

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

W. R. GRACE & CO.-CONN.,

Plaintiff,

v.

ELYSIUM HEALTH, INC.,

Defendant.

C.A. No. 20-1098-GBW-JLH

GRACE'S OPPOSITION BRIEF REGARDING UNENFORCEABILITY

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'058 Patent	U.S. Patent No. 10,323,058 (JTX-001)
'207 Patent	U.S. Patent No. 10,233,207 (JTX-002)
'872 Patent	U.S. Patent No. 10,189,872 (JTX-003)
AIA	The Leahy-Smith America Invents Act (P.L. 112-29)
Armitage	Elysium's Expert Mr. Robert Armitage
Carlson	Mr. Erik Carlson
ChromaDex	ChromaDex, Inc.
Cl or Cl ⁻	Chloride (Chlorine) ion
CoL	Grace's Proposed Conclusions of Law ¶
Critical Date	One year prior to the earliest asserted patent application priority date
Dkt. 339	Elysium's Opening Post-Trial Brief Regarding Unenforceability
Elysium	Elysium Health, Inc.
ECoL	Elysium's Proposed Conclusion of Law ¶ (Dkt. 338)
EFoF	Elysium's Proposed Findings of Fact ¶ (Dkt. 338)
FDA	U.S. Food and Drug Administration
FoF	Grace's Proposed Findings of Fact ¶
Grace	W. R. Grace & Co.-Conn
GRAS	Generally Recognized As Safe
GSK Patent	WO 2015/186068 (JTX-028)
<i>Helsinn</i>	<i>Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.</i> , 855 F.3d 1356 (Fed. Cir. 2017), <i>aff'd</i> , 139 S. Ct. 628 (2019)
IR	Infrared
Kelleman	Dr. Audrey Kelleman
Kunin	Grace's Expert Mr. Stephen Kunin
MPEP	PTO's Manual of Patent Examining Procedure
NR or NR ⁺	Nicotinamide Riboside
NR-Cl or NRCl	Nicotinamide Riboside Chloride
Park	Grace's Expert Dr. Aeri Park
Perni	Elysium's Expert Dr. Robert Perni
PTO	United States Patent & Trademark Office
Rogers	Grace's Expert Dr. Robin Rogers
Reynolds	Mr. Brett Reynolds
Short	Mr. David ("Dave") Short
Smith	Ms. Peggy Smith
Steed	Elysium's Expert Dr. Jonathan Steed
<i>Therasense</i>	<i>Therasense, Inc. v. Becton, Dick. & Co.</i> , 649 F.3d 1276 (Fed. Cir. 2011)
Tr. n:pp:11	Trial Transcript "n" at page "pp" line "11" where n=I is August 21; n=II is August 22; n=III is August 23; n=IV is August 24; n=V is August 25; n=VI is October 24, 2023.
XRD or XRPD or PXRD	X-ray Powder Diffraction

Elysium urges this Court to contradict the binding *en banc* decision in *Therasense* by: (1) adopting PTO Rule 56 as the standard for materiality; (2) using materiality to attempt to overcome the absence of intent; and (3) ignoring lack of knowledge of materiality. Elysium cites no authority for overturning *Therasense*, relying on a dissent, and fails to apply the actual standard. Elysium also insists no contemporaneous evidence shows batch 13101 was amorphous (and thus not material) without acknowledging *its own expert's* admission that a contemporaneous email—sent to all accused individuals—showed batch 13101 was amorphous. Further, Elysium groups the accused together rather than addressing them individually, as required by controlling precedent.

I. Elysium has no clear and convincing evidence that batch 13101 was material.

Elysium argues materiality under the PTO's Rule 56 standard for a "prima facie" case of unpatentability, "before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion." Dkt. 339 at 5. The *en banc* Federal Circuit rejected that standard, finding the language quoted by Elysium sets too "low [a] bar" because it does not consider "subsequent argument or explanation by the patentee" that could have led to allowance. *Therasense, Inc. v. Becton, Dick. & Co.*, 649 F.3d 1276, 1294-95 (Fed. Cir. 2011). Elysium thus failed to apply the controlling "but for" standard for materiality. For that reason alone, its inequitable conduct defense fails, as it ignores the evidence at trial that would have overcome any rejection based on batch 13101. *Novo Nor. A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1359 (Fed. Cir. 2013) (finding evidence "at trial" would have overcome a rejection); FoF 2, § III.

