SUPREME COURT OF NOVA SCOTIA
Citation: *Pineo v. Sona Nanotech Inc.*, 2024 NSSC 230

Date: 20240828
Docket: No. 502894
Registry: Halifax

Between:

Scott Pineo

Plaintiff

v.

Sona Nanotech Inc., David Regan and Daniel Whittaker

Defendants

DECISION

Judge:	The Honourable Justice John A. Keith
Heard:	July 25, 26, 27, 2022, in Halifax, Nova Scotia
Final Written Submissions:	September 27, 2022
Counsel:	Eli Karp and Sage Nematollahi, for the Plaintiff Roderick Rogers, K.C. and Jason Woycheshyn for the Defendants

By the Court:

OVERVIEW

[1] In 2020, COVID-19 spread across the globe and precipitated an extraordinary public health crisis. Many companies mobilized to assist governments in fighting the virus and meet an immediate need for cures, treatments, and rapid detection tests.

[2] Sona Nanotech Inc. ("**Sona**") entered the race to develop viable, medical responses to the COVID-19 pandemic. Sona hoped to adapt its proprietary toxin-free gold nanorods technology for use as a rapid antigen test to screen patients potentially infected with the COVID-19 virus. (the "**COVID-19 Test**") The broader, corporate objective was to bring the COVID-19 Test to market and commercialize its potential in fighting the pandemic. To achieve this objective, Sona required regulatory approval from the United States' Food and Drug Administration ("**FDA**") and Health Canada.

[3] Both the FDA and Health Canada developed emergency, accelerated processes for approving drugs and devices with a proven capacity for strengthening the available protections against COVID-19. The FDA emergency approval was called an Emergency Use Authorization (or "**EUA**"). The equivalent approval from Health Canada was called an Interim Order (or "**IO**").

[4] In 2020, Sona began the process of obtaining approvals for its COVID-19 Test from both the FDA and Health Canada. Sona also began publicly expressing rowing confidence in its COVID-19 Test, culminating with a 22-page document released September 29, 2020, and entitled "Management Discussion and Analysis" for the nine-months of its fiscal year, ending July 31, 2020 (the "**Q3 2020 MD&A**").

[5] Following the release of the Q3 2020 MD&A, the Plaintiff, Scott Pineo, acquired and/or disposed of shares in Sona.

[6] In this action, he alleges that the Q3 2020 MD&A contains actionable misrepresentations under s. 146C(1) of Nova Scotia's *Securities Act*, R.S.N.S. 1989, c. 418 (the "***Securities Act***"). The alleged misrepresentations focussed on a clinical, in-field evaluation study conducted by an entity known as SaudiVax, the results of which were submitted to the FDA and Health Canada for regulatory approval of its COVID-19 Test.

[7] Mr. Pineo states that Sona's Q3 2020 MD&A "failed to disclose that Sona's submissions for the regulatory approval of its COVID-19 test were not supported by

appropriate or adequate validation data." (Pineo Written Submissions at para. 4) Put slightly differently, Mr. Pineo alleges that the Q3 2020 MD&A misrepresented important details regarding the SaudiVax clinical in-field evaluation study of the COVID-19 Test and, in doing so, misrepresented the strength or viability of Sona's submissions for regulatory approval from either the FDA or Health Canada.

[8] The particulars of the alleged misrepresentations which ultimately undermined regulatory approval may be briefly summarized as follows:

1. In the Q3 2020 MD&A, Sona states that SaudiVax was engaged to deliver the results of "…an independent clinical, in-field evaluation study ("**CES**")" for its COVID-19 Test (at p. 5, emphasis added). Mr. Pineo alleges that SaudiVax was not independent;

2. Sona misrepresented its COVID-19 Test as being suitable for all critical settings. Mr. Pineo alleges that the evaluation protocols for the in-field study being completed by Sona (using SaudiVax) failed to incorporate the current FDA Guidance, more specifically, did not test infected patients who were "confirmed negative" or "asymptomatic". Mr. Pineo concludes that: "…not only is it the case that Sona's evaluation protocol failed to incorporate the applicable regulatory guidance, but it also seems to have been the case that Sona's test was not fit for its intended use, thus Sona at all times knew or ought to have reasonably known that its COVID-19 test could never obtain regulatory approval." (Pineo Written Submissions at para. 58); and

3. The information or data generated by SaudiVax's in-field study was inappropriate, questionable, inaccurate and/or unreliable. The Q3 2020 MD&A stated the SaudiVax study results showed that the COVID-19 Test "… achieved a sensitivity1 of 84.6% and a specificity2 of 90.0%" (Q3 2020 MD&A at p. 5). Mr. Pineo alleges that the "sensitivity" rate was either incorrect, vastly exaggerated, and/or unreliable. He points to Health Canada separately testing 6 patients with Sona's COVID-19 Test and arriving at a sensitivity rate of 17% - not 84.6%. Mr. Pineo also alleges that the SaudiVax dataset was "irregular on its face"

   (Pineo written submissions at paras. 66 - 67).

[9] Between October 29, 2020, and November 30, 2020, Sona issued several press releases which Mr. Pineo says began to expose these misrepresentations and meet the statutory requirement for "corrective disclosure" under the Securities Act. The market's response to these press releases was quick and sharp. On October 29, 2020, Sona's price at closing was $7.55/share. By November 30, 2020, it plummeted about 86% to $1.09/share.

[10] By Notice of Action filed December 18, 2020, Scott Pineo filed a class proceeding under Nova Scotia's *Class Proceedings Act*, S.N.S. 2007, c. 28, as amended (the "***Class Proceedings Act***") seeking damages for the alleged misrepresentation. He did so on behalf of himself and other investors who purchased Sona's securities between September 29, 2020, and November 30, 2020 (the "**Proposed Class Members**").

[11] In addition to alleged misrepresentations under the *Securities Act*, Mr. Pineo also claims that:

1. Sona's actions while pursuing regulatory approval for the COVID-19 Test were oppressive or unfairly prejudicial to, or unfairly discarded the interests of, Mr. Pineo and the Proposed Class Members. Sona is a federally incorporated company. As such, Mr. Pineo seeks a remedy under s. 241(2) of the *Canada Business Corporations Act*, R.S.C. 1985, c. C-44, as amended (the "***CBCA***") – sometimes referred to as the "oppression remedy"; and

2. David Regan and Daniel Whittaker failed to fulfill their obligations as directors and officers of Sona including the statutory duty of care and diligence described in s. 122(1) of the CBCA.3 Mr. Regan served as Sona's Chief Executive Officer from July 8, 2020, forward. Mr. Whittaker was Chair of Sona's Board of Directors. The material facts alleged in support of these individual claims similarly arise out of Sona's actions while pursuing regulatory approval for the COVID-19 Test.

[12] In this motion, Mr. Pineo seeks leave to proceed with this action as required under s. 146H(1) of the *Securities Act*. If leave is granted, Mr. Pineo seeks a related Order that his action be certified under Nova Scotia's *Class Proceedings Act*, S.N.S. 2007, c. 28, as amended (the "***Class Proceedings Act****").*

[13] Mr. Pineo also moves under the *Class Proceedings Act* to certify the additional claims of oppression and alleged failure by Mr. Regan and Mr. Whittaker to fulfill their statutory duties as officers and directors.

MISREPRESENTATION UNDER S. 146C(1) OF THE *SECURITIES ACT* AND THE ISSUES IN DISPUTE

[14] Section 146C(1) of Nova Scotia's *Securities Act* entitled "Right of action for misrepresentation" describes the cause of action as follows:

[15] Where a responsible issuer or a person or company with actual, implied or apparent authority to act on behalf of a responsible issuer releases a document that contains a misrepresentation, a person or company who acquires or disposes of the issuer's security during the period between the time when the document was released and the time when the misrepresentation contained in the document was publicly corrected has, without regard to whether the person or company relied on the misrepresentation, a right of action for damages against:

(a) the responsible issuer;

(b) each director of the responsible issuer at the time the document was released;

(c) each officer of the responsible issuer who authorized, permitted or acquiesced in the release of the document;

(d) each influential person, and each director and officer of an influential person, who knowingly influenced

(i) the responsible issuer or any person or company acting on behalf of the responsible issuer to release the document, or

(ii) a director or officer of the responsible issuer to authorize, permit or acquiesce in the release of the document; and

(e) each expert where:

(i) the misrepresentation is also contained in a report, statement or opinion made by the expert,

(ii) the document includes, summarizes or quotes from the report, statement or opinion of the expert, and

(iii) where the document was released by a person or company other than the expert, the expert consented in writing to the use of the report, statement or opinion in the document.4

[16] Breaking down the statutory language, the following elements of this statutory cause of action are not in dispute:

1. Sona was a reporting "issuer";

2. The Q3 2020 MD&A was a "core document", as that term is defined under section 146A(b)(i) of the *Securities Act*. This is important. Because the Q3 2020 MD&A is a "core document", the issues around liability narrow to whether the Q3 2020 MD&A contained a "misrepresentation" as defined in s. 2(1)(y) of the *Securities Act* and interpreted in the jurisprudence. I return to this issue below;

3. The "period between the time when the document was released and the time when the misrepresentation contained in the document was publicly corrected" (i.e. the chronological bookends or "time posts" for this claim). It is agreed that Mr. Pineo's claims:

    a. Begin on September 29, 2020, when Sona publicly released the Q3 2020 MD&A; and

    b. End on November 30, 2020, when Sona issued a news release stating, among other things, that an evaluation of the COVID-19 Test by Health Canada through the National Microbiology Lab produced results that were "discordant" with Sona's clinical studies. Mr. Pineo defines the September 29, 2020 – November 30, 2020, as the "Class Period" in para. 9 of the Statement of Claim;

    I pause to clarify that while Sona accepts that the claim period ends on November 30, 2020, Sona does not admit that it made a "public correction" on November 30, 2020, if that admission is used to infer that the Q3 2020 MD&A necessarily contained a "misrepresentation" that needed to be "publicly corrected". Again, I discuss the question of

alleged "misrepresentations" below. I also return to the related question of "public corrections". For present purposes, suffice it to say that the time period covered by this claim is not controversial;

4. Mr. Pineo was a person "who acquire[d] or dispose[d] of the issuer's security" during the relevant time period.

[17] As a result, the live issues which remain in respect of Mr. Pineo's claims under the *Securities Act*:

1. Whether the Q3 2020 MD&A contains a "misrepresentation", as that term is understood under s. 146(1) of the *Securities Act* and applied in the context of a motion for leave. For clarity and emphasis, Mr. Pineo only seeks leave to pursue these allegations at this stage of the proceeding. As such, the Court does not make any final determinations;

2. Whether the alleged misrepresentation relates to a material fact. Recall that a "misrepresentation" under the *Securities Act* means untrue statements or omissions of "material fact" (emphasis added) Sona argues in the alternative that even if statements in the Q3 2020 MD&A are untrue, there is no reasonable possibility any such statements can be considered "material"; and

3. Whether there could be a "public correction" in circumstances where, Sona argues, there was no "misrepresentation" which required correction. This issue raises additional questions around the nature and purpose of a "public correction" in the context of the statutory cause of action. That said, it is inextricably tied to the threshold questions described above around whether there was a "misrepresentation" of "material fact". For example, if there was no "misrepresentation" or a "material fact", any residual issues around "public corrections" are rendered academic.

