IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W. R. GRACE & CO.-CONN, Plaintiff, v. ELYSIUM HEALTH, INC., Defendant.	Civil Action No. 20-1098-GBW-JLH

MEMORANDUM OPINION

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Counsel for Defendant

June 25, 2026
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

On August 21, 2020, Plaintiff W. R. Grace & Co.-Conn. ("Grace" or "Plaintiff") filed the present patent infringement action against Defendant Elysium Health, Inc. ("Elysium" or "Defendant"), alleging Elysium's infringement of U.S. Patent Nos. 10,323,058 (the "'058 Patent"), 10,233,207 (the "'207 Patent"), and 10,189,872 (the "'872 Patent"). D.I. 1.

In August 2023, a jury trial was held in this action, at which time only the '058 Patent and the '872 Patent remained in suit. At the end of the jury trial, the jury returned a verdict finding, *inter alia*, that Elysium had infringed Claims 1, 2, and 21 of the '058 Patent, and that these claims were not invalid due to anticipation. D.I. 313. Subsequently, in October 2023, the Court presided over a one-day bench trial, wherein the parties disputed the enforceability of the '058 Patent. Having thoroughly and carefully reviewed the evidence, the trial record, and the parties' post-trial submissions (D.I. 338; D.I. 339; D.I. 340; D.I. 341; D.I. 342; D.I. 347; D.I. 348; D.I. 349; D.I. 350; D.I. 351; D.I. 352), the Court concludes that the '058 Patent is not unenforceable as a result of alleged inequitable conduct by Grace employees Erik Carlson ("Mr. Carlson"), David Short ("Mr. Short"), or Brett Reynolds ("Mr. Reynolds") during patent prosecution, or due to Grace's alleged unclean hands. Below, the Court separately sets forth its findings of fact and conclusions of law as required by Federal Rule of Civil Procedure Rule 52(a).

I. FINDINGS OF FACT

The Court divides its Findings of Fact into several subsections below.[1]

[1] Citations to a party's findings of fact or conclusions of law are labeled as Grace/Elysium FoF or CoL, and citations to the Court's Findings of Fact are labeled as FoF. The Court's Findings

A. The Parties

1. Plaintiff W. R. Grace & Co.-Conn. is a company organized and existing under the laws of the State of Connecticut. D.I. 299 (Facts That Are Admitted and Require No Proof) ¶ 24. Grace operates a principal place of business in Columbia, Maryland. *Id.*

2. Grace produces a material known as nicotinamide riboside chloride. *See, e.g.*, JTr. I, 215:20-22.[2] Nicotinamide riboside chloride is also referred to as "NRCl" or "NR-Cl."

3. Defendant Elysium Health, Inc. is a corporation organized and existing under the laws of the State of Delaware. D.I. 299 ¶ 25. Elysium operates a principal place of business in New York, New York. *Id.*

4. Grace filed this action on August 21, 2020, alleging infringement by Elysium of the '058 Patent, the '207 Patent, and the '872 Patent. D.I. 1.

5. As of the time of the jury trial, the remaining patents-in-suit were the '058 Patent and the '872 Patent. D.I. 299 ¶ 26; *see also* D.I. 313. On the cover of both patents, Grace is identified as the assignee of all rights, title, and interests. D.I. 299 ¶ 28.

B. The Experts

6. During the jury and bench trials, the parties presented expert testimony from several expert witnesses, including the following experts.

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of Fact are tailored to the discussion set forth in this Memorandum Opinion and do not seek to provide a complete recitation of all facts presented during the jury and bench trials.

[2] Citations to the bench trial transcript are denoted as BTr., and citations to the Jury Trial transcript are denoted as JTr. Given the non-consecutive pagination of the jury trial transcript, citations to the jury trial transcript are labeled with roman numerals corresponding to the day of the transcript cited (e.g., the transcript from the second day of the jury trial is cited as "JTr. II, [page:line]").

7. Dr. Aeri Park ("Dr. Park"), Grace's expert, holds a PhD in organic chemistry from the University of Oklahoma and had twenty-five years of experience in testing solid-state materials. JTr. II, 192:7-19. Dr. Park was admitted in this case as an expert in solid-state chemistry and the identification and characterization of solid forms. JTr. II, 195:8-13.

8. Dr. Robin Rogers ("Dr. Rogers"), Grace's expert, holds a PhD in inorganic chemistry from the University of Alabama and had approximately 45 years of experience in solid-state chemistry and crystallography. JTr. IV, 109:5-7, 109:16-20. Dr. Rogers was admitted in this case as an expert in solid-state chemistry and crystallography. JTr. IV, 111:18-23.

9. Dr. Jonathan Steed ("Dr. Steed"), Elysium's expert, was a professor of chemistry at Durham University in the United Kingdom and obtained his PhD in 1993 from University College London. JTr. III, 164:21-23, 165:4-12. Dr. Steed was admitted in this case as an expert in solid-state chemistry and the identification of crystallization of solid forms. JTr. III, 165:25-166:5.

10. Dr. Robert Perni ("Dr. Perni"), Elysium's expert, holds a PhD in organic chemistry from Dartmouth College and had over thirty-five years of research and development experience in the pharmaceutical industry. JTr. IV, 15:5-9, 15:16-20. Dr. Perni was admitted in this case as an expert in medicinal chemistry. JTr. IV, 18:2-3 (initial proffer as "expert in medicinal chemistry"), 25:4-7 (admission after second proffer "in the fields proffered").

11. Mr. Robert Armitage ("Mr. Armitage"), Elysium's expert, was a patent attorney and spent over a decade as a chief patent counsel of two multi-national companies. BTr. 161:3-8. During the bench trial, Mr. Armitage was admitted as an expert in United States Patent and Trademark Office ("PTO") practice and procedure, subject to the Court's *Daubert* ruling. BTr.

161:23-25; *see also* D.I. 290 at 7 (granting "Grace's motion to preclude testimony from Mr. Armitage" except as to the PTO's "practices and procedures").

C. The '058 Patent

12. The '058 Patent issued on June 18, 2019, and names Erik Carlson, Michael Standen, and Westin Morrill as inventors. D.I. 299 ¶ 36; *see also* JTX-001 ("'058 Patent").

13. The '058 Patent issued from U.S. Patent Application No. 15/328,664 (the "'664 Application"). D.I. 299 ¶ 31. The '664 Application was filed on July 24, 2015 as PCT/US2015/041956. *Id.*

14. The '664 Application claims the benefit of the filing date of U.S. Provisional Patent Application No. 62/028,702 (the "'702 Provisional Application"). D.I. 299 ¶ 32. The '702 Provisional Application was filed on July 24, 2014. *Id.*

15. It is undisputed for the purposes of this action that the priority date for the '058 Patent is July 24, 2014. D.I. 299 ¶ 32.

16. It is undisputed for the purposes of this action that the "critical date" for the '058 Patent is July 24, 2013. D.I. 299 ¶ 33; *see also* Elysium FoF ¶ 2; Grace FoF ¶ 1.

17. The '058 Patent is titled "Crystalline Form of Nicotinamide Riboside" and contains analytical data describing crystalline Form I of nicotinamide riboside chloride. *See generally* '058 Patent. Accordingly, the '058 Patent is also referred to as the "Form I Patent."

18. The background section of the '058 Patent identifies nicotinamide riboside as "a precursor to nicotinamide adenine dinucleotide (NAD) [that] represents a source of vitamin B3." '058 Patent at 1:41-43.

19. The specification further explains that:

> Crystalline forms of useful molecules can have advantageous properties relative to the amorphous form of such molecules. For

> example, crystal forms are often easier to handle and process, for example, when preparing compositions that include the crystal form. Crystalline forms typically have greater storage stability and are more amenable to purification. The use of a crystalline form of a pharmaceutically useful compound can also improve the performance characteristics of a pharmaceutical product that includes the compound. Obtaining the crystalline form also serves to enlarge the repertoire of materials that formulation scientists have available for formulation optimization, for example by providing a product with different properties, e.g., better processing or handling characteristics, improved dissolution profile, or improved shelf-life.

'058 Patent at 1:26-40.