Only a pre-critical date sale of *the claimed invention* could have prevented issuance of the '058 patent claims. See 35 U.S.C. §102(a)(1). Because every claim requires crystalline form I NRCl, a sale of batch 13101 is not "but for" material unless Elysium proves that it *was* crystalline form I. See *August Tech. Corp. v. Camtek Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (no materiality where withheld product "does not supply the missing [claim] element"). But

overwhelming evidence shows that batch 13101 was amorphous, not form I. For example, batch 13101 had much higher water content than batch 13202 (which *was* form I), consistent with the properties of amorphous material. FoF 22. Multiple witnesses testified that batch 13101 appeared to be amorphous, and a contemporaneous email referred it as “glassy,” (i.e., amorphous), and stated that it would help if we *found a way to crystallize* the material. FoF 27-28. Elysium’s own expert agreed that this email indicated batch 13101 was amorphous. FoF 29. Further, Elysium’s PXRD testing confirmed that batch 13101 was amorphous because, unlike the PXRD pattern for form I batch 13202, its PXRD pattern did not match form I’s and showed significant amounts of degradation products and amorphous content. FoF 14-21. It is no surprise that these batches differed because Grace modified the manufacturing process significantly. FoF 23-24. The IR data referenced by Elysium merely shows that batch 13101 contained NRCl—not that it was form I.¹ Elysium’s own expert admitted that IR data would be *expected* to be similar among forms, a scientific fact that would not be lost on the PTO. FoF 36. Because the invention is crystalline form I, not NRCl generally, the IR data would not even have raised a rejection by the PTO. FoF § III.

Finally, the jury’s verdict of no invalidity precludes materiality. CoL 2.

II. Elysium has no clear and convincing evidence of intent to deceive the PTO.

A. Elysium fails to show that any one person committed inequitable conduct.

Elysium grouped all accused (and unaccused, EFoF 58) individuals together because it cannot prove any one person committed inequitable conduct. But inequitable conduct must be proven as to a specific individual. CoL 4; *FMC Corp. v. Hennessy Indus.*, 836 F.2d 521, 525 n.5 (Fed. Cir. 1987) (rejecting argument that “A knew of X; A talked to B; therefore, B knew of X”).

¹ Elysium incorrectly argues that dependent claims with IR data could be invalidated by batch 13101’s sale even if it did not invalidate the broader claim 1. Dkt. 339 at 4 n.1; CoL 13. But the recited IR data does not negate the form I requirement—contained in all claims—which was not met by batch 13101. Moreover, batch 13101’s IR data does not match the patent’s data. FoF 37.

And “intent to deceive cannot be found” as to anyone because “multiple reasonable inferences” can be drawn that contradict the narrative concocted by Elysium. *Therasense*, 649 F.3d at 1290.

1. Reynolds did not intend to deceive the PTO.

Reynolds had no duty to disclose because he was not involved in the application’s *content*. CoL 5-6. Serving as a “commercial contact” (EFoF 3) for lawyers does not trigger any duty. *Id.* Elysium relies on a report with information from Reynolds’ colleagues that notes the filing date of an application. FoF 74. This does not show involvement in the application’s content. Elysium argues Reynolds “determined” an application filing “deadline,” but this cannot be correct because he had no prior patent experience or legal training. And he did not know about the on-sale bar until this litigation, so he could not have set a filing “deadline” based on prior sales. FoF 73-75.

