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Case No. 2023-0952-SKR

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

SHAREHOLDER REPRESENTATIVE SERVICES, LLC, solely in its capacity as Stockholders' Representative of the Stockholders of Potenza Therapeutics, Inc.,	)	
Plaintiff,	)	
v.	)	C.A. No. 2023-0952-SKR
ASTELLAS PHARMA INC, a corporation organized and existing under the laws of Japan,	)	
Defendant.	)	

Submitted: December 19, 2025
Decided: March 31, 2026
Corrected: April 2, 2026*

Upon Consideration of Plaintiff's Motion for Summary Judgment:
DENIED

Upon Consideration of Defendant's Motion for Summary Judgment:
GRANTED in Part and Denied in Part

Blake A. Bennett, Esq., Dean R. Roland, Esq., COOCH AND TAYLOR, P.A., Wilmington, Delaware, Joshua Konecky, Esq., Nathan Piller, Esq., SCHNEIDER WALLACE COTTRELL KIM, LLC, Emeryville, California, *Attorneys for Plaintiff.*

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CORRECTED MEMORANDUM OPINION

Rennie, V.C. (by designation)

*This decision has been reissued to correct the date of submission.

I. INTRODUCTION

At its heart, this is a case about a milestone that one party claims was reached and the other claims was never met. It involves a sophisticated pharmaceutical acquisition where the ultimate purchase price was tied to the clinical success of experimental cancer drugs. Under the terms of the parties' agreement, specific payments were triggered if and when the developed therapies advanced into the second phase of human clinical trials.

The Plaintiff, representing the former stockholders of the acquired company, alleges that the Defendant reached these milestones through expanded study protocols and must now pay the agreed-upon amounts. The Defendant, however, maintains that the studies were terminated before they ever officially crossed the threshold into Phase 2.

The Court is thus tasked with determining whether the scientific evolution of these clinical trials triggered a legal obligation to pay. While the parties' dispute involves complex medical protocols and "expansion cohorts," the fundamental question is one of contract: whether the Defendant's actions constitute the "initiation" of the phase required to trigger the next round of payments.

II. BACKGROUND[1]

A. The Parties

"Plaintiff Shareholder Representative Services LLC ("SRS") is an independent services company that acts as a representative, agent, and attorney-in-fact on behalf of the shareholders and stockholders of privately held companies after their acquisition."[2] It was appointed to serve as the Stockholders' Representative for the stockholders of Potenza Therapeutics, Inc. ("Potenza") on December 13, 2018.[3]

Defendant Astellas Pharma Inc. is a global life sciences company engaged in the research, development, manufacture, and sale of pharmaceutical and other therapeutic products.[4] Its U.S. headquarters are located in Illinois.[5]

B. Nature of the Case

i. The Collaboration and Acquisition

On April 21, 2015, Potenza, a developer of oncology therapies, entered into a Collaboration Agreement and a Warrant Purchase Agreement ("WPA") with Defendant Astellas.[6] The Collaboration Agreement, established a 42-month framework in which Potenza conducted pre-clinical discovery and development of

[1] The facts are drawn from the Amended Complaint (D.I. 29) and the documents incorporated therein. Additional facts are drawn from the parties' briefing. *See* D.I. No. 81 (DMSJ), No. 88 (PMSJ), No. 95 (DAB), No. 96 (PAB), No. 104 (DREPLY), and No. 108 (PREPLY).
[2] Am. Compl. ¶ 8.
[3] *Id*.
[4] *Id.* at ¶ 9.
[5] *Id.*
[6] PMSJ 4.

new drugs while Astellas led clinical development.[7] During this period, the parties developed three potential immuno-oncology therapies: ASP8374, ASP1948, and ASP1951.[8]

The WPA granted Astellas the option to purchase Potenza for an upfront payment of $164.4 million and various milestone payments (the "Milestone Payments") tied to the clinical development and commercialization of these compounds.[9] On December 14, 2018, Astellas exercised its option and acquired Potenza.[10] Plaintiff SRS was appointed as representative for Potenza's Stockholders.[11]

ii. The Clinical Trial Framework

The Milestone Payments under the WPA are related to the regulatory phases of drug development. Clinical trials in the United States, broadly speaking, follow a three-phase process, defined in 21 CFR § 312.21. Phase 1 focuses on establishing drug safety.[12] Phase 2 determines the efficacy of the drugs in targeted populations.[13] Phase 3 expands trials to evaluate the benefit-risk relationship of the drug.[14] In