The Test for Leave Under the *Securities Act*5 and Engaging with the Evidence

[18] The statutory framework for claims of misrepresentation under the *Securities Act* arose out of two historic concerns:

1. Deterrence: The regulatory deterrents for unfair, improper or fraudulent disclosure in the secondary markets were viewed as inadequate and needed to be strengthened; and

2. Compensation or a meaningful remedy: The remedies available at common law for misrepresentation had become so constrained and onerous as to be of little practical use to aggrieved investors.

(*Canadian Imperial Bank of Commerce v. Green*, 2015 SCC 60 ("***CIBC v. Green***") at paras. 63 and 64)

[19] The statutory scheme reflects an impulse to protect investors harmed by unfair, improper, or fraudulent disclosure and, as well, preserve the integrity of our capital markets. As the Ontario Court of Appeal wrote in *Baldwin v Imperial Metals Corporation*, 2021 ONCA 838 ("***Baldwin***"), one of the core purposes driving this cause of action is: "… to incentivize fair and accurate disclosure by public issuers." (at para. 57)

[20] A claim for misrepresentation under the *Securities Act* contains a number of unique features designed to achieve these important goals:

1. Unlike a claim for misrepresentation at common law, plaintiffs alleging misrepresentation under the *Securities Act* do not have to prove reliance. Section 146C(1) expressly confirms that the claim may be made "without regard to whether the person or company relied upon the misrepresentation". In other words, "[t]he statute effectively deems reliance." (*Baldwin v Imperial Metals Corporation*, 2021 ONCA 838 at para. 49. See also *Drywall Acoustic Lathing and Insulation (Pension Fund, Local 675) v. Barrick Gold Corporation*, 2024 ONCA 105 ("***DALI Appeal #2***"));

2. Plaintiffs claiming misrepresentation contained in a "core document" do not have to prove that the defendant issuer possessed a "guilty mind" or deliberately set out to mislead investors when publishing the Q3 2020 MD&A. (see s. 146C of the *Securities Act* regarding misrepresentations in "core documents" and compare it against section 146D regarding misrepresentations not contained in a "core document"); and

3. "Once the plaintiff shows a misrepresentation and a public correction, causation is presumed and damages are implied. In other words, causation, or more precisely the lack of it, is transformed into a defence under s.138.5(3) (the "attribution defence"), if the issuer can show that the decline in share price was not caused by the misrepresentation." (*Capelli v. Nobilis Health Corp.*, 2019 ONSC 2266 ("***Capelli***"), at para. 140)6

[21] In developing a statutory remedy to better protect investors against the deceits of misrepresentation, the legislature also recognized a corresponding risk: strike suits. "Strike suits are meritless actions launched in order to coerce targeted defendants into unjust settlements" (*CIBC v. Green* at para. 67).

[22] The legislature responded to this threat by requiring plaintiffs to seek leave from the Court before commencing an action. This screening mechanism was designed to weed out baseless claims at a very early stage in the proceeding. In *CIBC v. Green*, the Supreme Court of Canada confirmed that a primary goal of this leave requirement is "…to screen out strike suits as early as possible in the litigation process." (at para. 47) The Court further agreed that:

> This screening mechanism is designed not only to minimize the prospects of an adverse court award in the absence of a meritorious claim but, more importantly, to try to ensure that unmeritorious litigation, and the time and expense it imposes on defendants, is avoided or brought to an end early in the litigation process.
>
> (at para. 68).

See also *Theratechnologies Inc. v. 121851 Canada Inc.*, 2015 SCC 18 ("***Theratechnologies***") where the Supreme Court of Canada confirmed that the leave requirement promotes "…the legislative objective of a robust deterrent screening mechanism" (at para. 38).

[23] In *Rahimi v. SouthGobi Resources Ltd.*, 2017 ONCA 719 ("***SouthGobi***"), Hourigan, J.A. recognized the need to carefully calibrate the competing policy imperatives and fairly balance the interests of all participants in capital markets (at para. 45) On the one hand, investors who have been misled must be provided with an effective and meaningful remedy. On the other hand, issuers must be protected from unmeritorious or frivolous lawsuits.

[24] The same leave requirement in Nova Scotia's *Securities Act* is found at s. 146H(1)7. It states:

> No action may be commenced under Section 146C without leave of the court granted upon motion with notice to each defendant and the court shall grant leave only where it is satisfied that:
>
> (a) the action is being brought in good faith; and
>
> (b) there is a reasonable possibility that the action will be resolved at trial in favour of the plaintiff.

[25] The plaintiff (Mr. Pineo in this case) bears the evidentiary burden of satisfying the requirements of s. 146H(1). On this, Sona does not dispute that Mr. Pineo meets the requirements of s. 146H(1)(a). Mr. Pineo has brought the action in good faith (para. 125 of Sona Responding Brief). However, there is an issue surrounding s. 146H(1)(b). The question becomes: is there a "reasonable possibility that the action will be resolved in favour of the plaintiff"?

[26] The jurisprudence contains helpful guidance around how to both interpret and, in more practical terms, apply this evidentiary standard for leave (i.e. a "reasonable possibility" of success at trial). The applicable principles include:

1. The motion for leave is neither a trial nor a "mini-trial". (Theratechnologies at para. 39) The motion judge must be careful not to usurp the role of the trial judge and, for example, impose the evidentiary standard that will apply at trial. In DALI Appeal #2, the Ontario Court of Appeal issued a clear warning:

> …it is the trial judge that is to determine whether the matter in issue has been proved on the balance of probabilities. It is not the motion judge's role to do so. In considering the comparative strength of the competing case, the motion judge is therefore required to keep in mind the "relatively low merits-based threshold" of a realistic or reasonable chance of success: *Mask* , at para. 45. A motion judge who effectively assesses the case against the ultimate burden rather than this standard will err by conducting a mini-trial: *Nseir* , at para. 46.
>
> …. if a motion judge attempts to resolve realistic and contentious issues arising from conflicting credible evidence they will be lapsing into a mini-trial. In *SouthGobi*, at para. 75, the motion judge was found to have lapsed into a mini-trial by purporting to resolve a key issue that was in dispute because of conflicting, credible evidence. In *Cronos*, at paras. 77-78, the motion judge was found to have "tip[ped] into the

> realm of a mini-trial" by concluding that a misrepresentation was not material in the face of "credible, complex and competing evidence on whether misrepresentations have a material effect on share prices".
>
> (at paras. 37 - 38)

2. The Court in *DALI Appeal #2* also cautioned the motions judge to consider the procedural constraints which may impede the plaintiff's ability to put a complete record before the Court. The motion for leave is necessarily made before disclosure and discovery is complete. The Court must recognize this procedural constraint when assessing and weighing the evidence against the applicable standard. The Court must ensure that the absence of evidence does not unfairly operate to the prejudice of a plaintiff whose claims have merit and a reasonable chance of success. Writing for the Court, Paciocco, J.A. stated:

> …the completeness of the record should affect how a motion judge proceeds. If a motion judge determines that the record is capable of identifying the potential merit of the case, the motion judge may proceed on that record. But if the lack of a complete record could impede the evaluation, the motion judge must take the incompleteness of the record into account in coming to their decision. This is not to say that motion judges should operate on speculative assumptions that missing evidence would favour the plaintiff. After all, the motion judge is to engage in a "reasoned consideration": *SouthGobi*, at para. 46, citing Theratechnologies Inc., at para. 38. Instead, motion judges who have reason to be concerned about the incomplete state of the record should be mindful to not impose a standard that is so exacting that, given evidential limitations, it "can work to the prejudice of plaintiffs who have potentially meritorious claims": *SouthGobi* at para. 48.
>
> (at para. 40)

3. Mindful of the constraints described above and the lesser evidentiary standard applicable in a motion for leave, the Court still engages with the evidence. The following corollary principles apply:

   a. The Court is not obliged to accept the plaintiff's evidence at face value or presume it to be true. The Court may test the strength of the plaintiff's evidence against the cross-

examination of any affiant. The Court may also assess the reliability of the evidence presented. (*DALI Appeal #2* at para. 32)

b. The Court does not review the plaintiff's evidence in isolation. The Court assesses the evidence as a whole. Thus:

   i. The Court's review "… must include some weighing of the evidence that both parties are required to proffer under ss. 138.8(2) and (3) and scrutiny of the entire body of evidence'". (*DALI Appeal #2* at para. 31, quoting from *SouthGobi* at para. 46); and

   ii. "Within limits, the comparative strength of competing evidence is also to be considered; the evidence must be sufficiently strong to show a reasonable or realistic chance of success. Therefore, if evidence relied upon by the defendant is so compelling that there is no reasonable possibility that the appellant would succeed at trial, leave may be denied…. It follows that if critical evidence offered by a plaintiff is shown by other evidence to be "completely undermined by flawed factual assumptions" a motion judge may choose not to act on that evidence: *Mask* 8, at para. 48. In *Mask*, for example, the plaintiff's geologist provided evidence that the defendant underreported the amounts of material delivered from a mine, while overestimating the grade of ore produced. The motion judge did not err in finding that this evidence was undermined by competing, uncontroverted evidence provided by the defendant explaining why the testimony of the plaintiff's geologist was inaccurate: *Mask* at paras. 20-26, 48." (*DALI Appeal #2* at para. 33).

c. The Court may also consider the absence of evidence or what has been described as an incomplete record.

Misrepresentations and Materiality

[27] To obtain leave to pursue a claim for misrepresentation, the plaintiff must obviously offer sufficient evidence of a misrepresentation.

[28] Section 2(1)(y) of the *Securities Act* defines a "misrepresentation" as being:

> (i) an untrue statement of material fact, or
>
> (ii) an omission to state a material fact that is required to be stated or that is necessary to make a statement not misleading in the light of the circumstances in which it was made.

[29] In assessing an alleged misrepresentation, as indicated above, the Court engages with the evidence, having regard to the evidentiary and procedural limitations imposed upon the plaintiff at this early stage of the proceeding (e.g. the plaintiff has not yet received full disclosure or completed discovery examinations).

[30] Finally, s. 2(1)(y) of the *Securities Act* expressly limits the statutory cause of action to misrepresentations of "material facts" (emphasis added). Representations around that which is immaterial cannot ground the statutory claim. Section 2(1)(w) of the *Securities Act* defines a "material fact" as follows:

> Material fact, where used in relation to securities issued or proposed to be issued, means a fact that would reasonably be expected to have a significant effect on the market price or value of the securities.