Even if Reynolds had a duty to disclose, he could not have intended to deceive the PTO since he would not have “attribute[d] any legal significance to the sale[.]” *Robbins Co. v. Herrenknecht Tun. Sys. USA, Inc.*, 13-2113, 2015 WL 3454946, at *1, *5 (N.D. Ohio May 29, 2015); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1378 (Fed. Cir. 2009), *reinstated in rel. part*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc) (no evidence accused “appreciated the inherent anticipation theory”). Elysium relies on Reynolds’ misunderstanding (in 2023) that an amorphous material would not have been free flowing. This does not show he knew about the on-sale bar or associated free-flowing powders with a *claimed* crystalline form *during* prosecution. Nor has Elysium shown Reynolds read IR data on batch 13101. If anything, Reynolds’ candid testimony bolsters his credibility and reinforces that disclosure decisions would not have been based on his uninformed, lay views. *See* FoF § IV(C). Free-flowing powders are “not necessarily crystal[line],” as Elysium’s counsel admitted. FoF 31-32. Elysium’s admission is consistent with the evidence, which shows that crystalline forms are *more* free-flowing; not that amorphous material *cannot* be free-flowing. *Id.* Any contradictory evidence would at most permit multiple inferences.

Elysium also overlooks Reynolds’ receipt of the contemporaneous email showing batch 13101 was amorphous. FoF 28. The fact that Grace portrayed the material positively to a customer makes sense and provides no basis to disregard this “internal” assessment. EFoF 9 n.2. Elysium further relies on Reynolds’ “research project” on NRCl sales. But this could have related to ChromaDex’s requests, rather than to *Helsinn*. ChromaDex was seeking information on NRCl sales (not specific to form I) around that time (DTX-2162). Elysium offers no evidence that Reynolds had any awareness of *Helsinn*. And Reynolds stopping the project does not evidence an intent to deceive. Rather, he received the information he needed, as stated in the email. FoF 78. Indeed, an allegedly later version of the table fills in the information on dates (DTX-2169).

2. Carlson did not intend to deceive the PTO.

Carlson could not have had an intent to deceive because he believed batch 13101 was amorphous and form I first appeared in batch 13202 due to process changes. FoF 40-46. And he did not review IR data on batch 13101, which in any event would have only told him it contained NRCl, not that it was form I. *Id. DuraSys. Barriers Inc. v. Van-Packer Co.*, 19-1388, 2023 WL 3479150, *13 (C.D. Ill. 2023) (no inequitable conduct where individual may not have read reference). Mere existence of data within documents he received is insufficient. *Id.; Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996). Carlson also did not know of the sale. FoF 54-57; *Carpenter Tech. Corp. v. Allegheny Techs., Inc.*, 08-2907, 2013 WL 2250121, at *7 (E.D. Pa. May 22, 2013) (inventors with “primarily technical” responsibilities did not know of sales). Nor did Carlson know of, much less “determine,” any expedited “deadline.” Dkt. 339 at 2; FoF 53-56.

3. Short did not intend to deceive the PTO.

Short did not know of the allegedly overlapping IR data. FoF 60-61; *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1330 (Fed. Cir. 2009) (“[O]ne cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material information

contained in that reference.”). Even if he did, it would not have changed his belief that batch 13101 was amorphous and form I first appeared in batch 13202. *Id.* Thus, “from [his] perspective,” the “pre-critical date activity . . . did not entail the actual invention.” *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 979 (Fed. Cir. 2010). Like Reynolds, Short did not determine any deadline and did not know of *Helsinn*. FoF 68. So his spreadsheets could have related to a ChromaDex request.

B. Even Elysium’s allegations against the three individuals collectively fail.

1. Elysium does not and could not establish knowledge of materiality.

Elysium tacitly concedes that no one “knew . . . Batch 13101 contained crystalline NR-CI” (Dkt. 339 at 9), which rules out intent to deceive. Elysium deems such knowledge unnecessary under *Abbott Labs. v. Geneva Pharms., Inc.* 182 F.3d 1315, 1318 (Fed. Cir. 1999), where the Court invalidated claims notwithstanding a lack of knowledge of anticipation. But *Abbott* did not address inequitable conduct, which requires “knowledge of materiality.” *Ist Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1374-75 (Fed. Cir. 2012); *Therasense*, 649 F.3d at 1290 (holding that “should have known of its materiality” does not suffice). Accordingly, proof that an individual knew batch 13101 was form I is required. *August*, 655 F.3d at 1290. But the jury found no clear and convincing evidence that batch 13101 was form I, which is binding. Elysium cannot show by clear and convincing evidence any individual *knew* a batch *was form I* without clear and convincing evidence it *was form I*. This is why Courts have refused to find inequitable conduct where prior art did not invalidate the claims. *Id.*; CoL 2. They have abided by *Therasense*’s **holding** that intent and materiality, like invalidity, must be proven by clear and convincing evidence, rather than *Therasense*’s **dicta** that inequitable conduct may be based on prior art that did not render claims invalid.² CoL 1. At a minimum, the jury’s verdict shows “reasonable minds at [Grace] could have