[7] *Id.* at 5.
[8] DMSJ 15–16.
[9] *See* WPA. The WPA is available, among other places in the record, as Exhibit 5 Defendant's Motion for Summary Judgment.
[10] PMSJ 24.
[11] DMSJ, Ex. 4. Membership of the Advisory Committee has shifted over time. *See* DMSJ 30.
[12] 21 CFR § 312.21(a).
[13] *Id*. at § 312.21(b).
[14] *Id*. at § 312.21(c).

addition to these "integer-level" phases, firms often use gradated terms to label studies, such as "Phase 1b" or "Phase 2a."

During the parties' collaboration, each of the therapies was subject to FDA protocols that contemplated the potential use of a "Bayesian Optimal Phase 2 (BOP2) design Expansion Cohort"—the use of which sits at the center of this dispute.[15]

iii. The Present Dispute

*A*stellas continued developing the products for a time but eventually terminated the studies.[16] SRS now alleges that Astellas breached the WPA by failing to remit mandated Milestone Payments. The central question is whether the initiation of the "expansion cohorts" constituted the commencement of a Phase II Clinical Trial under the WPA thereby triggering the Defendant's duty to pay.

C. Procedural History

Plaintiff SRS commenced this action on September 20, 2023, originally naming several additional defendants.[17] Following a motion to dismiss filed by Astellas[18] the parties entered into a stipulation that resolved various preliminary

[15] *See e.g.* DMSJ 17–22; *Id.*, Ex. 25 at API00124312; *Id.*, Ex. 33 at API00160210; *Id*., Ex. 37 at APRI 00161146; *Id.*, Ex. 38 at API00018902.
[16] *See id.*, Ex. 63.
[17] D.I. No. 1.
[18] D.I. No. 20.

concerns.[19] Consequently, SRS filed an Amended Complaint,[20] which Astellas answered,[21] effectively narrowing the scope of the litigation to the present contractual dispute.

The Amended Complaint pleads a single count for breach of the WPA, though SRS advances two distinct theories of liability. First, SRS alleges that Astellas failed to remit two Milestone Payments triggered by the initiation of Phase 2 clinical trials.[22] Second, SRS contends that Astellas breached its contractual obligation to act in good faith and refrain from acting in bad faith throughout the development process. [23]

Upon the conclusion of discovery, the parties filed cross-motions for summary judgment on September 12, 2025,[24] each seeking a final ruling in their favor. The motions were fully briefed following the submission of opposition briefs on October 22, 2025,[25] and respective replies on November 21, 2025.[26] The Court heard oral argument on December 19, 2025, and the motions are now ripe for adjudication.

[19] D.I. No. 28.
[20] Am. Compl.
[21] D.I. No. 31.
[22] Am. Compl. ¶¶ 61–68, 70, 78.
[23] *Id*. at ¶¶ 65, 69, 71–78.
[24] DMSJ; PMSJ.
[25] DAB; PAB.
[26] DREPLY; PREPLY.

III. STANDARD OF REVIEW

Summary judgment is proper when there is no genuine issue of material fact, and the movant is entitled to judgment as a matter of law.[27] Accordingly, "[s]ummary judgment will not be granted if there is a material fact in dispute or if it seems desirable to inquire thoroughly into the facts in order to clarify the application of the law to the circumstances."[28] On a motion for summary judgment, "[a]ll facts and reasonable inferences must be considered in a light most favorable to the non-moving party."[29] Where, as here, the parties have filed cross-motions for summary judgment, the Court may "deem the motions to be the equivalent of a stipulation for decision," under the summary judgment standard.[30]

IV. ANALYSIS

A. The WPA's Definition of "Phase II Clinical Trial"

Although the relevant trials submitted to the FDA were labeled "Phase 1b" the Milestone Payments under the WPA are not governed by FDA labeling. Instead, the WPA defines a Phase II Clinical Trial as:

> [A] study in humans, conducted by or on behalf of any member of the R&D Program Rights Chain Group, of a Development Product that is designed to evaluate a Development Product's short-term safety and preliminary efficacy for patients with the disease or

[27] Ct. Ch. R. 56(c).
[28] *Gibbs v. 84 Lumber Co.*, 2020 WL 5798072, at *2 (Del. Super. Sept. 28, 2020) (internal quotation omitted).
[29] *Nutt v. A.C. & S. Co.*, 517 A.2d 690, 692 (Del. Super. 1986).
[30] Ct. Ch. R. 56(h). *See also Hastings Funeral Home, Inc. v. Hastings*, 2022 WL 16921785, at *4 (Del. Ch. Nov. 14, 2022).

> condition, as further described in 21 CFR §312.21(b), or similar clinical study in a country other than the United States.[31]

This contractual definition references 21 CFR § 312.21(b), which states:

> Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.[32]

The parties agree that the products at issue were evaluated for short-term safety and preliminary efficacy.[33] However, they diverge on whether that evaluation triggered a Phase II Milestone Payment. Astellas contends that preliminary efficacy can be evaluated within a Phase 1(b) study design without implicating the WPA's Phase II Clinical Trial.[34] Astellas further argues the use of the definite article "the" in the phrase "the disease or condition under study" requires a study design focused on one specific disease.[35] Astellas relies on the definition's reference to 21 CFR §312.21(b) to argue that a Phase II study must focus "on a particular indication or indications within "the disease or condition under study."[36]

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[31] WPA § 1.1.
[32] 21 CFR § 312.21.
[33] *See* DMSJ 53.
[34] *See* DAB 27.
[35] DMSJ 35.
[36] *Id.* at 36.

The interpretation of the phrase "disease or condition" is further complicated by WPA Section 1.3(d), which provides that "words denoting the singular shall include the plural and vice versa,"[37] "unless otherwise specified[.]"[38] Because the language at issue is part of a negotiated defined term, the Court finds that the parties have "otherwise specified" the meaning, and the general interpretive rules of Section 1.3(d) do not override the specific definition of a Phase II Clinical Trial.[39]

SRS takes the position that the Phase 1b studies transitioned into Phase 2 when they began evaluating preliminary efficacy under a "Phase 2 statistical rationale."[40] Specifically, SRS points to the use of a "Bayesian Optimal Phase 2 design" ("BOP2")— a futility test used to make go/no go development decisions based on whether a drug meets a specific efficacy hypothesis.[41]

Astellas takes umbrage with this focus on BOP2 design, noting that the argument regarding BOP2 Expansion Cohorts was absent from the amended complaint and prior discovery responses.[42]

Ultimately, for the purpose of the initial statute of limitations analysis, the Court will temporarily adopt the Plaintiff's framework without yet reaching a

[37] WPA § 1.3(d).
[38] *Id.* at § 1.3.
[39] *See id.* at § 1.1 ("Unless the context otherwise requires, the following terms in this Agreement with initial letters capitalized shall have the meanings set forth below[.]").
[40] PREPLY 6.
[41] PAB 39.
[42] DREPLY 3–5.

determination on the merits of the clinical classification. Because SRS's theory—that the "Phase 2" Milestone was triggered by the implementation of the BOP2 design—establishes the latest possible accrual date for its claims, the Court will utilize this timeline as the operative baseline. By assuming, *arguendo*, that the initiation of BOP2 Expansion Cohorts could satisfy the WPA's bespoke definition, the Court can first address the threshold issue of timeliness before turning to the substantive question of whether these trials actually met the contractual criteria for Phase II Clinical Trials.

B. Milestone Accrual

Only two of the WPA's Milestone Payments are in dispute. The first provides for a payment of $80,000,000 "upon Initiation of the first Phase II Clinical Trial of any Development product."[43] The second provides for a payment of $35,000,000 "upon Initiation of the first Phase II Clinical Trial of any Development Product other than the Development Product for which the [first] Milestone Payment …was previously paid[.]"[44] Under the WPA, each payment is "deemed earned as of the first achievement of the corresponding Milestone" and must be paid within sixty

