



1201 NORTH MARKET STREET SUITE 1400 WILMINGTON, DE 19801  
T 302.298.3535 F 302.298.3550 www.Venable.com

T 302.298.3523  
F 302.298.3550  
daobrien@venable.com

September 1, 2023

**Via E-Filing and Hand Delivery**

The Honorable Gregory B. Williams  
J. Caleb Boggs Federal Building  
844 N. King Street  
Unit 26  
Room 6124  
Wilmington, DE 19801-3555

Re: *W.R. Grace & Co.-CONN v. Elysium Health, Inc.*;  
C.A. No. 20-1098-GBW-JLH

Dear Judge Williams:

I represent Plaintiff W. R. Grace & Co.-Conn. (“Grace”) in the above-captioned matter. I write jointly on behalf of both Grace and Defendant Elysium Health, Inc. (“Elysium”) pursuant to paragraph 19 of the Scheduling Order (D.I. 183), which requires the Parties to submit, within seven days after a jury returns a verdict in any portion of a jury trial, (1) a form of order to enter judgment on the verdict and (2) a joint status report, indicating among other things how the case should proceed and listing any post-trial motions each party intends to file.

The jury returned a verdict on Friday, August 25, 2023 (D.I. 312, 313). Accordingly, attached as Exhibit 1 is Grace’s proposed form of order to enter judgment on the verdict, attached as Exhibit 2 is Elysium’s proposed form of order to enter judgment on the verdict, and below is the Parties’ joint status report.

Grace intends to file post-trial motions / briefing on the following issues:

1. Enhanced damages pursuant to 35 U.S.C. § 284 based on the jury’s verdict of willful infringement of claims 1, 2, and 21 of U.S. Patent No. 10,323,058 and claims 1, 6, and 15 of U.S. Patent No. 10,189,872 (collectively, “the Asserted Claims”);



The Honorable Gregory B. Williams  
September 1, 2023  
Page 2

2. Grace's attorneys' fees and non-taxable costs incurred in connection with this action pursuant to 35 U.S.C. § 285;<sup>1</sup>
3. Supplemental damages between March 2023 and the date of entry of final judgment;
4. Pre-judgment and post-judgment interest on the damages awarded;
5. Injunctive relief permanently enjoining Elysium from directly or indirectly infringing the Asserted Claims; and
6. In the event that a permanent injunction is not awarded, an ongoing royalty for Elysium's continuing future infringement of the Asserted Claims

Elysium intends to file post-trial motions / briefing on the following issues:

1. Elysium's opening brief on the issue of inequitable conduct, which was bifurcated from the jury trial;
2. Judgment as a matter of law that claims 1 and 21 of the '058 Patent are invalid for violating the on sale bar under 35 U.S.C. §102(a);
3. Judgment as a matter of law for a finding of no willful infringement;
4. Judgment as a matter of law that claim 2 of the '058 Patent and claim 6 of the '872 Patent are invalid for improper dependency under 35 U.S.C. §112(d), which was bifurcated from the jury trial by Party agreement; and
5. Judgment as a matter of law that the Asserted Claims of the '058 Patent and '872 Patent are invalid under 35 U.S.C. §112(a-b).

The Parties have two related disputes regarding the post-trial briefing in this matter, for which they seek guidance from the Court. First, the Parties dispute whether the jury's verdict on invalidity forecloses Elysium's inequitable conduct and unclean hands defenses. Second, the

---

<sup>1</sup> Pursuant to Fed. R. Civ. P. 54(d)(2)(B)(i), a motion for attorney's fees must be filed no later than 14 days after the entry of judgment. The Parties hereby stipulate, subject to the Court's approval, to extend such deadline, at a minimum to the deadline for opening post-trial briefs. The Parties dispute whether this deadline should be further extended until after the issue of inequitable conduct is heard.



The Honorable Gregory B. Williams  
September 1, 2023  
Page 3

Parties dispute whether Grace's motions related to damages, injunctive relief, and attorney's fees should be brought now or after the issue of inequitable conduct has been decided.