[31] The leading case explaining the nature and scope of "materiality" in a misrepresentation claim under the *Securities Act* is *Sharbern Holding Inc. v. Vancouver Airport Centre Ltd*, 2011 SCC 23 ("***Sharbern***"). In that decision, Rothstein, J. wrote:

> (i) Materiality is a question of mixed law and fact, determined objectively, from the perspective of a reasonable investor;
>
> (ii) An omitted fact is material if there is a substantial likelihood that it *would* have been considered important by a reasonable investor in making his or her decision, rather than if the fact merely *might* have been considered important. In other words, an omitted fact is material if there is a substantial likelihood that its disclosure would have been viewed by the reasonable investor as having significantly altered the total mix of information made available; [page 440]
>
> (iii) The proof required is not that the material fact would have changed the decision, but that there was a substantial likelihood it would have assumed actual significance in a reasonable investor's deliberations;
>
> (iv) Materiality involves the application of a legal standard to particular facts. It is a fact-specific inquiry, to be determined on a case-by-case basis in light of all of the relevant

> considerations and from the surrounding circumstances forming the total mix of information made available to investors; and
>
> (v) The materiality of a fact, statement or omission must be proven through evidence by the party alleging materiality, except in those cases where common sense inferences are sufficient. A court must first look at the disclosed information and the omitted information. A court may also consider contextual evidence which helps to explain, interpret, or place the omitted information in a broader factual setting, provided it is viewed in the context of the disclosed information. As well, evidence of concurrent or subsequent conduct or events that would shed light on potential or actual behaviour of persons in the same or similar situations is relevant to the materiality assessment. However, the predominant focus must be on a contextual consideration of what information was disclosed, and what facts or information were omitted from the disclosure documents provided by the issuer.
>
> (at para 61)

[32] The Ontario Court of Appeal's decision in *Badehsa v. Cronos Group Inc.* 2022 ONCA 663 ("***Badehsa***") provides a practical example of how the concept of "materiality" is applied in the context of a motion for leave. This case involved inflated reports of revenue through a scheme in which the company sold cannabis to a third party and then simultaneously bought the same product back and holding it as "inventory". It was effectively a financial shell game designed to exaggerate the company's revenues.

[33] Setting aside the obvious breach of the obligation to report revenues fairly and accurately, when the misrepresentations were publicly corrected, there was a contemporaneous drop in the company's share price. The combination of those facts suggested that the misrepresentation had "a significant effect on the market price or value of the securities", to quote from the definition of a "material fact". Writing for the Court and echoing the earlier decision in *South Gobi*, L. Favreau, J.A. concluded:

> These circumstances are sufficient to meet the reasonable possibility test. The evidence in support of the claim is well beyond *de minimis*. On a motion for leave, it is no doubt appropriate for the court to engage in some weighing of the evidence. On a case such as this one, where there was a drop in share prices, and there is credible, complex and competing evidence on whether misrepresentations have a material effect on share prices, the reasonable possibility threshold is met and the issue should be left for trial.
>
> (at para 78)

Public Correction

[34] Section 146(C)(1) confirms that a statutory claim of misrepresentation ends on the date "when the misrepresentation contained in the document was publicly corrected". The jurisprudence often refers to this part of the claim as a "public correction".

[35] A "public correction is a necessary part of the statutory scheme". (*Drywall Acoustic Lathing and Insulation, Local 675 Pension Fund v. Barrick Gold Corporation,* 2021 ONCA 104, leave to appeal to the Supreme Court of Canada denied [2021] S.C.C.A. No. 202 ("***DALI Appeal #1***") at para. 41 and *Baldwin* at para. 46).9

[36] For the purposes of this decision, the principles which help guide the Court's evaluation of the public correction include:

1. The purpose of a public correction is to correct a pre-existing misrepresentation. In *DALI Appeal #2*, the Ontario Court of Appeal observed that: "…this inquiry [into the existence of a public correction] may alternatively be profitably framed by asking "whether the alleged public correction was reasonably capable of being understood in the secondary market as correcting what was misleading in the impugned statement" (at paras. 77 and 79, quoting from DALI Appeal #1 at para. 76)

2. The misrepresentation (i.e. the impugned, actionable statement or omission) remains the focus of the claim. It "does the heavy lifting" (at para. 50) Thus, the misrepresentation: "… forms part of the context in which the public correction operates and would be understood by the market." (*Baldwin*, at para. 50). By contrast, the public correction plays a "modest role" (*Baldwin*, at para. 51).

3. "There need only be "*some linkage or connection* between the pleaded public correction and the alleged misrepresentation'" (*Baldwin*, at para. 54, quoting from *Swisscanto Fondsleitung AG v. BlackBerry Ltd.*, 2015 ONSC 6434 at para. 65, emphasis in decision). At the same time, and at the risk of repetition, the plaintiff must still demonstrate some linkage. On this point, note that the Court undertakes a separate analysis for each alleged misrepresentation to determine whether the claim will be resolved in the plaintiff's favour at trial. (*Maxar*, at para. 97) Analytical separation ensures that evidence surrounding otherwise distinct

claims of misrepresentation are not mixed together and presented as a single, cloudy evidentiary solution which somehow satisfies all the statutory requirements. For example, the "public correction" requirement for a misrepresentation (however modest it might be) is not achieved simply because a company issued a press release correcting a different misrepresentation. (*Capelli*, at paras. 20, 181 and 182);

4. Context is important when evaluating whether a public correction was made. In most cases, the judge "will be required to consider the misrepresentation(s) or omission(s), the alleged public correction, and the context of both to determine whether the misrepresentation was corrected." (*Baldwin* at para. 37) The need for context and engaging with the evidence becomes particularly necessary where the alleged misrepresentation is not "facially obvious" or when the alleged misrepresentation is an omission. (*Baldwin* at para. 39 and *DALI Appeal #1* at para. 78)

5. Consistent with the primary role of the misrepresentation and the comparatively modest role of the public correction requirement, the Court does not approach the public correction requirement with undue rigidity. The Court is not so protective of the public correction requirement as to impose exacting standards which might then, in a strange reversal, shift the focus of the claim away from the misrepresentation to the correction. To do so would potentially undermine the core statutory purpose of incentivizing fair and accurate disclosure. To that end:

    a) It is not necessary that the public correction "be a "mirror-image" of the alleged misrepresentation (*Baldwin* at para. 54); or be a "direct admission that a previous statement is untrue" (*Baldwin*, at para. 54); or reveal perfect "facial symmetry" with the alleged misrepresentation or omission. (*Baldwin* at para. 48); and

    b) An issuer cannot use its own "vague or general disclosures ('something has happened, and we are looking into it')" as a basis for attacking whether the plaintiff has satisfied this

> statutory requirement – or escape liability by deploying imprecise, hazy language. (*Baldwin*, at para. 57)

Application to the Facts

Alleged Misrepresentation 1: The SaudiVax Clinical Evaluation Study Was Not "Independent"

[37] As indicated, Sona's Q3 2020 MD&A stated that it engaged SaudiVax to deliver the results of "…an independent clinical, in-field evaluation study ("CES")" for its COVID-19 Test (at p. 5, emphasis added).

[38] I agree that:

1. Sona's Q3 2020 MD&A represented that SaudiVax was conducting an "independent" study;

2. Regulatory approval of the COVID-19 Test needed to be supported by an independent, in-field clinical study; and

3. The issue of whether SaudiVax was engaged to conduct an independent clinical in-field evaluation study, as stated by Sona in the Q3 2020 MD&A, is material and objectively significant from the perspective of a reasonable investor.

[39] The more critical questions become:

1. What is an "independent" clinical in-field evaluation study?

2. Has Mr. Pineo demonstrated a reasonable possibility of successfully demonstrating that Sona's statement regarding an "independent" clinical in-field evaluation study was a misrepresentation?

I address each question below.

What is an "independent" clinical, in-field evaluation study?

[40] "Independent" generally connotes a measure of freedom from external control or influences. This definition captures the word's essential meaning but is not sufficiently precise to be useful in a legal proceeding. For example, the phrases

"independent contractor", "independent legal advice", and an "independent judiciary" each have different, separate meanings at law depending on the context.

[41] In this case, an "independent clinical in-field evaluation study" is neither a legal term of art nor is it a contractual term to be interpreted having regard to the parties' intentions. Neither party located any jurisprudence or legal authority which defines the term "independent" in the context of a clinical in-field evaluation study.

[42] The Defendants did provide the "U.S. regulation regarding Financial Disclosure by Clinical Investigators" (the "**US Financial Disclosure Regulation**") to help develop a working definition for the phrase "independent in-field evaluation study". The Plaintiff accepted this regulation as helpful but argued that that it supported their position.

[43] I agree with the parties this regulation is neither binding nor can be simply adopted as codifying what constitutes an "independent clinical in-field evaluation study" from the perspective of a reasonable investor in these circumstances. First, Sona Q3 2020 MD&A does not purport to define the phrase "independent clinical in-field evaluation study" by reference to the US Financial Disclosure Regulation. Second, Sona was also applying approval from Health Canada. There is no indication that Health Canada adopts the US Financial Disclosure Regulation. Third, the US Financial Disclosure Regulation states that it is used by the FDA when evaluating "clinical studies submitted in marketing applications, required by law, for new human drugs and biological products and marketing applications and reclassification petitions for medical devices." The FDA's understanding of an "independent" study may overlap with those of a reasonable investor. However, the FDA's concerns ultimately relate to assessing the effectiveness and safety of a new human drug or biological product. A reasonable investor may generally share some of these concerns but, ultimately, the priorities and motivations of a reasonable investor are much different than those of a federal regulator concerned with the safety and effectiveness of a drug or medical device.

[44] That said, I also agree with the parties that there are elements of the US Financial Disclosure Regulation which assist in developing an appropriate definition of an "independent in-field evaluation study" for the purpose of this motion. Subject to the qualifications discussed above, I have taken it into account.

[45] In my view, defining the "independent clinical in-field evaluation study" for present purposes begins with three related and uncontroversial propositions:

1. The statutory claim of misrepresentation is powered by the goal of incentivizing fair and accurate disclosure by public issuers and that the primary, target audience for this disclosure is investors or potential investors;

2. The meaning and significance of an "independent" clinical in-field evaluation study is approached from the perspective of an objective, reasonable investor considering either acquiring or disposing of Sona shares – not, for example, a scientist whose demands and concerns may be very different; and

3. A reasonable investor would not make decisions based on an arbitrary, irrational, or uninformed understanding of an "independent" clinical, in-field evaluation study. On the contrary, a reasonable investor would incorporate into his/her decision-making a rationale and informed understanding as to the meaning and significance of this information.

[46] Using these basic propositions to establish the proper perspective and context, a definition begins to form for the purposes of this motion. In my view, a reasonable investor would understand that an "independent" clinical, in-field evaluation study includes:

1. A study conducted by a qualified, impartial, objective, and unrelated third party who is neither biased nor swayed by improper external (including financial) influences. The criteria for assessing whether the study was subjected to improper external influences include:

    a. Whether the compensation paid to conduct a clinical, in-field study was contingent upon a particular outcome or result;

    b. Whether the entity conducting the independent study was:

        i. Subject to control by (or common ownership with) the party requesting the independent study; and/or

        ii. An affiliated body corporate as that term is defined in section 2(2) of the *CBCA* (Sona's governing statute)

2. A study conducted in a manner that is:

a. transparent;

b. designed to generate objective, reliable data and conclusions which is preserved to enable further review for reliability and accuracy;

c. capable of being reviewed by peers; and

d. capable of being replicated in a separate setting to verify the results.

[47] Is there a reasonable possibility of demonstrating that Sona's statement regarding an "independent" clinical in-field evaluation study was a misrepresentation?

[48] Respectfully, in my view, Mr. Pineo has not demonstrated a reasonable possibility of successfully demonstrating that Sona's statement regarding an "independent" clinical in-field evaluation study was a misrepresentation.

