IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SOMAXON PHARMACEUTICALS, INC., and PROCOM ONE INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 10-1100-RGA-MPT
ACTAVIS ELIZABETH LLC et al.,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

Presently before the court in this Hatch-Waxman patent infringement action is the motion of defendants and counterclaim plaintiffs Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan") to enforce the Settlement and License Agreement dated July 17, 2012 (the "Agreement"), which was entered into between Mylan and plaintiffs and counterclaim defendants Somaxon Pharmaceuticals, Inc. ("Somaxon") and ProCom One, Inc. ("ProCom").[1] (D.I. 290) For the following reasons, I recommend that the court GRANT Mylan's motion to enforce the Agreement.

II. BACKGROUND

Somaxon was the holder of approved New Drug Application ("NDA") No. 22-036 for Silenor® doxepin hydrochloride tablets in 3 mg and 6 mg doses. (D.I. 20 at ¶ 28) Silenor® is used to treat insomnia characterized by difficulties with sleep maintenance. (D.I. 1 at ¶ 23) Silenor® is covered by a number of patents listed in the Orange Book, including United States

[1] The briefing and other filings related to the pending motion can be found at D.I. 291, D.I. 292, D.I. 302, D.I. 303, D.I. 304, and D.I. 306.

Patent No. 6,211,229 ("the '229 patent"), entitled "Treatment of Transient and Short Term Insomnia," and United States Patent No. 7,915,307 ("the '307 patent"), entitled "Methods of Improving the Pharmacokinetics of Doxepin." (D.I. 1 at ¶ 25) Somaxon had an exclusive license to the '229 and '307 patents. (D.I. 20 at ¶ 40)

On November 2, 2010, Mylan notified Somaxon and ProCom that it had submitted an Abbreviated New Drug Application ("ANDA") with a paragraph IV certification for the '229 patent, among others. (D.I. 20 at ¶¶ 45-48; D.I. 1 at ¶ 28) By filing the ANDA, Mylan indicated its intent to market, manufacture, and sell a generic version of Silenor® before the expiration of the '229 patent. (D.I. 1 at ¶ 28) In response, Somaxon and ProCom sued Mylan for infringement of the '229 patent on December 15, 2010. (D.I. 1) Somaxon separately sued Mylan for infringement of the '307 patent on June 28, 2011. (C.A. No. 11-571-RGA, D.I. 1)

On July 17, 2012, the parties executed the Agreement, which awarded Mylan the semi-exclusive right to sell an authorized generic version of Silenor® 3 mg and 6 mg doxepin hydrochloride for a period of 180 days beginning on January 1, 2020 (the "AG License Initial Period"). (D.I. 292, Ex. 1 at § 5.1(a)) Mylan's rights under Section 5.1(a) of the Agreement are "semi-exclusive" because Somaxon and ProCom "may grant one (1) additional License for the AG License Initial Period to a product that is AB rated to Silenor 3 mg and 6 mg doxepin hydrochloride tablets, but such product shall not be an Authorized Generic Product." (*Id.*) Actavis was granted the right to launch the AB-rated generic version of Silenor® beginning on January 1, 2020, and the record reflects that Actavis' generic product is currently on the market.[2] (D.I. 303 at ¶ 18; 3/3/2020 Tr. at 6:4-14)

[2] An AB-rated drug is a generic drug certified by the FDA to be bioequivalent to the branded drug, and it must have the same form, dosage, and strength as the branded drug. *See Abbott*

Following the execution of the Agreement, the Supreme Court issued its decision in *FTC v. Actavis, Inc.*, which changed the legal landscape regarding the enforceability of reverse payments in Hatch-Waxman-related settlement agreements. 570 U.S. 136, 141 (2013). The Supreme Court explained that a reverse payment settlement arises when "A, the plaintiff, pays money to defendant B purely so B will give up the patent fight." *Id.* at 152. The Supreme Court observed that, in such a scenario, "a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market." *Id.* The Supreme Court held that reverse payments violate principles of antitrust law when they seek to prevent competition: "If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.* at 158.

