that you have developed a formulation/manufacturing process that consistently produces drug product meeting those attributes related to identity, strength, quality, purity, and potency." Pl.'s Mot. Seal [#163-37] (sealed) Ex. 34 pp. 5–7 (Discipline Review Letter) at 5. Records show Defendants Friedmann and Barbier were forwarded a copy of the Discipline Review Letter on March 14, 2014. *See id.* [#163-37] (sealed) Ex. 34 at 2.

[5] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: INFORMATION REQUEST & DISCIPLINE REVIEW LETTERS UNDER THE PRESCRIPTION DRUG USER FEE ACT 2–3 (Nov. 2001), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm172134.pdf.

On April 6, 2011, Defendant Roddy made the following comments about REMOXY and the FDA-approval process during a Needham & Company healthcare conference:

> [W]e received the complete response from the FDA in December 2008. Again, no new clinical efficacy trials were required for approval, and no change to the formulation was required as well. But in particular, the FDA asked for additional stability data on REMOXY's novel formulation. That and other information was submitted to the FDA in December. Again the resubmission [was] accepted in January of this year.

Pl.'s Mot. Seal [#163-59] (sealed) Ex. 56 (Needham Conference Transcript) at 4.

On May 3, 2011, Pfizer, which had by that time acquired King, made the following statements regarding the REMOXY NDA during a public conference call with investment analysts:

> At this time we are working to address a specific issue in the manufacturing section of the [REMOXY] application, as well as to understanding [sic] potential implications for FDA's recent classwide REMS [Risk Evaluation and Mitigation Strategy] announcement for extended release opioids. These issues could delay the timing of approval for the launch of Remoxy.

Defs.' Mot. Seal [#160-11] (sealed) Ex. 6 (Pfizer Conference Call Transcript) at 6. That same day, the value of PTI shares dropped by approximately 7%, from $9.56 per share to $8.86 per share.

Defendant Barbier spoke about REMOXY and the FDA-approval process during a Bank of America Merrill Lynch healthcare conference on May 11, 2011. Specifically, Barbier stated:

> The NDA was originally filed in June of 2008. We received a complete response letter in December of that year, we ha[d] to go back to [do] some more work as is often the case with these things. [. . .]
>
> We received from the FDA priority review and we're [sic] granted priority review almost immediately. We had [an] FDA advisory panel in November of 2008 during which 11 were in favor of approving REMOXY versus eight that were against. Why were the eight against? I don't know. It's almost like there is always someone against Christmas, I suppose.
>
> We did receive a complete response from the FDA in December of 2008. It wasn't the right answer, but it was an answer. Particularly they confirm[ed] that no new

> clinical efficacy work is necessary. But they did ask us for more detailed stability work, which was done in the interim between 2008 and 2010.

Pl.'s Mot. Seal [#163-54] (sealed) Ex. 51 (Bank of America Conference Transcript) at 3, 5. Discussing Pfizer's statement it was "working to address a specific issue in the manufacturing section" of the REMOXY NDA during the May 3, 2011 conference call, Barbier continued:

> So what does it mean? First of all, I'm not the oracle for Pfizer. I'm not a spokesperson for Pfizer; they are a company, we are a company. So if there is a secret meaning in these words, I don't have it. But I've heard a lot of conspiracy theories behind this. I actually subscribe, I take this exactly as it is.
>
> First of all, I think it is extraordinary that the CEO of Pfizer during an earnings call would come up and talk about REMOXY, keep in mind this is a drug that five years ago people were still doubting whether it was a legitimate drug and whether there was room for REMOXY. Suddenly fast forward to today, you've got the CEO [of] arguably, one of the biggest pharmaceutical companies guiding on REMOXY. We like that, in fact, I think it is [an] extraordinarily positive signal.
>
> Furthermore in the Q&A session, I believe the CEO of Pfizer did affirm that it is not if REMOXY gets approved, but when REMOXY gets approved, again an affirmative action or sentence[.]

Id. at 5–6.