20. Various analytical methods for distinguishing solid-state materials are disclosed in the specification of the '058 Patent, including powder X-ray diffraction ("PXRD" or "XPRD"), infrared spectroscopy ("IR"), differential scanning calorimetry ("DSC"), thermogravimetric analysis ("TGA"), and dynamic vapor sorption ("DVS"). *See generally* '058 Patent.

21. The specification explains that "[a] crystal form may be referred to herein as being characterized by graphical data substantially 'as depicted in' a Figure." '058 Patent at 4:56-58.

22. With respect to IR spectra, the specification discloses that certain embodiments of "crystalline Form I of nicotinamide riboside chloride may be characterized by a solid-state IR spectrum having peaks substantially as provided in Table 2 . . . ±0.2 cm^{-1}." '058 Patent at 6:41-45. Table 2, in turn, discloses a series of solid-state IR peaks, which are denoted in cm^{-1} and listed out to the hundredths place. *Id.* at 6:46-7:40. Per the specification, "crystalline Form I of nicotinamide riboside chloride may also or alternatively be characterized by a solid-state IR spectrum having peaks at 671.7, 1035.6, 1061.8, 1398.9, and 1649.3 cm^{-1} ±0.2 cm^{-1}." *Id.* at 6:35-38. Table 2 lists peaks within 0.2 cm^{-1} of these five peaks. *See id.* at 6:46-7:40 (Table 2, listing peaks at 671.72, 1035.62, 1061.82, 1398.92, and 1649.34 cm^{-1}).

23. The specification also provides analytical data regarding the melting point of crystalline Form I of nicotinamide riboside chloride. For example, Table 4 provides the results of an analysis of "the measurement of melting points of the crystalline Form I of nicotinamide riboside chloride":

TABLE 4

Heating Rate	Endothermic Peak (° C.)
1 K/min	108.01
2 K/min	112.53
5 K/min	118.43
10 K/min	123.25
20 K/min	127.82

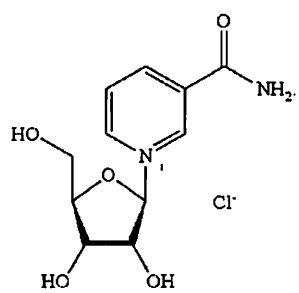
'058 Patent at 15:10-23. "As expected, DSC analysis of the *amorphous* form of nicotinamide riboside chloride yielded no melting point." *Id.* at 15:30-32 (emphasis added).

24. Following the jury trial, the jury was asked to determine whether Defendant had proven that Claims 1, 2, and 21 of the '058 Patent were invalid as anticipated because the claimed invention was sold or offered for sale before the critical date. D.I. 313 at 6. The jury returned a verdict of no invalidity due to anticipation on this basis. *Id.*

25. Claims 1, 2, and 21 (which depends from Claim 20), are replicated below:

> 1. A crystalline Form I of nicotinamide riboside chloride according to formula I

(I)



> 2. The crystalline Form I according to claim 1 that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG. 1.
>
> * * *
>
> 20. A method for increasing nicotinamide adenine dinucleotide (NAD) concentration in a subject in need thereof comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1.
>
> 21. The method according to claim 20 wherein said crystalline Form I is administered to said subject in a composition that further comprises a pharmaceutically acceptable excipient.

'058 Patent, Claims 1, 2, 20, 21.

26. Several claims that depend from Claim 1, like Claim 2 replicated above, claim "crystalline Form I according to claim 1 that is characterized by" the results of a particular analytical method. For example, Claim 6 recites "[t]he crystalline Form I according to claim 1 that is characterized by an IR spectrum having peaks substantially as shown in Table 2 ± 0.2 cm^{-1}." '058 Patent, Claim 6.

27. Chief Judge Colm F. Connolly[3] construed the term "crystalline Form I of nicotinamide riboside chloride according to formula I" to mean "Crystalline Form I of nicotinamide riboside chloride, according to Formula I, which can be identified by *one or more of the analytical methods described in the specification.*" D.I. 109 at 1 (emphasis added). Chief Judge Connolly also construed the term "characterized by" to mean "identifiable by reference to" and the term "substantially as shown" to mean "largely but not wholly." *Id.* at 1-2.

[3] This action was previously assigned to Chief Judge Connolly, and was later reassigned to this Court.

D. Brief Technological Background

28. Solid-state materials may be crystalline or amorphous. *See, e.g.*, JTr. II, 196:10-23 (Dr. Park). In this context, the term "amorphous" can sometimes be used to refer to a "non-crystalline" solid-state material. *See* JTr. II, 196:19-23 (Dr. Park).

29. Whether a solid-state material is crystalline or amorphous can have a substantial impact on the properties of a particular material. JTr. II, 196:16-23 (Dr. Park); JTr. III, 168:17-170:4 (Dr. Steed). For example, crystalline materials are typically "less hygroscopic," which means that "they do not absorb water as much as they do with amorphous material." JTr. II, 199:4-7 (Dr. Park); *see also* JTr. III, 170:3-4 (Dr. Steed) (similar).

30. There are various analytical methods that can be used to distinguish between solid-state materials, including PXRD and IR. *See, e.g.*, JTr. II, 193:10-15 (Dr. Park); JTr. III, 170:5-20 (Dr. Steed).

31. In practice, different analytical methods are not always identical in their ability to distinguish between solid-state materials. JTr. IV, 137:17-19 (Dr. Rogers, agreeing that two solid forms of the same material may have "indistinguishable IR spectra"); *see also* JTr. II, 204:21-205:6 (Dr. Park, agreeing that other techniques, including IR, DSC, and DVS, were not equal to PXRD in their ability to distinguish between forms), JTr. III, 35:12-15 (Dr. Park, agreeing that the "best technique will depend in some ways on the solid form" being tested).

32. PXRD is often referred to as the "gold standard" technique for distinguishing between solid-state forms. *See, e.g.*, JTr. II, 202:5-9 (Dr. Park, testifying that PXRD is the "best technique" for distinguishing between solid forms of a material because it "is the only technique that directly characterizes crystalline packing"), 202:10-204:16; JTr. III, 174:18-175:7 (Dr. Steed);

JTr. IV, 116:11-19 (Dr. Rogers, agreeing with the "caveat" that PXRD is not a chemical identification technique); *see also* JTr. II, 72:8-9 (Carlson).

33. IR spectroscopy can often, but not always, be used to distinguish between solid-state forms. *See, e.g.*, JTr. II, 269:23-24, 271:9-15, 272:4-6 (Dr. Park).

E. Grace's Initial Development of NCRI and Relationship with ChromaDex

34. Grace's Fine Chemicals Unit is in the business of designing and manufacturing specialty chemicals for the pharmaceutical and nutrition industries. JTr. I, 218:11-219:3.

35. In the second half of 2012, ChromaDex, Inc. ("ChromaDex") and Grace formed a relationship concerning Grace's development of a commercialized process to produce a form of nicotinamide riboside. In July 2012, Grace sent a product quote to ChromaDex regarding the development of a "new process for the production of Nicotinamide Riboside." DTX-2017; JTr. II, 121:17-122:17. In September 2012, ChromaDex issued a purchase order in connection with its request that Grace begin research and development work on the project. DTX-2019; JTr. II, 123:6-16.

36. In the subsequent months, Grace began research and development. The Grace employees that worked on research and development for the ChromaDex project included Mike Standen, Westin Morrill, and Erik Carlson. JTr. II, 88:4-6 (Carlson).

37. Grace's internal goal was to deliver a product to ChromaDex in the first or second quarter of 2013. JTr. II, 91:23-25 (Carlson).

38. In February 2013, Grace internally circulated a "close-out report" on NRCl development. JTX-168; JTX-169; *see also* JTr. II, 83:8-14 (Carlson, agreeing he was involved in drafting the close-out report, JTX-169), 86:2-87:2 (explaining that JTX-168 attached the close-out report). The close-out report described a process to produce NRCl, identified certain problems

encountered during the development of that process (e.g., "issues" related to "optimizing final crystallization and isolation"), and suggested next steps for future attempts (e.g., utilizing an alternative solvent). JTX-169.0004-.0008.

39. On February 20, 2013, Grace employee Dr. Audrey Kelleman ("Dr. Kelleman") sent an email directing Mr. Carlson to ship a sample of the product made in the lab to a ChromaDex representative. JTX-212; JTr. II, 95:7-96:14.