[49] With respect to SaudiVax's study:

1. There is no evidence that SaudiVax was not qualified to conduct the clinical in-field evaluation study;

2. There is no evidence that the compensation owed to SaudiVax for conducting the test was contingent upon a particular result or outcome;

3. SaudiVax was not subject to common ownership with (or control by) Sona. SaudiVax was also not an affiliate of Sona;

4. There is no evidence that the study conducted by SaudiVax was either:

    a. Not transparent. The SaudiVax study's scope and methodology was confirmed in terms and attached appendices of an agreement titled "General Contract Terms of Clinical Evaluation of Sona Nanotech COVID-19 Lateral Flow Assay" dated June 30, 2020 (the "General Contract Terms"). Appendix 1 to this agreement confirms

that the evaluation results will be (and were) used as part of submission to Health Canada and the FDA; or

b. Not designed to generate objective, reliable data and conclusions which is preserved to enable further review for reliability and accuracy. Appendix 1 to the governing June 20, 2024, agreement confirms the process for specimen collection, testing, and data collection. The data collected was inputted into spreadsheets and organized according to certain key data points including, for example, location, date, PCR results, and "Ct counts".10 Again, the results were delivered to the regulatory authorities for review. That said, Mr. Pineo refers to the fact that the National Microbiology Laboratory's own independent test generated results which were "discordant" when compared against Sona's test. He argues that the magnitude of the differences (or "discordance") is sufficient to create the reasonable possibility of successfully arguing that SaudiVax's data was inherently unreliable and that publishing this data in the Q3MD&A was, in itself, a misrepresentation. I return to that issue below; or

c. Not capable of being reviewed by peers. The study results were reviewed; nor

d. Not capable of being replicated in a separate setting to verify the results. The testing was reproduced in a separate setting although Health Canada was unable to reproduce and verify SaudiVax's results. That is a different matter which I address below, as indicated.

[50] As to the questions around SaudiVax's impartiality and whether there is a reasonable possibility of successfully demonstrating that SaudiVax was not "independent" or was subjected to improper external influences:

1. There is no evidence that the compensation paid to SaudiVax was in any way contingent upon a particular outcome or result which favoured Sona. Appendix 2 of the General Contract Terms clearly confirm that SaudiVax was to be paid a total of $40,000 USD as follows:

a. $8,000 USD upon signing the General Contract Terms;

b. $16,000 USD upon the commencement of the study; and

c. $16,000 USD upon completion of the data set.

Subsequently, on August 20, 2020, Sona agreed to pay an additional $30,000 USD for further testing designed to ensure that the testing included thirty (30) negative and thirty (30) positive tests. In any event, nothing in the agreement or the payments made to SaudiVax were conditional upon any particular outcome or, for example, receipt of a data set that would prove useful to Sona.

2. There is no evidence that:

a. Sona controlled SaudiVax, directly or indirectly;

b. Sona had an ownership stake in SaudiVax; or

c. SaudiVax was an affiliate of Sona, as that term is defined in s. 2(2) of the *CBCA*

[51] That said, Mr. Pineo's concerns around SaudiVax's impartiality centre mainly around the following documents which, he argues, support the conclusion that there is a reasonable possibility of successfully demonstrating that SaudiVax was not "independent" because it was improperly influenced by a financial interest in the validation, commercialization and approval of the COVID-19 Test:

1. A Letter of Intent dated June 30, 2020 (the "**Letter of Intent**") having regard to the fact that the General Contract Terms described above were signed on the same day;

2. An unsigned, draft agreement between Sona and SaudiVax entitled "SaudiVax Development Rights Agreement 1 July 2020 v5.docx." (the "**Draft Agreement for Development Rights**"); and

3. A "Distribution Agreement" with a company called the Bassam Trading Company (the "**Distribution Agreement**").

[52] As to the Letter of Intent, it purports "to confirm the basis on which [SaudiVax] and [Sona]…are willing to pursue their discussions on R&D Collaboration". The proposed R&D Collaboration "will focus on advancing technologies in the area of infectious disease diagnostics" with the primary purposes being:

1. To "maintain and expand Sona's technology leadership position in infectious disease diagnostics";

2. To "ensure [SaudiVax's] competitiveness in providing a solution to support global health for the OIC region and the safety of pilgrimage visitors to the Kingdom"; and

3. To "prepare for the future and guarantee a sustainable position for Sona and [SaudiVax] to be best-in-class infectious disease diagnostics players."

[53] For present purposes and taking all of this evidence into account, I do not find that this information (individually or collectively) demonstrates a reasonable possibility of successfully arguing a misrepresentation around the independence of SaudiVax's clinical in-field evaluation study.

[54] It is clear that the Letter of Intent was signed on the same day as the General Contract Terms. However, even on a generous interpretation as to its significance, the Letter of Intent is not even an unenforceable agreement to agree. It expressed confidence in their shared goals and capabilities but, at most, is a commitment to optimistically pursue discussions which might possibly lead to an unenforceable agreement to agree – or perhaps an agreement. In any event, I do not find it supports a reasonable possibility of exposing as an actionable misrepresentation the statement that the SaudiVax study was independent.

[55] As to the Draft Agreement for Development Rights, Mr. Pineo originally stated in written submissions that the document was not produced but "… its title seems to indicate that SaudiVax may have been negotiating a broader commercial interest in the development of Sona's COVID-19 test and/or other products." (Pineo Written Submissions, para. 42)

[56] In reply written submissions, Mr. Pineo clarified that this agreement and another document entitled "SaudiVax_Sona Lateral Flow Test IRB.docx." were produced on May 6, 2022, in response to the undertakings given on Mr. Regan's cross-examination." (Pineo Reply Submissions, at para. 32). Mr. Pineo then raised

issues as to the authenticity of the documents and demanded the underlying metadata, which was eventually disclosed.

[57] At that point, Mr. Pineo continued to raise concerns regarding the "SaudiVax_Sona Lateral Flow Test IRB.docx." (Pineo Reply Submissions at paras. 37 – 41). I return to those concerns below. In so far as the Draft Agreement for Development Rights is concerns, I understand that this agreement was produced. I further understand that there is no evidence this agreement was ever finalized, signed, or became binding on the parties. Finally, Mr. Pineo did not pursue any additional issues upon receiving the metadata attached to this agreement.

[58] Based on the evidence before me, I cannot elevate this document to the point where it would sustain the reasonable hope that Sona's claim around an independent study becomes an actionable misrepresentation.

[59] In reaching this conclusion, I recognize that a motion judge considering a leave application must be careful not to presume or usurp the role of the trial judge. In particular, the motions judge:

1. Should not conclude that an alleged misrepresentation is immaterial in the face of "credible, complex and competing evidence on whether misrepresentations have a material effect on share prices" (*SouthGobi* and *Badehsa*);

2. Should not impose such an exacting standard, make unwarranted credibility findings, and/or preside in a mini-trial having regard to the evidentiary and procedural restrictions which limit the moving party's ability to place a fulsome record before the Court.

[60] In response to these concerns, I would begin by noting that the facts in *SouthGobi* and *Badehsa* are relevant and distinguishable. On November 8, 2013, the proposed Defendant (*SouthGobi*) issued a formal restatement of its 2011 and 2012 financials. The restated financials resulted in a dramatic decease of the company's gross revenues. In the litigation that followed, the company and certain other proposed individual Defendants offered a new narrative. They argued that the restated financials was effectively a mistake; and that the financials actually did not have to be restated in the first place. They maintained that the company had no material weaknesses in its internal financial reporting controls; and that the restatement occurred under pressure from various regulators and accountants. The judge hearing the original motion for leave accepted the proposed Defendant's new narrative and dismissed the motion for leave.

[61] The Court of Appeal determined that there was conflicting evidence on a key issue and that the judge fell into error by "…coming to these unwarranted evidentiary conclusions regarding the credibility of the Individual Respondents as if the leave stage constitutes a mini-trial" (at para. 75) The Court concluded that:

> The residual credibility problems with the individual respondents' central defence, which could only be determined at trial, meant that this was not a case in which the policy objective of the leave requirement of protecting defendants from unmeritorious claims would be advanced by denying leave to Rahimi's claim on the basis of that defence.
>
> (at para. 75)

[62] As to *Badehsa*, the reporting issuer overstated actual revenues through a disengenuous method of reporting sales when the product was only notionally being sold and then immediately bought back and booked as "inventory". Here again, applying the diminished evidentiary burden, the financial reporting was plain and demonstrably inaccurate.

[63] Respectfully, these cases are distinguishable. First, *SouthGobi* and *Badehsa* both involved financial misreporting. Second, there ultimately was no attempt to hide or misrepresent existing evidence. Sona produced the documents in question and the underlying metadata. They did not yield additional evidence in support of Mr. Pineo's concerns. Moreover, unlike *SouthGobi*, neither Sona nor the individual proposed Defendants are not attempting to develop a new narrative that is inconsistent with the produced document or their past actions. They are not now hoping to diminish or reverse prior decisions. Fourth, and unlike both *SouthGobi* and *Badehsa*, the Defendants are not resiling from the documents in any manner. And they are not suggesting that a lack of independence would be immaterial. Rather, they state SaudiVax was independent and, more importantly for present purposes, that Mr. Pineo has not raised a reasonable hope of proving a lack of independence.

[64] In addition to these distinguishing features, I would also note that I am not being required to prematurely or unfairly assess credibility. Rather, I am simply considering the impact of the existing (mainly documentary) evidence on SaudiVax's independence.

[65] Overall, in my view, evidence of a draft, unsigned and non-binding Development Agreement dated the day after the signed Letter of Intent does not create a reasonable possibility of demonstrating that SaudiVax lacked independence in the circumstances.

[66] As to the Distribution Agreement, respectfully, Mr. Pineo's arguments weaken. In written legal argument, Mr. Pineo states:

> A press release of SaudiVax dated June 30, 2020 indicates that Bassam Trading Company is an integrated for-profit organization that carries on business in the healthcare and hospital industry, and that it made these arrangements with Sona in partnership with a further for-profit, Saudi Arabia-based entity called Ascend Health Solutions. Ascend Health Solutions, in turn, is the subsidiary of Al Fozan Holding Company, which describes itself as "one of Saudi Arabia's most renowned family businesses" that carries on business in "a multitude of industries including retail, manufacturing, real estate and trading." Of note, the Defendants' documentary production indicates that at least one employee of Ascend Health Solutions was involved with SaudiVax's clinical trial of Sona's COVID-19 test.
>
> (at para. 41)

[67] There is no further analysis as to the role or importance of the single overlapping employee.

[68] Respectfully, even accepting this information on its face, these tenuous connections do not allow for either the finding or inference that either Ascend Health Solutions or the Bassam Trading Company are affiliated with Sona. Similarly, there is no evidence of any form of shared ownership or control between Sona, SaudiVax, the Bassam Trading Company, and/or Ascend Health Solutions. Overall, this information does not support a reasonable possibility of successfully arguing misrepresentation regarding the independence of SaudiVax.

[69] This is sufficient to address the allegations of misrepresentation regarding SaudiVax's "independence". Were it is necessary to continue, I would also raise a concern around any connection between the alleged lack of independence, the statutory requirement that the alleged misrepresentation be "material", and the sudden drop in Sona's share price.

[70] As noted, the statutory cause of action is limited to misrepresentations of material (not immaterial) facts. Where an alleged misrepresentation is exposed or disclosed and then followed by a precipitous decline in share value, the Court does not adopt an overly stringent or exacting assessment as to whether the facts which comprise the alleged misrepresentation are material. An immediate and negative response by the market makes it very difficult to suggest that the alleged misrepresentation was somehow immaterial.

