IN THE COURT OF CHANCERY FOR THE STATE OF DELAWARE

SHAREHOLDER REPRESENTATIVE	
SERVICES, LLC, solely in its capacity as)
representative of the Securityholders,)
)
Plaintiff, Counterclaim)
Defendant,) C.A. No. 2020-1069-MTZ
v.	REDACTED PUBLIC VERSION FILED: APRIL 7, 2021
ALEXION PHARMACEUTICALS, INC.,	
Defendant, Counterclaim Plaintiff.))

DEFENDANT AND COUNTERCLAIM PLAINTIFF ALEXION PHARMACEUTICALS, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS COUNT I OF PLAINTIFF AND COUNTERCLAIM DEFENDANT SHAREHOLDER REPRESENTATIVE SERVICES, LLC'S <u>VERIFIED COMPLAINT</u>

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Alexion Pharmaceuticals, Inc. ("Alexion") respectfully submits this Reply Brief In Support Of Its Motion To Dismiss Count I of Shareholder Representative Services LLC's ("SRS") Verified Complaint ("Complaint").

I. <u>INTRODUCTION</u>

In its February 12, 2021, Motion to Dismiss Count I of SRS's Complaint, Alexion established that SRS's claim for breach of Commercially Reasonable Efforts ("CRE")¹ is not ripe for adjudication and should be dismissed under Rule 12(b)(1) because: (1) the material factual predicate underlying Count I is not complete, (2) SRS will face no hardship or prejudice if this litigation is delayed until the factual predicate is complete, and (3) the Court and parties should not waste resources prematurely litigating this case. *See* Dkt. 53 ("Mot." or "Alexion's Motion to Dismiss"). Rather than address the merits of these arguments under a Rule 12(b)(1) analysis, SRS's Answering Brief In Opposition To Alexion's Motion To Dismiss (Dkt. 68 ("Opp." or "SRS's Opposition")) parrots the allegations of its Complaint and principally argues, without foundation, that Count I passes muster under Rule 12(b)(1) because Alexion has not moved to dismiss the Count through a

¹ Capitalized terms used and not otherwise defined herein have the meaning ascribed to them in the Merger Agreement.

Rule 12(b)(6) challenge. Thus, SRS improperly conflates Rule 12(b)(1), which concerns whether the Court has subject matter jurisdiction over Court I, with Rule12(b)(6), which examines whether allegations in the Complaint meet the requisite pleading standard.

What SRS's Opposition does not do is dispute the recitation of the facts² in Alexion's Motion to Dismiss. For example, SRS does not dispute:

- that when Alexion acquired Syntimmune and all of its assets for four hundred million dollars (\$400,000,000), all of Syntimmune's drug substance and drug product was and unsafe for human use;
- that it takes to manufacture new ALXN1830 drug substance and process it into formulated drug product that is ready for clinical use;
- that shortly after Alexion remediated the manufacturing issues that it inherited from Syntimmune, manufactured safe drug substance, and processed it into safe drug product for clinical use, the COVID-19 pandemic caused a global economic shut-down that impacted clinical studies and still impacts our daily lives; or
- that, despite the foregoing challenges, Alexion continues to develop ALXN1830, with one new clinical trial already running, and two more scheduled for 2021, bringing Alexion closer to achieving Milestone Events triggering Earn-Out Payments.

² On a motion to dismiss pursuant to Rule 12(b)(1), the Court is free to consider facts not alleged in the complaint. *See, e.g., Appriva Shareholder Litig. Co. v. EV3, Inc.*, 937 A.2d 1275, 1284 n.14 (Del. 2007).

These factual concessions confirm that the ALXN1830 development record is not sufficiently complete for this Court to adjudicate a claim for breach of CRE under the Merger Agreement.

II. <u>ARGUMENT</u>

A. SRS Conflates Rule 12(b)(6) With Rule 12(b)(1)

SRS's central argument in opposition to Alexion's Motion to Dismiss is that Count I survives Alexion's challenge under Rule 12(b)(1) because Alexion did not move to dismiss under Rule 12(b)(6). See, e.g., Opp. at 2 ("Alexion does not and cannot dispute that the Complaint adequately alleges both a breach and a current, cognizable injury. That should be the end of the matter.") (emphasis added); 16 ("Alexion does not dispute that the Complaint properly states a breach of contract claim.").

As an initial matter, SRS misconstrues the fact that Alexion did not bring its motion to dismiss under Rule 12(b)(6) to suggest that Alexion has admitted that SRS suffered injury caused by the alleged breach. Not so. As SRS notes in its Opposition, this Court's treatment of Rule 12(b)(6) does not include a plausibility analysis and does not require a showing of proximate causation of damages. *See, e.g., Cambium Ltd. v. Trilantic Capital Partners III L.P.*, 2012 WL 172844, at *2 (Del. Jan. 20, 2012) (Delaware Supreme Court rejecting the federal *Iqbal/Twombly*

standard: "The Court of Chancery erred by applying the federal 'plausibility' standard in dismissing the amended complaint."); *Arkansas Teacher Ret. Sys. v. Alon USA Energy, Inc., No. CV 2017-0453-KSJM*, 2019 WL 2714331, at *15 (Del. Ch. June 28, 2019) ("At the pleadings stage, it is sufficient for the Complaint to aver damages resulting from the alleged contractual breaches generally."). Thus, Alexion's decision not to move to dismiss under Rule 12(b)(6) is by no means an admission or concession that SRS has stated a plausible claim for relief or has adequately alleged proximate causation of damages. SRS has not done either. Indeed, even if SRS's allegations of breach were credited, Alexion vigorously disputes that those alleged acts have caused or will cause SRS to lose out on any Earn-Out Payments, let alone all of them.

More fundamentally, though, SRS's Opposition misapprehends the different gating functions served by 12(b)(1) and 12(b)(6). Alexion has moved to dismiss under Rule 12(b)(1), which serves to ensure that the Court has subject matter jurisdiction over the claim. "Ripeness, the simple question of whether a suit has been brought at the correct time, goes to the very heart of whether a court has subject matter jurisdiction." *Bebchuck v. CA, Inc.*, 902 A.2d 737, 740 (Del. Ch. 2006). A principal purpose of the ripeness doctrine is the conservation of judicial resources. *Tenneco Automotive Inc. v. El Paso Corp.*, 2001 WL 1641744, at *6 (Del. Ch. Nov.

29, 2001) (citing Schick Inc. v. Amalgamated Clothing & Textile Workers Union, 533 A.2d 1235, 1239 (Del. Ch. 1987)). In addition, Rule 12(b)(1) involves prudential discretion, and "requires a commonsense assessment of whether the interests of the party seeking immediate relief outweigh the concerns of the court in postponing review until the question arises in some more concrete and final form." XI Specialty Ins. Co. v. WMI Liquidating Tr., 93 A.3d 1208, 1217 (Del. 2014).

This assessment involves considerations such as whether "the prospect of future factual development that might affect the determination to be made," "a practical evaluation of the legitimate interest of the plaintiff in prompt resolution of the question presented and the hardship that further delay may threaten," and "the need to conserve scarce resources," among others. *Id.* at n.43 (citing *Schick*, 533 A.2d at 1239). By contrast, "Rule 12(b)(6) serves a gatekeeping function and ensures" that "the plaintiff can make out the bare facts necessary to support a claim." *IMO the LW & T of Hurley*, No. CIV.A. 8473-ML, 2014 WL 1088913, at *1 (Del. Ch. Mar. 20, 2014).

Plainly, Rule 12(b)(1) and Rule 12(b)(6) serve different purposes. SRS's interpretation of Rule 12 (b)(6) would eviscerate Rule 12(b)(1) and render it meaningless. These are separate inquiries, however, and for Count I to survive dismissal, SRS must adequately allege breach of contract *and* the Court must have

subject matter jurisdiction over the claim. Here, the claim is not ripe for reasons stated in Alexion's Motion to Dismiss and discussed further below.

B. SRS's Allegation That A Breach Has Occurred Does Not Render its Claim Ripe³

SRS argues that Count I should proceed now, and the question of whether it is entitled to \$800 million in Earn-Out Payments should be decided solely on the facts that occurred before the filing of its Complaint. *See* Opp. at, *e.g.*, 22 ("the facts establishing Alexion's past breach have already 'come to rest and are not subject to change."); n.9 ("SRS's breach-of-contract claim requires the Court to assess whether Alexion has already breached the CRE provision...not to monitor Alexion's

³ None of the cases that SRS cites in support of this argument are on point. *Worrel, ISN Software, Whittle,* and *Dreis & Krump,* which SRS string cites for the proposition that "a claim for breach of contract is ripe when the breach occurs" (Opp. at 20-21), each deal with accrual of an action for purposes of statute of limitations, which is plainly not relevant to the question at hand. *See Worrel v. Farmers Bank of State of Del.,* 430 A.2d 469, 472 (Del. 1981); *ISN Software Corp. v. Richards, Layton & Finger, P.A.,* 226 A.3d 727, 732, n.22 (Del. 2020); *Whittle v. Loc. 641, Int'l Bhd. of Teamsters, Chauffeurs, Warehousmen & Helpers of Am.,* AFL-CIO, 56 F.3d 487, 489 (3d Cir. 1995). *Hayward* is also plainly distinguishable since, there, the Court expressly found that "here, all of the underlying material facts have come to rest and are not subject to change." *Alro Assocs., L.P. v. Hayward,* No. CIV.A. 19544, 2003 WL 22594526, at *5, n.22 (Del. Ch. Oct. 31, 2003), *aff'd*, 847 A.2d 1121 (Del. 2004). As explained throughout Alexion's Motion to Dismiss and this Reply, the facts of the present suit, by contrast, have not "come to rest," and are "subject to change."

future conduct."). SRS's argument should not be countenanced here, where the parties negotiated for and agreed to a diligence period, and only two of those years have passed. Thus, unless SRS contends that any intervening events between the date of its Complaint and the end of the diligence period will not affect the fact of its alleged injury — *i.e.*, the failure to achieve one or more of the Earn-Out Payments — Count I is not ripe for adjudication.

Here, *none* of the individual Earn-Out Payments is tied to a specific deadline. See Merger Agreement, § 3.8. Accordingly, SRS is only harmed if Alexion never achieves a Milestone Event, and even then, harm is not a forgone conclusion, because the Merger Agreement specifically provides that their achievement is not guaranteed. See Mot. at n.7. Critically, SRS does not allege that Alexion cannot or will not achieve some or all of the Milestone Events that give rise to Earn-Out Payments in the future. SRS's inability to do so highlights why its claim is not ripe: there are simply too many potential intervening events and decision points that will of Alexion's diligence period that will impact occur during the remaining whether the Milestone Events and Earn-Out Payments are ultimately achieved. Simply put, if events to come are such that the plaintiff may have no injury in fact, the claim is not ripe for adjudication — this is precisely why SRS's claim is not ripe. See Fazio Mech. Servs., Inc. v. Artex Risk Sols., Inc., No. CV N16C-08-119

JAP, 2017 WL 77001, at *2 (Del. Super. Jan. 6, 2017) (dismissing claim as unripe because "[i]t may be that [hypothetical occurs]. In such case, the instant plaintiffs will not have suffered any damages stemming from the alleged breach of contract and negligence.").⁴

Furthermore, SRS's position invites precisely the sort of serial litigation that this Court's ripeness rules are designed to prevent. *See UbiquiTel Inc. v. Sprint Corp.*, No. CIV. A. 1489-N, 2006 WL 44424, at *3 (Del. Ch. Jan. 4, 2006) ("Whenever a court examines a matter where facts are not fully developed, it runs the risk not only of granting an incorrect judgment, but also of taking an inappropriate or premature step in the development of the law."). Should the Court not dismiss Count I on ripeness grounds, it would establish a precedent that allows SRS (or any other shareholder representative) to turn this Court into a referee, calling balls and strikes over each and every decision made by Alexion (and other buyers) in real time. Further, it would strip away the bargained-for discretion over ALXN1830's development that the Merger Agreement confers on Alexion.

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⁴ While SRS attempts to distinguish *Fazio Mech*. on the grounds that, "at the time, there were no current damages" (Opp. at n.10), that is precisely why *Fazio Mech*. is analogous to the present situation: SRS will only suffer damages if Alexion never achieves any Milestone Events, which is impossible to adjudicate on the current record.

Tellingly, SRS has not cited a single analogous CRE case to support its position that a claim for breach of a CRE clause should proceed before the defendant's time to exercise CRE has lapsed or where the defendant was still pursuing the relevant Milestone Events and Earn-Out Payments:

- In *Neurvana Med. v. Balt*, Neurvana filed suit on Jan. 17, 2019, alleging that Balt had failed to use "Commercially Reasonable Efforts' to achieve the CE Mark Milestone on or before Sept. 30, 2018." *See Neurvana Med., LLC v. Balt USA, LLC*, No. CV 2019-0034-KSJM, 2020 WL 949917, at *4 (Del. Ch. Feb. 27, 2020). Thus, Balt's CRE diligence period had already lapsed.
- In *WeWork*, the plaintiffs filed suit on April 7, 2020, alleging that "SBG and Vision Fund breached various provision[s] in the MTA, including their obligation to use reasonable best efforts to consummate the JV Roll-Ups" "by November 9, 2019." *See In re WeWork Litig.*, No. CV 2020-0258-AGB, 2020 WL 6375438, at *4-*5 (Del. Ch. Oct. 30, 2020). Thus, the reasonable best efforts diligence period had already lapsed.
- In *Himawan v. Cephalon*, the plaintiffs alleged "that Cephalon did not use 'commercially reasonable efforts' to develop and commercialize RSZ for EoE." *See Himawan v. Cephalon, Inc.*, No. CV 2018-0075-SG, 2018 WL 6822708, at *6 (Del. Ch. Dec. 28, 2018). While Cephalon's CRE diligence period had not yet lapsed, Cephalon "had abandoned its efforts to develop and commercialize RSZ as a treatment for EoE." *See id.* at *5 ("Plaintiff's bring a breach of contract ... alleging that by abandoning efforts").
- In *BrowserCam v. Gomez*, the plaintiff alleged "that defendant breached the purchase agreement because it failed to expend at least \$250,000 on marketing" "by June 30, 2008." *See BrowserCam Inc. v. Gomez, Inc.*, No. C 08-02959 WHA, 2008 WL 4408053, at *7 (N.D. Cal. Sept. 26, 2008). While the *BrowserCam* complaint was

filed "on June 13," two weeks before June 30, 2008, this is hardly analogous to the present situation, where SRS has filed suit only two years into Alexion's diligence period. *Id.* Moreover, the *BrowserCam* deadline had come and passed by the time the motion to dismiss was briefed and decided. *Id.*

In Amato v. Mesa Labs., plaintiff Anthony Amato alleged that his termination breached "the Earn-Out Agreement's requirement to use commercially reasonable efforts to grow, market, and develop the business," since he was "the only management-level Mesa employee with first-hand knowledge of the [relevant] market." Amato v. Mesa Labs., Inc., No. 14-CV-03228-REB-KMT, 2015 WL 5332117, at *7 (D. Colo. Aug. 14, 2015), report and recommendation adopted in part, rejected in part, No. 14-CV-03228-REB-KMT, 2015 WL 5321446 (D. Colo. Sept. 14, 2015). Notably, the Colorado court found that "Plaintiffs cannot show any resultant damages" from the alleged breach, but permitted Amato to maintain his claim because Colorado law, unlike Delaware law, permits a party to bring a claim for immaterial breach of contract. Compare id. (emphasis added) with VLIW Tech., LLC v. Hewlett-Packard Co., 840 A.2d 606, 612 (Del. 2003) ("resultant damage to the plaintiff" is required to state a claim for breach of contract) (emphasis added).

In contrast, *UMB Bank v. Sanofi* is on point. That case considered a "diligent efforts" challenge analogous to SRS's CRE claim, and the claims were dismissed. Pursuant to Sanofi's acquisition of Genzyme, Sanofi agreed to use "diligent efforts" (*i.e.* "such efforts employing such resources normally used by Persons in the pharmaceutical business...") to meet certain enumerated "Product Sales Milestones" ("PSMs") for Genzyme's drug Lemtrada. *See Umb Bank., N.A. v. Sanofi*, No. 15 CIV. 8725 (GBD), 2016 WL 4938000, at *1-*2 (S.D.N.Y. Sept. 8, 2016).

Genzyme's successor in interest, UMB Bank, alleged that Sanofi "failed to use diligent efforts" because it "embarked on a slow path to FDA approval and departed from its own drug commercialization patterns and those of others in the industry, causing [Sanofi] to miss the product sales milestones." Id. at *5 (internal punctuation omitted). The diligence period associated with milestone 1 ("PSM #1"), i.e. sales of \$400 million, had come and passed, so the court allowed UMB Bank's claim to proceed on that milestone. See id. at *1, *6. The Court declined to proceed on allegations directed to milestones 2-4 ("PSM #2-4"), however, since the diligence period for those milestones ran for another four years. Id. at n.6; see also UMB Bank, N.A. v. Sanofi, No. 15CIV8725GBDJCF, 2017 WL 4005627, at *3 (S.D.N.Y. Aug. 23, 2017) ("the court has ruled that claims for payment default under the outyear Product Sales Milestones are not yet ripe," ... "there can be no present claim based on sales milestones two through four."). Count I of SRS's Complaint is analogous to milestones 2-4 in UMB Bank v. Sanofi, and is similarly not ripe since Alexion's diligence period extends for another and Alexion is actively pursuing ALXN1830 for regulatory approval and commercialization.⁵

⁵ SRS alleges that "according to Alexion, no controversy over CRE could be ripe for adjudication until …" Opp. at 2. Not so. If the facts were such that Alexion's ability to achieve Milestone Events before the end of the diligence period were irretrievable, *e.g.* if Alexion discontinued the ALXN1830 program, as in

Further, in just the short span of time since SRS filed its Complaint, and even since Alexion filed its Motion to Dismiss, there have been multiple events in the ongoing development of ALXN1830 that demonstrate precisely why SRS's CRE claim should not be adjudicated at this time. For example, on for a Phase 2 clinical trial for ALXN1830: study ALXN1830-WAI-202 for patients with warm autoimmune hemolytic anemia (WAIHA). Ex. 7 at 2. On another Phase 2 clinical trial for ALXN1830: study ALXN1830-gMG-201 for patients with myasthenia gravis (gMG). Id. Alexion plans to begin dosing subjects in both of these new studies in the second half of 2021 (id.), bringing Alexion closer to achieving at least Milestone . See Mot. at 18; Merger Agreement, § 3.8(a). Additionally, on **Events** , ALXN1830-HV-108, moving Alexion nearer to achieving Milestone Event .6 Id.; see also Mot. at 10-11 (describing the ALXN1830-HV-108 trial, which had

Himawan v. Cephalon, a claim for breach of CRE could conceivably be ripe. Those are not the present facts, however.

The allegation from SRS's Opposition that "no clinical trials are currently underway" (Opp. at 8), is plainly false.

when Alexion filed its Motion to Dismiss). Moreover, by the time Alexion's Motion to Dismiss is argued and decided, further clinical developments may have taken place.

Clearly, the events that took place between Alexion's acquisition of Syntimmune and SRS's filing of this suit cannot be viewed and litigated in an isolated vacuum, as SRS suggests, because they form an interconnected web of decision points and developments that begin with decisions Syntimmune made preacquisition, and continue to Alexion's present clinical developments and commercialization plans and efforts. SRS's allegations of present breach — which Alexion disputes — do not cure the fact that the record needed to adjudicate the claim is incomplete, and SRS has cited no authority to suggest that a CRE claim should proceed under these circumstances.

C. SRS's Damages Arguments Are Irrelevant

SRS's Opposition argues that Count I is ripe because "the Complaint also plainly alleges injury and damages caused by that breach." Opp. at 24-25. Again, this is a Rule 12(b)(6) argument directed to the elements for stating a claim for breach of contract; this is not a ripeness argument. SRS's Opposition never explains why SRS would be prejudiced if this litigation is delayed until the underlying factual predicate is complete. In fact, just the opposite is true: SRS seeks an advance of

hundreds of millions of dollars in Earn-Out Payments before such Milestone Events are achieved. To the extent there is any prejudice, it is borne by Alexion, not SRS. Moreover, SRS is not requesting any form of specific performance or time-sensitive equitable relief, and SRS's damages claim, *i.e.* "the sum total of all unpaid Earn-Out Payments," will be the same regardless of when it brings this suit. Complaint, ¶ 215.

As explained above, SRS can only show harm if Alexion never achieves certain Milestone Events, but even then, harm is not a foregone conclusion. SRS cannot claim that it has been harmed simply because it hasn't been paid *yet*, particularly since none of the Milestone Events have been achieved and remain on a diligence period.^{7, 8} Thus, unless SRS posits that, given the difficulties and delays over the first two years of the diligence period, the situation

⁷ For this reason, SRS's argument that Alexion's "theory would make a breach of contract claim unripe in countless cases where a party fails to make require payments—based on nothing more than the defendant's assertion that it might pay some point in the future" (Opp. at 25-26), is plainly based on a false analogy. No Milestone Events have been achieved to date by Alexion, but remain on a diligence period. Plainly, Alexion has not "fail[ed] to make required payments" that are due and owing to SRS. *Id*.

⁸ SRS criticizes Alexion's reliance on "declaratory judgment cases," arguing that they are distinguishable since the "Securityholders have [already] suffered monetary damages." Opp. at 22-23. To the contrary, since SRS has not been harmed, SRS's supposed factual distinction is actually why these cases and their holdings are analogous to SRS's claims, and support a finding that Count I is not ripe.

is irretrievable and its alleged injury inevitable, SRS's Count I is premature because future intervening events may prevent any injury in fact. The bargained-for terms of the Merger Agreement further illustrate the lack of prejudice to SRS for at least two significant reasons.

First, the Merger Agreement contains a "catch-up" provision that protects SRS by obligating Alexion to pay SRS any Earn-Out Payments which "would reasonably have been anticipated to precede" any subsequent Earn-Out Payments. *See* Merger Agreement, § 3.8(d). Thus the parties specifically contemplated a scenario where early Milestone Events might not be met, but later ones would be. Under such a scenario, SRS would still receive payment for earlier milestones, albeit at a later point in time.

Second, SRS negotiated a diligence period without any interim deadlines. SRS cannot retroactively change the terms of its bargain by claiming prejudice for not having been paid *before* Alexion achieves any of the Milestone Events. Thus, SRS's complaints about "postpon[ing] consideration of SRS's claim" ring hollow (*see* Opp. at 30-31) and its suggestion that Alexion's ripeness defense could postpone consideration of SRS claim "indefinitely" (*id.* at 30) simply takes Alexion's argument too far.