40. On April 16, 2013, a representative of ChromaDex sent an email to Mr. Reynolds and Dr. Kelleman referencing "[d]raft specifications." DTX-2040. The attached vendor specification sheet stated that one of ChromaDex's acceptance criteria was that the product be a "[f]ree flowing powder." DTX-2040.0002.

F. Batch 13101

41. Following its research and development into processes to commercially produce NRCl, Grace began batch production. In the spring of 2013, Grace began to produce a "pilot batch" of NRCl in connection with the ChromaDex project, which came to be known as "Batch 13101." JTr. II, 6:22-25 (Short).

42. At Grace, a "pilot batch" refers to "a small batch [] testing out the process, going from the R&D laboratory into manufacturing . . . but usually much smaller than a commercial manufacturing batch." JTr. II, 7:1-4.

43. Throughout April 2013, Mr. Carlson circulated internal updates on the progress of Batch 13101 to others at Grace, including Mr. Short. DTX-2042.

44. On April 15, 2013, the manufacturing of Batch 13101 began. JTX-146.0001.

45. On April 19, 2013, Mr. Carlson sent an update that "deacetylation is currently running in the pilot plant. The reaction is complete and moving into the crystallization and isolation." DTX-2042.0003-0004.

46. During the drying of Batch 13101, Grace employees circulated contemporaneous communications with varying descriptions of the product. On April 26, 2013, Mr. Carlson sent an update that "[t]he 15kg plant batch is complete and isolated. The product is currently drying." DTX-2042.0002. This email further stated that a sample was being dried to send to ChromaDex. *Id.*

47. On April 26, 2013, Grace's Dr. Kelleman sent an email to a ChromaDex representative describing Batch 13101 as "a fine, free flowing powder, with a slightly pink tinge to it." JTX-199.0004.

48. Also on April 26, 2013, Dr. Kelleman sent an internal email to several Grace employees, including Mr. Carlson, Mr. Short, and Mr. Reynolds, stating that "[i]t would also help if we found a way to crystallize the material as the *glassy nature of the solid is problematic.*" JTX-173.0001 (emphasis added). During trial, when analyzing this email by Dr. Kelleman, one of Elysium's experts agreed that this email indicated that Grace was having "amorphous" problems in the production of NRCl. JTr. IV, 54:1-8 (Dr. Perni); *see also id.* at 54:13-16 (Dr. Perni) ("Q. But you said in your expert report that this [email] indicated Grace was having amorphous and glassy problems with its product, right? A. Yes."). Dr. Perni disagreed, however, that this communication necessarily showed that the product was amorphous. JTr. IV, 54:9-12.

49. In connection with the production of Batch 13101, Grace produced a batch record. JTX-146. This batch record reported that drying of Batch 13101 was completed on April 27, 2013,

and that the dryer had been shut off at approximately midnight on April 26, 2013. JTX-146.0045, .0047; BTr. 39:3-40:4 (Carlson).

50. In addition to producing a batch record for Batch 13101, Grace produced a finished product report for Batch 13101. DTX-2007A; JTr. II, 33:25-34:8.

51. The finished product report included analytical data obtained regarding Batch 13101, including melting point data and IR spectra. DTX-2007A.0001-.0005. The "appearance" section of the finished product report indicates that the appearance of the product was an off-white to light brown powder. DTX-2007A.0001; JTr. II, 34:15-19.

52. The melting point data in the finished product report for Batch 13101 reported that the measured melting point was 110.9° to 123.8° C. DTX-2007A.0003. It is unclear, from the finished product report alone, the methodology from which this melting point range was generated. *See* JTr. III, 226:9-19 (Dr. Steed, not recalling whether melting point data in the final product report was done by DSC). However, the melting point data from within the finished product report for Batch 13101 (110.9° to 123.8° C) fits within the range of the results of the melting point analyses disclosed in Table 4 of the '058 Patent (108.01° at 1 K/min up to 127.82° at 20 K/min). *See* FoF ¶ 23.

53. The IR data in the finished product report for Batch 13101 reported the positions of peaks in the IR spectrum out to two decimal places. DTX-2007A.0005; DTX-2007C; *see also* JTr. III, 185:24-186:4 (Dr. Steed) (testifying that this was "really, really high precision").

54. The IR peak positions in the finished product report for Batch 13101 were nearly identical to the IR peak positions provided in Table 2 of the '058 Patent, with the caveat that one peak from the finished product report was not present within Table 2 of the '058 Patent. JTr. III, 186:10-12, 187:6-8 (Dr. Steed); *see also* DTX-2813 (comparison table of the peaks). The IR peak

positions in the finished product report for Batch 13101 also include peaks at 671.7, 1035.6, 1061.8, 1398.9, and 1649.3 $cm^{-1} \pm 0.2\ cm^{-1}$. *See* DTX-2813; DTX-2007C.

55. Regarding hygroscopicity, water retention analysis from finished batch records indicates that Batch 13101 had a higher water content than the other initial NRCl batches. JTr. II, 54:4-55:23 (Short); *see also* JTr. III, 194:8-15 (Dr. Steed); JTr. IV, 133:3-12 (Dr. Rogers).

56. Grace did not perform contemporaneous PXRD analysis on Batch 13101. JTr. II, 7:18-23 (Short).

57. Grace retained samples of its NRCl batches that it made in 2013 and 2014, including Batch 13101. JTr. II, 20:24-21:1 (Short).

58. Grace's samples of retained NRCl were stored in the same place and conditions. JTr. II, 21:13-24 (Short).

59. During the pendency of the present action, Grace provided Elysium with retained samples of Batch 13101 (the "Retained 13101 Material") for testing. JTr. IV, 114:23-25 (Dr. Rogers).

60. Both parties presented expert testimony analyzing the PXRD pattern of the Retained 13101 Sample. Though the parties' experts disagreed as to whether the Retained Batch 13101 Samples contained crystalline Form I of NRCl, their testimony confirmed at least that the PXRD pattern of the Retained 13101 Sample (1) showed the existence of impurities and (2) looked different than PXRD patterns of samples from other batches. For example, Dr. Steed, Elyium's expert, acknowledged that the PXRD pattern for the Retained 13101 Sample was a "bit more of a mess," as compared to PXRD analysis of other retained samples. JTr. III, 198:10-12; *see also id.* at 198:13-15 (referencing a "significant amount of impurity"); JTr IV, 124:5-8 (Dr. Rogers, agreeing that there were other "crystalline components and amorphous material" in the sample);

JTr. IV, 124:21-125:2 (Dr. Rogers, comparing PXRDs between different batches). Indeed, in analyzing Retained 13101 Sample's PXRD pattern, Dr. Steed admitted that it might potentially be "faintly conceivable to scientists that the noisy pattern . . . for batch 13101 could be some other substance that happens to have a really complicated X-ray diffraction pattern that by chance has all the Form I peaks and other peaks, as well." JTr. III, 200:17-21.

61. PXRD analysis of other retained samples, including those confirmed around the time of production to be crystalline Form I of NRCl (e.g., Batch 13202), demonstrate that crystalline Form I of NRCl was stable after ten years. *See* JTr. IV, 124:13-125:2 (Dr. Rogers).

G. Grace Sells NRCl from Batch 13101 to ChromaDex

62. On April 29, 2013, ChromaDex's representative responded to Dr. Kelleman's email expressing interest in reviewing the product and making a decision on specifications going forward, further stating, "[w]e can sell the 15KG and we are willing to give you a majority of the revenue if you are still interested in this." JTX-199.0003-.0004.

63. On April 30, 2013, ChromaDex's representative requested that Grace send a sample of the product to ChromaDex so ChromaDex could conduct its own testing. JTX-199.0002. Dr. Kelleman then sent the email chain internally to Grace employees, directing them to send a sample to ChromaDex. *Id.* at .0001. Subsequent email correspondence from May 2013 confirms that ChromaDex received the sample. DTX-2045.0003.

64. On May 22, 2013, Dr. Kelleman sent an email to several Grace employees stating that Grace had received approval to ship 17 kilograms of NRCl. DTX-2045.0001.