² This is dicta because prior art in *Therasense* invalidated the claims. *Therasense*’s dicta can be

held the same beliefs during” prosecution. *Gen. Elec. Co. v. Mitsubishi Heavy Indus. Ltd.*, 946 F. Supp. 2d 582, 621 (N.D. Tex. 2013) (finding no intent); *Therasense*, 649 F.3d at 1290.³

Elysium alleges that Grace’s filing date suggests knowledge of materiality. But the cited email referred to an “internal risk assessment” and did not mention the ’058 patent. Elysium’s speculative link is not the only inference; the “risk” could have related to, e.g., infringement of third-party patents. And the evidence contradicts Elysium’s inference because one year from “60 days” after the May 24, 2013 delivery to ChromaDex is July 23, 2014. Elysium miscalculated that date as July 24. Dkt. 339-2. Grace thus filed its application *after* Elysium’s contrived deadline. Elysium’s story also falls apart in view of its allegation that Grace knew about a public sale in June 2013 (EFoF 14), which would have set an even earlier deadline if material.

Moreover, any alleged rush to file could have resulted from the late 2013 manufacture of batch 13202 (with a new process) and recognition that it materially differed from the previous batches. Or Grace could have “accelerated” the filing process because the sooner it filed, the sooner it could enforce its rights. But even if Elysium’s conjecture were true, it still would not show any knowledge of materiality because Grace could have set a filing deadline out of an abundance of caution based on sales of NRCl generally, to avoid even a weak argument during litigation (like Elysium’s) that amorphous sales invalidated the claims. The documents cited by Elysium lend

reconciled with its holding where, unlike here, the broadest reasonable construction (BRI) meaningfully differs from the *Phillips* construction in litigation. Elysium not only failed to disclose any BRI, its expert called this issue “moot” because the BRI is “identical” to the *Phillips* construction in this case. Dkt. 339-1 at 8 n.6 (mentioning in reply only that BRI might matter to the extent Grace’s expert raises it, which he did not). Elysium offers no reason to disregard its own expert’s opinions. And the deposition transcript that Elysium submitted to try to evidence a BRI should be struck because it has nothing to do with claim construction and relates instead to materiality, which the Court prevented Armitage from testifying about. In any event, Armitage’s views on materiality are worthless because he did not consider Grace’s rebuttal technical expert testimony, as the PTO would have under the correct materiality standard. (Tr. VI:175:24-176:2.)

³ Elysium’s request to infer intent from the “significance of the . . . information” (Dkt. 339 at 2) contravenes *Therasense*, as Elysium admits by relying on the *Therasense* dissent. ECoL 3 n.8.

more support to this inference than Elysium's inference because they discuss sales of "NRCI" rather than "form I NR-CI," as Elysium misleadingly contends. Dkt. 339 at 7; DTX-2001. And the scope of the claims may not have been determined when Grace allegedly set its filing deadline, so materiality could have been assessed later in view of the claims being prosecuted. And again, even if Grace set a "deadline," none of the accused individuals set it or knew why it was set.