On June 24, 2011, PTI announced its receipt of a second Complete Response Letter (the Second CRL) from the FDA rejecting the REMOXY NDA resubmission. *See* Defs.' Mot. Seal [#160-12] (sealed) Ex. 7 (June 24, 2011 Press Release) at 1. The press release stated only "that a Complete Response Letter was received from the [FDA]" and that "Pfizer is working to evaluate the issues described" in the Second CRL. Following the announcement, PTI's share price plummeted by nearly 43%.

In the Second CRL, the FDA informed Pfizer REMOXY's "fundamental design" was "unacceptable as the product fails to provide consistent drug release performance[,]" a deficiency

"highlighted by . . . application of a variable holding [curing] period, dependent on drug release performance, prior to final drug product release." Second CRL at 4. On June 27, 2011, PTI disclosed the specific reasons for the second rejection to the public, informing investors the FDA:

> raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Certain drug lots showed inconsistent release performance during *in vitro* testing. It is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency.
>
> Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the [Second CRL]. In the opinion of Pain Therapeutics, potential regulatory approval of REMOXY in the U.S. is unlikely to occur in less than one year, and could be delayed significantly longer than a year.

Id. [#160-13] (sealed) Ex. 8 (June 27, 2011 Press Release) at 1. After the announcement, PTI shares declined once again by nearly 26%, closing at $3.93 per share on June 27, 2011.

C. Procedural History

Plaintiff filed its initial complaint on December 2, 2011. *See* Compl. [#1]. Following Defendants' motion to dismiss, Plaintiff filed an amended complaint on June 8, 2012. *See* Am. Compl. [#48]; Order of June 20, 2012 [#50] (dismissing first motion to dismiss as moot). On July 5, 2012, Defendants filed their motion to dismiss the amended complaint. *See* Mot. Dismiss [#51]. The Court granted Defendant's motion on September 26, 2012, ordered Plaintiff to file a third complaint, and informed Plaintiff if a third motion to dismiss was granted, this case would be dismissed with prejudice. *See* Order of Sept. 26, 2012 [#68] at 24–25. On October 15, 2012, Plaintiff filed the currently operative second amended complaint, bringing claims against PTI, Barbier, Friedmann, and Roddy. *See* Second Am. Compl. [#70].

The second amended complaint alleges (1) all Defendants violated § 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, and (2) the three individual defendants violated

§ 20(a) of the Securities Exchange Act based upon their positions as controlling persons within PTI. The Court certified the class on June 3, 2013, but denied without prejudice, pending resolution of liability, Plaintiff's motion for an order establishing a schedule for notice to the class. *See* Order of June 3, 2013 [#112] at 26; Order of Nov. 5, 2014 [#138]. Following multiple motions for extension of time, the entry and re-entry of scheduling orders, and the resolution of several contentious discovery and expert disputes, the instant motion for summary judgment followed.

Analysis

I. Legal Standard

Summary judgment shall be rendered when the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986); *Washburn v. Harvey*, 504 F.3d 505, 508 (5th Cir. 2007). A dispute regarding a material fact is "genuine" if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, the court is required to view all inferences drawn from the factual record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986); *Washburn*, 504 F.3d at 508. Further, a court "may not make credibility determinations or weigh the evidence" in ruling on a motion for summary judgment. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *Anderson*, 477 U.S. at 254–55.

Once the moving party has made an initial showing that there is no evidence to support the nonmoving party's case, the party opposing the motion must come forward with competent summary

judgment evidence of the existence of a genuine fact issue. *Matsushita*, 475 U.S. at 586. Mere conclusory allegations are not competent summary judgment evidence, and thus are insufficient to defeat a motion for summary judgment. *Turner v. Baylor Richardson Med. Ctr.*, 476 F.3d 337, 343 (5th Cir. 2007). Unsubstantiated assertions, improbable inferences, and unsupported speculation are not competent summary judgment evidence. *Id.* The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his claim. *Adams v. Travelers Indem. Co. of Conn.*, 465 F.3d 156, 164 (5th Cir. 2006). Rule 56 does not impose a duty on the court to "sift through the record in search of evidence" to support the nonmovant's opposition to the motion for summary judgment. *Id.*

"Only disputes over facts that might affect the outcome of the suit under the governing laws will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 248. Disputed fact issues that are "irrelevant and unnecessary" will not be considered by a court in ruling on a summary judgment motion. *Id.* If the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to its case and on which it will bear the burden of proof at trial, summary judgment must be granted. *Celotex*, 477 U.S. at 322–23.