65. On May 24, 2013, Grace delivered NRCl that was produced as a part of Batch 13101 to ChromaDex. JTr. II, 127:21-25.

66. Material produced within Batch 13101 was the subject of a commercial offer for sale prior to the critical date of the '058 Patent. JTr. III, 207:7-9 (Dr. Steed); *see also* JTr. IV, 114:15-20 (Dr. Rogers, disagreeing that Batch 13101 was a sale of *crystalline Form I* of NRCl, but not disputing that Batch 13101 was sold or offered for sale before July 24, 2013); Grace FoF ¶¶ 1-2 (not disputing that Batch 13101 was sold prior to July 24, 2013). By this point, the material produced within Batch 13101 had been reduced to practice, as shown in the batch record and the finished product report. *See, e.g.*, FoF ¶¶ 49-55.

67. Since the '058 Patent discloses that crystalline Form I of NRCl may be characterized by its IR peaks as provided in Table 2, contemporaneous testing of Batch 13101 showed that Batch 13101 had substantially the same IR spectrum peaks as those provided in Table 2, and NRCl produced within Batch 13101 was the subject of a commercial offer for sale prior to July 24, 2013, the critical date of the '058 Patent, the pre-critical date sale of Batch 13101 was material to the issuance of Claims 1 and 6 of the '058 Patent.

H. Relevant Subsequent Batches of NRCl Produced by Grace

68. After Batch 13101, Grace made modifications to its manufacturing processes. JTr. II, 68:2-70:2.

69. Between December 10, 2013, and December 30, 2013, Grace produced Batch 13202. BTr. 57:19-24.

70. As with Batch 13101, Grace produced a batch record for Batch 13202. JTX-148; BTr. 57:16-20.

71. Batch 13202 had a lower water content than Batch 13101. JTr. IV, 133:5-12 (Dr. Rogers).

72. Despite being slightly less pure than Batch 13101 (98.9%, as compared with 98.5%), Batch 13202 degraded less over time. JTr. IV, 133:24-134:1 (Dr. Rogers).

73. Batch 13202 was made using a different laboratory process than Batch 13101. BTr. 58:18-59:2 (Carlson); BTr. 99:14-21 (Short).

74. On April 4, 2014, Dr. Kelleman sent an email to Mr. Carlson, Mr. Short, Mr. Reynolds, and other Grace employees stating, "[s]ince 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*." JTX-174 (emphasis added). On April 7, 2014, Mr. Carlson replied that he had already sent samples for analysis and would "continue to communicate with [Columbia] and request XRD analysis if necessary to help determine if we have a singular crystal form." *Id.*

75. In or around May 2014, Grace received PXRD results on the samples tested from Batch 13202. JTX-176; BTr. 56:16-57:9. These results confirmed to Grace that Batch 13202 was crystalline Form I of NRCl. BTr. 56:21-57:9 (Carlson); BTr. 101:5-21 (Short); *see also* JTr. IV, 124:22-24 (Dr. Rogers) ("Batch 13202 was actually determined to be Form I of NRCl by Grace around the time that it was made, so 10 years ago.").

I. Facts Related to Inequitable Conduct by the Accused Individuals

1. Facts Relevant to the Prosecution of the '058 Patent

76. On July 1, 2014, Dr. Kelleman emailed a representative of ChromaDex, copying Mr. Reynolds, stating that Grace was working on an "internal risk assessment." DTX-2110. Dr. Kelleman specified that "[a] question has come up about the first time material we manufactured was put out for sale to the public. Do you have any idea when that was?" *Id.*

77. On the same day, July 1, 2014, the ChromaDex representative responded, "[w]e should [*sic*] the 15kg pilot batch. Just say 60 days after the delivery of that lot." DTX-2110.

78. A few weeks later, on July 24, 2014, the '702 Provisional Application was filed. *See* FoF ¶ 14.

79. On July 25, 2014, one day after the filing of the '702 Provisional Application, Mr. Reynolds sent an email to several Grace employees, including Mr. Short and Mr. Carlson, thanking Mr. Short and Mr. Carlson for their "focused effort" supporting the provisional filing process of a patent application, noting that, if the patent were granted, it would be a "huge win for Grace." DTX-2112.

80. After the filing of the '702 Provisional Application (at least per the dates provided in the slide), Grace employees prepared a presentation slide titled "Development Timeline of NR-Cl." DTX-2001.0002. This slide states that "NR-Cl was included in a formulation . . . and made available to the public" on July 24, 2013, and includes the filing date of the '702 Provisional Application. *Id.* The slide references "NR-Cl" and a "solid form of NR-Cl" but does not mention "crystalline Form I" of NRCl. *See* DTX-2001.0002. Mr. Reynolds testified that he may have been involved in the preparation of the presentation but could not confirm the nature of his involvement. BTr. 134:12-19, 140:3-5. Mr. Short had a copy of this document in his files. BTr. 84:8-85:22.

81. On June 4, 2018, a representative of ChromaDex reached out to Mr. Reynolds, asking him if he could send the "melting point data on the first Niagen batch," referencing an earlier discussion. DTX-2162.0002. Mr. Reynolds initially responded that it would be no problem. *Id.* at .0001. Then, Reynolds later followed up asking whether the information was necessary, because it would be "a lot of work" to gather it for the 2013 lot. *Id.* Elysium did not

elicit any testimony from Mr. Reynolds regarding whether this information was ultimately gathered or provided to ChromaDex. *See* BTr. 149:22-151:6.

82. By no later than September 2018, Mr. Short created a spreadsheet collecting information regarding shipments of NRCl titled "Grace early lot order – ship data." DTX-2165; DTX-2165-M (metadata); BTr. 68:1-3 (Mr. Short, agreeing that it seemed "reasonable" that the document was created no later than September 2018). The column referencing shipment dates was left blank. DTX-2165.

83. Similarly, by no later than September 2018, Grace employees created a spreadsheet titled "NRCl Ship Schedule_BR" that gathered data on NRCl batches, including batch number, manufacturing date, and shipping date, wherein the first row of that document was devoted to Batch 13101. DTX-2169; *see also* BTr. 73:22-24 (Mr. Short, initially agreeing that he prepared DTX-2169), 74:19-21 (Mr. Short, agreeing that it was created no later than September 2018), 74:14-16 (Mr. Short, indicating that he was uncertain whether he drafted it); DTX-2169-M (metadata). The initials "BR" indicate that Mr. Reynolds may have been involved in the preparation of this file or drafted it. *See* BTr. 74:7-16 (Short).

84. On September 25, 2018, Mr. Reynolds emailed a Grace employee asking for her help on a "research project" concerning NRCl. DTX-2168; BTr. 151:20-23 (Reynolds). Elysium did not elicit further testimony from Mr. Reynolds regarding why this research project concluded. *See* BTr. 151:7-152:5 (Reynolds).

2. Mr. Carlson

85. Mr. Carlson joined Grace in 2009 and worked as a research and development chemist for Grace. JTr. II, 58:3-4, 59:2.

86. Mr. Carlson's responsibilities included "bringing in the tech package, of viewing the tech package that [Grace had] for the technology, taking that material into the lab, working on the process, developing chemistry and then overseeing the scale-up of the manufacturing of that material." JTr. II, 58:6-10.

87. As a chemist, Mr. Carlson was typically not involved in sales of materials that he helped to develop, including NRCl. BTr. 61:14-19.

88. Mr. Carlson began working on nicotinamide riboside projects in the "tail end of 2012." JTr. II, 62:1-3.

89. Mr. Carlson is not an attorney or patent agent, and did not have any training in patents. BTr. 46:8-13.

90. Mr. Carlson was one of the named inventors listed on the '058 Patent. *See* FoF ¶ 12.

91. In the application that ultimately led to the issuance of the '058 Patent, Mr. Carlson signed an oath attesting to his duty of disclosure to the PTO. BTr. 33:3-18; JTX-004.0052.

92. Mr. Carlson understood that he had a duty to disclose prior art to the PTO that was material to patentability. BTr. 33:25-34:4.

93. As a named inventor of the '058 Patent, Mr. Carlson had duties of candor, good faith, and disclosure under Rule 56. *See* 37 C.F.R. § 1.56(c).

94. Contemporaneously with the production of Batch 13101 and throughout the prosecution of the '058 Patent, Mr. Carlson believed that Batch 13101 included only amorphous material. JTr. II, 67:1-3; BTr. 47:16-48:2, 49:7-10. This belief was based off of his understanding of the scientific literature, the properties of the material produced in Batch 13101, and his personal inspection of Batch 13101. *See, e.g.*, JTr. II, 67:3-11; BTr. 47:20-48:20.