2. Known materiality is not enough; no one accused decided to withhold.

Elysium's argument also fails because it identifies no deliberate decision to withhold information. Knowledge that disclosure would prevent allowance does not establish such a decision. CoL 3; *see GE*, 946 F. Supp. 2d at 590-91 (upholding the "obligation to enforce the Federal Circuit's nearly insurmountable standards for deliberateness outlined in *Therasense* and *Ist Media*" and finding no intent where "players analyzed and considered the materiality of the prior art" and "failed to disclose *all* of the relevant" art, while disclosing less relevant art) (emphasis original). Elysium assumes attorneys and other "employees" (EFoF 58) who are not accused of inequitable conduct were involved in prosecution. EFoF 15, 57 (alleging non-lawyers understood *Helsinn*); EFoF 3 (calling Reynolds a "contact" for Grace's IP lawyers). But it did not seek discovery from these people. *J&M Indus. v. Raven Indus.*, 574 F. Supp. 3d 941, 953 (D. Kan. 2021) (party could have "depose[d] [a] patent attorney" and "clearly shown why the [information] was not disclosed"). Elysium fails to account for the inference that the accused individuals did not decide to withhold anything. *See Ariad*, 560 F.3d at 1378 (finding non-lawyer "justified in her expectation that her attorneys would determine the legal significance of [information] and take appropriate actions"). It never even showed anyone accused knew if batch 13101 was disclosed or not. *McKesson Auto., Inc. v. Swisslog It. S.P.A.*, 712 F. Supp. 2d 283, 306 (D. Del. 2010) (no intent for person who "did not know whether the references were disclosed"). Nor can Elysium infer a decision to withhold based on privilege. CoL 7; *GE*, 946 F. Supp. 2d at 591 (no inequitable conduct

where privilege “obscured the Court’s ability to fully judge the record”).

3. No one had any obligation to test batch 13101.

Elysium faults Carlson and Short for not further testing batch 13101 to confirm their observations that it was amorphous. But they had data showing it was not form I, and contemporaneous evidence shows they believed batch 13202 (form I) behaved differently. FoF 22-35. Regardless, they had no duty to test. CoL 8. Elysium misplaces reliance on *Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp.*, 267 F.3d 1370 (Fed. Cir. 2001), which is not good law. CoL 9. In any event, *Brasseler* lends no support to Elysium’s argument because the attorney and inventors there knew “sales of the invention” had occurred roughly a year before the filing date. 267 F.3d at 1383. The Court held on summary judgment those sales anticipated the claims. And it found the decision to ignore the sales and “hope for the best” gave rise to inequitable conduct. *Id.* at 1376. Here, no evidence shows anyone knew of a sale of “the invention.” Indeed, the Court denied motions for summary judgment on the on-sale bar. *See Carpenter*, 2013 WL 2250121, at *7 (fact disputes regarding on sale bar precluded inequitable conduct because multiple inferences could be drawn). The jury found Elysium did not prove batch 13101 was the invention. This case is thus the opposite of *Brasseler*. Moreover, had they performed further testing like the PXRD analysis conducted by Elysium, it would have confirmed batch 13101 was not form I and thus not material. Any alleged difficulties with testing batch 13101 (EFoF 49) do not support Elysium’s argument. *See Highway Equip. Co., Inc. v. FECO, Ltd.*, 469 F.3d 1027, 1037 (Fed. Cir. 2006) (finding no intent to deceive where individual had discussed withheld reference with counsel, investigated its relevance, but could not determine its characteristics).

4. Elysium cannot ignore all testimony that is fatal to its defense.

Elysium acknowledges that the testimony of Grace’s witnesses (*see* FoF 40-78) rules out any inequitable conduct but dismisses that testimony as “self-serving.” Elysium fails to provide

any basis for discrediting Grace's witnesses. *J&M*, 574 F. Supp. 3d at 952 ("A great deal of testimony is 'self-serving,' but that does not necessarily render it unworthy of belief."). Courts routinely rely on "self-serving" testimony. See *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 923 F. Supp. 2d 602, 693 (D. Del. 2013) (relying on "state[ment] that he did not make a deliberate decision to deceive the PTO"). Elysium misplaces reliance on cases where explanations did not accord with the other evidence. CoL 11-12. Here, Short's and Carlson's observations that batch 13101 was amorphous comport with Kelleman's email, contemporaneous data for the batch, and Elysium's PXR results. FoF 14-35. Elysium dismisses Kelleman's email as "hearsay." The email is not hearsay because it shows, irrespective of its truth, a scientist informed Reynolds, Carlson, and Short that batch 13101 was amorphous, supporting a reasonable inference (and testimony) that they believed it to be amorphous at the time. The email also would be excepted from hearsay as a present sense impression. F.R.E. 803(1). And Elysium's own expert relied on the email for the truth of its assertion—the material discussed therein was amorphous—albeit without appreciating (until trial) that the material was batch 13101. FoF 29. In any event, the Court admitted the email after Elysium introduced similar evidence. (Tr. II:129:4-136:16; IV:52:21-53:8). Elysium also ignores contemporaneous evidence that the first form I batch, 13202, was made by a different process. FoF 23-24. None of this was disclosed to the PTO, further undercutting any intent to deceive. *Cancer Res. Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 733-34 (Fed. Cir. 2010) (no inequitable conduct where applicant "did not selectively withhold information; the withheld information includes both positive and negative data").