II. Application

Section 10(b) of the Securities Exchange Act of 1934 empowers the SEC to promulgate rules to prevent manipulative or deceptive practices in the sale or purchase of securities. 15 U.S.C. § 78j(b). Under that authority, the SEC issued Rule 10b-5, which makes it unlawful:

> (a) To employ any devise, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,

in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. The elements of a securities fraud claim based on violations of § 78j(b) and Rule 10b-5 are: "'(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.'" *Spitzberg v. Hous. Am. Energy Corp.*, 758 F.3d 676, 683 (5th Cir. 2014) (quoting *Erica P. John Fund, Inc. v. Halliburton Co.*, 131 S. Ct. 2179, 2184 (2011)).

In this case, Plaintiff alleges Defendants committed securities fraud by leading investors to believe the stability issues which resulted in denial of the 2008 REMOXY NDA were resolved in the December 2010 REMOXY NDA resubmission, although Defendants were aware of persisting material deficiencies in the resubmitted stability data. Defendants deny making any false or misleading statements or omissions regarding the NDA resubmission or REMOXY's stability testing, and have moved for summary judgment, arguing Plaintiff has failed to establish material misrepresentation, scienter, and loss causation.

A. Material Misrepresentation or Omission

Plaintiff contends the following communications made by Defendants are actionably misleading: (1) the December 27, 2010 press release, where PTI stated King resubmitted the REMOXY NDA "in response to" the First CRL; (2) PTI's 2010 Form 10-K, which described the information requested by the FDA in the First CRL only as "additional non-clinical data"; (3) Roddy's statements during the Needham & Company healthcare conference on April 6, 2011,

that the FDA "asked for additional stability data" on REMOXY "[t]hat . . . was submitted in December" and was "accepted" by the FDA in January; and (4) Barbier's statements during the Bank of America healthcare conference on May 11, 2011, that "more detailed stability work . . . was done in the interim between 2008 and 2010" and that "it is not if REMOXY gets approved, but when REMOXY gets approved." Further, Plaintiff alleges three specific omissions demonstrate the misleading nature of those statements. According to Plaintiff's complaint, as King worked toward resubmission of the NDA, PTI became aware of and failed to disclose that: (1) PTI had previously rejected King's stability-testing methodology as ineffective; (2) King's test results indicated REMOXY was insufficiently stable; and (3) approximately 25% of REMOXY tested within the first three months after manufacture did not meet FDA stability specifications. Second Am. Compl. [#70] ¶ 33.

This Court has previously held, in the context of a motion to dismiss, that those three alleged omissions were material and that Defendants had a duty to disclose the information they allegedly withheld. *See* Order of Sept. 26, 2012 [#68] at 12–13. The Court explained that because Defendants chose to make the FDA's concerns about REMOXY's stability data public by telling the market that "the generation of six-month stability data" was "the rate-limiting factor" in the REMOXY resubmission, reasonable investors would consider at least certain types of information about the stability-testing methodology and testing results important in making the decision to invest. *Id.* at 12. Additionally, the Court held that by disclosing the stability issue, Defendants obligated themselves to disclose significant related facts, particularly those regarding compliance with FDA stability standards. *Id.* at 13.

On summary judgment, Defendants' key argument is there is no evidentiary support for any of Plaintiff's pleaded omissions. Specifically, Defendants contend that contrary to Plaintiff's claims, PTI never rejected King's stability-testing methodology as ineffective, and because the FDA allows applicants to design their own stability testing methodology and justify the results, Defendants could not have known REMOXY remained insufficiently stable or otherwise did not meet FDA stability specifications until the FDA actually rejected the second NDA. Defendants further point out that while Plaintiff's complaint made "sweeping" allegations that Defendants resubmitted the NDA with full knowledge it contained stability data the FDA would not approve, Plaintiff's response backs away from those claims, reformulating its allegations as highly granular attacks on the methodological choices Defendants made to bring their data within FDA specifications.