95. Mr. Carlson believed that the earliest batch that resulted in crystalline form I of NRCl was Batch 13202. *See, e.g.*, JTr. II, 73:7-10. In comparison with Batch 13101, he believed that Batch 13202, "which was identified as crystalline material, handled much better, did not have the same kind of issues with absorbing water out of the atmosphere, did not have the same kind of issues [such as] getting sticky and doughlike . . . [a]nd dried much more efficiently." JTr. II, 73:11-20; *see also* BTr. 48:7-20 (similar).

96. Mr. Carlson did not know that the sale of Batch 13101 was material to the issuance of the '058 Patent because he believed that Batch 13101 was amorphous NRCl. Nor was he aware of the sale of Batch 13101. Mr. Carlson did not engage in inequitable conduct rendering the '058 Patent unenforceable.

3. Mr. Short

97. Mr. Short began working for Grace in August 2012. JTr. II, 5:22-25. Since 2014, Mr. Short has been a business and technology manager for Grace and his responsibilities included business development, sales, and R&D management for Grace's fine chemicals business in Albany, Oregon. JTr. II, 6:1-7. Mr. Short's manager was Mr. Reynolds. JTr. II, 27:1-4.

98. Mr. Short is a chemist, but not a solid-state chemist, a crystallographer, or an expert in solid-state forms of chemical compounds. BTr. 90:4-20. Mr. Short was not an attorney. BTr. 107:22-24.

99. Mr. Short personally observed Batch 13101. JTr. II, 8:7-9. From his observation, early NRCl produced by Grace was "kind of sticky" and "glassy, not very well behaved." JTr. II, 8:3-6. This included Batch 13101, which Mr. Short described as a "sticky" or "glassy solid." JTr. II, 8:10-13; *see also* BTr. 97:16-23 (similar).

100. Mr. Short believed that Batch 13101 was amorphous material and has never believed otherwise. BTr. 97:24-98:9; *see also id.* at 106:22-107:1.

101. According to Mr. Short, Grace did not perform PXRD testing on early batches of NRCl because "it was not a specification by the customer or internal[ly] at that time" and "the early material . . . did not look good." BTr. 95:12-16.

102. Mr. Short believed that Grace first suspected it had made a crystalline form of NRCl in the first half of 2014, when Grace produced Batch 13202. JTr. II, 9:15-17; *see also* BTr. 101:8-13 (testifying as to his personal belief). This belief was developed after Grace had sent samples of Batch 13202 for PXRD testing confirming that Batch 13202 was crystalline Form I of NRCl. JTr. II, 10:20-11:4; BTr. 101:8-18; *see also* JTX-174; JTX-176.

103. Mr. Short believed that the only way to distinguish between crystalline and amorphous forms of a substance was through PXRD analysis. BTr. 92:3-23. In his personal experience, Mr. Short has observed that IR spectra between different forms of a chemical substance "can be identical." BTr. 93:17-20; *see also id.* at 93:21-94:16.

104. Mr. Short never compared the IR spectrum for Batch 13101 to the spectrum provided in the '058 Patent. BTr. 102:22-25. Mr. Short did not, prior to 2019, compare the peak positions of the IR spectrum for Batch 13101 to the peak listings provided in the '058 Patent. BTr. 103:1-10. However, even assuming he had done so, to Mr. Short, this comparison would not necessarily show that Batch 13101 was crystalline Form I of NRCl. BTr. 103:11-19.

105. Mr. Short reviewed the applications that led to the patents-in-suit prior to their filing and helped provide information that was later incorporated into the patents. JTr. II, 25:5-24, 26:1-9; *see also* BTr. 94:17-95:3.

106. Mr. Short was personally unaware of any changes in the law regarding the on-sale bar between 2014 and 2019 or the *Helsinn* decision. BTr. 108:1-8.

107. As an individual that was substantively involved in the prosecution of the '058 Patent and who was associated with the inventor(s) of the '058 Patent, Mr. Short owed duties of candor, good faith, and disclosure. *See* 37 C.F.R. § 1.56(c).

108. Mr. Short did not know that the sale of Batch 13101 was material to the issuance of the '058 Patent because he believed that Batch 13101 was amorphous NRCl. Mr. Short's involvement in inquiries into early sales of NRCl by Grace does not demonstrate that he, himself, believed that the sale of Batch 13101 was material, nor does his involvement in the initial filing of the '702 Provisional Application. Thus, Mr. Short did not engage in inequitable conduct rendering the '058 Patent unenforceable.

4. Mr. Reynolds

109. Mr. Reynolds began working for Grace in 2010, when Grace purchased Mr. Reynolds' previous employer, and Mr. Reynolds served as its global sales director. JTr. II, 111:1-4. As part of his work as Grace's global sales director, Mr. Reynolds had oversight over sales, including management of the sales pipeline and its opportunities. JTr. II, 111:5-9. Mr. Reynolds was Grace's global sales director during the 2013 to 2014 time period. BTr. 154:1-2.

110. Mr. Reynolds was not a chemist, scientist, patent attorney, patent agent, or registered to practice before the PTO. BTr. 154:9-19.

111. Prior to the issuance of the '058 Patent, Mr. Reynolds did not investigate whether Batch 13101 was claimed by the patent, perceive a need to do so, or stop any investigation into such information. BTr. 155:5-16. Nor did Mr. Reynolds form any belief as to whether Batch 13101 was the invention claimed by the '058 Patent. BTr. 155:1-4. Mr. Reynolds never believed

that Grace sold its claimed crystalline Form I of NRCl more than a year prior to the filing of the '058 Patent. BTr. 155:17-20; *see also id.* at 155:21-156:10.

112. During the bench trial, in response to a question posed by the Court asking whether amorphous NRCl would have suited ChromaDex's needs, Mr. Reynolds answered that it would not have. BTr. 158:24-159:1. However, Mr. Reynolds' testimony generally indicated some confusion over the difference between solid-state materials and salt forms, JTr. II, 122:21-123:5, BTr. 158:17-24, which is explained by his relative lack of scientific expertise, *see* FoF ¶¶ 109-10.

113. The '058 Patent was the first patent that Mr. Reynolds had ever been "involved with" in his career. *See* BTr. 140:19-22. Mr. Reynolds did not have any responsibility for communicating with the PTO regarding the '058 Patent and had "[v]ery limited involvement" in preparing the patent application. *See* BTr. 140:23-141:5 (Mr. Reynolds, answering that he had "[v]ery limited involvement" in a question directed to the filing of the "patent application for Form I"), 154:22-25.

114. Mr. Reynolds served as the "main contact" for Grace's intellectual property lawyers on the commercial side of the ChromaDex account. BTr. 197:25-198:3. He was also copied on some communications with Grace's counsel during the time period when the patent applications were being prepared and while the patent applications were pending. BTr. 141:6-10. Similarly, Mr. Reynolds attended in-person meetings concerning the filing of the relevant patent applications and likely attended other meetings during the prosecution of the patents prior to their issuance. BTr. 142:21-25, 144:16-145:3.

115. Mr. Reynolds did not understand the on-sale bar at the time of the filing of applications leading to the patents-in-suit, but understood it as of the time of the bench trial. BTr. 140:15-22.

116. As an individual that was not substantively involved in the *content* of the application leading to the issuance of the '058 Patent or decisions related thereto, Mr. Reynolds did not owe any duties of candor, good faith, and disclosure to the PTO. 37 C.F.R. § 1.56(c).

II. LEGAL STANDARDS

A. Inequitable Conduct

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011) (en banc); *see also Astellas Pharma Inc. v. Ascent Pharms., Inc.*, C.A. No. 23-486-JFB-EGT, 2025 WL 2697299, at *2 (D. Del. Sept. 22, 2025), *report and recommendation adopted*, 2025 WL 2938778 (D. Del. Oct. 16, 2025) (same). "Unlike validity defenses, which are claim specific, inequitable conduct regarding a single claim renders the entire patent unenforceable." *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343, 1350 (Fed. Cir. 2017) (citing *Therasense*, 649 F.3d at 1288).