Finally, SRS's arguments regarding "offset" of damages are likewise inapposite. Alexion has never argued that SRS's harm may be "offset" or "reduced" because Alexion may achieve some or all of the Milestone Events and make the corresponding Earn-Out Payments. By contrast, Alexion argues that SRS will suffer no harm at all if Alexion achieves some or all of the Milestone Events and makes Earn-Out Payments, since none of them are tied to specific deadlines. See Mot. at 19, 22-23. For this reason, SRS's heavy reliance on Nama Holdings is misplaced, since, there, "the alleged injury still exist[ed] despite the occurrence of intervening events." NAMA Holdings, LLC v. Related World Mkt. Ctr., LLC, 922 A.2d 417, 435 (Del. Ch. 2007). SRS has, therefore, devoted pages of argument to the refutation of a point that Alexion never made.

Simply put, Alexion's arguments are not directed to "offset," "mitigation," or "recoupment" (Opp. at 27-28), all of which relate to calculation of damages; rather, Alexion's arguments go to whether damages, in fact, exist, and thus whether the claim is even ripe for adjudication. Indeed, all of SRS's cited cases address the calculation of damages, rather than the threshold issue of whether damages (or injury in fact) have occurred. *See Levien v. Sinclair Oil Corp.*, 314 A.2d 216 (Del. Ch. 1973) (post-trial opinion on computation of damages); *Bobcat N. Am., LLC v. Inland Waste Holdings, LLC*, No. CVN17C06170PRWCCLD, 2020 WL 5587683, at *7

(Del. Super. Sept. 18, 2020) (denying summary judgment motion on whether certain settlement payments should be subtracted from any awarded damages). Notably, SRS cannot say that its alleged injury will still exist despite the occurrence of intervening events over the next of the diligence period.

D. Alexion's Direct Claim For Indemnification Does Not Share A "Nearly Identical Nexus Of Facts" With SRS's Claim For Breach Of CRE

SRS argues that this Court should not dismiss Count I because it shares "a nearly identical nexus of facts" with Count II of SRS's Complaint and Alexion's Counterclaim against SRS. Opp. at 4, 31-32. SRS's argument fails.

Alexion's Counterclaim asserts that Syntimmune breached representations and warranties that it made to Alexion in the Merger Agreement since all the drug substance and drug product that Alexion acquired at the time of acquisition was unsafe for human use, and unusable. *See generally*, Alexion's Counterclaim, Dkt. 48. Whether Syntimmune breached the representations and warranties that it made to Alexion in Section 4.13 of the Merger Agreement is a discrete question that involves an examination of the manufacturing practices that Syntimmune put in place *before the Merger Agreement was executed*.

By contrast, whether Alexion has used Commercially Reasonable Efforts in its development and commercialization of ALXN1830 involves an examination of

the events that took place *after the Merger Agreement was executed* and Alexion took over. These are separate universes of fact. While remediating the manufacturing issues that underlie Syntimmune's breach of its representations and warranties is necessarily related to the decisions that Alexion made as it exercised commercially reasonable efforts to develop ALXN1830, the inverse is not true, *i.e.* Alexion's exercise of commercially reasonable efforts after acquisition is unrelated to whether or not Syntimmune breached its representations and warranties before the acquisition. Accordingly, these claims are separable and dismissing Count I of SRS's Complaint, while proceeding on Count II and Alexion's Counterclaim, will not "undermine judicial economy." Opp. at 32.

III. <u>CONCLUSION</u>

For the reasons articulated in Alexion's Opening Brief and the foregoing Reply in support thereof, Alexion respectfully requests that this Court grant its Motion to Dismiss Count I of SRS's Complaint.

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