[71] In this case, there is no doubt that Sona's share price plummeted immediately upon Sona publicly disclosing the FDA decision to deprioritize the COVID-19 Test. Sona's share price subsequently continued to tumble downhill upon disclosing Health Canada's findings as being "discordant" with the SaudiVax test results prompting Sona to withdraw its application for an IO.

[72] However, there is no evidence that the FDA decision to deprioritize was based upon anything related to SaudiVax's independence or the SaudiVax testing results. Even on a generous view of the evidence, there is nothing upon which the Court might infer or imply that the FDA decision was influenced or caused by concerns regarding SaudiVax's independence or the SaudiVax test results. There is an absence of evidence which connects the FDA decision and resulting drop in share value to the alleged misrepresentations regarding SaudiVax's independence and the quality of SaudiVax's test results.

[73] There is evidence that Sona's share price collapsed again after disclosing the Health Canada findings regarding the SaudiVax test results and Sona's subsequent decision to withdraw a request for an IA. However, respectfully, the connection between the steep, sudden slide in Sona's share price and SaudiVax's alleged lack of independence is lacking. At no time did Health Canada express any concern regarding SaudiVax's independence – or lack thereof.

[74] Moreover, Sona never expressed concerns regarding SaudiVax's independence - publicly or privately. This is unlike the facts in *SouthGobi* or *Bahesda* where restated financials immediately triggered a drop in share value. Here, Mr. Pineo's allegations regarding a lack of independence are based on what Health Canada's findings may reveal or imply about earlier representations regarding SaudiVax's independence and the SaudiVax test results.

[75] I do agree that:

1. The events which triggered a drop in Sona's share prices (i.e. the FDA decision to deprioritize and Health Canada's inconsistent or "discordant" test results) formed part of Sona's public disclosure;

2. It is important not to overstate the importance of the public disclosures which triggered a drop in Sona's share price. The jurisprudence is clear that the public correction requirement is not so stringent that a valid misrepresentation claim suddenly vanishes because the issuing report failed to directly address the

> issue (e.g. was not a "mirror image"). Similarly, a reporting issuer cannot hide behind vague or incomplete media releases and thereby avoid the statutory requirement of a "public correction". Thus, for example, a reporting issuer cannot avoid a claim for misrepresentation simply by deliberately refusing to publicly correct a misrepresentation that would otherwise have a reasonable hope of success at trial.

[76] I also repeat the earlier cautions that a motion for leave not be converted into a mini-trial where the motions judge usurps the role of the trial judge.

[77] However, for reasons discussed above, I do not find that there is credible, complex and competing evidence on whether misrepresentations regarding SaudiVax's alleged lack of independence would have a material effect on share prices.

[78] In fairness, and although not expressly argued by Mr. Pineo, SaudiVax's alleged lack of independence might be viewed as supportive of an inference that the SaudiVax data was questionable or unreliable. In other words, taking the evidence as a whole, SaudiVax's alleged lack of independence helps explain and strengthen the argument around the broader allegation that SaudiVax's activities and test results were generally questionable or unreliable.

[79] I have considered the alleged misrepresentation around SaudiVax's independence both individually and in the context of the evidence as a whole. I return to Mr. Pineo's concerns regarding SaudiVax's data below.

Alleged Misrepresentation 2: Failure to Comply With or Follow FDA Regulatory Guidance

[80] The Q3 MD&A released on September 29, 2020, stated, *inter alia*:

> "The EUA studies followed the FDA 's guidance for antigen testing, including assessments for sensitivity, specificity, cross-reactivity, and interfering substances using patient samples and contrived (live viral culture) samples. The results of this assessment has [sic.] been included as part of the Company's regulatory submissions to Health Canada for an IO and the FDA for an EUA. The Company expects to benefit from the regulatory relief offered by the FDA to expedite the availability of diagnostics associated with the COVID-19 disease, subject to certain conditions."

[81] Mr. Pineo maintains that this statement includes a misrepresentation because the SaudiVax study did not "follow" the FDA guidance. More accurately for the

purposes of this motion, Mr. Pineo states that there is a reasonable possibility of successfully arguing that this statement is an actionable misrepresentation because:

1. Sona failed to incorporate the appropriate, current FDA guidance into the clinical, in-field evaluation study conducted by SaudiVax; and

2. Sona specifically failed to validate the test on any asymptomatic patients. In advancing this allegation, Mr. Pineo equates the FDA requirement to collect and test "30 confirmed negative specimens" as being taken from an asymptomatic patient.11

[82] To more fully understand this allegation, the following chronology provides additional, necessary context:

May 11, 2020

The FDA released a regulatory guidance was entitled "Policy for Coronavirus Disease – 2019 Tests During Public Health Emergency" and dated May 11, 2020 (the "**May 11, 2020 FDA Guidance**"). The introductory sections of this document illuminated how the existing public health crisis impacted the development of its policy goals and guidelines. For example, it states:

> FDA is issuing this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency. Rapid detection of COVID-19 cases in the United States requires wide availability of testing to control the emergence of this rapidly spreading, severe illness. This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve a more rapid and widespread testing capacity in the United States.
>
> (at page 4)

June 30, 2020

Sona entered into the General Terms Contract with SaudiVax on June 30, 2020. That agreement incorporated a table entitled "FDA Table 1: Clinical study recommendations" which purported to summarize key methodological and testing requirements presumably extracted from the May 11, 2020, FDA Guidance. This table stated, among other things, that there should be a minimum of 30 "natural positive clinical specimens" collected from

symptomatic patients in an endemic region and 30 “natural negative clinical specimens” from an endemic region. I mention this specific requirement because Mr. Pineo states that this requirement included a corresponding obligation to test patients who were infected with the COVID-19 virus (i.e. positive) but were also asymptomatic. During cross-examinations conducted on March 28, 2022, Mr. Regan admitted that the SaudiVax study did not include tests on infected, asymptomatic patients. He explained that there was no requirement to test asymptomatic patients as it would have required a much larger study.

July 2, 2020

Sona issued a news release confirming that it will enter into an independent clinical, in-field evaluation study with a university affiliated laboratory outside of the United States. And that the results of this study would then be used to support a submission to Health Canada and the FDA for emergency approval of its COVID-19 Test.

July 29, 2020

The FDA released a new regulatory guidance document (the “**July 29, 2020 FDA Guidance**”)

August 6, 2020

Sona issued a news release which stated, in part, that it now expected the results of its in-field evaluation results to be delivered within two weeks. It further stated that: "The evaluation protocol for [Sona’s] studies incorporates aspects of the revised guidance released by the FDA on July 29, 2020."

August 20, 2020

Sona and SaudiVax signed an Addendum to the General Contract Terms. Under this Addendum, SaudiVax agreed to do “additional sample collection and analysis” for $30,000 USD. The additional samples were designed to achieve a total of thirty negative and thirty positive tests. Finally, the new work was to proceed “following the same prior approved protocol detailed in the original [General Contract Terms]”

August 25, 2020

SaudiVax delivers to Sona a table showing the results of its clinical in-field evaluation study. The table indicates that SaudiVax tested 99 patients between August 18 – 25, 2020. The results were sent along to Health Canada. That same day, Sona issued a news release in which it was "pleased to announce that its rapid detection COVID-19 antigen test achieved a sensitivity of 84.6% and a specificity of 90.0% in a study across 99 collected clinical patient samples, which included 39 positive samples and 60 negative samples, as determined by RT-PCR testing."

August 26, 2020

Sona delivers to Health Canada additional clinical data regarding the SaudiVax tests results for the same 99 patients.

September 29, 2020

Sona releases its Q3 MD&A for the nine-months which ended on July 31, 2020. It contained the statement quoted above, indicating that its evaluation study "followed the FDA's guidance for antigen testing". It also confirmed that:

> In-field collection of a minimum of 30 confirmed negative and 30 confirmed positive specimens and the associated data analysis has been completed. The Company engaged the King Fahd Research Center lab at King Abdulaziz University within SaudiVax, a life sciences joint venture between PnuVax Inc. of the United States and UYC Inc. of Saudi Arabia, to deliver the results of the study.
>
> (at page 5, para. 3)

October 28, 2020

The FDA told Sona that its COVID-19 Test was not a priority and that it would not continue its evaluation of the test further. The FDA did not allege non-compliance with its recommended guidelines. Sona announced the FDA decision on October 29, 2020.

[83] With respect to the allegation that Sona failed to properly incorporate the updated July 29, 2020, FDA Guidance, a critical piece of evidence was not placed in evidence: the July 29, 2020, Guidance itself.

[84] Respectfully, the statutory cause of action targets misrepresentations of material fact. I agree that a motion for leave should not be converted into a mini-trial where the allegations must be proven on a balance of probabilities. The evidentiary burden on a motion for leave is much more relaxed and based on the reasonable possibility of success. I am also mindful of the fact that the Plaintiff is operating under significant procedural impediments having not, for example, yet had the benefit of full disclosure and discovery examinations.

[85] Nevertheless, as indicated, the Court is not obliged to accept the plaintiff's allegations and evidence at face value. Nor is the Plaintiff entitled to a presumption that its claims are true. The Court may engage with the evidence and is entitled to consider the allegations against a modicum of evidence, particularly where the evidence is readily accessible.

[86] In this case, the evidence includes the May 11, 2020, FDA Guidance. However, again, the July 29, 2020, FDA Guidance was in evidence.

[87] Thus, I have no evidence upon which I am able to make any assessment as to the reasonable possibility of successfully arguing that:

1. The evaluation or validation requirements in the May 11, 2020, FDA Guidance were different from the July 29, 2020 FDA Guidance;

2. The SaudiVax clinical in-field evaluation study failed to incorporate whatever new requirements were included in the July 29, 2020, FDA Guidance; and

3. A reasonable investor would find those differences to be material.

[88] I am mindful that this motion occurs in the early stages of litigation. The Plaintiff does not have the benefit of full disclosure or discovery examinations. The jurisprudence repeatedly confirms that the evidentiary burden imposed upon the Plaintiff must be properly attuned to take these limitations into account.

[89] However, the FDA Guidance is a public document. There is no suggestion or argument that the July 29, 2020, FDA Guidance was not readily available to Mr. Pineo. Mr. Pineo does point out that Sona failed to produce the July 29, 2020, FDA Guidance as part of an undertaking request. However, respectfully, Mr. Pineo bears the evidentiary burden. Where there is no evidence or suggestion that the July 29, 2020, FDA Guidance (a public document) was somehow not readily available to Mr.

Pineo, I am not prepared to reverse the burden of proof and draw an adverse inference against Sona (e.g. that there is a reasonable possibility it failed to incorporate material parts of the July 29, 2020, FDA Guidelines and that these implied omissions would have been material to a reasonable investor).

[90] In sum, this is not a case where I am unfairly imposing an obligation to meet an overly onerous evidentiary burden which, among other things, fails to account for the procedural impediments facing a Plaintiff at this stage of the proceedings. Rather, in my view, I simply conclude that the Plaintiff cannot ask the Court to conclude that there is a reasonable possibility of proving that Sona misrepresented compliance with the July 29, 2020 FDA Guidelines without putting those same guidelines into the evidence – provide the Court with a minimal or modicum of accessible evidence sufficient to meet the modest evidentiary burden.