[43] WPA § 3.4(a)(v)(A). Initiation is also a defined term in the WPA, meaning "as to a clinical trial, the first dosing of the first study participant with a pharmaceutical product in such clinical trial." *Id.* at § 1.1.
[44] *Id.* at § 3.4(a)(v)(B).

days of achievement.[45] Further, if a development phase is skipped, the corresponding Milestone is "deemed achieved."[46]

SRS contends that these payments should be triggered by the first Phase II Clinical Trial of *any* development product, arguing that a triable issue of fact exists as to whether later-originating products—such as the combination of ASP1951 with pembrolizumab—could trigger the obligation to make the Milestone Payments.[47]

The Court finds that this proposed reading contorts the plain language of the WPA. When read in conjunction with Section 3.4(b) the agreement clearly establishes that the $80 million Milestone Payment is earned upon the initiation of the first Phase II Clinical Trial for the *initial* Development Product to reach that stage.[48] Likewise, the $35 million payment is due upon initiation of the first Phase II Clinical Trial for a *different* Development Product.[49]

This interpretation is further bolstered by WPA Section 3.4(c), which states: "For the avoidance of doubt: . . . each Milestone Payment shall become payable only upon the first occurrence of the applicable Milestone."[50]

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[45] *Id.* at § 3.4(b).
[46] *Id*.
[47] PAB 46–49.
[48] WPA § 3.4(a)(v)(A).
[49] *Id.* at § 3.4(a)(v)(B).
[50] *Id.* at § 3.4(c).

C. Bad Faith

In addition to the specific Milestone Payments, Astellas could also be liable to SRS under a theory of bad faith. Section 3.4(d) of the WPA includes a commitment by Astellas to "(A) act in good faith and use Commercially Reasonable Efforts to achieve the Milestones and (B) refrain from taking any action in bad faith or contrary to Commercially Reasonable Efforts the primary effect of which is to prevent, the realization or achievement of any of the Milestones."[51] This contractual duty was set to persist until the earlier of the payment of all potential Milestones or the tenth anniversary of the Collaboration term.[52]

While the parties dispute whether Astellas met this standard during its development and eventual termination of the studies, a threshold procedural question exists as to whether these claims, alongside the payment claims, were timely filed.

D. Statute of Limitations

Astellas contends that SRS's claims are time-barred.[53] The parties do not dispute that the claims for failure to pay Milestone Payments, sounding in breach of contract, are subject to a three-year statute of limitations.[54] However, they disagree on the applicable period for the Section 3.4(d) claim regarding the implied duty of

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[51] *Id.* at § 3.4(d).
[52] *Id*.
[53] DMSJ 43–63.
[54] *See Sykes v. Touchstream Techs., Inc.,* 2024 WL 1299928, at *10 (Del. Ch. Mar. 27, 2024). Plaintiff does not raise any argument about the relevant length of the statute of limitations as to the Milestone Claims.

good faith and fair dealing. SRS suggests that the period extends until the tenth anniversary of the end of the R&D collaboration term, while Astellas maintains it is three years from the date of the alleged breach.

Resolving this dispute first, the Court finds that although Astellas had a duty to act in good faith throughout the contractual period, any claim for breach of that duty accrued at the moment of the alleged breach. Accordingly, such a claim is subject to the standard three-year statute of limitations, from the date of accrual.

i. Accrual of Claims

SRS commenced this action on September 20, 2023.[55] To fall within the three-year limitations period, the alleged breaches must have occurred no earlier than September 20, 2020. In this context, a breach occurs if Astellas failed to remit either the $80 million or $35 million Milestone Payment within 60 days of the "Initiation" of a Phase II Clinical Trial.

Even if the Court adopts SRS's theory that BOP2 Expansion Cohorts are the trigger for initiation of a Phase II Clinical Trial, the record indicates that the BOP2 Expansion Cohorts began receiving treatment well before the September 2020 cutoff. Specifically, dosing for the ASP8374 Monotherapy began in March 2019,[56] followed by the ASP8374 Combination therapy started in May 2019.[57] The

[55] D.I. No. 1.
[56] DREPLY 20 (citing DMSJ, Ex. 22).
[57] *Id*.