"Inequitable conduct is an equitable issue committed to the discretion of the trial court and is, therefore, reviewed by [the Federal Circuit] under an abuse of discretion standard." *Energy Heating, LLC v. Heat On-The-Fly, LLC*, 889 F.3d 1291, 1299 (Fed. Cir. 2018) (citations omitted); *see also In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 519 (Fed. Cir. 2012) ("The district court's findings on materiality and intent are reviewed for clear error, and the court's ultimate decision as to inequitable conduct is reviewed on the standard of abuse of discretion." (citation omitted)). "To prevail on inequitable conduct, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference or prior commercial sale, knew that it was material, and made a deliberate decision to withhold it." *Energy Heating*, 889 F.3d at 1299 (citing *Therasense*, 649 F.3d at 1290). "Intent and materiality are separate requirements."

Therasense, 649 F.3d at 1290 (citing *Hoffmann–La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003)).

A "threshold inquiry in the inequitable conduct analysis" is whether "the individual involved in the alleged misconduct owed a duty of candor to the PTO." *Avid Identification Sys., Inc. v. Crystal Imp. Corp.*, 603 F.3d 967, 976 (Fed. Cir. 2010). "Once a court finds that the individual had a duty of candor, the court must proceed to the dual prongs of materiality and deceptive intent, to determine whether that duty was violated." *Id.* at 976-77.

"For purposes of identifying who owes a duty of candor to the PTO, Rule 56 defines 'individual[s] associated with the filing or prosecution of a patent application' as (1) each named inventor, (2) each attorney or agent that prepares or prosecutes the application, and (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor or assignee." *Id.* at 973 (quoting 37 C.F.R. § 1.56(c)). In this context, "substantively involved," means "that the involvement relates to the *content of the application or decisions related thereto*, and that the involvement is not wholly administrative or secretarial in nature." *Id.* at 974 (emphasis added) (citation omitted). "Individuals other than the attorney, agent, or inventor, who are 'substantively involved in the preparation or prosecution of the application,' may comply with their duty of candor by disclosing known material information to one of the attorney, agent, or inventor." *Id.* (quoting 37 C.F.R. § 1.56(d)).

Regarding intent, "a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality." *Therasense*, 649 F.3d at 1290. "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." *Id.* (citing *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009)). "However, to meet the clear

and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Id.* (quoting *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)). "Indeed, the evidence 'must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.'" *Id.* (emphasis in original) (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 873 (Fed. Cir. 1988)). "Negligence, however, even gross negligence, is not sufficient to establish deceptive intent." *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1292 (Fed. Cir. 2012) (collecting cases). "Partial disclosure of material information about the prior art to the PTO cannot absolve a patentee of intent if the disclosure is intentionally selective." *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1190 (Fed. Cir. 2014) (citations omitted).

Regarding materiality, the Federal Circuit held in *Therasense* that, "as a general matter, the materiality required to establish inequitable conduct is but-for materiality." 649 F.3d at 1291. "When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* Accordingly, "in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference." *Id.* "In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." *Id.* at 1291-92 (citation omitted). "Often the patentability of a claim will be congruent with the validity determination—if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires clear and convincing evidence, a higher evidentiary burden than that used in prosecution at the PTO." *Id.* at 1292. "However, even if a district court does not invalidate a claim based on a deliberately

withheld reference, *the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards*." *Id.* (emphasis added) (citation omitted).

"Determining but-for materiality requires that the court place itself in the shoes of a patent examiner and determine whether, had the reference(s) been before the examiner at the time, the claims of the patent would have still issued." *Regeneron*, 864 F.3d at 1351 (citing *Therasense*, 649 F.3d at 1291-92); *see also Glob. Tubing LLC v. Tenaris Coiled Tubes LLC*, 167 F.4th 1357, 1370 (Fed. Cir. 2026) ("For a prior art reference to be material, it must be shown by a preponderance of the evidence that, but-for the reference having been withheld, the patent would not have been granted." (citing *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1352 (Fed. Cir. 2021))). "'Prior art is but-for material if the PTO would have denied a claim had it known of the undisclosed prior art,' but it 'is not but-for material if it is merely cumulative.'" *Glob. Tubing*, 167 F.4th at 1370 (quoting *Cal. Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 991 (Fed. Cir. 2022)). "A reference is cumulative when it teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO." *Id.* (quoting *Regeneron*, 864 F.3d at 1350).

B. Unclean Hands

The doctrine of unclean hands is doctrinally related to the doctrine of inequitable conduct. *Therasense*, 649 F.3d at 1287 ("The unclean hands cases of *Keystone*, *Hazel–Atlas*, and *Precision* formed the basis for a new doctrine of inequitable conduct that developed and evolved over time."). "A court may find unclean hands when the misconduct of a party seeking relief 'has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation . . . for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication.'" *Luv n' Care, Ltd. v. Laurain*, 98

F.4th 1081, 1094 (Fed. Cir. 2024) (quoting *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933)). A district court's ruling of unclean hands is reviewed for abuse of discretion, and its factual findings are reviewed for clear error. *Id.* (citing *Gilead Scis., Inc. v. Merck & Co.*, 888 F.3d 1231, 1240 (Fed. Cir. 2018)).

III. DISCUSSION

Below, the Court analyzes the parties' core contentions regarding inequitable conduct and unclean hands. First, the Court analyzes whether Elysium has shown that Messrs. Carlson, Short, and Reynolds engaged in inequitable conduct rendering the '058 Patent unenforceable. Second, the Court analyzes whether the '058 Patent is unenforceable due to Grace's unclean hands.

A. Elysium Has Not Shown that the Accused Individuals Engaged in Inequitable Conduct

The Court divides its discussion of materiality and intent into separate subsections.

1. Materiality

Elysium contends that Grace's pre-critical date sale of Batch 13101 to ChromaDex was "but-for" material to the issuance of claims of the '058 Patent under *Therasense*. D.I. 339 at 2-6. The Court agrees with Elysium regarding materiality.

As a threshold matter regarding materiality, Grace contends that the jury's verdict of no anticipation precludes a finding of materiality. D.I. 341 at 2. This is incorrect. "District courts and the PTO employ different evidentiary standards and rules for claim construction." *Calcar*, 768 F.3d at 1189. Thus, "even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards." *Id.* (citing *Therasense*, 649 F.3d at 1291-92). For example, in *Calcar*, the Federal Circuit held that a jury's finding of non-obviousness "d[id] not weigh on the determination of materiality for inequitable conduct . . . ." *Id.*; *see also Aventis*

Pharma S.A. v. Hospira, Inc. 675 F.3d 1324, 1334 (Fed. Cir. 2012) ("Unlike the clear and convincing evidence standard for invalidating a patent in the district court under 35 U.S.C. §§ 102 and 103, the standard for establishing but-for materiality in the inequitable conduct context only requires a preponderance of the evidence, 'giv[ing] claims their broadest reasonable construction.'" (alteration in original) (quoting *Therasense*, 649 F.3d at 1291-92)). Thus, the Court rejects Grace's contention that the jury's verdict forecloses the inquiry. *See, e.g.*, *Lindis Biotech, GmbH v. Amgen Inc.*, C.A. No. 22-35-GBW, 2025 WL 2413188, at *13-14 (D. Del. Aug. 20, 2025) (rejecting the contention that the jury had already determined the materiality issue by virtue of its invalidity finding under *Therasense* and *Aventis*).

The Court now turns to the substance of the parties' contentions regarding materiality. In undergoing this analysis, the Court acknowledges that "[d]etermining but-for materiality requires that the court place itself in the shoes of a patent examiner and determine whether, had the reference(s) been before the examiner at the time, the claims of the patent would have still issued." *Regeneron*, 864 F.3d at 1351 (citing *Therasense*, 649 F.3d at 1291-92). Having thoroughly considered the record, the Court concludes that Elysium has met its burden to prove by a "preponderance of the evidence" and "giv[ing] claims their broadest reasonable construction," *Therasense*, 649 F.3d at 1291-92, that, had Grace's sale of Batch 13101 been placed in front of the patent examiner at the time, that at least Claims 1 and 6 of the '058 Patent would not have issued.