The Third Circuit subsequently extended the Supreme Court's ruling in *FTC v. Actavis* to non-monetary reverse payments. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 252 (3d Cir. 2017); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016). Specifically, the Third Circuit held that a brand-

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Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 415 (D. Del. 2006). In contrast, an authorized generic drug is a branded drug that is marketed, sold, and distributed "under a different labeling, packaging, . . . product code, labeler code, trade name, or trade mark than the listed drug." 21 U.S.C. § 355(t)(3)(B); *see also In re Zetia (Ezetimibe) Antitrust Litig.*, 2019 WL 1397228, at *14 (E.D. Va. Feb. 6, 2019), *report and recommendation adopted*, 400 F. Supp. 3d 418 (E.D. Va. 2019) (explaining that authorized generic drugs are approved under the brand's NDA, whereas AB-rated generic drugs are approved under a competitor's separate ANDA). The 180-day generic exclusivity period awarded to the first ANDA filer under the Hatch-Waxman Act does not prevent a brand manufacturer from launching an authorized generic product or licensing its product to another company to sell an authorized generic to compete with the ANDA product during the exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 543 (1st Cir. 2016) ("[T]he generic manufacturer may still face competition from a generic version of the drug produced by the brand manufacturer, also known as an authorized generic ('AG'), at any time, including during the exclusivity period.").

name manufacturer's promise not to produce an authorized generic to compete with the generic manufacturer amounted to a non-monetary reverse payment equivalent to the anticompetitive reverse payment at issue in *FTC v. Actavis* because the arrangement had the effect of maintaining supracompetitive prices in the market. *King Drug Co.*, 791 F.3d at 409-10 ("[A] no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason."). The Third Circuit characterized such agreements not as an exercise of the right to grant licenses, but rather as "a right to use valuable licensing in such a way as to induce a patent challenger's delay." *Id.* at 406.

In December 2012, Pernix Therapeutics Holdings, Inc. ("Pernix") entered into an agreement to acquire Somaxon. The acquisition was consummated in March 2013. (D.I. 292, Ex. 2) Pernix filed for Chapter 11 bankruptcy in February 2019. In April 2019, Pernix entered into an amended asset purchase agreement ("APA") with Currax Holdings, LLC. (D.I. 292, Ex. 3 at 6) Pursuant to the APA, Currax Pharmaceuticals LLC, Currax Holdings LLC, and Currax Holdings USA LLC (collectively, "Currax") became Somaxon's successors-in-interest to the Silenor® NDA, the '229 and '307 patents, other patents listed in the Orange Book for Silenor®, and the Agreement. (D.I. 292, Ex. 4 at ¶¶ 15-23; Ex. 5)

In October 2019, Currax informed Mylan of its plan to launch its own AG product on or before January 1, 2020. (D.I. 303 at ¶¶ 4, 14) Currax, questioned the enforceability of the Agreement regarding Silenor®, arguing that the Agreement raised antitrust issues. (*Id.* at ¶¶ 12-14) On December 16, 2019, Currax and/or its subsidiary, Macoven Pharmaceuticals, L.L.C. ("Macoven"), began marketing doxepin hydrochloride 3 mg and 6 mg oral tablets at a wholesale

acquisition cost ("WAC") of $349.20 per package of 30 tablets. (D.I. 292, Ex. 6) Mylan learned of Macoven's marketing activity on December 20, 2019 and filed the pending motion to enforce the Agreement three days later. (D.I. 290)

III. LEGAL STANDARD

A district court has jurisdiction to enforce a settlement agreement in a case pending before it. *See Hobbs & Co. v. Am. Inv'rs Mgmt., Inc.*, 576 F.2d 29, 33 & n.7 (3d Cir. 1978); *Leonard v. Univ. of Del.*, 204 F. Supp. 2d 784, 786 (D. Del. 2002). A motion to enforce a settlement agreement closely resembles a motion for summary judgment and employs a similar standard of review. *See Tiernan v. Devoe*, 923 F.2d 1024, 1031-32 (3d Cir. 1991); *Parker-Hannifin Corp. v. Schlegel Elec. Materials, Inc.*, 589 F. Supp. 2d 457, 461 (D. Del. 2008). Therefore, the court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Pennsylvania Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995). When material facts are in dispute, the court should hold an evidentiary hearing before enforcing the settlement agreement. *See Tiernan*, 923 F.2d at 1031.