Elysium's "complaint that [Grace] has not corroborated the testimony [also] reverses the burden of proof." *J&M*, 574 F. Supp. 3d at 952. Grace has no burden to provide a "good faith explanation" for any conduct. *Therasense*, 649 F.3d at 1291. Grace did not need to further explain

Reynolds’ decision to stop collecting sales data after receiving what he needed. EFoF 32. Elysium had to show he stopped to deceive the PTO—but did not even question him about it. “In failing to ask, [Elysium] failed to carry its burden.” *Barry v. Medtronic, Inc.*, 245 F. Supp. 3d 793, 806 & n.16 (E.D. Tex. 2017), *aff’d*, 914 F.3d 1310 (Fed. Cir. 2019) (rejecting argument that inventor “never offered an explanation for how this misrepresentation occurred” and finding it “incumbent upon [defendant] to solicit testimony on this point”). Elysium also failed to elicit testimony on, much less corroborate, the lynchpin of its argument—accused non-lawyers knew about *Helsinn*—despite uncontroverted testimony that they did not. FoF 68, 73. Without such knowledge, Elysium’s inequitable conduct theory falls apart, as the individuals (according to Elysium) at most merely misapprehended the significance of non-public sales. *See Reactive Metals & Alloys Corp. v. ESM, Inc.*, 769 F.2d 1578, 1584 (Fed. Cir. 1985) (no inequitable conduct where inventor was aware of “sales prior to the critical date and . . . signed the oath for the application with a misunderstanding and disregard of its significance”); *FMC*, 836 F.2d at 525 (similar); *Ariad*, 560 F.3d at 1378 (no inequitable conduct in view of “legally incorrect” explanation).

III. The unclean hands defense fails because no one committed inequitable conduct.

As Elysium’s case law makes clear, unclean hands does not avoid the “important limits” in *Therasense. Gilead Sci., Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1240 & n.3 (Fed. Cir. 2018). It therefore rises and falls with inequitable conduct when based on a failure to disclose to the PTO. CoL 10. Elysium does not cite a single decision finding unclean hands, but no inequitable conduct, based on not disclosing information to the PTO. Its unclean hands defense thus fails for the reasons above, as well as for a failure to satisfy the pleading requirements.⁴ *Id.*

⁴ Reynolds “rebuff[ing]” ChromaDex’s requests (Dkt. 339 at 8 n.3) contradicts Elysium’s theory that they conspired against Elysium (which is not even improper, much less “unconscionable”). It also has nothing to do with materiality, but rather relates to ChromaDex’s disclosure of Grace’s manufacturing process in an FDA GRAS filing, allowing Elysium to copy it. (Tr. II:170:6-12.)

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VENABLE LLP

/s/ Daniel A. O'Brien
Daniel A. O'Brien (#4897)
1201 N. Market Street, Suite 1400
Wilmington, Delaware 19801
(302) 298-3523
daobrien@venable.com

Of Counsel:

Christopher P. Borello
James R. Tyminski
Joshua D. Calabro
Katherine E. Adams
Jerrit Yang
VENABLE LLP
151 W 42nd St.
New York, NY 10036

Counsel for Plaintiff

CERTIFICATE OF SERVICE

I, Daniel A. O'Brien, hereby certify that on this 12th day of December 2023, a copy of the foregoing document was electronically filed with the court and served via CM/ECF, on parties with counsel of record identified on the Court's docket.

/s/ Daniel A. O'Brien

Daniel A. O'Brien (No. 4897)