The Court agrees Plaintiff has failed to adduce any admissible evidence showing PTI previously rejected the stability-testing methodology as ineffective, as the only evidence of same is hearsay testimony provided by a confidential witness (which Plaintiff notably failed to cite in its response). *See* Second Am. Compl. [#70] ¶ 35 ("According to CW1, Zamloot believed that King was headed down the wrong path . . . . The methodologies that King employed to test REMOXY's stability were methods that PTI[] had ruled out years prior."). Additionally, the Court agrees Plaintiff appears to have abandoned its allegation Defendants knew approximately 25% of the REMOXY tested within three months after manufacture did not meet FDA specifications, as Plaintiff does not discuss that claim at all in its response to the motion for summary judgment. However, the Court finds Plaintiff has raised a genuine issue as to whether PTI knew and failed to disclose material information about ongoing stability problems with REMOXY revealed by testing

conducted prior to resubmission of the NDA—and therefore, as to whether the statements Plaintiff identifies were materially misleading.

Defendants knew by March 2010 that King's new dissolution methodology had failed to produce test results appreciably better than those produced by the methodology PTI used prior to submission of the first NDA. *See* Mar. 11, 2010 Remoxy Update at 5. Specifically, REMOXY's dissolution variability remained greater than ±10% from the mean of all batches, the range the FDA had described in the First CRL, as PTI knew, as the "maximum allowable." Further, Defendants knew by March 2011 that the FDA had grave concerns about the variable curing period included in the NDA resubmission, given its directive in the Discipline Review Letter to remove that variability and admonishment the three- or six-month curing period indicated the manufacturing process for REMOXY produced inconsistent results. Despite this knowledge, Defendants failed to communicate details regarding the stability testing problems to the public. Instead, Defendants chose to tell the market they resubmitted the REMOXY NDA "in response to" the First CRL, repeatedly stated they had submitted the additional stability testing requested by the FDA, and affirmed "that it is not if REMOXY gets approved, but when REMOXY gets approved." A reasonable juror could conclude these statements kept investors ignorant of material risks associated with purchasing PTI stock by presenting an incomplete picture of REMOXY's persistent stability problems. Whether Defendants' statements were in fact materially misleading is a question for the jury, not for the Court.

Finally, Defendants attempt to resurrect an argument this Court has already rejected, claiming their choice to tell the market "the generation of six-month stability data" was the "rate-limiting step" in the REMOXY resubmission process did not create a duty to disclose information related to REMOXY's stability. Mot. Summ. J. [#160-2] (sealed) at 8. Again, the Court cannot agree. While

disclosure of material information is not always compulsory, it is required when necessary "'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011) (quoting 17 C.F.R. § 240.10b-5(b)). Thus, companies "can control what they have to disclose . . . by controlling what they say to the market." *Id.* at 1322. Here, following the FDA's first rejection of REMOXY, Defendants chose to make concerns about REMOXY's stability data public. Defendants thereby "obligated themselves to disclose significant facts related to the stability of REMOXY." Order of Sept. 26, 2012 [#68] at 13. Whether Defendants failed to fulfill that obligation is a question of fact which will be resolved at trial.

B. Scienter

Defendants next claim Plaintiff cannot carry its burden to show scienter. In the Fifth Circuit, "scienter generally encompasses severe recklessness." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 697 (5th Cir. 2005) (citing *Broad v. Rockwell Int'l Corp.*, 642 F.2d 929, 961–62 (5th Cir. 1981) (en banc)). "Thus, a securities fraud plaintiff must prove that the defendant either consciously misbehaved . . . or was so severely reckless that it demonstrates that the defendant must have been aware of the danger of misleading the investing public." *Id.*; *see also Tellabs*, 551 U.S. at 319. Scienter is "limited to those highly unreasonable omissions or misrepresentations that involve not merely simple or even inexcusable negligence, but an extreme departure from the standards of ordinary care." *Shivangi v. Dean Witter Reynolds, Inc.*, 825 F.2d 885, 889 (5th Cir. 1987). Scienter must be specifically shown for each defendant. *See Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 365 (5th Cir. 2004).