ASP1948 Monotherapy commenced in September 2019,[58] and the ASP1948 Nivolumab Combination Therapy began in January 2020.[59] Assuming, as SRS contends, without deciding, that a Phase II Clinical Trial is initiated when dosing begins in an expansion cohort subject to BOP2 statistical design, SRS's claims would have accrued after the first and second Initiations of trials utilizing ASP8374, meaning that both claims would have accrued by May 2019—sixty days after the March 2019 Initiation. Even assuming that the Milestones can only be met by different products, SRS's claims would have accrued no later than November 2019, following dosing of the ASP 1948 Monotherapy. Because this date precedes the September 20, 2020 cutoff, SRS's claims are time-barred unless the Court finds a basis to toll the statute of limitations.

ii. Equitable Tolling

"[W]hen a complaint asserts a cause of action that on its face accrued outside the statute of limitations, 'the plaintiff bears the burden to show that a viable tolling

[58] *Id.* at 20–21 (citing DMSJ, Ex. 31). In SRS's Answering Brief, it argues that this exhibit is produced without foundation or explanation of its source and reserves its right to object. However, SRS fails to provide specific grounds for this objection and, notably, relies on that same exhibit to establish the timing of the ASP1948 Pembrolizumab Combination Therapy. *See Id.* 8–9. Discovery in this matter is now complete, and SRS has offered no contrary evidence regarding the dosing dates. Because there is a proffer made by one side without opposing evidence, this does not constitute a disputed issue of material fact. Accordingly, the Court is satisfied in relying on the dosing dates set forth in the exhibit for the purpose of its analysis.
[59] DREPLY 21 (citing DMSJ, Ex. 31).

doctrine applies.'"[60] SRS argues that a triable issue of fact exists as to whether equitable estoppel should toll the statute of limitations. Equitable tolling is an exception to the general rule, and is not lightly invoked.[61] To prevail, SRS must demonstrate by clear and convincing evidence that it (1) lacked knowledge or the means of obtaining knowledge of the truth of the facts in question, (2) relied on the conduct of the party against whom estoppel is claimed; and (3) suffered a prejudicial change of position because of that reliance.[62]

It is undisputed that the Shareholder Representative acquired actual knowledge of Astellas' use of BOP2 Expansion Cohorts no later than October 14, 2020.[63] SRS contends that if the Court finds this was the date of discovery and that tolling is warranted, its claims would be timely.

The Court is not persuaded, however, that SRS lacked the means of obtaining this knowledge prior to October 2020. As established *supra*, Potenza was aware during the collaboration period that BOP2 Expansion Cohorts were contemplated. Further, the fact that dose expansion was occurring was disclosed to SRS no later

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[60] *Saunders v. Lightwave Logic, Inc.*, 2024 WL 4512227, at *6 (Del. Super. Oct. 17, 2024) (quoting *Nalda v. Green Valley Home Inspections, LLC*, 2021 WL 3783640, at *4 (Del. Super. Aug. 24, 2021)).
[61] *Ambase Corp. v. City Investing Co.*, 2001 WL 167698, at *6 (Del. Ch. Feb. 7, 2001). *See also Pomeranz v. Museum P'rs, L.P.*, 2005 WL 217039, at *13 (Del. Ch. Jan. 24, 2005) ("Equitable exceptions to statutes of limitations are narrow and designed to prevent injustice.").
[62] *Pivotal Payments Direct Corp. v. Planet Payment, Inc.*, 2020 WL 7028597, at *4 (Del. Super. Nov. 30, 2020).
[63] PMSJ, Ex. FF.

than January 17, 2020.[64] Despite this, SRS failed to inquire into the specifics of the report, and appears to have relied on Astellas' representation that no Milestone had been achieved and that a "global Phase 1 study is ongoing."[65]

An estoppel may not rest upon an inference that is merely one of several possible interpretations.[66] As the parties' briefing makes clear, there is substantial disagreement regarding what constitutes a Phase I or Phase II Clinical Trial. Notwithstanding the WPA's use of a bespoke definition for these phases, SRS failed to inquire whether Astellas was utilizing FDA nomenclature or the specific WPA definition.

However, based on the combination of Astellas' January 2020 representation that no Milestones had been achieved and its concurrent representation that a "global Phase 1 study is ongoing," the Court finds that an outstanding issue of fact exists. The applicability of equitable tolling is a fact-intensive determination, and the Court is unwilling to rule as a matter of law that it does not apply based on the present record. Therefore, the availability of equitable tolling remains an issue for trial.

