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 PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW REGARDING UNENFORCEABILITY

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases ..... **Page(s)**

Statutes

Other Authorities

CONSOLIDATED TABLE OF ABBREVIATIONS

'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)
Helsinn	*Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), *aff'd*, 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
Therasense	*Therasense, Inc. v. Becton, Dick. & Co.*, 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

FINDINGS OF FACT

I. Background and Prior Proceedings

1. Elysium bases all its unenforceability allegations on a single event: the sale of the only NRCl batch (13101) Grace manufactured before the July 24, 2013 critical date for the '058 patent.[1]

2. The jury heard four days of expert and fact witness testimony, and over 200 exhibits were admitted. Elysium contended that the '058 patent was invalid for anticipation based upon the sale of batch 13101, the very same allegation that underlies its unenforceability defenses. The jury rejected Elysium's contentions and returned a verdict of no anticipation based on prior sale, i.e., it determined that Elysium did not prove batch 13101 was form I. (Dkt. 311, 312.)

II. The '058 Patent

3. Claim 1 of the '058 patent recites "[a] crystalline form I of nicotinamide riboside chloride according to [the chemical formula for NRCl]." (JTX001 at 20.) All other claims refer to claim 1; thus, all the claims require crystalline form I NRCl. *See id.*

4. The '058 patent contains analytical data for crystalline form I, including powder X-ray diffraction ("PXRD"), infrared spectroscopy ("IR"), differential scanning calorimetry ("DSC"), thermogravimetric analysis ("TGA") and dynamic vapor sorption ("DVS"). These are well-known methods that a POSA would have had experience with. (Tr. III:238:1-239:12 (Steed); Tr. II:193:10-15 (Park).) It is undisputed that, for some methods, a POSA cannot always rely on one method alone to distinguish between two solid forms of a substance. (Tr. IV:137:2-138:10 (Rogers), Tr. II:204:4-205:14 (Park), Tr. III:226:16-227:15, 241:5-16 (Steed).)

5. The Court construed "crystalline Form I of nicotinamide riboside chloride according to formula I" to mean "[c]rystalline Form I of nicotinamide riboside chloride, according to Formula

[1] Elysium dropped its argument that the '872 patent is unenforceable.

I, which can be identified by one or more of the analytical methods described in the specification." (Dkt. 109.) Thus, for a product to satisfy the claims, a POSA must be able to identify it as form I using one or more of the methods in the specification. If this cannot be done—or if the data indicate that the product is a different form—then the claims do not read on the product.

6. In its *Markman* ruling, the Court noted that form I is "defined with respect to ***some subset***, but not all of the testing data provided" in the '058 patent. (Dkt. 120 at 13:10-13 (emphasis added).) It also specifically emphasized that the patents state that form I ***"may be"*** characterized by particular methods, not that it must be—or necessarily can be—characterized by one particular method alone. (*Id.* 13:20-14:9.) Indeed, this Court's claim construction does ***not*** mean or suggest that form I can always be positively identified by a single method in all cases.

7. The Court construed the term "characterized by" appearing in several dependent claims to mean "identifiable by reference to." (Dkt. 109.) These dependent claims are narrower than Claim 1. They also require form I, but additionally require that the product in question be "identifiable" as form I "by reference to" the specific data points recited in the dependent claim.

8. Neither Elysium nor its experts proposed any alternative claim constructions or offered any evidence that the PTO would have applied different constructions under the "broadest reasonable interpretation standard." Its experts did not discuss any differences in their analysis if they were to apply the broadest reasonable interpretation standard, or if they were to apply a preponderance of the evidence standard instead of a clear and convincing evidence standard.

9. In fact, Elysium's expert Mr. Armitage testified that the distinction is moot where, as here, claim terms are directed to a chemical compound or form thereof because the broadest reasonable construction is typically the same as the *Phillips* construction. (Tr. VI:175:24-177:23.)

III. Batch 13101 Was Not Crystalline Form I NRCl and Is Therefore Not "But-For" Material to the Patentability of the '058 Patent Claims

10. The crux of Elysium's unenforceability allegations is that the sale of batch 13101 was a sale "of the claimed invention." (Dkt. 339 at 2.) Because every claim requires ***form I*** NRCl, Elysium must prove that batch 13101 ***was*** form I, after considering all the evidence Grace could have presented to the PTO, not just evidence cherry-picked by Elysium. Thus, Elysium must prove by clear and convincing evidence that the PTO would not have ultimately ***allowed*** one or more claims of the '058 patent after Grace had an opportunity to overcome any rejections.

11. Elysium argues that Grace "had no argument or evidence available to overcome [a] rejection." (Dkt. 339 at 5.) This is incorrect and ignores hours of testimony and dozens of exhibits presented at the jury trial showing that batch 13101 was not form I NRCl. Elysium failed to even address much of this evidence, let alone prove by clear and convincing evidence that, after reviewing all of the evidence and arguments, the examiner would not have allowed the claims.

12. Scientists identify solid forms using analytical methods and data; crystalline forms cannot be identified by visual inspection alone. (Tr. III:204:12-13 (Steed).) The only method that directly measures the crystalline structure of a sample is PXRD, which is considered the "fingerprint" of a solid and the "gold standard" for identifying crystalline forms. (Tr. II:17:11-20 (Short), 59:20-60:2, 72:4-12 (Carlson), 201:3-202:9, 203:2-205:6 (Park); 174:13-175:7, 239:2-12 (Steed); Tr. IV:116:2-16, 151:10-18, 153:15-154:1 (Rogers).) PXRD can also identify amorphous forms because, unlike crystalline forms, they do not produce PXRD patterns with well-defined peaks. (Tr. II:201:23-202:4 (Park); IV:122:1-12 (Rogers).)

13. Because crystalline structure ***may*** impact a substance's physical and chemical properties, the crystalline form of sample can ***sometimes*** be determined by other, indirect methods such as IR, DSC (which measures, among other thermal events, melting points), TGA, and DVS. Still, it is undisputed that these indirect methods cannot ***always*** distinguish between crystalline

forms. (Tr. II:204:17-205:14 (Park); III:47:23-48:13 (Park), 226:16-227:15, 241:5-16 (Steed).)

14. ***Powder X-Ray Diffraction Analysis of Retainer Samples.*** Grace retained small samples of its NRCl batches, which Elysium had a laboratory perform PXRD analyses on in this litigation. (JTX-032.) Grace's scientific expert, Dr. Rogers, analyzed this PXRD data and concluded that batch 13101 was amorphous NRCl, not form I. (DTX-2871 at 1.)

15. Dr. Rogers testified that the batch 13101 sample's PXRD pattern is not the PXRD pattern "substantially as shown" in Figure 1. (Tr. IV:121:6-9.) And Elysium's own expert Dr. Steed essentially conceded as much, saying that batch 13101 "is a bit more of a mess isn't it? So this doesn't look on the face of it, nearly as much as the other two matches." (Tr. III:198:10-12.)

16. Dr. Rogers pointed to several significant differences between the two PXRD patterns in concluding that batch 13101 did not match form I's PXRD pattern. First, the most intense peaks in the form I PXRD are largely found on the left side of the pattern at angles below 25 degrees two theta. The opposite is true of batch 13101's pattern—the most intense peaks are largely found on the right side of the pattern at angles above 25 degrees two theta. (Tr. IV:121:10-22.) Dr. Steed did not provide any explanation for these differences in relative intensity. (Tr. IV:121:23-25.)

17. Second, batch 13101's pattern was missing peaks that appear in the PXRD pattern for form I. (Tr. IV: 123:5-124:4 (Rogers).) If the sample was form I, peaks would not be missing. (Id.)

18. Third, batch 13101's pattern had a rising baseline, or "halo," signifying a significant amount of amorphous material in the retainer sample PXRD that does not appear in the form I PXRD. (Tr. IV:122:1-12.) This was evidence the batch was amorphous at the time it was made as other retainer samples that were actually form I NRCl at the time they were made, such as batch 13202, did not show such significant amorphous content. (Tr. IV:124:13-125:2, 125:22-126:12.)

19. Fourth, the retainer sample PXRD contains extra peaks that do not match any peaks in

the form I PXRD. (Tr. IV:122:20-123:4, 124:5-18 (Rogers); Tr. III:248:14-24 (Steed).) The extra peaks represent crystalline degradation products in the sample that Elysium's expert Dr. Steed could not identify. (Tr. IV:124:5-18 (Rogers).) Critically, Dr. Steed failed to provide any evidence that the peaks he alleges match those of form I are actually due to the presence of form I NRCl. In fact, PXRD patterns for the polymorphs of the potential crystalline degradation products of NRCl "take up all of the diffraction space across the entire diffractogram." (Tr. IV:126:19-127:18 (Rogers).) All of the peaks that Dr. Steed alleges come from form I NRCl could actually come from other crystalline substances present in the retainer sample, and Dr. Steed did not provide any evidence that any given peak comes from form I NRCl. (Tr. IV:126:19-128:22 (Rogers).)[2]

20. The fact that batch 13101 degraded over time, whereas samples of batches known to be crystalline form I NRCl did not, proves conclusively that batch 13101 was not form I when it was made and sold. Grace retained samples of all the NRCl batches it made in 2013 and 2014. (Tr. II:20:9-21:1 (Short).) These samples were stored in the same place, under the same conditions. (Tr. II:20:24-21:24 (Short).) Dr. Rogers compared the PXRD pattern for batch 13101 with the PXRD patterns of the remaining batches. He concluded that the PXRD pattern for batch 13202, which was determined to be form I NRCl by Grace around the time it was made, still matched crystalline form I with very little degradation when tested during this litigation, despite being manufactured the same year as batch 13101. (Tr. IV:125:22-126:3; Tr. III:198:10-12 (Steed).)

21. The contemporaneous testing data also shows that the vast difference in degradation of batch 13101 compared to batch 13202 is not attributable to impurities present at the time the

[2] Dr. Steed attempted to characterize the substances in the batch 13101 retainer sample by a procedure called nuclear magnetic resonance spectroscopy ("NMR"). (DTX-2871.) Dr. Steed's NMR analysis does not identify what the potential degradation products are nor does it quantify them. (Tr. IV:128:23-131:12 (Rogers).)

batches were put into storage. (Tr. IV:133:13-134:1 (Rogers).) Contrary to Dr. Steed's assertion, batch 13101 was no less pure than batch 13202 at the time of manufacture. In fact, HPLC data collected at the time shows that batch 13101 was 98.9% pure at the time it was made, while batch 13202 was slightly ***less*** pure at 98.5%. (JTX-163-01; JTX-164-01; Tr. IV:133:13-134:1 (Rogers).) In short, the only reasonable explanation for why batch 13101 degraded significantly and other batches like batch 13202 did not is that it was a different form of NRCl. (Tr. IV:124:13-125:2, 125:22-126:12 (Rogers); Tr. II:21:2-24:7 (Short).) If batch 13101 were form I when it was made and sold, it would not have significantly degraded and would have looked more like the PXRD patterns of all the other batches from that time period. (*Id.*)[3] The fact that batch 13202 (known to be form I when made) matched the form I PXRD pattern when Elysium tested it, but batch 13101 did not means that batch 13101 simply could not have been form I at the time it was made and sold. It was amorphous, which is known to be less stable and more susceptible to degradation. (*Id.*; *see also* Tr. IV:131:25-132:9, 133:13-134:1 (Rogers).)

22. ***Water Content.*** Batch 13101 was determined to have a water content of 1.7605% at the time it was made. This is over 12 times higher than the 0.14% water content of batch 13202, which was known to be form I at the time it was made. (JTX-163-01; JTX-164-01; Tr. IV:132:10-133:12 (Rogers); Tr. VI:113:11-114:1 (Short); DTX2709; *see also* Tr. II:55:1-23 (Short).) No later Grace NRCl batch had such a large water content. Amorphous materials tend to be hygroscopic, meaning that they generally have a higher water content compared to crystalline forms. (Tr. IV:132:20-133:2 (Rogers).) As Dr. Rogers explained, water is a small molecule, "so on a

[3] Elysium cites Mr. Carlson's and Mr. Short's testimony that a later test of the XRD material may not have been reliable (Dkt. 339 at 5), but this mischaracterizes their testimony. Both testified that the material tested at a later date may not have been representative of the material that was sold (Tr. VI:49:11-19 (Carlson); Tr. VI: 95:7-16, Tr. II:7:18-23 (Short).), but this would not have accounted for the difference in degradation between batch 13101 and all the other batches.

molecular basis, that's a lot of water." (Tr. IV:133:3-12.)[4] Thus, the elevated water content is strong evidence that batch 13101 was amorphous at the time it was made and sold.

23. ***Manufacturing Process.*** Batch 13101 was made using a significantly different manufacturing process than the process described in the specifications of the '058 patent. (Tr. IV:139:9-13.) The only antisolvent specified in the '058 patent is MTBE. (JTX-001-19 at 13:1017, 14:14-16.) Instead of MTBE, the batch 13101 process used acetone as an antisolvent, which the '058 patent identifies as a solvent. A solvent, used to dissolve solids into solution, is the ***opposite*** of an antisolvent, which is used to crash solids out of solution. (Tr. IV:139:14-140:4 (Rogers).)

24. There were "significant changes" made to the manufacturing process between batch 13101 and batch 13202, which was later shown to be form I by PXRD. These changes included switching the antisolvent to MTBE, scaling up, replacing the methanol strip acetone precipitation with a nonstrip MTBE precipitation, and changing how the ammonia was charged, the amount of methanol and MTBE, the charge rates, and the temperatures. (JTX-147-0002; JTX-148-0005; Tr. II: 67:25-68:10, 69:19-70:2, Tr. VI:58:4-59:2 (Carlson).) Inventor Erik Carlson believes these changes led to the formation of form I. (Tr. VI:58:4-59:2 (Carlson).)

25. Elysium points to the use of terms like "crystallization" and "crystalizing" to suggest that batch 13101 was form I. But these terms were used and understood at the Grace manufacturing facility to merely indicate getting solids out of solution; they did not mean creating a crystalline form of a compound. (Tr. II:64:15-24; Tr. VI:50:20-51:7 (Carlson).) Individuals at Grace would use terms like "crystallization" even when they believed they were manufacturing amorphous products, or without confirming whether a product was crystalline or amorphous. (Tr. VI:50:20-

[4] Elysium focuses on "moisture analyzer" data and ignores the Karl Fischer water content testing data. (*See, e.g.*, Dkt. 339 at 4; EFoF 10.) But Elysium adduced no expert testimony or any other evidence explaining what the "moisture analyzer" data is or what it means.

51:7 (Carlson); Dr. Rogers concurred, testifying that "organic chemists use this term very loosely. They are essentially just saying bringing it out of solution, but . . . a POSA would know that . . . that's either as an amorphous solid or a crystalline solid." (Tr. IV:144:2-12 (Rogers).)

26. This is consistent with Dr. Perni's GSK Patent which states: "[o]ne synthesis described the anomerically pure NR bromide salt as crystalline, but the product was not adequately described to ascertain whether the material was ***truly crystalline*** or merely an amorphous solid." (JTX-028-04.) Thus, even Elysium's own expert has acknowledged that skilled artisans often describe a product as "crystalline" without ascertaining whether it is ***truly crystalline*** or merely amorphous.

27. ***Contemporaneous Observations and Physical Appearance.*** According to Mr. Carlson and Mr. Short—who observed batch 13101 at the time it was made—it appeared glassy, sticky, wet, and waxy; it was difficult to dry and absorbed moisture; it was difficult to handle from a manufacturing standpoint; and it overall behaved like an amorphous material. (Tr. II:8:3-25 (Short), 67:1-11 (Carlson); Tr. VI:47:16-48:20 (Carlson), 96:25-98:9 (Short).)

28. An April 26, 2013 e-mail from Grace employee Audrey Kelleman, Ph.D. to Mr. Carlson, Mr. Short, Mr. Reynolds, and others corroborates their testimony. Dr. Kelleman wrote that "[t]he process ran well in the plant. . . We feel that the process needs further development to improve the yields. ***It would also help if we found a way to crystallize the material as the glassy nature of the solid is problematic***." (JTX-173.) Mr. Carlson and Mr. Short each confirmed that this email was referring to batch 13101, that the term "glassy" is commonly used to refer to amorphous materials, and that the NRCl from batch 13101 was indeed "glassy" and "problematic." (Tr. VI:54:2-55:13 (Carlson), 96:14-97:23 (Short).)

29. Even Elysium's own expert Dr. Perni agreed that this email "indicated that Grace was having amorphous and glassy problems with its product" and that Dr. Kelleman "had to be talking

about batch 13101." (Tr. IV:54:1-55:19.). This admission alone should be fatal to Elysium's case, as it shows that a scientist would have believed that batch 13101 was amorphous NRCl.

30. Elysium cites another email sent by Dr. Kelleman to ChromaDex a few minutes earlier where she describes the same batch as a "fine free flowing powder." (JTX-199.) This statement is not contradictory to her later email. Mr. Short testified, a powder can "[a]bsolutely" be sticky, and the presence of water "certainly could" make a material sticky. (Tr. II:53:18-54:1; *see also* Tr. III:229:1-230:16 (Steed); Tr. VI:48:7-20 (Carlson: "material would sometimes be handled a little better initially but certainly when exposed to atmospheric conditions would absorb water readily and become more problematic").) Alternatively, even if there were a contradiction, it is most reasonable to infer that Dr. Kelleman was puffing or painting a rosier picture about the quality of the material in her conversations with the customer than she privately admitted to internally.

31. Moreover, this statement does not imply that batch 13101 was even crystalline, let alone crystalline form I NRCl. As Elysium's lead counsel admitted, free-flowing powder does not mean crystalline, and ChromaDex would have accepted any "free-flowing powder, not necessarily crystal[line]" material. (Tr. VI:219:17-24; *see also* 187:4-16 (ChromaDex corporate representative testifying that ChromaDex did not require crystalline NRCl or any specific crystal form of NRCl).) Even if batch 13101 had been "free-flowing," amorphous materials—including amorphous NRCl—can have the appearance of a "free-flowing powder." Contrary to Elysium's assertions, not all amorphous NRCl is "gooey" or "oily." For example, the '058 patent indicates that some samples of amorphous NRCl are "easier to handle (less sticky)" than others. (JTX001-0019 at 14:50-58.) And an internal report described amorphous NRCl as "powder" and recommended performing a "powder flowability study" on it. (JTX-104-0009, 13, 19.)

32. About a year after batch 13101 was made, Mr. Short and Mr. Carlson personally

observed a change in Grace's NRCl. The physical properties of the batch made with a new ammonium hydroxide process, batch 13202, "were different. It didn't absorb water the same in the standard atmospheric conditions. It didn't become sticky and problematic. The material physically appeared to be different." (Tr. VI:56:1-22 (Carlson), 98:25-99:22 (Short: "we saw a distinct change in the physical nature of the material").) The material "looked much ***more*** free-flowing. It looked more granular, certainly more consistent with material that could be crystalline." (Tr. VI:99:21-100:1 (Short); *see also* Tr. II:9:11-10:2 (Short), 73:7-20 (Carlson).)

33. An email sent around this time in April 2014 from Dr. Kelleman to Mr. Carlson, Short, Reynolds, and others corroborates these observations: "Since the new material from the NH4OH process seems to be more crystalline, can we please work with Columbia or a service company and run some tests to find out if the material is a crystal? This is very important."[5] (JTX-174.)

34. In response to this email (JTX-174), the material was sent for PXRD analysis. (Tr. VI:56:16-22 (Carlson), 100:6-17 (Short); Tr. II:10:20-11:4 (Short).) The results, received in the form of an analytical summary from the Grace Analytical Library Services around May 20, 2014, showed that Grace had a unique crystal form in batch 13202. (JTX-176; Tr. VI:56:16-57:15 (Carlson), 100:2-101:13 (Short); Tr. II:10:20-11:4 (Short).)

35. Batch 13202 is the first batch for which Grace has data showing that the NRCl is crystalline form I. (Tr. VI:101:8-21 (Short).) The patent application that led to the '058 patent was filed a few months later on July 24, 2014. (Tr. VI:57:1-15 (Carlson); JTX-001 at 1.)

36. ***Infrared Spectroscopy.*** Elysium points to contemporaneous IR data as evidence that batch 13101 was form I. (*See, e.g.*, Dkt. 339 at 2; EFoF 38.) But both parties' experts agreed that

[5] Mr. Carlson confirmed that "material" as used by Dr. Kelleman in this email refers to NRCl. (Tr. VI:55:23-56:7.)

IR is a test for chemical identity, not a direct measurement of crystal form; IR results would therefore be expected to be similar between two samples of the same molecule regardless of their crystal form. (*See, e.g.*, Tr. III:241:5-16 (Elysium's Dr. Steed agreeing that "the IR spectra for two samples of the same molecule ***must*** show significant similarities" (emphasis added); Tr. IV:137:17-23 (Dr. Rogers agreeing that "two different solid forms of a substance [could] have indistinguishable IR spectra").)[6] In order to determine whether IR could be used to distinguish crystal forms for a particular molecule, a POSA would require reference IR spectra for all existing solid forms. (Tr. IV:137:20-138:6 (Rogers).) Dr. Steed admitted that he has never seen the IR spectrum for amorphous NRCl, and, moreover, that he is capable of making amorphous NRCl and testing it by IR but that Elysium did not ask him to do so. (Tr. III:244:1-245:7 ("[T]hat wasn't part of my mandate.").) It is Elysium's burden to prove that batch 13101 was form I, not Grace's burden to prove that batch 13101 was amorphous.

37. The graphical IR spectrum provided in Fig. 2 of the '058 patent is not the same as the IR spectrum for batch 13101, and the peak listing in Table 2 of the '058 patent is missing a peak that appears in the IR peak listing of batch 13101. (Tr. IV:138:11-139:5 (Rogers); 30:5-12 (Perni).)

38. ***Liquefaction Temperature.*** Contrary to Elysium's argument, batch 13101's broad liquefaction temperature range is inconsistent with the'058 patent's melting point data. (*See, e.g.*, Dkt. 339 at 2; EFoF 42.) The patent reports results of five different DSC experiments, each with a sharp melting point, not a broad "range." (JTX-001 at Table 4; Tr. IV:136:12-21 (Rogers); Tr. III:232:7-233:21 (Steed).) The data packet for batch 13101, on the other hand, reports a single

[6] Elysium mischaracterizes Dr. Park's cited testimony related to her White Paper. (Dkt. 339 at 5.) As she made clear, "if you don't have a reference standard for one of the known forms of a compound for a particular method," it will "not be possible to confirm" that "an unknown sample is that form or not." (Tr. III:45:20-46:12.)

experiment taken on a visual melting point apparatus that yielded a broad liquefaction temperature range. (JTX-163-03; Tr. IV:134:7-24 (Rogers: range is "only specified when you're doing this visually"); Tr. III:232:7-22 (Steed).) It is not possible to distinguish between crystalline "melting" and an amorphous "glass transition" using such methods. (Tr. IV 134:7-135:9.) And the sample decomposed during the analysis, which is not consistent with melting. (JTX-163-03; Tr. VI:76:14-19 (Short).) The use of the term "Melting Point" does not mean batch 13101 truly "melted" because the data packet forms are standardized and preprinted. (Tr. IV:134:7-13 (Rogers).)

IV. None of the Accused Individuals Believed Batch 13101 Was Form I Nor Intended to Deceive the USPTO

39. Elysium has not proven by clear and convincing evidence that any of the three accused individuals (a) knew that batch 13101 was crystalline form I NRCl, and (b) made a deliberate decision to withhold information about that batch from the USPTO with deceptive intent.

A. Erik Carlson

40. ***Batch 13101.*** Mr. Carlson believed batch 13101 was amorphous at the time it was made based on literature precedent and his personal observation that the properties and physical handling of the material were similar to what would be expected for an amorphous material, both before and after it finished drying. (Tr. VI:47:16-48:20; Tr. II:62:10-16, 63:23-64:5, 66:17-67:11; *see* ¶¶27-29 *supra*.) For example, the material tended to absorb water out of the atmosphere and to become sticky and somewhat clay-like. He experienced various issues with handling and with the material not being as stable as one would often expect for a crystalline material. (Tr. II: 63:23-64:5; Tr. VI:47:16-48:20.) The material was "glassy and problematic." (Tr. VI:54:22-55:13.)

41. Mr. Carlson testified that amorphous NRCl sometimes handled a little better initially, but when exposed to atmospheric conditions would absorb water readily and become more problematic. (Tr. VI:48:14-20.)

42. Mr. Carlson did not consider batch 13101 to be material to the patentability of the '058 patent because, in his view, batch 13101 was amorphous NRCl, not form I. (Tr. VI:49:20-50:1.)

43. Mr. Carlson does not believe that IR testing discloses anything independently about the crystal form of a compound (Tr. VI:52:7-12.) He testified that his understanding is that IR is used to identify a general chemical material, i.e., to determine the chemical identity of a sample, not its crystalline form. (*Id.*) Elysium attempts to establish that Mr. Carlson has relied on IR alone to distinguish crystal forms (EFoF ¶20), but this is incorrect and the testimony it cites is consistent with the rest of Mr. Carlson's testimony about IR. Indeed, he testified that when IR results were "brought to our attention as a possibility" of showing a mixture of two crystalline forms, the team had PXRD testing performed on the sample "to get confirmation because we didn't feel like the IR was significant by itself." (Tr. VI:42:8- 43:1; *see also id.* 52:13-18.) And when asked if the IR peaks in the patent are representative of crystal form I, he said that "[t]hey're representative of the ***material*** nicotinamide riboside chloride." (Tr. VI:32:10-21 (emphasis added).)

44. Mr. Carlson does not perform IR testing; that is done through Grace's Quality Control ("QC") department. (Tr. VI:52:19-23.) It is not his general practice as an R&D chemist to review IR peaks and spectra. Instead, he reviews only QC's conclusion as to whether the molecule "conforms to structure" of the desired molecule or not. (Tr. VI:52:25-53:11.) He never reviewed the IR data for batch 13101, and never compared the IR peak listing for batch 13101 to the peak listing in the '058 patent prior to this lawsuit. (*Id.* 53:12-20.)

45. The earliest plant batch that Mr. Carlson is aware of containing crystalline form I NRCl was batch 13202, which completed manufacturing on Dec. 30, 2013. (Tr. VI:57:13-24; JTX-148-001.) He concluded this based on PXRD testing of that batch (and other laboratory batches) in May 2014. (Tr. VI:56:16-57:15; Tr. II:72:4-73:10.) Mr. Carlson testified that PXRD analysis is

the "gold standard" for determining the crystalline form of a sample. (Tr. II:59:20-60:2, 72:4-9.)

46. There were "significant changes" between the manufacturing process used to make batch 13101 and that used to make batch 13202, including how the solid material was generated; Mr. Carlson testified that he believes those changes led to the formation of crystalline form I. (Tr. II:67:22-70:2; Tr. VI:58:18-59:2.)

47. No PXRD testing was performed on batch 13101, because it was believed to be amorphous. (Tr. VI:49:1-6.) Mr. Carlson never at any time before the '058 patent issued believed that the NRCl in batch 13101 was a crystalline form of NRCl, and he never at any time before the '058 patent issued thought the retainer sample of batch 13101 should be analyzed by PXRD. (Tr. VI:49:7-50:1.) This was, in part, because he never doubted that the material was amorphous. (*Id*.)

48. Mr. Carlson understands that batch 13101 was the only plant batch made more than one year before the filing of the patent application that led to the '058 patent. (Tr. VI:50:2-5.) Thus, Mr. Carlson never believed that Grace had made crystalline form I NRCl more than a year before the filing of the patent application that led to the '058 patent. (Tr. VI:50:6-9.)

49. Mr. Carlson testified that he was "happy and excited" that Grace had a new, unique crystal form in batch 13202. (Tr. II:73:1-6.) Determining whether the material was crystalline was important to the team because "[h]aving a unique crystal would be important for valuable assets, as well as improved handling and isolation, drying of the material, just improving the process all around." (Tr. II:71:1-13.) Mr. Carlson and others at Grace had PXRD analysis done on batch 13202 as soon as they thought a crystalline form was made. (Tr. II:55:14-57:12.) It is reasonable to infer Mr. Carlson would have proposed PXRD testing on batch 13101 if he thought it were crystalline.

50. In sum, the most reasonable inference based on all the evidence is that Mr. Carlson did not believe Grace made form I NRCl before the PXRD results on batch 13202 were obtained in

May 2014 and did not believe batch 13101 was form I.

51. ***Patent Application.*** Mr. Carlson is a research and development chemist, not an attorney nor a patent agent, and he has no training in patents. (Tr. VI:46:5-13.) Mr. Carlson did not draft the entirety of the '058 patent application, only providing information pertaining to the processing and development of the claimed NRCl forms. (Tr. VI:46:19-47:1.) He testified that he did not provide any IR data. (Tr. VI:47:2-3.)

52. Mr. Carlson testified that he is not aware of anything material to the patentability of the '058 patent that was not disclosed to the PTO before the patent was issued. (Tr. VI:47:11-15.)

53. There was no delay in filing the '058 patent application once the new crystalline form of NRCl was confirmed by PXRD. The application was filed in July 2014, only a few months after form I was first identified. (Tr. VI:57:6-12; JTX-001-01.) Mr. Carlson does not recall rushing to file an application due to any concerns regarding prior sales of NRCl. (Tr. VI:47:4-7.)

54. Mr. Carlson does not recall any conversations about a concern that Grace had offered for sale or sold crystalline form I too far before the filing of the '058 application. (Tr. VI:59:3-7.) Before this lawsuit, Mr. Carlson was not involved in any discussions about when any batches of NRCl were sold or offered for sale. (Tr. VI:59:8-11.) He had minimal, if any, involvement with sales of NRCl. (Tr. VI:61:13-19.) He has done work during his employment at Grace that was not sold to customers, and he has worked on products that have not been scaled up. (Tr. II:80:6-81:1.)

55. To the extent he was later added to email chains discussing sales, it was not Mr. Carlson's general practice to read all of the emails in a chain that he was not originally copied on when he was not directed to do so. For example, he has no recollection of reading emails contained in DTX-2043 / JTX-199 that were sent prior to his being added to the chain. (Tr. VI:59:23-61:12.) Batch 13101 was a small-scale pilot batch. (Tr. II:65:23-66:16.)

56. Elysium has not established that Mr. Carlson was involved with or aware of at least DTX-2001, DTX-2011, DTX-2012, DTX-2014, DTX-2040, DTX-2045, DTX-2052, DTX-2064, DTX-2079, DTX-2110, DTX-2111, DTX-2132, DTX-2151, DTX-2153, DTX-2157, DTX-2161, DTX-2162, DTX-2165, DTX-2166, DTX-2167, DTX-2168, DTX-2169, DTX-2188, DTX-2189, DTX-2277, DTX-2317, DTX-2709, DTX-2836, JTX-054, JTX-055, JTX-104, JTX-215, earlier emails in the DTX-2043 / JTX-199 chain, or any document evidencing the sale of batch 13101. Thus, there is no evidence Mr. Carlson was aware that batch 13101 was sold, let alone when it was sold. There is also no evidence that he knew of or determined a "deadline" for filing the patent.

57. Mr. Carlson was never told not to test batch 13101 using PXRD or not to investigate when any batches of NRCl were sold or offered for sale, and he never failed to disclose, or tried to hide, anything from the PTO that he believed was material to patentability. (Tr. VI:59:12-22.)

58. Mr. Carlson testified that he personally worked with two crystalline forms and the amorphous form of NRCl, but that it was possible that others crystalline forms exist. (Tr. II:60:3-6, 78:20-79:8; Tr. VI:45:18-46:4.) For example, GSK reported that it had NRCl crystalline forms that were different than Grace's form I and form II. (Tr. VI:45:25-46:4.)

B. David Short

59. ***Batch 13101***. At the time batch 13101 was made, Mr. Short believed it was amorphous NRCl based on its appearance and handling. (Tr. VI:97:24-98:3; Tr. II:53:4-7.) For example, after personally observing the batch, he testified it looked like a "glassy solid. It wasn't very free flowing." (Tr. II:8:7-13.) The material "looked wet," "sticky, not free-flowing," "very waxy or glassy." (Tr. VI:97:12-23.) Consistent with his observations, Mr. Short received an e-mail from Dr. Kelleman on April 26, 2013 confirming that batch 13101 was "glassy" and "problematic." (Tr. VI:96:3-98:9.) He maintains his belief today and has not seen any evidence to the contrary. (*Id.*)

60. Mr. Short's understanding is that IR spectroscopy is used for chemical identification of

a given molecule and that it cannot be used to conclusively distinguish between solid forms of a substance. (Tr. VI:93:7-20.) He has encountered cases where two different solid forms of the same compound have indistinguishable IR spectra. (Tr. VI:93:14-94:8.) In his experience, if two samples of the same substance had identical or nearly identical IR spectra, he would conclude only that they were the same chemical compound. (Tr. VI:94:9-12.) To his knowledge, an amorphous form and a crystalline form of a substance may have identical IR spectra. (Tr. VI:94:13-16.)

61. Mr. Short never compared the IR peak positions of batch 13101 to the IR peak listings in the '058 patent. (Tr. VI:102:22-103:6.) While the application was pending, he never realized whether any IR peaks listed therein were the same as any IR peaks in batch 13101's IR spectrum. (Tr. VI:103:7-10.) Even if the peaks did match and he were aware of it, that would have only indicated to him that batch 13101 was NRCl, not that it was form I. (Tr. VI:103:11-19.)

62. The only NRCl Grace made at its production plant before the critical date was batch 13101. (Tr. VI:101:25-102:11.) Mr. Short never believed batch 13101 was form I. (*Id*.) To his knowledge, Grace never made, offered to sell, or sold form I NRCl before the critical date. (*Id*.)

63. Mr. Short first suspected that Grace had made a crystalline form of NRCl after personally observing the physical properties of batch 13202. (Tr. VI:99:10-100:5; *see* ¶¶32-33 *supra*.) It was, in fact, determined by PXRD testing that batch 13202 was crystalline form I NRCl. (Tr. VI:100:6-101:21.) This is the first PXRD data for NRCl that Mr. Short had seen and therefore he believes form I NRCl first appeared at Grace in batch 13202. (Tr. VI:101:8-21.)

64. Mr. Short believes that PXRD is the only way to conclusively distinguish between crystalline and amorphous forms of a chemical substance, and that in general, no other methods can be used. (Tr. VI:92:3-14.) He has never encountered a case where two crystalline forms of the same substance had the same PXRD pattern. (Tr. VI:92:15-93:6.)

65. In sum, based on all of the evidence, the most reasonable inference is that Mr. Short did not believe Grace made form I NRCl before the PXRD results on batch 13202 were obtained in May 2014 and did not believe batch 13101 was form I.

66. ***Patent Application***. Mr. Short is not an attorney, a registered patent agent, nor a patent professional, and he has no formal education in patent law. (Tr. VI:105:16-23.)

67. Mr. Short is not an inventor and he was not responsible for directly communicating with the PTO or Patent Examiner. (Tr. VI:105:24-106:5.) While the '058 patent was pending, he did not know all the elements and requirements of the on-sale bar beyond a general understanding that he would have needed to disclose to the legal team if Grace offered for sale or sold crystalline form I NRCl more than 1 year before the application was filed. (Tr. VI:106:6-21). While the application was pending, he did not know of any such offers for sale or sales and also does not know of any today. (Tr. VI:106:22-107:2.)

68. Mr. Short has no personal understanding or knowledge of a change in the law related to the on-sale bar between 2014 and 2019 and has never heard of the *Helsinn Healthcare v. Teva* case. (Tr. VI:107:22-108:8.) There is no evidence he knew of or determined a "deadline" for filing.

69. Mr. Short is not an expert in metadata. (Tr. VI:109:2-3.) In reviewing the metadata that he was requested to review after he was subpoenaed in this case, he learned more things about those documents than he was aware of while the patent was pending. (Tr. VI:109:4-17.)

70. Elysium has not established that Mr. Short was involved with or aware of DTX-2011, DTX-2012, DTX-2014, DTX-2040, DTX-2041, DTX-2045, DTX-2052, DTX-2110, DTX-2111, DTX-2157, DTX-2162, DTX-2168, DTX-2188, DTX-2189, DTX-2317, DTX-2836, JTX-054, JTX-055, JTX-199.

C. Brett Reynolds

71. Mr. Reynolds is Grace's global sales director, having responsibility for overseeing sales

and managing the pipeline and opportunities. (Tr. II:111:3-12.) Mr. Reynolds is neither a chemist nor a scientist of any kind. (Tr. VI:154:9-12.) For example, he testified that he lacked expertise to say which salt forms of a chemical compound are acceptable for use in products for human consumption. (Tr. II:122:21-123:5.) There is no evidence Mr. Reynolds possessed the scientific knowledge needed to determine whether an NRCl batch was a particular crystalline form or not.

72. Elysium has not established that Mr. Reynolds was involved with or aware of at least DTX-2006A/JTX-146, DTX-2007A, DTX-2009, DTX-2010, DTX-2011, DTX-2012, DTX-2013, DTX-2014, DTX-2017, DTX-2027, DTX-2041, DTX-2052, DTX-2064, DTX-2116, DTX-2132, DTX-2157, DTX-2165, DTX-2167, DTX-2169, DTX-2188, DTX-2189, DTX-2709, JTX-028, JTX-104, any documents or information evidencing the physical characteristics or analytical testing data of batch 13101, or any documents related to sales or offers for sale to or from HPN.

73. Mr. Reynolds is not a patent attorney, agent, or professional, and had no prior exposure to patents. (Tr. VI:140:21-22, 154:13-21.) He is not registered to practice before the PTO and was not responsible for communicating with the PTO about the ’058 patent. (Tr. VI:154:17-25.)

74. Mr. Reynolds’ involvement in preparing the ’058 patent application was “[v]ery limited.” (Tr. VI:140:23-141:5.) There is no evidence that he had any responsibility for the content of the application or that he was involved in determining a purported “deadline” for filing it. Elysium assumes without support that Mr. Reynolds drafted statements in documents that multiple people prepared. (Tr. VI:132:19-133:16, 134:12-19.) In any event, the documents lend no support to Elysium’s conclusions that Mr. Reynolds determined the filing deadline and was involved in “the content of” the ’058 patent application.

75. There is no evidence that, while the patent was pending, Mr. Reynolds understood that patent applicants have a duty to disclose information that is material to patentability to the PTO.

(*See* Tr. VI:140:10-22.) At the time the patent application was filed, Mr. Reynolds testified that he did not understand that an offer for sale or sale of an invention more than a year before a patent application is filed on that invention could be material to patentability. (Tr. VI:140:15-22.)

76. Before the issuance of the '058 patent, Mr. Reynolds never investigated or formed a belief concerning whether batch 13101 was the invention claimed by the patent. (Tr. VI:155:1-8.) He never perceived a need to investigate this and never stopped any investigation because he thought it would have prevented the issuance of the patent. (Tr. VI:155:9-16.)

77. Mr. Reynolds never believed that Grace sold its patented form I of NRCl more than a year before the filing of the '058 patent, was never aware of any information that in his view would have prevented issuance of the '058 patent, never decided not to disclose any information to the PTO, never decided not to disclose information about sales of NRCl to attorneys involved in prosecution of the '058 patent, and never had any involvement in deciding to test or not test any batches of NRCl with respect to a pending patent application. (Tr. VI:155:17-156:10.)

78. Elysium points to an email chain between Mr. Reynolds and his direct report, Ms. Smith. (DTX-2168.) In this email, Mr. Reynolds receives information from Ms. Smith and then states, "I got what I needed." The email identifies other sources from which Mr. Reynolds was seeking the information. *Id.* There is no evidence that this investigation had anything to do with the '058 patent application, much less deceiving the PTO with respect to that application. The most reasonable inference is that Mr. Reynolds told Ms. Smith to stop working on his request because he simply got the information he needed from another source, not for any nefarious purpose.

79. It is reasonable to infer that the accused individuals did not believe batch 13101 was form I, and this is consistent with Dr. Kelleman's contemporaneous email and Dr. Perni's admission that the email indicated the batch was amorphous. (*See, e.g., supra* ¶¶27-29.)

CONCLUSIONS OF LAW

1. Inequitable conduct requires clear and convincing evidence that an individual having a duty of disclosure specifically intended to deceive the PTO by deliberately deciding to withhold material information that he/she knew would prevent allowance—***after*** consideration of evidence and arguments in response to any rejection. *Therasense, Inc. v. Becton, Dick. & Co.*, 649 F.3d 1276, 1290-96 (Fed. Cir. 2011) (*en banc*) (affirming invalidity). Elysium's cases confirm "the required level of materiality is not that found in PTO Rule 56." *Regeneron Pharm., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 559 n.23 (S.D.N.Y. 2015), *aff'd*, 864 F.3d 1343 (Fed. Cir. 2017).

2. "[W]hen a case involves claims of law and equity and the legal claims are tried by a jury, the jury's verdict is binding on the trial court in its disposition of the equitable claims." *S. Clay Prods., Inc v. United Cat., Inc.*, 43 F. App'x 379, 385 (Fed. Cir. 2002); *see Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 995-96 (Fed. Cir. 1995) (court erred in making findings for inequitable conduct that conflicted with jury verdict on validity); *Triangle Soft., LLC v. Garmin Int'l, Inc.*, 10-cv-1457, 2012 WL 527223, at *4 (E.D. Va. Feb. 14, 2012), *aff'd* 497 F. App'x 70 (Fed. Cir. 2013) (rejecting post-*Therasense* inequitable conduct claims because, in part, "the jury found all of the patents in-suit valid as not anticipated by the prior art. A finding of inequitable conduct would, therefore, be inconsistent with the jury's verdict and evidence assessments on the issue of invalidity"); *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 569 F. Supp. 2d 819, 831 (W.D. Wis. 2008), *vacated in part on other grounds*, 607 F.3d 784 (Fed. Cir. 2010) (inequitable conduct defense could not succeed once the jury found a withheld reference did not anticipate); *Xpertuniverse, Inc. v. Cisco Sys.*, 09-157-RGA, 2013 WL 6118447, at *7-9 n.8 (D. Del. Nov. 20, 2013) ("[T]he jury did not find Cisco proved an on-sale bar. . . . The Court would be hard pressed to find a basis for ruling the same activities meet the standard of but-for materiality in this context."); *Linear Tech. Corp. v. Monolithic Power Sys., Inc.*, 06-476-GMS, 2011 WL 4014467,

at *7 (D. Del. Sept. 9, 2011) ("The jury's verdict of non-obviousness implicitly rejected [invalidity] arguments . . ., and the court does not perceive any basis to conclude that the PTO would have rejected the asserted claims if it had been presented, as the jury was, with more information."). By contrast, no inequitable conduct argument in *Am. Calcar, Inc. v. Am. Honda Motor Co*., 768 F.3d 1185, 1189 (Fed. Cir. 2014), relied "on the jury's determination" of validity.

3. "[W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Therasense*, 649 F.3d at 1290-91. *In 1st Media, LLC v. Elec. Arts, Inc*., 694 F.3d 1367, 1374-75 (Fed. Cir. 2012), the Court reversed an inequitable conduct holding due to insufficient evidence of a deliberate decision to withhold. Such a decision could not be inferred from "knowledge of materiality." *See Siemens Gamesa Renewable Energy A/S v. GE Co.*, 617 F. Supp. 3d 55, 67-68 (D. Mass. 2022) (similar); *Xpertuniverse*, 2013 WL 6118447, at *9 (similar).

4. "[O]nly individuals, rather than corporations such as [Grace], owe a duty of candor to the PTO. . . . Accordingly, only individuals can breach that duty and give rise to a finding of inequitable conduct." *Avid Id. Sys., Inc. v. Crystal Import Corp*., 603 F.3d 967, 974 n.1 (Fed. Cir. 2010); *see FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 525 n.5 (Fed. Cir. 1987) ("One . . . must prove by clear and convincing evidence that the conduct of the person *charged* was inequitable."); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009).

5. Individuals other than inventors and prosecuting attorneys who are not involved in the ***content*** of an application have no duty of disclosure. *See Summit 6 LLC v. Rsch. in Motion Corp.*, 11-367, 2013 WL 12124321, at *12 (N.D. Tex. June 26, 2013) (finding insufficient involvement for an individual despite her communications with patent prosecution counsel and the inventor, responsibility for the patent portfolio, and sending / receiving emails on prosecution progress); *Volterra Semi. Corp. v. Primarion, Inc*., 796 F. Supp. 2d 1025, 1135 (N.D. Cal. 2011) (company

founder's "involvement in the project that led to the invention" and "decision to file the applications," as well as signing documents filed during prosecution, insufficient); *CSB-Sys. Int'l, Inc. v. SAP Am., Inc.*, 10-2156, 2012 WL 1645582, at *10-11 (E.D. Pa. May 10, 2012) (finding no substantive involvement where individual "did not review any of the documents filed in connection with the application"); *EIS, Inc. v. WOW Tech Int'l GmbH*, 19-1227-LPS, 2020 WL 7027528, at *10 (D. Del. Nov. 30, 2020) (finding insufficient allegation that executive "was aware of the relevant patents, the status of those patents in Germany, and the subject matter of the patents, and that he had the authority to engage in business transactions relating to those patents"). Even if such an individual had a duty, it can be discharged by disclosing to an attorney or inventor. 37 C.F.R. 1.56(d); *see also Kemin Foods, L.C. v. Pigmentos Veg. Del Centro S.A. de C.V.*, 464 F.3d 1339, 1346 (Fed. Cir. 2006) (tangential involvement militated against intent).

6. In *Avid*, 603 F.3d at 974, the "president and founder" of a "closely held company," who "hired the inventors to reduce his [claimed] concept to practice," had substantive involvement in prosecution because, among other things, he was one of only two recipients (along with prosecuting counsel) of an email regarding the content of the application.

7. "[N]o adverse inference shall arise from invocation of the attorney-client . . . privilege." *Knorr-Bremse Sys. Fuer Nut. GmbH v. Dana Corp.*, 383 F.3d 1337, 1344 (Fed. Cir. 2004) (*en banc*); *Summit*, 2013 WL 12124321, at *12 n.14 (refusing "to draw an inference from [a] privilege log as to whether [an individual] was substantively involved in prosecution").

8. The MPEP provides that an applicant need not "derive or independently discover a fact, such as by experimentation." MPEP 704.11; Tr. VI:178:1-5 (Armitage). This comports with the case law, *FMC*, 836 F.2d at 526 & n.6, where the Court upheld the "general rule" that applicants have "no duty to conduct a prior art search" or "to disclose art of which an applicant could have

been aware." The Court found no inequitable conduct based on applicants' failure to investigate on-sale activity. *Id*. at 524-26. While it suggested, "without deciding," that circumstances may "raise a duty to inquire," it tied this dicta to the "'should have known' factor" that the Court later rejected *en banc. Compare id.* at 526 & n.6 *with Therasense*, 649 F.3d at 1290 ("Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive."); *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1238 (Fed. Cir. 2005) ("A requirement that an applicant disclose art of which the applicant should have been aware overlooks the intent element.").

9. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp*. relied on *FMC*'s dicta and applied the "should have known" standard that *Therasense* rejected. 267 F.3d 1370, 1381 (Fed. Cir. 2001) (finding intent when attorney "knew or should have known that the transaction was material"). *Brasseler* also applied a sliding scale, inferring intent from materiality. *Compare id.* at 1378, 1381 ("[T]he degree of intent to mislead necessary to trigger culpability varies in proportion to the materiality of the information. . . . When balanced against high materiality, the showing of intent can be proportionally less."), *with Therasense*, 649 F.3d at 1290 (district court "should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. . . . Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality."). Courts have refused to follow *Brasseler* for this reason. *Robbins Co. v. Herrenknecht Tun. Sys. USA, Inc*., 13-2113, 2015 WL 3454946, at *5 (N.D. Ohio May 29, 2015). *Brasseler* also applied a wrong materiality standard, whether a "reasonable examiner" would have found the information "important." 267 F.3d at 1380.

10. Inequitable conduct-based unclean hands defenses are stricken *sua sponte* if they do not satisfy Rule 9. *Barry v. Stryker Corp.*, 20-1787, 2023 WL 2733652, at *8-10 (D. Del. Mar. 20,

2023). Unclean hands requires "unconscionable" conduct. *Honeywell Int'l, Inc. v. Universal Avi. Sys. Corp*., 343 F. Supp. 2d 272, 321 (D. Del. 2004), *vacated in part*, 488 F.3d 982 (Fed. Cir. 2007). An unclean hands defense based on the failure to disclose information to the PTO "rises and falls" with inequitable conduct. *Baxalta Inc. v. Bayer Healthcare LLC*, 17-1316-RGA-SRF, 2020 WL 5445375, at *13 (D. Del. July 13, 2020); *Sprint Commc'ns Co. v. Charter Commc'ns, Inc.,* 17-1734-RGA, 2021 WL 982726, at *12 (D. Del. Mar. 16, 2021); *Chamberlain Grp., Inc. v. Techtronic Indus. Co*., 16-6097, 2017 WL 1101092, at *16 (N.D. Ill. Mar. 22, 2017); *Collaboration Props., Inc. v. Tandberg ASA*, 05-1940, 2007 WL 205065, at *7 (N.D. Cal. Jan. 25, 2007); *Human Genome Scis., Inc. v. Genentech, Inc*., 11-6519, 2011 WL 7461786, at *8 (C.D. Cal. 2011) (noting allegations did not match those that had given rise to unclean hands, *e.g.*, "paying witnesses to lie" or "publishing false articles under the names of industry experts").

11. Discredited testimony in *Belcher Pharms., LLC v. Hospira, Inc.,* 11 F.4th 1345, 1354 (Fed. Cir. 2021) and *Aventis Pharma S.A. v. Hospira, Inc*., 675 F.3d 1324, 1335-36 (Fed. Cir. 2012) contradicted the documents, lacked corroboration, and did not alone evidence intent. *See Santarus, Inc. v. Par Pharm., Inc*., 694 F.3d 1344, 1349 (Fed. Cir. 2012) (no intent despite lack of credibility); *Oh. Willow Wood Co. v. Alps. S., LLC*, 813 F.3d 1350, 1359-60 (Fed. Cir. 2016).

12. In *In re Method of Proc. Ethanol By. & Rel. Sub. ('858) Pat. Lit.*, 10-ml-02181, 2016 WL 4919980, at *22, *32 (S.D. Ind. Sep. 15, 2016), *aff'd*, 951 F.3d 1310 (Fed. Cir. 2020), inventors and attorneys "kn[e]w for certain" a declaration was false yet delayed in submitting another one that, in any event, "repeat[ed] false information." *TransWeb, LLC v. 3M Inn. Props. Co*., 812 F.3d 1295, 1306 (Fed. Cir. 2016), likewise involved a known "inaccurate disclosure."

13. Prior art that does not invalidate an independent claim cannot invalidate its dependent claim. *Callaway Golf Co. v. Acushnet Co*., 576 F.3d 1331, 1344 (Fed. Cir. 2009).

Dated: December 12, 2023

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)