Claims 1 and 6 recite "[a] crystalline Form I of nicotinamide riboside chloride according to formula I," and "[t]he crystalline Form I according to claim 1 that is characterized by an IR spectrum having peaks substantially as shown in Table 2 ±0.2 cm^{-1}," respectively. *See* FoF ¶¶ 25, 26. Relatedly, the specification of the '058 Patent explains that "[i]n further embodiments, the crystalline Form I of nicotinamide riboside chloride may be characterized by a solid-state IR

spectrum having peaks substantially as provided in Table 2, below, ±0.2 cm^{-1}" and "may also or alternatively be characterized by a solid-state IR spectrum having peaks at 671.7, 1035.6, 1061.8, 1398.9, and 1649.3 cm^{-1} ±0.2 cm^{-1}." *See* FoF ¶ 22. Here, the finished product batch record for Batch 13101, which was in existence during the prosecution of the '058 Patent, contains IR peaks reported out two decimal places that match up almost exactly with the peaks shown in Table 2 and includes peaks at 671.7, 1035.6, 1061.8, 1398.9, and 1649.3 cm^{-1} ±0.2 cm^{-1}. *See* FoF ¶¶ 50, 54. Accordingly, Grace's pre-critical date sale to ChromaDex was material to Claims 1 and 6 of the '058 Patent. In light of the above, the Court finds Grace's response on this point, that the IR data "merely shows that batch 13101 contained NRCl—not that it was form I," unpersuasive. D.I. 341 at 2.

Grace's other assertions regarding whether Batch 13101 was amorphous or crystalline center around Batch 13101's water content, contemporaneous emails referring to Batch 13101 as "glassy," and subsequent PXRD testing of a different batch, Batch 13202. *See id.* None of these persuade the Court regarding whether the reference would be material under the PTO's different evidentiary standards. First, regarding hygroscopicity, while Batch 13101 had a higher water content than subsequent batches, this alone does not move the needle since the relevant claims do not specify a water content for crystalline Form I of NRCl. Second, the email regarding glassiness to which Grace refers was sent prior to the completion of the final drying of Batch 13101, according to its batch record. *See* FoF ¶¶ 48-49.[4] Moreover, this email conflicts with an email sent by the same individual on that same date. *See* FoF ¶ 47. Third, any perceived differences in

[4] In its briefing, Grace overstates the testimony of Elysium's expert regarding this email. *See* D.I. 341 at 2 (claiming that that Elysium's "own expert agreed that this email indicated batch 13101 was amorphous." (citing Grace FoF ¶ 29)); *cf.* FoF ¶ 48.

the PXRD patterns between the Retained Batch 13101 Sample and Batch 13202 do not materially change the analysis. Neither Claim 1 nor Claim 6 recite crystalline Form I with reference to a particular PXRD spectrum, nor does Claim 1 require PXRD analysis to confirm the identity of the material. *See also* D.I. 120 at 15:11-17 ("The patents are, thus, clear. Where the claimed crystalline forms may be characterized by some values, but may also or alternatively be characterized by others, and where different embodiments are characterized by different measurements and even completely different analytical techniques. No one testing technique is mandatory.").[5] Importantly, as Chief Judge Connolly recognized during claim construction, "if the claim terms were interpreted to require that all tests be satisfied, then the recitation of additional, more specific testing metrics in other claims would be surplusage." D.I. 120 at 16:1-4; *cf. Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005) (en banc) ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." (citation omitted)).

For the foregoing reasons, the Court concludes that Grace's pre-critical date sale of NRCl to ChromaDex was "but-for" material to the issuance of Claims 1 and 6 of the '058 Patent under *Therasense* and its progeny.

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[5] The Court recognizes that the examiner would be applying the broadest reasonable interpretation of the claim language. Neither party appears to contend that the examiner's interpretation would be *narrower* than the Court's construction. *See, e.g.*, *Facebook, Inc. v. Pragmatus AV, LLC*, 582 F. App'x 864, 869 (Fed. Cir. 2014) ("The broadest reasonable interpretation of a claim term may be the same as or broader than the construction of a term under the *Phillips* standard. But it cannot be narrower."); *Image Processing Techs. LLC v. LG Elecs. Inc.*, No. 2023-2136, 2025 WL 323779, at *5 (Fed. Cir. Jan. 29, 2025) ("IPT is right that, in district court litigation, the proper construction cannot be broader than the [broadest reasonable interpretation], as such a construction would not be reasonable." (citing *TF3 Ltd. v. Tre Milano, LLC*, 894 F.3d 1366, 1371 (Fed. Cir. 2018)).

2. Intent

Regarding intent, Elysium contends that Messrs. Reynolds, Short, and Carlson deliberately withheld information from the PTO regarding Batch 13101's characteristics, despite knowledge of materiality. D.I. 339 at 6. In essence, Elysium's theory of inequitable conduct is as follows: in 2014, Grace initially calculated the deadline for filing the '702 Provisional Application believing that Batch 13101 was on sale as of July 24, 2013; then, by 2018, after realizing that the application "should have" been filed in May 2014, Grace deliberately chose not to disclose the sale of Batch 13101. *See id.* at 1, 6-10.

Part of Elysium's theory involves the Federal Circuit's decision in *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), *aff'd*, 586 U.S. 123 (2019), which issued during the pendency of the prosecution of the '058 Patent. *See* D.I. 339 at 1, 6-7. In *Helsinn*, the Federal Circuit addressed "whether the [Leahy-Smith America Invents Act ('AIA')] changed the meaning of the on-sale bar under 35 U.S.C. § 102 . . . ." 855 F.3d at 1367. In so doing, the Federal Circuit concluded that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Id.* at 1371. As discussed above, none of the individuals accused of inequitable conduct were attorneys, and to the extent they were asked about *Helsinn* or changes to the on-sale bar, none of them were aware of the decision or its implications. FoF ¶¶ 89, 98, 106, 110.

"To prevail on an inequitable conduct claim, a party must prove at least one specified individual acted with 'the specific intent to deceive the PTO' by withholding material information." *Glob. Tubing*, 167 F.4th at 1370 (citation omitted); *see also Avid*, 603 F.3d at 974 n.1 ("[O]nly individuals, rather than corporations such as Avid, owe a duty of candor to the PTO." (citation omitted)). Below, the Court separately analyzes Elysium's inequitable conduct

contentions with respect to Messrs. Reynolds, Short, and Carlson. Ultimately, the Court finds that Elysium has not met its burden with respect to any of the three individuals.

a. Mr. Carlson

As a named inventor of the '058 Patent, Mr. Carlson owed a duty of disclosure to the PTO. FoF ¶ 93. Elysium contends that it has shown, through clear and convincing evidence, that Mr. Carlson knew of the sale of Batch 13101, knew it was material, and yet made a deliberate decision not to disclose it, despite his duty to do so. *See* D.I. 339 at 6. In opposition, Grace responds that Mr. Carlson did not believe Batch 13101 was crystalline Form I, did not review the Batch 13101 IR data, did not know of the sale of Batch 13101, and did not determine any deadline surrounding the filing of the patent. *See* D.I. 341 at 4.

Several factual determinations undergird the Court's conclusion that Elysium has not met its burden under *Therasense* with respect to Mr. Carlson. First, Mr. Carlson was generally unaware of any sale of Batch 13101, as he was not involved in sales of NRCl. *See* FoF ¶ 87. This testimony was generally corroborated by the facts adduced at trial, which indicated that Mr. Carlson was primarily involved in the research and development of Grace's NRCl process, as opposed to the sales and commercialization of NRCl. *See* FoF ¶¶ 85-87. Second, Mr. Carlson believed Grace had not been successful in making crystalline Form I until Batch 13202, based in part on his own personal observation of Batch 13101. FoF ¶¶ 94-96. Indeed, Elysium's own expert admitted that Dr. Kelleman's contemporaneous email reflected certain problems relating to the nature of Batch 13101. FoF ¶ 48.

Post-*Therasense*, the Federal Circuit has affirmed district courts that rejected "post hoc rationales for withholding material prior art." *Belcher*, 11 F.4th at 1354 (citing *Aventis*, 675 F.3d at 1335-37). In contrast, in the present case, Mr. Carlson's rationale for nondisclosure is supported

by contemporaneous record evidence and his personal observation of Batch 13101, undermining Elysium's contention that he possessed the requisite intent under *Therasense*. The Court finds that Mr. Carlson's testimony relevant to his specific intent was fairly credible and adequately supported by corroborating evidence, making *Belcher* and *Aventis* distinguishable. The same is true, as discussed further below, for the other individuals accused of inequitable conduct.