[91] As to the allegation that there was a failure to test asymptomatic patients:

1. The FDA guidelines which were placed before the Court (not the July 29, 2020, FDA Guideline) do not require validation testing on patients who were infected with the COVID-19 virus and yet asymptomatic. I note, for example:

    a. Section A(V)(2) of the May 11, 2020, FDA Guidelines entitled "Clinical Evaluation" "…recommends that developers confirm performance of their assay by testing a minimum of 30 positive samples and 30 negative samples as determined by an authorized assay." (p. 18) It does not require that the 30 positive samples (or any subset of those samples) come from asymptomatic patients;

    b. It is agreed that the Sona COVID-19 Test was an antigen test. In very basic terms, an antigen test seeks to detect organic material which forms part of the COVID-19 virus itself. By contrast, an "antibody" test seeks to detect the antibodies developed by the body specifically to combat the COVID-19 virus. Section B of the May 11, 2020, FDA Guidelines entitled "Antigen Detection Tests" similarly does not establish a requirement to test asymptomatic patients infected with COVID-19; and

c. The May 11, 2020, FDA Guidelines include a recommended template for developers seeking FDA approval of an EUA. The Example Template attached for COVID-19 antigen tests includes a Section A entitled "Purpose for Submission" which specifically concludes with the statement "Performance in unknown in asymptomatic patients" (p. 2). Moreover, Section F entitled "Proposed Intended Use" includes the statements:

   i. That the test in question is for "individuals who are suspect of COVID-19 by their healthcare provider" (at p.2 of the Template); and

   ii. "Antigen is generally detectable in [specimen type] during the acute phase of infection" (at p. 2 of the Template).

2. The SaudiVax test results includes a column which indicates the results of a PCR test and thus confirms whether the patient infected with the COVID-19 virus (i.e. positive) or not (i.e. negative). Subject to Mr. Pineo's concerns regarding the accuracy or reliability of this data, there is no evidence that Sona did not test at least 30 patients who were negative or not infected with COVID-19. Thus, the statement in Sona's press release dated July 2, 2020, that it's collections a minimum of "30 confirmed negative" and "30 confirmed positive" was, based on the evidence, accurate. There is no evidence that Sona falsely represented to have tested asymptomatic patients who were infected with COVID-19.

[92] I have no evidence or reasonable argument that Sona was somehow compelled to include asymptomatic patients among its test subjects in order to fulfill the July 29, 2020, FDA Guideline or any prior guideline.

[93] In light of the foregoing, I am unable to accept the possibility that a reasonable investor would conclude that the FDA required testing on asymptomatic patients for antigen testing – or that the Q3 MD&A misrepresented compliance on this issue. On the contrary, the evidence suggests that the FDA did not require testing on asymptomatic patients for developmental diagnostic antigen tests.

[94] Based on the evidence, and again being sensitive to the Plaintiff's limited ability to assemble evidence at this stage, I am unable to conclude that there is a reasonable possibility of successfully demonstrating that Sona's Q3 MD&A statement that it "followed the FDA's guidance for antigen testing" was an actionable misrepresentation.

[95] While it was not a relevant factor in my ultimate determinations, it also bears mentioning that the FDA did not reject Sona's COVID-19 Test for failing to comply with its requirements or recommendations. At most, the FDA concluded that this type of test was no longer a "priority".

[96] Before leaving this issue, I note that Mr. Pineo's allegations regarding a failure to comply with regulatory guidance focusses primarily upon the FDA recommendations. This is understandable given that allegations of misrepresentation focus on the statement in the Q3 MD&A that Sona followed the FDA requirements. It does not make a similar statement regarding Health Canada. And, indeed, Mr. Pineo's Statement of Claim limits the allegations around failure to comply with the regulator's guidelines to the July 29, 2020, FDA Guideline. (Statement of Claim, at para. 42(b))

[97] Nevertheless, Mr. Pineo observes that Health Canada raises a concern that "no asymptomatic patients were tested". (Mr. Pineo's Written submissions at para. 51) I do not find that Sona misrepresented (or is alleged to have misrepresented) failure to comply with Health Canada's guidelines. Indeed, again, no such guidelines were tendered in evidence.

[98] In summary and given the absence of evidence around this alleged misrepresentation, it does not support an actionable misrepresentation either taken individually or in the context of the evidence as a whole.

[99] That said, Mr. Pineo goes further to allege that Sona misrepresented that the data generated by SaudiVax in support of approval by both the FDA and Health Canada as being appropriate and reliable when, Mr. Pineo alleges, it was "inappropriate, questionable, inaccurate and/or unreliable" (Statement of Claim, at para. 42(c)). As such, the submissions for approvals from the FDA and Health Canada were contaminated and doomed to fail from the start. I turn to that issue of SaudiVax's date next.

Alleged Misrepresentation 3: Inappropriate, Questionable, Inaccurate, and/or Unreliable Data

[100] The following chronology helps to frame the issues:

August 25, 2020

As indicated, SaudiVax delivers to Sona a table showing the results of its clinical in-field evaluation study. The results were sent along to Health Canada although the evidence shows that the first 11 tests conducted August 16, 2020, were excluded as, Mr. Regan testified, an inappropriate buffer mixture was used and the results were therefore unreliable. As such, Sona only passed along the data pertaining to tests conducted on the next 99 patients between August 18, 2020, and August 25, 2020;

This same day (August 25, 2020), Sona issued a news release in which it was "pleased to announce that its rapid detection COVID-19 antigen test achieved a sensitivity of 84.6% and a specificity of 90.0% in a study across 99 collected clinical patient samples, which included 39 positive samples and 60 negative samples, as determined by RT-PCR testing."

There is no evidence that that Sona altered or manipulated the data received from SaudiVax – or otherwise failed to accurately report that data in its submissions to Health Canada, the FDA, and to the public.

August 26, 2020

Sona delivers to Health Canada additional clinical data regarding the SaudiVax tests results for the same 99 patients. On this same date, Sona provided Health Canada with a document entitled "SaudiVax_Sona Lateral Flow Test IRB.docx". Mr. Pineo states that there is credible evidence that this document was somehow manipulated.

September 29, 2020

Sona releases its Q3 MD&A for the nine-months which ended on July 31, 2020. It contained the statement quoted above, indicating that its evaluation study "followed the FDA's guidance for antigen testing". It also confirmed SaudiVax's clinical, in-field evaluation study in late August 20, 2020. It repeated the information contained in the August 25, 2020, news release.

October 28, 2020

The FDA told Sona that its COVID-19 Test was not a priority and that it would not continue its evaluation of the test further. The FDA did not allege non-compliance with its recommended guidelines or comment on the viability of Sona's Test. Sona was still awaiting word back from Health Canada.

That same day (October 28, 2020), Sona issued a news release announcing the FDA decision. At that time, it also stated that Health Canada was continuing in its evaluation of the COVID-19 Test and repeated that:

> The Company has also posted the results of its analytical trial data from MRIGlobal and its in-field, clinical trial results with SaudiVax on its website which provides background data on the test's performance. The Company believes that these studies provide strong support for the use of its test for screening, which it believes is essential to mitigate against the need for business shutdowns from virus outbreaks and subsequent waves of COVID-19…. Sona's Nanotech's rapid COVID-19 antigen test offers results within 15 minutes, using a pregnancy-type lateral flow test that is easy to administer and interpret by non-experts without the need for either laboratory equipment or a device to read its results. Underpinned by Sona Nanotech's proprietary, patent-pending, gold nanorod technology, its test showed 85% agreement to RT-PCR results in patients in an in-field study of 99 patients and 96% sensitivity in laboratory studies.
>
> (at paras. 6 and 8)

November 17 – 26, 2020

Sona and Health Canada engage in discussions regarding Health Canada's independent evaluation of the COVID-19 Test. In the midst of these discussions, on November 25, 2020, Sona withdrew its application for an Interim Order. Very briefly:

1. November 17, 2020 - Health Canada sent along a report from the National Microbiology Laboratory ("**NML**"). It noted that a laboratory assessment of the COVID-19 test resulted in an "apparent poor analytical sensitivity". (at p. 2) As such, the NML undertook a clinical performance evaluation using samples collected from 6 patients known to be infected with COVID-19. A "weak positive result was detected for 1 of the 6 patient specimens with a corresponding Ct of 19.43 who was within 6 days of post-onset of symptoms" (p. 6). As a result of these poor results, "the clinical arm of the evaluation was suspended due to ethical concerns". (p. 6) The nature of these "ethical concerns" were not described. Based on this report, Health Canada recommended "refusal of the application for authorization of the Sona antigen test."

2. Later that same day (November 17, 2020), Sona sent along a number of questions seeking further detail of the NML tests.

3. November 18, 2020 – NML responded to Sona's questions

4. November 19, 2020 – Sona raised further questions and concerns regarding the NML tests

5. November 25, 2020 – Sona issued a news release announcing its decision to withdraw the application for an IO from Health Canada. In doing so, Sona continued to repeat the results from SaudiVax and expressed confidence in the COVID-19 Test. Sona also filed a Material Change Report that day. Among other things, Sona confirmed that the NML's evaluation "produced discordant results" to the laboratory results generated by MRIGlobal and in the clinical, in-field evaluation study completed by SaudiVax. Sona further expressed concern as to whether the NML "followed a uniform evaluation process for both rapid antigen tests that detect nucleocapsid and those, like Sona's, that detect spike proteins."

6. November 26, 2020 – Health Canada provided a detailed summary of the various communications with Sona between November 17 – 26, 2020.

November 30, 2020

Sona issued a news release that repeated NML tests produced "discordant results" compared to the laboratory tests completed by MRI Global and then SaudiVax's clinical, in-field evaluation study. Sona expressed confidence in its testing results but noted that its own tests included only 7 samples from patients who were with 6 days of symptom onset. Sona intended to obtain more data with a focus on those types of patients "[w]ith a view to reconciling the discordancy".

[101] There is no evidence that the FDA evaluated or critiqued the SaudiVax data. As indicated, the FDA simply confirmed that the COVID-19 Test was no longer a priority, without elaborating further.

[102] This misrepresentation relates primarily to the testing of the COVID-19 Test completed by Health Canada.

[103] Mr. Pineo's concerns regarding SaudiVax's results were triggered by (and largely premised on) the differences between the SaudiVax results and the NML results commissioned by Health Canada. He argues that, for the purposes of this motion, "these circumstances are sufficient to conclude that the SaudiVax data was

"inappropriate, questionable, inaccurate and/or unreliable," as pleaded. (Pineo Written Submissions at para. 65)12

[104] Respectfully, the differences between the NML results and the SaudiVax results are not, by themselves, sufficient to find there to be a reasonable possibility of proving that including the SaudiVax results in the Q3 2020 MD&A were misrepresentations under the *Securities Act*.

[105] It "is important 'to recognize the dangers of hindsight in coming to this conclusion and to be careful not to look at the situation based on what subsequently happened.'" (*Markowich v. London Mining Corporation*, 2022 ONSC 81 at para 161 and *DALI Local 675 Pension Fund (Trustees) v. Barrick Gold Corporation*, 2022 ONSC 1767 at paras 200, 234, 236, and 241) Backwards reasoning based on a sharp drop in share value can lead to error and unfair assumptions. The Court should exercise a degree of caution before leaping to the conclusion that differences in the results of a study performed by the regulator must be considered definitive and must equally mean that the results submitted by the applicant (Sona, in this case) misrepresented the capabilities of the drug or device being tested or that there has been a material change in the company's business, operations or capital.

[106] For clarity, I am not purporting to delve into Sona's state of mind. All parties recognize that this is not appropriate. I also do not say that different or conflicting test results generated independently by a regulator can never constitute sufficient evidence to ground a claim for misrepresentation under the *Securities Act*.

[107] That said, in this case, something more is required to demonstrate a reasonable possibility of demonstrating that including the SaudiVax data in the Q3 2020 MD&A constitutes an actionable misrepresentation. My reasons include:

1. There is no evidence that Sona interfered with (or intervened in) SaudiVax's study. I repeat my factual findings above regarding SaudiVax's independence. Similarly, there is no evidence Sona altered or misstated the data received from SaudiVax before communicating it to either the FDA, Health Canada, or the general public;

2. As mentioned, there is no evidence that the FDA decision to deprioritize the COVID-19 Test was based on any concerns regarding its effectiveness. Equally, even approaching the matter generously and taking all applicable evidentiary and procedural limitations into account, there is nothing upon which

the Court might infer that deprioritizing the COVID-19 Test reflects a concern over SaudiVax and its test results;

3. As to Health Canada, Health Canada does not approve submission. And reporting issuers do not necessarily face claims of misrepresentation if the information submitted to Health Canada is not accepted and/or is disputed. Similarly, the fact that Health Canada's own testing produced contrary result does not, by itself, mean that there is a reasonable hope of demonstrating that the data submitted by the reporting issuer was contaminated or contains a misrepresentation. Were it otherwise, every time Health Canada was unable to independently produce the same result as the party seeking approval of its experimental drug or medical device, a claim for misrepresentation under the *Securities Act* would arise. The scientific process admits the possibility of trial and error. The reality is that not every clinical in-field evaluation will yield identical results. There are variables which may only be revealed when a drug or device is re-examined and subjected to further testing. A reasonable investor would appreciate that reality;

4. I recognize the differences between the SaudiVax results and the NML results. And I recognize Health Canada's refusal to recommend that COVID-19 Test device for approval based its inability to replicate and rely upon the SaudiVax results - described by Health Canada summarily as "the device's inability to produce clinically significant results in a real-world setting." (Health Canada email dated November 17, 2020, attaching a document entitled "Preliminary Analytical and Clinical Valuation of the Sona Nanotech COVID-19 Lateral Flow Assay".) However, again, this does not by itself constitute credible, complex, and completing evidence that renders the SaudiVax Test data inappropriate, inaccurate, questionable and/or unreliable. Again, the different test results do not, by themselves, support a claim for misrepresentation. To do so, respectfully, grounds the claim in speculative inferences - not credible, complex, and competing evidence. There must be something more than conflicting results. At the risk of repetition, I confirm that I have taken into account the flexibility

shown applicants in these circumstances who face certain clear evidentiary and procedural restrictions;

5. Even after the submissions to the FDA and Health Canada failed, Sona did not correct the potential of its diagnostic technology or admit that this technology was a failure. On the contrary, Sona continued to publicly express confidence in its COVID-19 Test and the underlying technology. Sona stated it need more time to unlock its commercial and diagnostic potential; and

6. The broader context (including the urgent and accelerated manner in which these studies were being performed) is a relevant factor. The circumstances were unique, unprecedented, and complex. The cases of *South Gobi* and *Bahesda* involved misrepresentations in financial reporting where the information and methodology are understood and well-established. This case involves the rushed development of experimental drugs and diagnostics tests in an immediate response to a crippling, raging pandemic. Governments were desperate to find solutions that might offer relief. The introductory paragraphs to the FDA's Financial Disclosure Regulation (discussed above) reflects the nature of the emergency:

> FDA is issuing this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency. Rapid detection of COVID-19 cases in the United States requires wide availability of testing to control the emergence of this rapidly spreading, severe illness. This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve more rapid and widespread testing capacity in the United States.

7. Mr. Pineo acknowledged on cross-examination that Sona was at the development stage and had yet to commercialize its technology. He also acknowledged the race to develop a marketable rapid COVID-19 test. In my view, a reasonable investor would understand that start-up companies which suddenly re-deploy or re-focus their resources to hurriedly

develop cures, treatments and diagnostic devices in the fight against a previously unknown virus which, in turn, triggered a catastrophic public health crisis and brought the world to a standstill may face unexpected challenges (and an enhanced risk of failure) when attempting to launch their technologies. Not every proposed diagnostic test or drug was approved. Obviously, this does not mean that companies are free to be untruthful or misrepresent material facts. However, the manner in which the entire world was developing experimental drugs and diagnostic devices; wrestling with the considerable health risks and uncertainties associated with COVID-19; and attempting to find solutions is necessary context when evaluating the SaudiVax data and how a reasonable investor would understand the disclosure being made. Indeed, the impugned Q3 MD&A contains the following express warning for its current and prospective shareholders:

> The Company cautions that its rapid detection COVID-19 antigen test is not yet approved by the FDA, Health Canada or other regulatory bodies and Sona will update the market as appropriate. The Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain the COVID-19 virus (or SARS-2 Coronavirus) at this time.
>
> (at p. 5)

[108] Again, in the circumstances, it is not enough to simply identify that the NML test results were markedly different from SaudiVax. There must be something more.

[109] Mr. Pineo offers the following additional arguments and evidence in support of this claim:

1. That data received from SaudiVax, on its face, revealed irregularities that cast doubt on the reliability of the information. More specifically, Mr. Pineo points to August 24 – 25, 2020, when SaudiVax tested 27 patients who were suspected of being infected with COVID-19. The data relates to these 27 patients was received on August 25, 2020, – immediately after the testing process was presumably completed. Mr. Pineo characterizes these

samples as "the problematic, new patient samples that were provided on the morning of August 25, 2020". (Pineo Written Submissions, at para. 30) He argues it is implausible or questionable that:

a. None of these 27 patients suspected of being infected with COVID-19 would ultimately test positive for the virus (i.e. all suspected infections proved unfounded); and

b. SaudiVax could effectively test 15 of the 27 patients suspected of being infected with COVID-19 on one day (August 25, 2020) and still respect the testing and data collection requirements. Mr. Pineo states that: "It is questionable whether this process could have been performed and completed in compliance with the evaluation protocol, or at all, in such a short time, given a PCR test takes a few hours to return its own result." Thus, the argument continues, Sona released the data publicly before taking a reasonable amount of time to review and verify potentially deficient data.

(Mr. Pineo's Written Submissions, paras. 66 – 67)

2. That there is ancillary evidence which casts doubt on the authenticity of a document entitled "SaudiVax_Sona Lateral Flow Test IRB.docx" and, more generally, raises concerns regarding the reliability and accuracy of information presented by Sona.

(Mr. Pineo's Reply Submissions, paras. 37 – 41)

[110] I pause here to note that Mr. Pineo also mentions a concern around the first 11 patients tested by Saudi Vax on August 16, 2020, were removed from the data sent along to the regulators – with certain summary information being publicly announced. However, during cross-examination, Mr. Regan explained that:

> …there were 11 samples that the scientists on either side agreed were inappropriate because an inappropriate buffer mixture had been used, and the inclusion or exclusion of those 11 would not have made a material difference to the results of the study.

[111] This issue was not pursued beyond suggesting that Mr. Regan was uncertain about these 11 samples. The focus of Mr. Pineo's complaint became the "problematic, new samples" described above.

[112] I do not find these additional pieces of evidence (either separately or as a whole) create a reasonable possibility of successfully demonstrating that the summary of SaudiVax's study results in the Q3 2020 MD&A was a misrepresentation under the *Securities Act*. I remain mindful that Mr. Pineo is arguing these issues without full disclosure or discovery. However:

1. I am not prepared to infer that a reasonable hope of establishing that the SaudiVax data was "inappropriate, questionable, inaccurate, and unreliable" because none of the 27 patients tested on August 24 – 25, 2020, were infected with COVID-19. All of these patients were tested in Jeddah. Mr. Pineo does not refer to the other tests which occurred in Jeddah, but all 9 patients tested in Jeddah on August 20, 2020, were also not infected with COVID-19. And 2/5 patients tested in Jeddah on August 18, 2020, were not infected with COVID-19. The total number of patients who tested negative for COVID-19 in Jeddah was 38/41. In other words, the test results from Jeddah were relatively consistent over a one-week period. I am unable to conclude that this evidence is inherently suspicious or creates a reasonable hope of proving that the data was collected in a manner that is inappropriate, unethical, or inaccurate. Yet, I have no evidence or reasonable basis for reaching that conclusion beyond speculating around patients consistently testing negative for COVID-19;

2. Similarly, beyond speculative inferences around a more sinister motive, there is nothing inherently implausible or questionable about:

    a. Collecting data (including a PCR test) for 15 patients on August 25, 2020, – particularly when the FDA, at the time, was urging efficient, accelerated responses; and

b. Passing this data along to regulators and the public.

[113] As to the document entitled "SaudiVax_Sona Lateral Flow Test IRB.docx", Mr. Pineo raises the following concerns:

1. The associated metadata establishes that the document was "modified" on August 26, 2020, the date it was submitted by Mr. Sandy Morrison to Health Canada, even though the document purports to be dated July 12, 2020, on its face.

2. On May 27, the Defendants produced 28 pages for this document, whereas they had previously produced only 1 page of the document. The complete, 28-page version of this document confirms the Plaintiff's opening submissions: contrary to Mr. Morrison's representation to Health Canada, this document is not the ethical review board's approval of the clinical trial.

3. Every page of the document is purportedly signed and dated by a Dr. Hassanain of SaudiVax on July 12, 2020, except for one page of the document, which carries two dates and two signatures, one of which is for June 2, 2020. Mr. Pineo notes that the June 2, 2020, predates the date upon which Sona entered into an agreement with SaudiVax (June 30, 2020). Mr. Pineo notes that "[I]t seems logically impossible that SaudiVax would have submitted an application for ethical approval of the clinical trial study of Sona's test approximately one month before it was contractually retained to do so"; and

4. Based on Plaintiff's Counsel's review of both the English and Arabic texts of this document, there is no mention of Sona in it, whatsoever. Mr. Pineo observes that it seems counterintuitive that SaudiVax would have sought the ethical review board's approval of the clinical trial of Sona's test without having identified its manufacturer. Thus, he argues, the legitimacy of this document (and SaudiVax's processes as a whole) are placed in question.

[114] I agree that certain issues arise out of Mr. Pineo's careful, forensic examination of this document. Respectfully, however, I do not agree that they are

material or sufficient to create a reasonable hope of demonstrating that the SaudiVax data was inaccurate, questionable, inappropriate and unreliable.

[115] There is no evidence that this document was reviewed by Health Canada or had any bearing on its decision-making regarding the COVID-19 Test. On the contrary, Health Canada's explanations focussed exclusively on contrasting the results of NML's independent tests to the SaudiVax results. There was no mention of this document as having influenced its concerns.

[116] Respectfully, Mr. Pineo also questions the significance of this document. He writes:

> At the end of the day, what is clear is that on August 26, 2020, this document was submitted on behalf of Sona to Health Canada, with the representation that it was the ethical review board's approval. It is also clear that, despite Mr. Morrison's representation to Health Canada, the document is not the approval of the ethical review board. What is, however, currently unclear is who created this document and for what purpose, and how it ended up in Sona's submissions to the regulators.
>
> (Pineo Reply Submissions, para. 40, emphasis added)

[117] However, respectfully, I cannot agree that bare, rhetorical questions constitute sufficient evidence to demonstrate a reasonable hope of successfully establishing misrepresentation.

[118] As mentioned, I have considered this issue around the SaudiVax data both separately and as part of the evidence as a whole. My conclusions are the same.

[119] The concerns around the SaudiVax data and the alleged misrepresentations regarding SaudiVax's independence do not individually give rise to a reasonable hope of success at trial. Furthermore, they do not collectively support one another in a way that would amount to a sustainable claim. The underlying problems with the evidence and arguments are simply insurmountable.

[120] The fact that the Sona's applications to the FDA and Health Canada failed was clearly a disappointment to the company and its shareholders. These events also caused Sona's share price to slide, quickly and steeply. However, based on the evidence before me, they do not generate the reasonable possibility that this disappointment was attributable to either a misrepresentation or otherwise constituted a material change of business.

[121] In the end, the COVID-19 Test proved to be a failure. And the hopes of Mr. Pineo along with other Sona shareholders for quick regulatory approval and commercial success were sunk. However, respectfully, the evidence and arguments, taken both individually and as a whole, are insufficient to establish a reasonable possibility that the alleged misrepresentations will succeed at trial.

Certification of Claim for Secondary Market Liability

[122] As indicated, Mr. Pineo also seeks to certify certain common issues under Nova Scotia's *Class Proceedings Act*.

[123] Section 7(1)(a) states that:

> "The court shall certify a proceeding as a class proceeding on an application under Section 4, 5 or 6 if, in the opinion of the court, the pleadings disclose or the notice of application discloses a cause of action"

[124] For reasons given above, Mr. Pineo's application for leave to pursue a claim for secondary market liability under the *Securities Act* is dismissed. The request to certify the same claim necessarily falters under s. 7(1)(a) of the *Class Proceedings Act* because the pleadings cannot disclose a reasonable cause of action where the same claim cannot proceed under the *Securities Act*. (*Capelli v. Nobilis Health Corp.*, 2018 ONSC 2266 and *Poirier v. Silver Wheaton Corp*, 2022 ONSC 80)

[125] The request to certify this cause of action is dismissed.

Certification of Claim for Oppression

[126] Section 7(1) of the *Class Proceedings Act* codifies the test for certification. It states:

> 7(1) The court shall certify a proceeding as a class proceeding on an application under s. 4, 5 or 6 if, in the opinion of the court,
>
> (a) the pleadings disclose or the notice of application discloses a cause of action;
>
> (b) there is an identifiable class of two or more persons that would be represented by a representative party;
>
> (c) the claims of the class members raise a common issue, whether or not the common issue predominates over issues affecting only individual members;

> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the dispute; and
>
> (e) there is a representative party who
>
> (i) would fairly and adequately represent the interests of the class,
>
> (ii) has produced a plan for the class proceeding that sets out a workable method of advancing the class proceeding on behalf of the class and of notifying class members of the class proceeding, and
>
> (iii) does not have, with respect to the common issues, an interest that is in conflict with the interests of other class members.

[127] In *Bishop v. Northview GP Inc.,* 2021 NSSC 225, Brothers, J. distilled the criteria as follows:

> 1. the pleadings must disclose a cause of action;
>
> 2. there must be an identifiable class;
>
> 3. the representative must be appropriate;
>
> 4. there must be a common issue; and
>
> 5. a class action must be the preferable procedure.
>
> (at para. 24)

[128] There is no reasonable challenge to the first three criterion.

[129] The controversy arises in the last two criterion:

> 1. Whether Mr. Pineo has properly raised common issues; and
>
> 2. Whether a class action is the preferable procedure in the circumstances

[130] With respect to his allegations of oppression, Mr. Pineo proposes to certify the following common issues:

> 1. Did an act or omission of Sona effect a result, or were the business or affairs of Sona carried on or conducted in a manner, or were the powers of the directors of Sona exercised in a manner, that was oppressive or unfairly prejudicial to or that unfairly disregarded the interests of the Class Members?
>
> 2. If the answer to question 124(1) above is yes, should the Court make an order that Sona, Regan and/or Whittaker compensate the Class Members?
>
> 3. If the answer to question 124(2) above is yes, what is the appropriate measure of compensation to be paid to the Class Members?
>
> 4. If the answer to question 124(1) above is yes, are there other remedies that should be ordered by the Court in order to rectify the matters complained of?
>
> (Mr. Pineo's Written Submissions, Appendix "B", p. 57)

[131] These common issues are expressed so broadly that the argument on certification becomes somewhat tautological in nature. Effectively, the Court is being asked to certify an action in oppression because the action sounds in oppression. That said, the Statement of Claim offers some additional clarity around the nature of the claim and, in particular, the reasonable expectations that must ground every claim of oppression. Mr. Pineo provides the following description of these reasonable expectations:

> ... the Defendants manage the regulatory approval processes with Health Canada and the FDA diligently and responsibly, obtain and submit appropriate, accurate and reliable data from independent validation studies, consistent with the FDA 's guidelines, and that they promptly and truthfully disclose all material information concerning those processes.
>
> (Pineo Written Submissions, at para. 69)

[132] These alleged expectations repeat the alleged statutory misrepresentation. Mr. Pineo's written submissions on oppression similarly demonstrate the degree to

which the facts alleged in support of oppression effectively overlap the claims of statutory misrepresentation.

[133] In my view, the battleground is over the question of whether a class action is the preferred proceeding in the circumstances.

[134] Neither side has provided comprehensive law on certifying a claim for oppression in these types of circumstances.

[135] I begin with the following basic principles:

1. The statutory requirement of preferability incorporates the following two basic concepts:

    a. Whether a class proceeding would be an appropriate method of advancing the claims of the class members; and

    b. Whether a class proceeding would be better than other methods such as joinder, test cases, consolidation, and any other means of resolving the dispute.

    (*Hollick v. Metropolitan Toronto (Municipality)*, [2001] 3 S.C.R. 158 ("***Hollick***"); *Fischer v. IG Investment Management Ltd.*, 2013 SCC 69 (S.C.C.))

2. A class proceeding must represent a fair, efficient, and manageable procedure – preferable to the alternative dispute resolutions mechanisms.(*Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 (Ont. C.A.) at paras. 73-75, leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 50 (S.C.C.))

3. "The preferability inquiry should be conducted through the lens of the three principal advantages of class actions — judicial economy, access to justice, and behaviour modification." (*Hollick* at para. 27)

[136] In the circumstances and even on a generous approach to the issue, a class action is not the preferred proceeding. A degree of judicial economy may be achieved. However, given my decisions regarding secondary market liability and the clear overlap between that issue and the allegations of oppression:

1. A class action for oppression would neither be efficient nor meaningfully advance access to justice; and
2. The residual impact of behaviour modification is significantly diminished in the circumstances.

[137] I dismiss the request to certify the allegations of oppression as a class proceeding. Mr. Pineo is at liberty to continue these claims in his personal capacity.

Keith, J.

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[1] "Sensitivity" relates to a mathematical formula designed to show the concordance between the rapid test picking up patients infected with the COVID-19 virus and a PCR test picking up the infected patient. The PCR test is demonstrably accurate and considered the "gold standard" in terms of detecting infection. Thus, "sensitivity" measures the degree to which the rapid test was able to detect a person infected with COVID-19 when compared against the proven reliability of a PCR test. However, it also comes with unacceptable risks in the context of a pandemic involving a highly contagious virus (e.g. the PCR test is more complicated, costly, and time-consuming creating a delay that becomes unacceptable in a pandemic).

[2] "Specificity" is the opposite of "sensitivity" in that it focusses on those persons who are not infected with COVID-19. It refers to a mathematical formula which combines the data around persons who tested negative for COVID-19 with other persons who were "false positive" (i.e. persons who tested positive for COVID-19 but were not actually infected). "Specificity" takes the number of patients which the test detected as not being infected and expresses it as a percentage of the total number of patients which were not infected – including the "false positive" results. In very simple terms, "specificity" measures the degree to which the rapid test was able to detect a patient not infected with COVID-19 after taking "false positives" into account.

[3] Section 122(1) of the CBCA states: **"**Every director and officer of a corporation in exercising their powers and discharging their duties shall: (a) act honestly and in good faith with a view to the best interests of the corporation; and (b) exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances."

[4] As mentioned above, this provision is nearly identical to the corresponding provisions in Ontario's *Securities Act.* See s. 138.3(1).

[5] As indicated, this proceeding is governed by Nova Scotia's *Securities Act*. That said, almost all the relevant case law in this motion emanates from Ontario. The relevant jurisprudence in Nova Scotia is scant, by comparison. Helpfully, the statutory provisions in Nova Scotia's *Securities Act* are virtually identical to their counterpart provisions in Ontario's *Securities Act*. As such, the parties agree that the jurisprudence from Ontario is both instructive and persuasive.

[6] Section 138.5(3) of Ontario's *Securities Act* corresponds to section 146E of Nova Scotia's statute.

[7] The corresponding provision in Ontario's *Securities Act* is s. 138.8(1).

[8] "*Mask*" is a reference to the Court's earlier decision in *Mask v. Silvercorp Metals Inc.*, 2016 ONCA 641.

[9] A public correction is clearly part of the statutory scheme. Section 146(C)(1) explicitly refers to the date upon which an alleged misrepresentation was "publicly corrected". It is less clear whether the public correction simply serves as a statutory "time-post" signifying the end of the class period or, alternatively, whether the public correction is an essential element of the statutory cause of action. In *Baldwin* the Ontario Court of Appeal raises this question but found it unnecessary to resolve the issue at the motion for leave. I similarly decline to resolve that issue at this stage of the proceedings. These reasons should not be interpreted as suggesting otherwise.

[10] While not particularly germane to this decision, "Ct" stands for "cycle threshold". In very basic terms, genetic material (or RNA) doubles in cycle. The "Ct count" refers to the number times certain identified genetic material (RNA) must double to reach a detection threshold. This detection threshold is called the "low Ct value". Thus, the more RNA (or genetic material) from the COVID-19 that is present in a patient, the fewer times it will need to double to reach the detection threshold. So, a "low Ct value" means that the patient began with a high viral load of COVID-19 – and therefore did not have to be duplicated many times to reach the detection threshold. By contrast, a high Ct value" means that the patient began with a low viral load which then had to be duplicated many times before reaching a detection threshold.

[11] I note that in his written submissions, Mr. Pineo appeared to expand the scope of the alleged misrepresentation by arguing that Sona not only misrepresented regulatory compliance but also misrepresented that "its test would be suitable for use in all critical settings." (Mr. Pineo's Written Submissions at para 15). That said, that written submissions connect this allegation to the lack of testing on asymptomatic patients.

[12] I do not agree that the data generated by SaudiVax was "inappropriate" to the extent that this word connotes that delivering a clinical, in-field evaluation study to the FDA and Health Canada was wrong or "inappropriate". That said, I understand Mr. Pineo used the word "inappropriate" as a synonym for "inadequate" thus returning the focus to the quality of (or, Mr. Pineo would say, deficiencies with) the SaudiVax data. Mr. Pineo makes this connection clear in para. 4 of his Written Submissions where he states that "Sona's submissions for the regulatory approval of its COVID-19 test were not supported by appropriate or adequate validation data." (emphasis added)