Under controlling Federal Circuit law in a 2011 en banc decision, the jury's validity findings do not foreclose Elysium's inequitable conduct counterclaim and defense. The Court should proceed to try this issue at a one day bench trial consistent with the Parties' agreement memorialized in the pretrial order (*see* D.I. 299 at 101; *see also* Aug. 25, 2023 Tr. at pgs. 133-134), and the Parties should submit pretrial briefing on this issue. As the Federal Circuit explained in *Therasense Inc., v. Becton Dickinson Co.*, "even if a district court does not invalidate a claim based on a deliberately withheld reference (or information), the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards." 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc). These include the PTO's "preponderance of the evidence" and "broadest reasonable construction" standards." *Id.* citing MPEP §§ 706, 2111. Because juries apply a "higher evidentiary burden than that used in prosecution at the PTO," the jury's verdict does not foreclose Elysium's equitable defenses based upon inequitable conduct. *Id.* (Citations that pre-date the en banc *Therasense* determination are of limited relevance to this issue.) Indeed, applying its binding guidance from its en banc *Therasense* decision, the Federal Circuit specifically affirmed a finding of inequitable conduct even though the jury found "the patents at issue non-obvious" over the disputed information:

District courts and the PTO employ different evidentiary standards and rules for claim construction. Therefore, 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.** The jury's verdict finding the patents at issue non-obvious thus does not weigh on the determination of materiality for inequitable conduct, and indeed, Calcar does not make any arguments on appeal that rely on the jury's determination.

*Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1189 (Fed. Cir. 2014) (internal citations and quotations omitted) (emphasis in original).<sup>2</sup> Elysium also disputes that it waived asserting how the *examiner* would have viewed Grace's hidden sales of NR-C1, as set out even in its Amended Answer and Counterclaims (*e.g.*, at pp. 42-43): "Information concerning Grace's

---

<sup>2</sup> Grace focuses on the "and indeed" language in the *Am. Calcar* case which the Federal Circuit uses as an additional reason for its determination while ignoring that language in the preceding sentences quoting the *en banc Therasense* decision. The *Triangle Software v. Garmin* case Grace points to is distinguishable because, in contrast to Elysium, "Garmin did not put on any evidence of a specific intent to deceive the PTO."



The Honorable Gregory B. Williams  
September 1, 2023  
Page 4

pre-application critical date offers to sell and sales ... – if it had been disclosed as required –  
**would have led the patent examiner to issue a rejection ... .”**

Moreover, Elysium is narrowly moving for JMOL that claims 1 and 21 of the '058 Patent are invalid for violating the on sale bar; this motion, if granted, would separately render Grace's argument premised on *materiality*, moot.

Elysium also intends to file for a judgment as a matter of law based upon §112, as to those issues that are strictly court decisions as a matter of law; the jury could consider issues of underlying facts but §112(a, b, d) determinations as to indefiniteness, enablement, and improper dependent claim form are legal questions for the Court. Finally, because inequitable conduct has not been decided and because the resolution of this issue may affect the relief available to Grace and the availability of attorney's fees for either Grace or Elysium, Elysium believes that the briefing on damages, injunctive related issues, and attorney's fees Grace now proposes is premature. Elysium also believes that the issue of unclean hands should be reserved for after a determination on inequitable conduct, since both defenses include within their scope the same underlying conduct by Grace (unclean hands has an additional element related to Grace's litigation conduct).<sup>3</sup>

It is Grace's position that briefing and holding a hearing on inequitable conduct would waste the Court's and the Parties' resources because the jury's rejection of Elysium's on sale bar defense forecloses a finding of materiality, as the same batches of Grace's product underlie Elysium's inequitable conduct and on sale bar defenses. *See Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 995 (Fed. Cir. 1995) (court erred in making findings for inequitable conduct that conflicted with jury verdict on validity); *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 569 F. Supp. 2d 819, 831 (W.D. Wis. 2008), *rev'd in part on other grounds*, 607 F.3d 784 (Fed. Cir. 2010) (once jury found withheld reference did not anticipate claims, inequitable conduct defense could not succeed); *see also S. Clay Prod., Inc. v. United Catalysts, Inc.*, 43 F. App'x

---

<sup>3</sup> Elysium disagrees that it failed to adequately plead unclean hands under Rule 9(b), as it set out in response to Grace's Motion in Limine #2. Pleading unclean hands is subject to a combination of Rule 8 and Rule 9. Elysium plead the facts underlying its inequitable conduct defense—which Grace previously recognized forms a substantial part of Elysium's unclean hands defense—with the required specificity. The only additional factual issues for Elysium's unclean hands defense relate to Grace's litigation conduct, and these are not required to be plead under the Rule 9(b) standard. *Allergan USA, Inc. v. Sun Pharm. Indus.*, 2022 U.S. Dist. LEXIS 191468, at \*8 (D. Del.). Nevertheless Elysium put Grace on notice of its specific factual allegations related to Grace's litigation conduct in its discovery responses, and denies Grace's allegations that Elysium waived its unclean hands defense or that the jury's verdict would be controlling on the issue of inequitable conduct during a phone call.