E. No Phase II Clinical Trials Occurred

Having determined that a triable issue of fact exists as to equitable tolling, the Court turns to the merits of the parties' positions. At this juncture, the Court departs

[64] DMSJ, Ex. 3.
[65] PMSJ, Ex. EE.
[66] *Employers' Liab. Assurance Corp. v. Madric,* 183 A.2d 182, 188 (Del. 1962).

from the temporary assumption that the BOP2 design serves as the distinguishing factor between trial phases and relies instead on the language of the WPA.

As discussed *supra*, the Court is persuaded that the use of the definite article "the" in the WPA's definition of Phase II Clinical Trial refers to a singular disease or condition. This creates an initial bar to SRS's argument, as each of the relevant trials involved patients with multiple diseases or conditions.[67] Under the specific terms of the WPA, a trial that studies multiple diseases cannot constitute a Phase II Clinical Trial. Accordingly, no Phase II Clinical Trials were initiated prior to termination of the studies.

SRS proposes that the Court consider expert deposition testimony and industry practice in its interpretation of the defined term "Phase II Clinical Trial." To do so, the Court would first need to find the term ambiguous, which it does not. Even if ambiguity existed, SRS has emphasized that "[t]he parties created their own definition of 'Phase II Clinical trial' based on functionality rather than label."[68] Consequently, general industry practices would be of limited value in guiding the Court's interpretation of this bespoke definition.

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[67] The ASP8374 study references administration of the drug to people with "locally advanced (unresectable) or metastatic solid tumor malignancies including but not limited to squamous cell carcinoma of the head and neck (SCCHN), non-small cell lung cancer (NSCLC), metastatic castration resistant prostate cancer (mCRPC), ovarian cancer, colorectal cancer (CRC), bladder cancer and gastric cancer." DMSJ, Ex. 25 at API00124297. Trials for ASP1948 (DMSJ Ex. 33 at API00160206–07) and ASP1951 (DMSJ, Ex. 38 at API00018899) were similarly broad.
[68] PMSJ 39.

The Court finds that a Phase II Clinical Trial means exactly what the WPA says: "a study in humans . . . that is designed to evaluate a Development Product's short-term safety and preliminary efficacy for patients with *the* disease or condition under study."[69] Because none of the trials at issue meet this definition, the Court finds that no Phase II Clinical Trials occurred and the Milestones Payments were not triggered. Accordingly, the Court GRANTS summary judgment in favor of Astellas on the issue of whether these trials initiated the Phase II Clinical Trial Milestones.

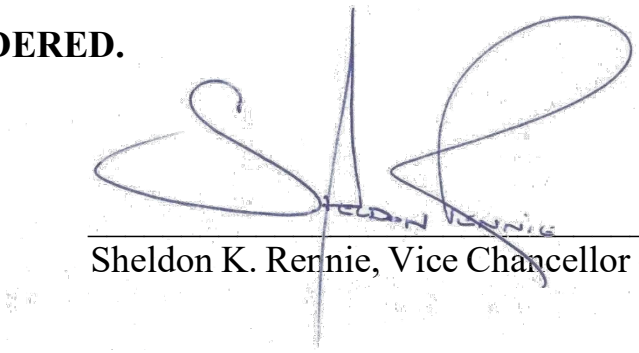
Finally, regarding the Section 3.4(d) claim, it is plausible that, viewing the facts in the light most favorable to the nonmovant, SRS could show that the trials were designed to avoid triggering Phase II Milestones in instances where the products did not progress to Phase III trials. As addressed in the statute of limitations analysis, SRS must still prove a theory of tolling to establish that its claim was timely. Nevertheless, the potential for tolling means the Court cannot grant full summary judgment to either party on this issue.

[69] WPA § 1.1 (emphasis added).

V. CONCLUSION

For the reasons set forth above, Plaintiff's Motion for Summary Judgment is **DENIED** and Defendant's Motion for Summary Judgment is **GRANTED in Part and DENIED in Part**.

IT IS SO ORDERED.



Sheldon K. Rennie, Vice Chancellor (by designation)