Principles of contract law govern the enforcement of settlement agreements. *See Jacob's Limousine Transportation, Inc. v. City of Newark*, 688 F. App'x 150, 151 (3d Cir. 2017); *Parker-Hannifin Corp. v. Schlegel Elec. Materials, Inc.*, 589 F. Supp. 2d 457, 461 (D. Del. 2008). If the court determines that the nonmovant breached a duty created by a binding agreement and the breach caused the movant to suffer damages, the court must grant the motion to enforce. *See Sheet Metal Workers Int'l Ass'n Local Union No. 27, AFL-CIO v. E.P. Donnelly, Inc.*, 737 F.3d 879, 900 (3d Cir. 2013). The moving party bears the burden of proving by a preponderance of

the evidence that the nonmoving party breached a duty under the terms of the Agreement. *Jacob's Limousine*, 688 F. App'x at 153 n.2.

IV. ANALYSIS

As a preliminary matter, the parties do not dispute that this court has jurisdiction to resolve the pending motion to enforce the Agreement in accordance with the Consent Judgment and Dismissal Order, which provides that "[t]his Court retains jurisdiction over the parties for purposes of enforcing this Order." (D.I. 234 at 2)

A. Enforceability of the Agreement

1. Existence and enforceability of a no-AG provision

Currax alleges that Section 5.1(a) of the Agreement is not enforceable because it contains a "no-authorized generic" ("no-AG") term that is anticompetitive and unlawful under the antitrust laws. (D.I. 302 at 9-14) Mylan challenges Currax's characterization of Section 5.1(a) as a no-AG provision because the provision explicitly allows Mylan to launch an authorized generic in addition to the permitted third-party launch of an AB-rated licensed generic of Silenor® to compete with Mylan's authorized generic and the brand drug. (D.I. 306 at 1-2, 4-5)

Section 5.1(a) of the Agreement does not contain a no-AG provision because it expressly permits Mylan to market an authorized generic with the brand company's permission: "Plaintiff hereby grants to Mylan . . . a semi-exclusive . . . license under the Licensed Patents, to offer for sale and sell the Mylan Authorized Generic Product." (D.I. 292, Ex. 1 at § 5.1(a)) The Third Circuit has defined a no-AG agreement as "a brand-name manufacturer's promise not to produce an authorized generic to compete with the generic manufacturer" during the 180-day exclusivity period guaranteed to the first-filing generic manufacturer under the Hatch-Waxman Act. *In re*

Lipitor Antitrust Litig., 868 F.3d 231, 252 (3d Cir. 2017); *see King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 393 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016). But in this case, Currax licensed Mylan to produce an authorized generic to compete with Actavis' AB-rated generic product during the 180-day generic exclusivity period:

> [B]y semi-exclusive, it is meant that Plaintiffs may grant one (1) additional License for the AG License Initial Period to a product that is AB rated to Silenor 3 mg and 6 mg doxepin hydrochloride tablets, but such product shall not be an Authorized Generic Product. For the further avoidance of doubt, Plaintiffs and their Affiliates shall not, and shall not license, encourage, or otherwise authorize any Third Party to, offer for sale, market, or sell an Authorized Generic Product before or during the AG License Period."

(D.I. 292, Ex. 1 at § 5.1(a); D.I. 303 at ¶ 18) According to the Federal Trade Commission, Currax's license to Mylan to produce the authorized generic does not change the resulting product to something other than an authorized generic: "An authorized generic may be marketed by the brand name drug company, or another company with the brand company's permission." *In re Impax Labs., Inc.*, 2019 WL 1552939, at *3 n.5 (F.T.C. Mar. 28, 2019). Because Section 5.1(a) authorizes Mylan to manufacture and sell an authorized generic to compete with Actavis' AB-rated generic product during the 180-day exclusivity period, the provision lacks the key features of a no-AG clause.

Regardless, the relevant case authorities do not support Currax's position that Section 5.1(a) contains an illegal non-monetary reverse payment on its face. (D.I. 302 at 11) Courts have recognized that a no-AG term may constitute a non-monetary reverse payment subject to scrutiny under the antitrust laws. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 411 (3d Cir. 2015) (observing that a no-AG promise may amount to a non-monetary reverse payment if restrictions on authorized generic competition are exchanged for

settlement of litigation to eliminate the risk of invalidation or noninfringement).[3] But these courts have declined to reach a final determination of the illegality of a no-AG clause prior to conducting the fact-intensive "rule of reason" analysis to assess whether the reverse payment will result in anticompetitive harm.[4] *See id.* at 412 ("The Court does not foreclose other justifications, and we need not decide today what those other justifications might be."); *In re Zetia Ezetimibe Antitrust Litig.*, 2019 WL 1397228, at *13, 20 (E.D. Va. Feb. 6, 2019) ("[A]pplication of a per se rule would appear to preclude a mechanism for even examining the Defendants' proffered justifications for [reverse payment] settlement;" therefore, rule of reason analysis should apply); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245 (D. Conn. 2015)

[3] Currax addressed the Third Circuit's decision in *King Drug Co.* in its briefing as follows: "The Third Circuit found that a settlement agreement in which a generic manufacturer is awarded an exclusive license to launch an authorized generic product functions as an illegal reverse payment—withholding valid competition to delay generic entry." (D.I. 302 at 11) This statement is inaccurate. First, the Third Circuit did not find the no-AG term to be an illegal reverse payment under the antitrust laws. Instead, the Third Circuit held that the pleading adequately alleged facts to support the survival of the allegation at the pleading stage. *King Drug Co.*, 791 F.3d at 409 ("We believe plaintiffs' allegations, and the plausible inferences that can be drawn from them, are sufficient to state a rule-of-reason claim under *Twombly* and *Iqbal* on the ground that GSK sought to induce Teva to delay its entry into the lamotrigine tablet market by way of an unjustified no-AG agreement."). Second, the no-AG provision in the settlement agreement authorized Teva to launch a generic, as opposed to an authorized generic as suggested by Currax—the purpose of the no-AG clause was to prohibit the launch of an authorized generic during Teva's 180 days of generic exclusivity. *Id.* at 393-94 ("They agreed Teva would end its challenge to GSK's patent in exchange for early entry into the $50 million annual lamotrigine chewables market and GSK's commitment not to produce its own, 'authorized generic' version of Lamictal tablets for the market alleged to be worth $2 billion annually."). Third, although the brand manufacturer characterized the no-AG agreement as an "exclusive license," the Third Circuit declined to adopt this characterization: "We do not believe the no-AG agreement was in fact an 'exclusive' license. However, since the issue of whether such agreement is an exclusive license is not necessary for our decision here, we will leave its determination for another day." *Id.* at 406 n.27.

[4] In the context of reverse payments, courts performing the rule of reason analysis must consider "antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *FTC v. Actavis*, 133 S. Ct. at 2231.

(observing that a reverse payment settlement, "under *Actavis*, is not *ipso facto* unlawful" and may have procompetitive justifications). The Supreme Court made clear that "the likelihood of a reverse payment bringing about anticompetitive effects depends on its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Actavis*, 570 U.S. at 159.

The Third Circuit has held that, "to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition." *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016). But Currax offers no support for its position that enforcement of Section 5.1(a) would lead to anticompetitive harm. In its briefing on the issue, Currax identifies the anticompetitive harm as "Mylan's attempt to remove a competitor from the market."[5] (D.I. 302 at 9) Currax further explains that "Currax would be agreeing with its horizontal competitor, Mylan, not to launch a product Currax has a right to sell." (*Id.* at 11) But Section 5.1(a) of the Agreement does not remove a competitor from the market. In fact, Section 5.1(a) permits competition among Currax's branded product, Mylan's authorized generic product, and Actavis' AB-rated generic product during the 180-day exclusivity period. Section 5.1(a)'s reallocation of Currax's right to market an authorized generic product to Mylan does not amount to a suppression of the right to market an authorized generic product, and it has no demonstrated negative impact on competition during the exclusivity period.

[5] Currax does not address the other forms of competitive harm that may arise from a no-AG provision in a settlement agreement, such as avoidance of the risk of patent invalidation or a finding of noninfringement, or an extended monopoly for the brand company if the generic company's entry date is later than the entry date the generic company would have otherwise accepted. *King Drug Co.*, 791 F.3d at 405 (quoting *Actavis*, 133 S. Ct. at 2236).

Currax does not dispute the fact that most of the no-AG cases it cites involved only one generic drug competing in the market against the brand-name drug during the 180-day exclusivity period. *See In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d at 546 (Warner agreed not to market, supply, or license an authorized generic version of Loestrin 24 during Watson's generic exclusivity period); *In re Zetia Ezetimibe Antitrust Litig.*, 2019 WL 1397228, at *8 (Merck agreed to delay launching an authorized generic version of Zetia during Glenmark's exclusivity period); *FWK Holdings*, 2017 WL 11449668, at *3 (Actavis agreed to delay the entry of its generic in exchange for Shire's functional agreement not to launch an authorized generic version of Intuniv during the exclusivity period); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d at 713 (Endo agreed not to launch an authorized generic version of Opana ER during Impax's generic exclusivity period); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 744 (Kos agreed not to launch an authorized generic version of Niaspan during Barr's generic exclusivity period); *Teikoku Pharma*, 74 F. Supp. 3d at 1070 (Endo/Teikoku agreed not to release an authorized generic to compete with Watson's generic during the exclusivity period). In these cases, "[t]he no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly." *King Drug Co.*, 791 F.3d at 405. In contrast, Section 5.1(a) expressly permits Mylan to launch an authorized generic to compete with Actavis' AB-rated generic and Currax's brand-name version of Silenor®. (D.I. 292, Ex. 1 at § 5.1(a)) The "generic duopoly" is preserved, and there can be no concern that "the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Actavis*, 133 S. Ct. at 2235. This

reallocation of the right to market an authorized generic product, as opposed to a suppression of the right to market an authorized generic product, does not reduce competition during the exclusivity period.

Relying on the District of Connecticut's decision in *In re Aggrenox Antitrust Litigation*, counsel for Currax suggests that an agreement not to license a third generic product may constitute an anticompetitive no-AG agreement even if the brand maintains its right to sell an authorized generic and the settlement agreement licenses a generic product. (3/3/2020 Tr. at 25:3-23) Currax represents that *In re Aggrenox* involved a situation in which the generic company was awarded a license to launch a generic, but the settlement agreement also gave brand manufacturer Boehringer the right to launch an authorized generic through its generic subsidiary, Roxane.[6] (*Id.*) In fact, the defendants disputed the issue of whether Boehringer had

[6] Currax represents that Roxane did, in fact, launch an authorized generic product during the 180-day exclusivity period: "And in fact, it did that. It actually did launch an authorized generic through the relevant time period. And the parties briefed that." (3/3/2020 Tr. at 25:14-17) The briefing in the case is heavily redacted, and the court was unable to substantiate the launch of an authorized generic by Roxane during the exclusivity period. The operative complaint suggests that Boehringer declined to launch an authorized generic because of the settlement agreement:

> On information and belief, BI has launched at least four authorized generics between 1999 and 2012. On information and belief, in at least two of those instances, BI launched an authorized generic through its subsidiary Roxane Laboratories, Inc. On information and belief, these two launches were not the result of the settlement of patent litigation involving the presumed FTF. On information and belief, BI would have launched an authorized generic version of Aggrenox upon market entry by Barr/Teva in the absence of the anticompetitive agreement here.

(D. Conn. C.A. No. 3:14-md-2516, D.I. 97 at ¶ 71; *see also* D.I. 194 at 15 ("Had Barr not accepted the payments and delayed entry, it would have faced stiff competition from Boehringer's authorized generic version of Aggrenox and six months later from other generic entrants."); D.I. 149 at 47 (arguing that "BI retained the freedom to introduce an AG through its generic affiliate Roxane," without suggesting that Roxane in fact launched an authorized generic

the right to launch an authorized generic during the 180-day generic exclusivity period: "First, and quite notably, the defendants do not agree among themselves whether the challenged settlement agreement actually does prevent Boehringer from introducing an authorized generic: by Boehringer's interpretation, it does not; but by Barr's reckoning it does." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d at 244.

Ultimately, the court held, "I need not determine how who is correct by ruling on the construction of the agreement, but the plaintiffs allege that there is such a provision and that it is very valuable, and at least on the latter point the defendants clearly agree." *Id.* The focus of the court's decision in *In re Aggrenox* was on whether the reverse payment was made to avoid the risk of patent invalidation. *Id.* at 243, 245 (analyzing a reverse payment of $4 million cash plus over $120 million in royalties in addition to non-cash consideration). The court explained that, if the brand manufacturer avoids the invalidation of weak patents by entering into a settlement agreement, it can extend its monopoly by paying the generic manufacturer to delay the generic's market entry. *Id.* at 234. Thus, the inquiry focuses on the avoidance of patent invalidation by the brand manufacturer:

> The plaintiffs do not appear to allege that "no-authorized generic" agreements are *per se* unlawful, nor that any individual feature of the settlement agreement would have constituted an antitrust violation as part of some other agreement. Rather, they allege that Boehringer gave much more than it got in the settlement agreement; and under *Actavis*, that can constitute an antitrust violation if it did so in order to avoid the risk of patent invalidation.

Id. at 245. In contrast, the only anticompetitive harm alleged by Currax on the present motion is the alleged reduction in the number of generic competitors during the exclusivity period.

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during the exclusivity period)). Regardless, the court did not acknowledge the existence of two competing generics in its decision.

(3/3/2020 Tr. at 21:4-6; 26:19-23) For the reasons previously discussed, there is no such restriction on competition in the present case.

Having recommended that Section 5.1(a) is enforceable because it does not fit the definition of a no-AG clause and it has not been shown to reduce competition, the court need not reach the question of severability under Section 12.4 of the Agreement, which provides that the remainder of the Agreement "will be valid and enforceable to the fullest extent permitted by applicable law" even if one provision is "held to be invalid or unenforceable." (D.I. 292, Ex. 1 at § 12.4)

2. California reverse payment legislation

Currax also contends that Section 5.1(a) of the Agreement is invalid and unenforceable because California law now prohibits no-AG restraints in reverse payment settlements. (D.I. 302 at 14) California's new legislation regarding reverse payment settlements, which went into effect on January 1, 2020, provides that

> an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, shall be presumed to have anticompetitive effects and shall be in violation of this section if both of the following apply:
>
> > (A) A nonreference drug filer receives anything of value from another company asserting patent infringement, including, but not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug.
> >
> > (B) The nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time.

Cal. Health & Safety Code § 134002(a)(1) (West 2020). Section 134002 does not render Section 5.1(a) of the Agreement invalid or unenforceable for at least three reasons.

First, Currax has not shown that the statute applies retroactively. "In California, [i]t is an established canon of interpretation that statutes are not to be given a retrospective operation unless it is clearly made to appear that such was the legislative intent." *Gadda v. State Bar of Calif.*, 511 F.3d 933, 937 (9th Cir. 2007) (quoting *Aetna Cas. & Sur. Co. v. Indus. Accident Comm'n*, 30 Cal.2d 388 (Cal. 1947) (internal quotation marks omitted)); *see also Evangelatos v. Superior Court*, 753 P.2d 585, 642 (Cal. 1988) ("[I]n the absence of an express retroactivity provision, a statute will not be applied retroactively unless it is very clear from extrinsic sources that the Legislature or the voters must have intended a retroactive application."). Neither the text of the statute nor the legislative history suggests that Section 134002 was intended to apply retroactively. To date, no California state or federal case authorities have issued applying the statute retroactively. Because the parties executed the Agreement on July 17, 2012, and the statute did not go into effect until January 1, 2020, Section 134002 does not invalidate Section 5.1(a) of the Agreement.

Second, Section 134002(e)(4) provides that "[a]n action to enforce a cause of action for a violation of this section shall be commenced within four years after the cause of action accrued." The parties executed the Agreement on July 17, 2012, and the statute did not go into effect until January 1, 2020. There can be no dispute that the four-year statute of limitations under the statute has expired in this case.

Third, Section 134002(e)(1)(B) provides that "[a]ny penalty . . .shall accrue only to the State of California and shall be recovered in a civil action brought by the Attorney General in its own name . . . against any party to an agreement that violates this section." Consequently,

Currax may not invoke the statute in this litigation because there is no private right of action under the California statute.

B. Material Breach

The parties do not dispute that Currax marketed and offered for sale another authorized generic product during the AG License Initial Period: "Currax has made its authorized generic ('AG') version of its Silenor® product, consisting of doxepin tablets in 3 and 6 mg dosage amounts, available to customers." (D.I. 303 at ¶¶ 1-3) Moreover, the parties do not dispute that Currax's conduct violates Section 5.1(a) of the Agreement, which grants Mylan a "semi-exclusive" license to market and sell its authorized generic product without competition from another authorized generic. (D.I. 292, Ex. 1 at § 5.1(a)) Section 5.1(a) of the Agreement expressly prohibits the award of a license for another authorized generic product before or during the AG License Initial Period. (*Id.*)

Mylan contends that Currax's marketing and sale of its authorized generic of Silenor® amounts to a material breach of Section 5.1(a) of the Agreement because Mylan negotiated to obtain 180 days of semi-exclusivity to market and sell its authorized generic, as evidenced by contemporaneous press releases. (D.I. 291 at 10-11; D.I. 306 at 3) In response, Currax challenges Mylan's assertion that the 180-day term of generic semi-exclusivity is similar to the statutory exclusivity period for generics in the absence of the Agreement, noting that ANDA filers are not entitled to 180 days of generic exclusivity when they settle their patent cases and launch under a license from the patent holder. (D.I. 302 at 15) Even if Mylan could establish that Section 5.1(a) is material to the Agreement, Currax contends that this would confirm the

term was a reverse transfer of considerable value from the patentee to the alleged infringer, rendering it void and unenforceable under the antitrust laws. (*Id.*)

The record before the court supports a finding that the semi-exclusivity provision of Section 5.1(a) is material to the Agreement. Mylan negotiated for the right to market and sell an authorized generic during Actavis' generic exclusivity period without competition from Currax's authorized generic. (3/3/2020 Tr. at 15:16-24) The press releases accompanying the Agreement confirm that Mylan's rights under Section 5.1(a) were material to its execution of the Agreement. (D.I. 292, Ex. 1 at Ex. B)

C. Harm Resulting from Breach

In its briefing, Mylan contends that it is entitled to monetary damages in the form of lost revenues, loss of market share, price erosion, and loss of customer goodwill as a result of Currax's breach of the Agreement. (D.I. 291 at 11) Mylan represents that it is also entitled to specific performance of the Agreement and, accordingly, Currax should be required to pull its Silenor® AG product off the market. (D.I. 306 at 10) At oral argument, Mylan limited its present request to specific performance of the Agreement to stop Currax's unauthorized sales of its authorized generic product and reserved its right to seek monetary compensation at a later time. (3/3/2020 Tr. at 13:5-15; 18:1-11)

I recommend that the court grant Mylan's request for specific performance of the Agreement and order Currax to cease sales of its authorized generic product for the duration of the AG License Initial Period. For the reasons previously stated, Currax breached Section 5.1(a) in a manner that deprived Mylan of a material benefit of the Agreement.

V. CONCLUSION

For the foregoing reasons, I recommend that the court GRANT Mylan's motion to enforce the Agreement and order Currax to cease sales of its authorized generic product for the duration of the AG License Initial Period. (D.I. 290)

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties shall jointly submit a proposed redacted version by no later than **April 16, 2020**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within thirty (30) days of the date the Report and Recommendation issued.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objection and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right

to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: April 9, 2020

Sherry R. Fallon
United States Magistrate Judge