The Honorable Gregory B. Williams  
September 1, 2023  
Page 5

379, 385 (Fed. Cir. 2002) (“[I]t is well-settled law that when 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.”) (citing *Therma-Tru*, 44 F.3d at 995). Elysium dismisses all pre-*Therasense* cases because the Court there acknowledged that the Patent Office applies a preponderance of the evidence and broadest reasonable construction standard. But so did pre-*Therasense* inequitable conduct cases. See *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006) (assessing materiality under “the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction”) (quoting 37 C.F.R. § 1.56(b)).<sup>4</sup> And plaintiff in Elysium’s authority did “not make any arguments [regarding materiality] that rely on the jury’s determination.” *American Calcar*, 768 F.3d at 1189. Accordingly, the holding of *Therma-Tru* controls over the dicta in *American Calcar* quoted by Elysium. See also *Triangle Software, LLC v. Garmin Int'l., Inc.*, No. 1:10-cv-1457, 2012 WL 527223, at \*4 (E.D. Va. Feb. 14, 2012) (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.”), *aff'd*, *Ontario Ltd. v. Garmin USA, Inc.*, 497 F. App'x 70, 71 (Fed. Cir. 2013).

In addition, the Court should not permit briefing on unclean hands based on inequitable conduct because Elysium failed to satisfy Rule 9(b)'s heightened pleading standard for a fraud-based theory of unclean hands. See *Barry v. Stryker Corp.*, No. 20-1787-RGA-SRF, 2023 U.S. Dist. LEXIS 54436, at \*24, \*22-27 (D. Del. Mar. 20, 2023) (striking an unclean hands defense sua sponte for failing to satisfy Rule 9(b)).

Finally, at a minimum briefing on inequitable conduct and unclean hands should occur concurrently with briefing on damages and injunctive relief. Further delaying Grace’s recovery and ability to exclude others from practicing its patented inventions—based on defenses that cannot succeed—is unduly prejudicial. See *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008) (“The essential attribute of a patent grant is that it provides a right to exclude competitors from infringing the patent.”).

The Parties propose the following schedule and page limits for post-trial briefing. The Parties note that paragraph 20 of the Scheduling Order (D.I. 183) limits all sides to a maximum

---

<sup>4</sup> Elysium never argued for a broader claim construction in connection with its inequitable conduct defense and therefore waived this argument. As to the alleged “agreement” of the Parties to hold a bench trial on inequitable conduct, Grace has consistently argued that the jury’s verdict will moot inequitable conduct (see Grace’s MIL No. 2), and Elysium’s counsel agreed with Grace during a telephone call on the eve of the pretrial conference, when Elysium stipulated for the first time to bifurcate enforceability.



The Honorable Gregory B. Williams  
 September 1, 2023  
 Page 6

of 20 pages of opening briefs, 20 pages of answering briefs, and 10 pages of reply briefs. Due to the number of issues to be briefed, to ensure that the Parties have final trial transcripts, and to allow time for the Court to consider the Parties' dispute over whether the Court should hear the issue of inequitable conduct, the Parties respectfully request an increased page limit and an extension of briefing dates as described below:

Filing	Deadline	Page Limit
Opening post-trial briefs (including Elysium's opening brief on inequitable conduct if the Court hears this issue)	Grace's proposal: 30 days after judgment  Elysium's proposal: Friday, October 6, 2023	45 pages (or 50 pages if the Court hears all issues proposed by the Parties, including inequitable conduct)
Answering post-trial briefs (including Grace's responsive brief on inequitable conduct if the Court hears this issue)	Grace's proposal: 30 days after opening briefs  Elysium's proposal: Friday, November 9, 2023	45 pages (or 50 pages if the Court hears all issues proposed by the Parties, including inequitable conduct)
Reply post-trial briefs (including Elysium's reply brief on inequitable conduct if the Court hears this issue)	Grace's proposal: 14 days after answering briefs  Elysium's proposal: Friday, December 1, 2023	20 pages (or 25 pages if the Court hears all issues proposed by the Parties, including inequitable conduct)

To the extent that the Court hears the issue of inequitable conduct, Elysium further requests that the Court schedule a one day bench trial following the Parties' completion of their briefing on this issue, as discussed above.

Respectfully,

/s/ Daniel A. O'Brien  
 Daniel A. O'Brien (No. 4897)