Viewing the evidence in the light most favorable to Plaintiff, the Court concludes Plaintiff's evidence raises a triable issue on scienter. In support of their argument Plaintiff cannot prove Defendants were aware of REMOXY's ongoing stability issues during the class period, Defendants offer little more than self-serving statements and rely heavily on excerpts from declarations provided by Defendants Barbier, Friedmann, and Roddy. *See* Mot. Summ. J. [#160-4] (sealed) at 10–12. Plaintiff, however, has adduced evidence showing King had a contractual obligation to keep PTI updated on the resubmission; committees comprised of King and PTI employees—including the JOC, of which Barbier, Friedmann, and Roddy were members—met and discussed aspects of the REMOXY resubmission process, including stability issues, in detail; teams of people were established within PTI to work on the issues raised in the First CRL; two King employees worked in PTI's offices while the resubmission was ongoing; Barbier and Brian Markinson, King's CEO, communicated regularly during the class period; and Friedmann and Barbier received a copy of the FDA Discipline Review Letter informing King the resubmitted stability data was problematic. *See* Apr. 6, 2010 JOC Minutes at 1–3; Seto Dep. at 42:10–43:11, 48:1–49:16; Touw Dep. at 124:10–25; Zamloot Dep. at 74:2–15; Pl.'s Mot. Seal [##163-11, -12, -37] (sealed) Exs. 8, 9, 34, 63, 65, 66, 67, 68. The parties' competing evidence creates a fact question. If it is true that PTI, Barbier, Friedmann, and Roddy were aware of REMOXY's ongoing stability problems at the time the alleged misstatements and omissions were made, a reasonable juror could find Defendants "must have been aware of the danger of misleading the investing public." Defendants' argument to the contrary is rejected.

C. Loss Causation

Finally, Defendants argue they are entitled to summary judgment because Plaintiff cannot carry its burden to prove loss causation. Loss causation is simply "a causal connection between the material misrepresentation and the loss." *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 342 (2005). In fraud-on-the-market cases, loss causation can be demonstrated circumstantially by "'(1) identifying a corrective disclosure (a release of information that reveals to the market the pertinent truth that was previously concealed or obscured by the company's fraud); (2) showing that the stock price dropped soon after the corrective disclosure; and (3) eliminating other possible explanations for this price drop, so that the factfinder can infer that it is more probable than not that it was the corrective disclosure—as opposed to other possible depressive factors—that cause at least a 'substantial' amount of price drop.'" *Pub. Emps. Ret. Sys. of Miss. v. Amedisys, Inc.*, 769 F.3d 313, 320–21 (5th Cir. 2014) (quoting *FindWhat Investor Grp. v. FindWhat.com*, 658 F.3d 1282, 1311–12 (11th Cir. 2011)). In the Fifth Circuit, "the testimony of an expert—along with some kind of analytical research or event study—is required to show loss causation." *Fener v. Operating Eng'rs Const. Indus. & Misc. Pension Fund (Local 66)*, 579 F.3d 401, 409 (5th Cir. 2009).

In Defendants' view, Plaintiff has failed to introduce expert testimony demonstrating disclosure of the information regarding REMOXY's stability problems caused the drops in PTI stock on May 3, 2011 (following the Pfizer conference call), June 24, 2011 (following the announcement the FDA had rejected the resubmitted NDA), and June 27, 2011 (following the announcement the FDA rejected the resubmitted NDA because of problems in the CMC section and specifically with inconsistent release data). Specifically, Defendants contend Plaintiff has failed to disaggregate the effects on the stock price of non-stability-related information disclosed on those dates. On May 3,

2011, Defendants note, in addition to disclosing problems in the manufacturing section of the resubmitted NDA, Pfizer disclosed it was working to "understand[] potential implications for FDA's recent classwide REMS [Risk Evaluation and Mitigation Strategy] announcement for extended release opioids." Pfizer Conference Call Transcript at 6. Defendants characterize the June 24, 2011 announcement of the NDA rejection as a "materialization of a known risk"—the risk the resubmitted NDA might not be approved—rather than the disclosure of any concealed stability information. Finally, Defendants point out the June 27, 2011 press release referenced not only stability problems, but also "other matters" in explaining the FDA's reasons for denying the NDA, and noted approval of REMOXY could be delayed "significantly longer than a year." June 27, 2011 Press Release at 1.

Plaintiff responds the expert report of Frank Torchio satisfies its obligation to introduce expert testimony on loss causation. Plaintiff introduced Torchio's testimony and report during the class certification stage of this litigation in order to establish market efficiency, an essential element of the fraud-on-the-market theory common to securities fraud class actions. *See* Pl.'s Mot. Seal [#163-105] (sealed) Ex. 102 (Torchio Decl.) at 5 ("I have been asked to provide my opinion regarding the efficiency of the market for the common stock of PTI between December 27, 2010 and June 26, 2011[.]"); *Erica P. John Fund*, 131 S. Ct. at 2185 (noting plaintiff must demonstrate market efficiency to trigger the fraud-on-the-market reliance presumption); *see also* Order of June 3, 2013 [#112] at 24–25 (finding Torchio's declaration sufficient evidence of an efficient market to trigger the presumption and certifying the class). As part of his report, Torchio conducted a study of the cause-and-effect relationship between public announcements made concerning REMOXY and the price of PTI stock during the year encompassing the class period. Torchio examined the ten days

during which PTI had the largest changes in its stock price, upward or downward, which included May 3, June 24, and June 27, 2011. *See* Torchio Decl. Ex. G. Torchio found a causal relationship between the news disclosed on those three days and the major movement of the stock price. *Id.* ¶¶ 35–36. Plaintiff claims Torchio's testimony and event study also suffices to demonstrate loss causation at this stage of the litigation.

Defendants are correct Torchio's testimony regarding the May 3, 2011 conference call cannot serve as evidence of loss causation. In analyzing the effect of the call on PTI's stock price, Torchio did not disaggregate the effect of Pfizer's stability-related disclosure (that Pfizer was "working to address a specific issue in the manufacturing section" of the REMOXY NDA) from the other negative information discussed during the call (that Pfizer was still "working to understand the implications" of the FDA's "recent classwide REMS announcement" bearing on REMOXY). *See* Pfizer Conference Call Transcript at 6; Torchio Decl. Ex. G. Rather, Torchio examined the conference call as one disclosure. The Fifth Circuit "reject[s] any event study that shows only how a stock reacted to the *entire bundle* of negative information, rather than examining the evidence linking the *culpable* disclosure to the stock-price movement." *Fener*, 579 F.3d at 410.

However, the Court finds Torchio's analysis of the stock price movement on June 27, 2011, is competent evidence on the loss causation issue. Defendants argue that Torchio's analysis of the June 27, 2011 press release suffers from a disaggregation problem because the press release stated the stability issues were "among other matters" identified by the FDA in the Second CRL and informing the market REMOXY's FDA approval could be delayed significantly longer than one year. *See* Mot. Summ. J. [#160-4] (sealed) at 19. The Court declines to hold the vague and generic statement "among other matters" constitutes a disclosure of additional negative information which

Plaintiff's expert was required to disaggregate in his analysis. Further, PTI's statement regarding the potential delay in approval for REMOXY was directly tied to the stability issues explicitly disclosed: the press release noted the Second CRL "raised concerns related to" stability, explained the source of the stability problems was "not known at this time," stated "[s]ufficient information does not yet exist to accurately assess the time required to resolve the concerns raised[,]" and opined that delay in REMOXY's approval was likely to result. June 27, 2011 Press Release at 1. The June 27, 2011 press release was a single piece of news—it made an allegedly culpable stability-related disclosure and noted the potential ramifications, in terms of delay, of the stability problems identified—and may be analyzed as such.

As for the June 24, 2011 press release announcing the Second CRL, Defendants argue the press release "at no point mentions any stability-specific issues" and "therefore announced only the materialization of a known risk for which there can be no liability," namely, the possibility the FDA might not approve the resubmitted REMOXY NDA. The Court disagrees with Defendants' characterization of the announcement. The fact the press release does not disclose any stability-specific issues does not mean the event it disclosed—the failure to obtain FDA approval—could not have been a relevant loss-inducing event. *See In re Vivendi Univ., S.A. Sec. Litig.*, 605 F. Supp. 2d 586, 598 (S.D.N.Y. 2009) (explaining the loss-inducing event need not be a corrective disclosure by the company itself, but could be "the failure to obtain agency approval," which "may reveal the risk of a non-viable product"). In allegedly misrepresenting or omitting material information regarding REMOXY's ongoing stability problems from the public and, by doing so, leading the public to believe the stability problems which led to the rejection of the first NDA were resolved,

Defendants concealed from the market a salient risk the resubmitted NDA would not be approved. That risk materialized when the FDA issued the Second CRL, citing REMOXY's stability problems.[6]

Defendants cite *Monroe County Employees' Retirement System v. YPF Sociedad Anonima*, 15 F. Supp. 3d 336 (S.D.N.Y. 2014), in support of their position, but *Monroe County* is distinguishable. In *Monroe County*, the court held the plaintiffs failed to adequately plead loss causation because a drop in the defendant energy company's share price after it announced it was being nationalized "likely represented the materialization of a known risk, rather than the disclosure of a concealed one." *Id.* at 358. However, the court made that finding "in light of the extensive media coverage about the risk of nationalization" throughout the months leading up to the announcement. *Id.* at 357. Here, Defendants have pointed to no "extensive media coverage" about REMOXY's stability problems or the concomitant risk the resubmitted NDA would not be approved. The FDA's rejection of REMOXY was a loss-inducing event which may have revealed previously concealed information—the ongoing stability problems with REMOXY—to the market. The Court concludes Plaintiff has raised a genuine issue of fact concerning loss causation.

III. Motions to Seal

As previously noted, a dispute regarding the propriety of sealing the briefing and exhibits related to Defendants' motion for summary judgment is also before the Court. Having reviewed the record for purposes of resolving the merits dispute, the Court could not be less surprised to see yet another disagreement unrelated to the substantive issues in this litigation bubble up between these

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[6] The Fifth Circuit has yet to comment on the validity of "materialization of the risk" as a method of showing loss causation. This Court, however, has previously permitted litigants to proceed under such a theory, *see Aubrey v. Barlin*, No. A-10-CA-076-SS, 2010 WL 3909332, at *12 (W.D. Tex. Sept. 29, 2010), and several circuits have approved of it. *See Nakkhumpun v. Taylor*, 782 F.3d 1142, 1156 (10th Cir. 2015); *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 513 (2d Cir. 2010); *Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 550 (8th Cir. 2008); *Ray v. Citigroup Global Mkts., Inc.*, 482 F.3d 991, 995 (7th Cir. 2007).

parties.[7] The parties have designated a number of documents as confidential pursuant to the protective order throughout the course of this litigation, and in accord with the protective order, Defendants seeks to file those documents under seal. Plaintiff opposes Defendants' motion, and has filed its own perfunctory motion to seal its response and all of the exhibits attached thereto "pending the Court's ruling" on Defendants' motion.

Defendants represent that although Plaintiff initially agreed certain deposition transcripts and exhibits containing communications with the FDA should be filed under seal because the parties and

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[7] In light of their collegial relationship, as demonstrated below, the parties' frequent disputes may have been all but inevitable:

> MS. WEINRIB: We're not taking a break. We're staying on the record.
> MR. SCHILLER: We're going to go off the record.
> MS. WEINRIB: We are not going off the record. You can leave the room—
> MR. SCHILLER: We're going off the record.
> MS. WEINRIB: —if you'd like, but we are still on the record. There is—
> MR. SCHILLER: We're going to go off the record.
> MS. WEINRIB: —a document that's been handed to the witness—
> MR. SCHILLER: We believe that it's not what you represented it to be, and we want to confirm it.
> MS. WEINRIB: Then you can address that during the next break.
> MR. SCHILLER: Yeah. We're going to take a break right now. Thank you.
> MS. WEINRIB: You can leave the room if you like. We're not taking a break.
> MR. SCHILLER: We're taking a break.
> MS. WEINRIB: You can go ahead and take a break. We're not taking a break.
> MR. SCHILLER: All right. Let's go.
> MS. WEINRIB: Are you instructing your witness to leave the room during a deposition while it is still going?
> MR. SCHILLER: We're going—we're taking a break.
> MS. WEINRIB: You're taking a break.
> MR. SCHILLER: If you would come outside and discuss this with me, we can do it outside—
> MS. WEINRIB: Are you—
> MR. SCHILLER: —the presence of the—
> MS. WEINRIB: —instructing your witness to leave the room in the middle of a deposition while it is still on the record?
> [The attorneys continue fighting.]
> MS. WEINRIB: Are you finished? Are you done yelling at me? Because we can talk like rational people—
> MR. SCHILLER: I'm not yelling. I'm talking directly.
> MS. WEINRIB: I think the video will reflect that you yelled, but that's fine.

Zamloot Dep. at 99:6–102:13. Believe it or not, this is neither the only such exchange which took place during this deposition nor even the conclusion of this one in particular. Counsel for both parties, the Court is certain, would prefer this and other colloquies conducted during deposition be permanently shielded from the public record.

Pfizer have designated those documents as confidential, Plaintiff now takes the position nothing should be filed under seal. Defendants note Plaintiff has never challenged the designation of those documents as confidential pursuant to this Court's protective order, and point out Plaintiff has represented the depositions in question would remain confidential and opposed Defendants' attempt to designate only portions thereof as confidential. Plaintiff responds the materials Defendants wish to seal are neither trade secrets nor privileged material, and claim the fact it did not previously object to the confidential designation of the materials does not mean it may not do so at this time.

It is true Plaintiff has failed to follow proper procedure, as set forth in the Court's protective order, to challenge the confidential designation of the documents Defendants wish to file under seal. An opposition to Defendants' motion to seal is clearly not the proper vehicle to contest the designation. *See* Protective Order [#79] ¶ 11(a). Further, Plaintiff's inconsistent position on the confidentiality issue is unimpressive to the Court and smacks of gamesmanship. Yet, it is also true the Court's review of the exhibits Defendants wish to seal reveals that several appear to contain no confidential information or trade secrets. Moreover, it is not this Court's typical practice to permit the sealing of memoranda of law absent a compelling justification for doing so, and the Court is not inclined to seal deposition transcripts in their entirety. Additionally, with respect to certain key FDA documents, such as the two CRLs and the Discipline Review Letter, the Court is, as things presently stand, unclear concerning what confidential information Defendants are attempting to protect and skeptical that the interest in keeping any such information shielded from public view outweighs the public's interest in access to judicial records, particularly where the records in question play an important role in the litigation.

Both parties have failed in their obligations to the Court and have demonstrated an unprofessional unwillingness to reasonably compromise. The Court is all but certain it is the enmity and lack of respect between counsel for the parties that has repeatedly led to an inability to resolve issues such as this one in a professional manner. Consequently, the parties have ten days from date of entry of this order to meet and confer and submit an agreed order regarding the confidentiality and propriety of sealing documents in this record. Failure to agree will lead to undesirable consequences for all.

Conclusion

Accordingly:

IT IS ORDERED that Defendants Pain Therapeutics, Inc., Remi Barbier, Nadav Friedmann, and Peter Roddy's Motion for Summary Judgment [##158, 160-4] is DENIED;

IT IS FURTHER ORDERED that Defendants' Opposed Motions to File Pleadings Under Seal [##160, 165] are DISMISSED;

IT IS FURTHER ORDERED that Plaintiff's Motion to File Pleadings Under Seal [#163] is DISMISSED;

IT IS FURTHER ORDERED that the parties meet and confer and submit, within ten (10) days from date of entry of this order, an agreed order disposing of their sealing and confidentiality dispute in whatever manner they see fit; and

IT IS FINALLY ORDERED that the parties' summary judgment briefing and exhibits presently filed under seal remain under seal pending submission of the parties' agreed order.

SIGNED this the 16th day of June 2015.

SAM SPARKS
UNITED STATES DISTRICT JUDGE