For the foregoing reasons, the Court finds that Elysium has failed to meet its burden to show by clear and convincing evidence that Mr. Carlson made a deliberate decision to withhold a known material reference. *Cf. Therasense*, 649 F.3d at 1290. Thus, the '058 Patent is not unenforceable due to inequitable conduct by Mr. Carlson.

b. Mr. Short

As with Mr. Carlson, the Court finds that Elysium has not met its burden to show through clear and convincing evidence that Mr. Short knew of the sale of Batch 13101, knew it was material, and yet made a deliberate decision not to disclose it.

Like Mr. Carlson, Mr. Short did not believe that Grace had made crystalline Form I of NRCl until Batch 13202, after he had seen PXRD confirmation. *See* FoF ¶ 102. This was further supported by his personal observation of the batches and by contemporaneous communications by others at Grace. *See* FoF ¶¶ 48, 99. Though he participated in inquiries relating to the sale of early batches of NRCl during the pendency of the '058 Patent and produced spreadsheets collecting information regarding early sales of NRCl, these spreadsheets were not limited to solely Batch 13101, and the Court cannot conclude that the evidence at trial "[is] sufficient to *require* a finding of deceitful intent in the light of all the circumstances," *Therasense*, 649 F.3d at 1290 (emphasis in original) (citation omitted), especially in light of Mr. Short's contemporaneous observations and beliefs regarding when Grace first achieved the production of crystalline Form I of NRCl. *See,*

e.g., FoF ¶¶ 99-102. Here, the evidence presented during trial gives rise to the reasonable inference that Mr. Short was unaware of the materiality of the sale of Batch 13101. *See Therasense*, 649 F.3d at 1290 ("[W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." (citation omitted)). The Court has thoroughly considered Elysium's contentions regarding how to interpret Mr. Short's knowledge and intent and ultimately finds them to be unavailing.[6]

For the foregoing reasons, the Court finds that Elysium has failed to meet its burden to show by clear and convincing evidence that Mr. Short made a deliberate decision to withhold a known material reference. *Cf. Therasense*, 649 F.3d at 1290. Thus, the '058 Patent is not unenforceable due to inequitable conduct by Mr. Short.

c. Mr. Reynolds

As with Messrs. Carlson and Short, the Court finds that Elysium has not met its burden to show through clear and convincing evidence that Mr. Reynolds knew of the sale of Batch 13101, knew it was material, and yet made a deliberate decision not to disclose it.

As set forth above, the Court finds that Mr. Reynolds did not owe a duty of disclosure to the PTO. FoF ¶ 116. Mr. Reynolds is the only individual for whom the parties dispute this issue. In analyzing this issue, the Court has considered "a variety of factors," including Mr. Reynolds' "position within the company, role in developing or marketing the patented idea, contact with the inventors or prosecutors, and representations to the PTO . . . ." *Avid*, 603 F.3d at 976 n.3. In *Avid*, the Federal Circuit found that Avid's Dr. Stoddard – who served as president and founder of Avid,

[6] In particular, the Court declines to infer the intent to deceive from the purported absence of any good faith explanation for any conduct by Mr. Short or for the other individuals accused of inequitable conduct. *See Therasense*, 649 F.3d at 1291 ("The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.").

a closely held company, hired the inventors to reduce his invention to practice, was involved in all aspects of the company's operation, received substantive communications from inventors containing content for a patent application, and signed the small entity status affidavit – owed a duty of disclosure under Rule 56. 603 F.3d at 974-76; *see also id.* at 976 ("Although Dr. Stoddard did not contribute enough to the patentable features of the claims to be considered an inventor, the functionality of the system described in the [asserted] patent was his idea."). In contrast, while Mr. Reynolds was one of the individuals tasked with commercializing the patented idea (e.g., maintaining the ChromaDex account) and served as a "commercial contact" to Grace's counsel, he was not involved in developing the patented idea, had very limited involvement in the filing of the application, and did not make any representations to the PTO. *See* FoF ¶¶ 109, 113-114; *see also Summit 6 LLC v. Rsch. in Motion Corp.*, C.A. No. 3:11-CV-367-O, 2013 WL 12124321, at *12 (N.D. Tex. June 26, 2013) (distinguishing *Avid* with respect to an individual that "(1) had communications with patent prosecution counsel and [the inventor], (2) was on the board of Summit 6, a small company, (3) was responsible for the patent portfolio, and (4) sent and received emails speaking about the progress of the prosecution").

Even assuming that Mr. Reynolds did owe a duty under Rule 56, he did not possess the requisite intent for inequitable conduct. Mr. Reynolds was a non-lawyer, did not understand or appreciate the on-sale bar until this litigation, and did not form a belief as to whether Batch 13101 embodied the claims of the '058 Patent. *See* FoF ¶¶ 110-11, 115. For the foregoing reasons, the Court finds that, assuming Mr. Reynolds owed a duty of disclosure to the PTO, Elysium has failed to meet its burden to show by clear and convincing evidence that Mr. Reynolds made a deliberate decision to withhold a known material reference. *Cf. Therasense*, 649 F.3d at 1290. Thus, the '058 Patent is not unenforceable due to inequitable conduct by Mr. Reynolds.

B. Elysium Has Not Shown that Grace has Unclean Hands

Elysium contends that the same actions that it believes give rise to inequitable conduct by Messrs. Carlson, Short, and Reynolds give rise to unclean hands by Grace. *See* D.I. 339 at 10 (referencing only the alleged "scheme" to deceive the PTO regarding the applications involving crystalline Form I of NRCl). Elysium has not raised any issues relating to Grace's litigation conduct or any false testimony by Grace witnesses. *Cf. Luv n' Care*, 98 F.4th at 1094-96 (affirming district court's unclean hands ruling where the district court had found, *inter alia*, that the party engaged in misconduct during litigation by failing to disclose patent applications until after the close of dispositive motion practice and that the parties' witnesses "repeatedly gave purposefully evasive testimony" during their depositions and trial).

For substantially the same reasons as stated above regarding the Court's analysis of the alleged inequitable conduct, the Court finds that Grace has not engaged in misconduct that "has immediate and necessary relation to the equity that [it] seeks in respect of the matter in litigation . . . ." *Luv n' Care*, 98 F.4th at 1094 (quoting *Keystone Driller*, 290 U.S. at 245).[7] Thus, the '058 Patent is not unenforceable due to unclean hands by Grace.

[7] *See also, e.g.*, *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, No. 16 C 6097, 2017 WL 1101092, at *16 (N.D. Ill. Mar. 22, 2017) ("Where an accused infringer's unclean hands defense is based on alleged acts of inequitable conduct, it rises and falls based on those allegations." (citation omitted)); *Sprint Commc'ns Co. L.P. v. Charter Commc'ns, Inc.*, C.A. No. 17-1734-RGA, 2021 WL 982726, at *12 (D. Del. Mar. 16, 2021) ("Defendants' unclean hands defense rests on the same evidence and arguments that supported their arguments against summary judgment on inequitable conduct. Therefore, the motions for summary judgment on inequitable conduct and summary judgment on the unclean hands defense will rise or fall together." (cleaned up)).

IV. CONCLUSION

For the foregoing reasons, the Court finds that Elysium has failed to show that the '058 Patent is unenforceable due to inequitable conduct or due to unclean hands. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W. R. GRACE & CO.-CONN, Plaintiff, v. ELYSIUM HEALTH, INC., Defendant.	Civil Action No. 20-1098-GBW-JLH

ORDER

AND NOW, this 25th day of June 2026 and based on the reasons set forth in the accompanying Memorandum Opinion, **IT IS HEREBY ORDERED** that:

1. U.S. Patent No. 10,323,058 is not unenforceable due to alleged inequitable conduct or unclean hands.

2. By no later than twenty-one (21) days from the entry of this Order, the parties shall meet and confer and file a proposed judgment consistent with the Memorandum Opinion accompanying this Order and a joint status report indicating which post-trial issues and motions, if any, will require resolution by the Court.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE