

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LINDIS BIOTECH, GMBH)	
)	C. A. No.: 22-00035-GBW
Plaintiff,)	
)	
v.)	
)	
AMGEN INC.,)	
)	
Defendant.)	

DEFENDANT AMGEN INC.’S REPLY IN SUPPORT OF ITS PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW REGARDING INEQUITABLE CONDUCT

Young Conaway Stargatt & Taylor, LLP
Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Stephanie N. Vangellow (No. 7277)
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
svangellow@ycst.com

PERKINS COIE LLP
Michael J. Wise
Joseph P. Hamilton
Lara J. Dueppen
Courtney M. Prochnow
Alisha C. Burgin
Doris Alvarez-Reyes
1888 Century Park East
Suite 1700
Los Angeles, CA 90067-1721
(310) 788-9900

Garmai Gorlorwulu
Blake A. Winn
11452 El Camino Real, Suite 300
San Diego, CA 92130-2080
(858) 720-5700

AMGEN INC.
Brian Kao
J. Drew Diamond
Blake Greene
Wendy A. Whiteford
Carolyn S. Wall
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
(805) 447-1000

O'MELVENY & MYERS LLP

Lisa B. Pensabene

Hassen Sayeed

Jing Ying (Amy) Zhao

1301 Avenue of the Americas

Suite 1700

New York, NY 10019

(212) 326-2000

Luann L. Simmons

Sorin Zaharia

Two Embarcadero Center

28th Floor

San Francisco, CA 94111

(415) 984-8700

AUTZ IP LLC

Lindsay H. Autz

115 Lampwick Lane

Fairfield, CT 06824

(203) 526-1307

Attorneys for Amgen Inc.

Dated: April 16, 2025

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. THE COURT SHOULD ADOPT AMGEN’S PROPOSED FINDINGS OF FACT	2
A. The Asserted Patents Identify Two Premises of Invention	2
B. Dr. Lindhofer Relied on the False Premises During Prosecution and the Examiner Granted the Asserted Patents Based on Them	3
C. Dr. Lindhofer’s Knowledge and Intent Is Largely Undisputed	5
D. Lindis’s Excuses Are Red Herrings	5
1. Lindis’s meritless excuses regarding the “surprising finding”	6
2. Lindis’s meritless excuses on the “totally unknown” premise.....	8
III. AMGEN’S PROPOSED CONCLUSIONS OF LAW	9
A. Amgen Has Proven <i>Per Se</i> and <i>But-For</i> Materiality on Multiple Grounds.....	9
1. The two false premises of invention are <i>per se</i> and but-for material.....	9
2. The Examiner’s actual reliance on the false premises to allow the claims establishes that the premises are but-for material.	12
3. The withheld information is but-for material because the Patent Office would have rejected the claims had it been disclosed.....	12
4. The pattern of misrepresentations, omissions, and false statements is <i>per se</i> material.	15
5. The jury neither assessed nor decided materiality.	15
B. Amgen Has Proven Dr. Lindhofer’s Specific Intent to Deceive the PTO.	16
1. Dr. Lindhofer made conscious decisions to assert the false premises and withhold the Trion Report, EMA Assessment, and Huhn.	16
2. Lindis does not dispute that Dr. Lindhofer had motivation to deceive.	16
3. Dr. Lindhofer has no credible explanation for the misrepresentations, omissions, and false statements.	16
4. Lindis’s argument that Dr. Lindhofer made a mistake is another post hoc rationalization in its ever-changing narrative in this case.....	20
5. The single most reasonable inference is intent to deceive.	20
IV. CONCLUSION.....	20

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Apotex Inc. v. UCB, Inc.</i> , 763 F.3d 1354 (Fed. Cir. 2014).....	12
<i>Belcher Pharms., LLC v. Hospira, Inc.</i> , 11 F.4th 1345 (Fed. Cir. 2021).....	17
<i>Enzo Life Scis., Inc. v. Roche Molecular Sys.</i> , 928 F.3d 1340 (Fed. Cir. 2019).....	14
<i>Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co.</i> , 837 F. Supp. 1444 (N.D. Ind. 1992), <i>aff'd</i> , 1993 U.S. App. LEXIS 28844 (Fed Cir. 1993).....	17, 20
<i>In re eSpeed, Inc. v. BrokerTec USA, L.L.C.</i> , 480 F.3d 1129 (Fed. Cir. 2007).....	19
<i>In re Rosuvastatin Calcium Patent Litig. v. Aurobindo Pharma Ltd.</i> , 703 F.3d 511 (Fed. Cir. 2012).....	12
<i>Kangaroos U.S.A., Inc. v. Caldor, Inc.</i> , 778 F.2d 1571 (Fed. Cir. 1985).....	20
<i>Molins PLC v. Textron, Inc.</i> , 48 F.3d 1172 (Fed. Cir. 1995).....	19
<i>Ohio Willow Wood Co. v. Alps S., LLC</i> , 735 F.3d 1333 (Fed. Cir. 2013).....	15
<i>Purdue Pharma L.P. v. Endo Pharms, Inc.</i> , 438 F.3d 1123 (Fed. Cir. 2006).....	10
<i>Regeneron Pharms., Inc. v. Merus N.V.</i> , 864 F.3d 1343 (Fed. Cir. 2017).....	20
<i>Ring Plus Inc. v. Cingular Wirelesss Corp.</i> , 614 F.3d 1354 (Fed. Cir. 2010).....	10
<i>Senju Pharmaceutical Co. Ltd. v. Apotex Inc.</i> , 717 F. Supp. 2d 404 (2010).....	14
<i>Therasense, Inc. v. Becton, Dickinson & Co.</i> , 649 F.3d 1276 (Fed. Cir. 2011).....	15, 20
Other Authorities	
MPEP 2164.02(I).....	16

I. INTRODUCTION

Lindis does not dispute that the “surprising finding” and the “totally unknown” premises are the bases of the invention and were submitted under oath to the Patent Office. The plain words of the EMA Assessment (a report of the European drug regulatory authority), the Trion Report (a report signed by Dr. Lindhofer), and Huhn (a reference cited in the Trion Report) directly contradict the two premises. Knowing of that contrary information, Dr. Lindhofer repeated the two premises throughout prosecution as bases for patentability and the Examiner relied upon them to allow the claims, as Lindis admits. To do so, Dr. Lindhofer withheld the contrary information from the Patent Office. None of this was “negligence” or “mistake”—but affirmative acts of deception.

Each of these acts on their own amounts to inequitable conduct. Take the withholding of the EMA Assessment, which is undisputedly material. The regulatory authority analyzed the data, concluded that Removab antibody action “was inhibited” by pretreatment with glucocorticoids, and did not recommend their use. That conclusion contradicted the specification’s “surprising finding” that glucocorticoids could be used “without the action of the antibody . . . being impaired.” At trial, Dr. Lindhofer first disclaimed knowledge of the EMA Assessment and then, after admitting he knew of the EMA Assessment, he had no explanation when asked why he withheld it from the examiner. His undisputed actions reveal his intent. Dr. Lindhofer disclosed the EMA Assessment in an unrelated patent prosecution where he felt it was “helpful.” Just a month later in prosecution of the Asserted Patents, he argued the “surprising finding” to convince the Examiner to issue the claims—despite knowing that the EMA had concluded the opposite. The Examiner allowed the claims, based on the surprising finding. That would not have been the case had Dr. Lindhofer disclosed the EMA Assessment. And the same is true had Dr. Lindhofer submitted the Trion Report or Huhn to the Patent Office.

The single most reasonable inference is that Dr. Lindhofer intended to deceive the Patent Office through this pattern of misrepresentation and omission. There is no credible excuse otherwise—Lindis offers only unavailing post-hoc rationalizations. This is inequitable conduct.

II. THE COURT SHOULD ADOPT AMGEN'S PROPOSED FINDINGS OF FACT

A. The Asserted Patents Identify Two Premises of Invention

1. Lindis does not dispute that the Asserted Patents identify two bases for the supposed of invention—the “surprising finding” and the “totally unknown” premises (Op. FoF ¶ 1-10¹):

“Surprising Finding” Premise: “that the combination of immunostimulating antibodies of defined specificity together with glucocorticoids results in a reduction of the non-specific release of cytokine by immunological cells **without the action of the immunostimulating antibodies directed against the defined antigen(s) being impaired.**” Op. FoF ¶ 2. The specification explains that this means that “the immune activity of the antibody or antibodies, directed against the defined antigen(s), **remains largely unchanged.**” Op. FoF ¶ 2.

“Totally Unknown” Premise: “in the state of the art, an administration of **glucocorticoids in connection with the stimulation of the immune system of a patient by antibody therapies**, for example with trifunctional antibodies (trAB), **is totally unknown.**” Op. FoF ¶ 7.

2. At the jury trial, coinventor and CEO Dr. Lindhofer testified that the “surprising finding” means glucocorticoids would reduce non-specific release of cytokines “without reducing the antitumor killing activity.” JTr. at 274:19-276:4 (Lindhofer) (admitting this was the “decisive finding” described in his patents). This is the plain meaning of the words in the Asserted Patents.

3. Lindis makes belated evidentiary challenges, but does not dispute that the EMA Assessment says the opposite of the “surprising finding” premise. Lind. FoF ¶¶ 42-52. The EMA Assessment concludes that “[d]examethasone dose-dependently and markedly inhibited Removab-induced cytokine release and granzyme B release[,]” that “[Removab]-induced tumour

¹ Amgen’s Opening Findings of Fact (D.I. 371) abbreviated as Op. FoF ¶____. Amgen’s Opening Conclusions of Law (D.I. 371) abbreviated as Op. CoL ¶____. Lindis’s Answering Finding of Facts (D.I. 393) abbreviated Lind. FoF ¶____. Lindis’s Answering Conclusions of Law (D.I. 393) abbreviated Lind. CoL ¶____. Amgen’s Reply Findings of Fact abbreviated as Rep. FoF ¶____.

cell killing was inhibited by dexamethasone at all tested concentrations in conditions of a low [Removab] concentration,” and that “[h]ydrocortisone showed weaker inhibition of cytokine and granzyme B release and had no effect on [Removab]-induced tumor cell killing.” DTX201 at 13. Based on this conclusion, the EMA’s recommendation for treatment of “cytokine release related symptoms” of Removab omits glucocorticoids, saying that “standard pre-medication with analgesic/antipyretic/**nonsteroidal** antiphlogistic medicinal products is recommended.” *Id.* at 45.

4. Lindis does not dispute that the Trion Report says the opposite of the “surprising finding” premise at least ten times. Lind. FoF ¶¶ 12-14, 20. For example, it says: glucocorticoid premedication “showed **negative impact on [R]emovabs’ [sic] killing abilities** even at high [R]emovab concentrations of 50ng/ml and 10ng/ml.” DTX335 at 17.

5. Lindis also does not dispute that the Trion Report says the opposite of the “totally unknown” premise: that the use of glucocorticoids with monospecific antibodies, like Rituxan, had been “established successfully in the clinic” to minimize cytokine side effects and was “common practice,” citing Huhn. Op. FoF ¶ 12, 20, 23; DTX335 at 6, 17, 19 n.7; Lind. FoF ¶ 12.

B. Dr. Lindhofer Relied on the False Premises During Prosecution and the Examiner Granted the Asserted Patents Based on Them

6. Lindis does not dispute that Dr. Lindhofer relied upon the “surprising finding” and “totally unknown” premises during prosecution of the Asserted Patents to argue for patentability. Op. FoF ¶¶ 39-50. Specifically, Lindis does not dispute Dr. Lindhofer repeatedly argued that a person of skill in the art would have expected impairment of killing action because glucocorticoids are immunosuppressive, but with the invention, killing action surprisingly was not impaired. *Id.*

7. During prosecution, the Examiner specifically noted that a critical point was whether an immunostimulating monospecific antibody had been used with a glucocorticoid to decrease cytokines because, if so, the claim would be obvious. Lindis’s brief called out the

Examiner's statement in a boxed quote: "if an immunostimulating monospecific antibody can be combined with steroid, one skilled in the art would expect an immunostimulating bispecific antibody can be combined with steroid." Lind. FoF ¶ 57.

8. In response, Dr. Lindhofer did not identify and candidly correct or qualify the "totally unknown" premise, nor even acknowledge and disclose what the Trion Report said based on Huhn: that immunostimulating monospecific antibodies had been combined with glucocorticoids to reduce side effects caused by cytokines, despite knowing this was an "established" and "common" practice. Lind. CoL ¶ 48, 59; Op. FoF ¶¶ 14-15.

9. Instead, Dr. Lindhofer withheld the Trion Report, surreptitiously amended the claims and continued to argue the "surprising finding": "[t]he combination of the cited references does not provide guidance or predictability on how a glucocorticoid (which is immunosuppressive) can be used together with a bispecific immunostimulating antibody to reduce the non-specific release of cytokine without impairing the ability of the bispecific immunostimulatory antibody to recruit and activate various immune cells to destroy tumor cells." JTX104 at 480; Op. FoF ¶ 14.

10. As a result, the Examiner allowed the '421 Patent claims based on Dr. Lindhofer's misrepresentations that combining glucocorticoids with immunostimulatory antibodies to reduce cytokines was previously unknown and, surprisingly, did not impair killing action as would have been expected. *See e.g.*, Op. FoF ¶ 39-50; JTX104 at 453 (Reasons for Allowance: "Given the fact that glucocorticoid was known in the prior art to be immunosuppressive, it would have not been obvious to one [sic] ordinary skill in the art to have treated cancer patients with a glucocorticoid immediately before, concurrently, or immediately after treatment of the patients with a bispecific, trifunctional, immunostimulating antibody."); BTr. at 58:21-60:5 (Marasco) ("[T]he basis of allowance that it was a 'surprising finding' because of the prior history in the art.").

11. Dr. Lindhofer continued these misrepresentations through the prosecution of the '158 Patent. Op. FoF ¶ 48-50.

C. Dr. Lindhofer's Knowledge and Intent Is Largely Undisputed

12. Lindis does not dispute the following facts as to Dr. Lindhofer's intent:

- Dr. Lindhofer had duties of candor, good faith and disclosure to the Patent Office during prosecution of the Asserted Patents under Rule 56 and he knew of them. Op. FoF ¶¶ 11-13.
- Dr. Lindhofer had a central role in the EMA approval process answering the EMA's questions for approval of Removab. BTr. 193:2-194:17 (Lindhofer).
- On February 8, 2011, Dr. Lindhofer submitted the EMA Assessment to the Patent Office for an unrelated patent application because it was "helpful." Op. FoF ¶ 38.
- One month later, on March 9, 2011, and then again on November 1, 2011, Dr. Lindhofer argued the "surprising finding" in support of patentability to the Patent Office, but he did not reveal to the Patent Office the contrary conclusion of the EMA Assessment. Op. FoF ¶¶40-22.
- Two weeks before he filed his priority patent application, Dr. Lindhofer attested to the accuracy of the conclusions of the Trion Report, which he testified was conducted to confirm the "quick and dirty" data of the patent specification. JTr. at 276:18-25, 278:19-279:11 (Lindhofer).
- Dr. Lindhofer embarked on a "roadshow," that included Amgen, to try to raise capital and needed broad patent claims for this purpose. Op. FoF ¶ 51-55, 68-69.

13. Lindis admits that Dr. Lindhofer knew that the EMA Assessment and the Trion Report concluded that glucocorticoids did, in fact, inhibit tumor cell killing with Removab. Lind. FoF ¶¶ 13, 33. Neither was submitted to the Examiner and Dr. Lindhofer never corrected the "surprising finding." When asked at trial why he did not disclose the EMA Assessment, after disclaiming he had the Assessment, Dr. Lindhofer had no answer. BTr. at 193:2-194:17 (Lindhofer) ("I cannot recall totally, to be honest").

14. It is also undisputed that Dr. Lindhofer and Lindis's counsel continued to rely on the two premises throughout the jury trial and prevented any evidence relating to materiality issues from being presented to the jury. Op. FoF ¶ 70; JTr. at 296:2-297:6.

D. Lindis's Excuses Are Red Herrings

1. Lindis’s meritless excuses regarding the “surprising finding”

15. Lindis argues that the EMA Assessment was not based on the Trion Report data. Lind. FoF ¶ 43. The EMA Assessment says it is relying on submitted data from the applicant, Lindis’s partner and predecessors. DTX201 at 3 (relying on “non-clinical and clinical data based on applicants’ own tests and studies”), 13. Three of Lindis’s witnesses testified, without objection, that the Trion Report data was the source of the EMA’s conclusion. Op. FoF ¶ 31. But whatever underlying data was provided to the EMA, the EMA Assessment’s conclusion was the same: “[Removab]-induced tumour cell killing was inhibited by dexamethasone at all tested concentrations in conditions of a low [Removab] concentration.” Op. FoF ¶¶ 33-34. There is no dispute that “low” Removab concentration refers to the concentration of drug in patients undergoing treatment. *Id.* ¶ 33.

16. Lindis argues that the EMA’s approval to use glucocorticoids with Removab was not requested. Lindis FoF ¶¶ 50-51. Despite that, the EMA was compelled to underscore that use of Removab with dexamethasone impairs killing activity. Indeed, based on the reviewed data, the EMA did not recommend premedication with glucocorticoids for Removab. DTX201 at 26, 44, 45. The EMA recommended the use of only **non**-steroidal treatments for cytokine release. *Id.*

17. As to the Trion Report, Dr. Lindhofer testified that it was commissioned to confirm the “quick and dirty” experiments in the specification. Op. FoF ¶ 17. Relying on Dr. Lindhofer’s alternative testimony, Lindis argues the Trion Report was to be used for “a lung cancer indication.” Lind. FoF ¶ 68. Nevertheless, the Trion Report makes conclusions from testing glucocorticoids with Removab, the example antibody of the Asserted Patents. The Asserted Patents are not limited to treating any particular type of cancer and do not exclude lung cancer. Op. CoL ¶ 30.

18. Lindis rationalizes that, when parsed now for litigation, the data of the Trion Report Figure 12 could be seen as “consistent with” the patent specification, picking four figures in the

patent, Figures 5A-5D, from amongst 51 others. Lind. FoF ¶¶ 9-11, 24-25, 33. To do so, Lindis offers a re-interpretation of the experimental results in Figures 5A-D, which lacked reliable controls and which even Dr. Lindhofer agrees is an impenetrably complicated experiment. *Id.* at ¶¶ 9-11; BTr. at 125:23-126:8, 132:25-134:20 (Lindhofer), 109:2-8 (Marasco).

19. But, the corresponding conclusions of the patents and the Trion Report are the opposite. The Asserted Patents' specification reconciles the results of Figure 5 to mean that the killing action "was not influenced significantly." Op. FoF ¶ 78. Figure 12 of Trion concludes the exact opposite, that "dexamethasone showed a clear inhibition of tumor cell killing at all dexamethasone concentrations." DTX335 at 16.

20. While Lindis spends pages dissecting Figures 5 of the patent and Figure 12 of the Trion Report, Lindis hides from the rest of both. The contradictions are there in black and white—with the Trion Report concluding ten times (including as to Figure 12) the opposite of the "surprising finding" premise. Op. FoF ¶¶ 22, 43. The Asserted Claims are broad, with no limitation on antibody concentration, in conjunction with any concentration of glucocorticoid (limited to dexamethasone in the '158 Patent). *Id.* at ¶ 62. The Trion Report tested the effects of different glucocorticoids on the activity of Removab at more physiologically relevant concentrations covered by the patent, and found the invention did not "work." *Id.* at ¶¶ 63-67.

21. Lindis attempts to fix Dr. Lindhofer's impeached testimony that the ten conflicting statements in the Trion Report were an employee's "mistake." Lind. CoL ¶ 62. To do so, Lindis blames Dr. Lindhofer's testimony on "Amgen's semantic argument" that inhibition means "total inhibition." *Id.* ¶¶ 12, 61-62. The record shows that the "semantic" arguments came directly from Dr. Lindhofer. BTr. at 160:1-5, 183:20-184:1. Amgen relies on the plain words of the Trion Report and patent. What's more, Dr. Lindhofer had attested to the accuracy of the conclusions in the Trion

Report when it was written—there was no “mistake.” Op. FoF ¶ 20.

22. The former Patent Commissioner, Mr. Stoll, explained that an examiner would have considered the Trion report with its ten contradictory conclusions to be material. He testified that Dr. Lindhofer’s opinion that the Trion Report was not contradictory does not excuse submission—“you submit the references for analysis by the examiner.” BTr. at 218:12-219:12.

23. As to Lindis’s argument that the Examiner did not make a Section 112 rejection, the Trion Report was not before the Examiner. The only expert testimony at trial was that had the Examiner received the Trion Report, he would have issued rejections under Section 112 because “it would take undue experimentation” for a POSA to find a combination of glucocorticoid and antibody doses that can be used to practice the full scope of the Asserted Claims and the “inventors were not in possession of the full scope of the claimed method.” BTr. at 74:21-76:17, 77:6-11, 16-19, 79:3-80:3, 82:10-85:10, 113:9-114:4, 114:8-15 (Marasco), 270:15-271:7 (Stoll).

2. Lindis’s meritless excuses on the “totally unknown” premise

24. Lindis argues that the “totally unknown” premise should be read as limited to bispecific antibodies that stimulate T cells. Lind. FoF ¶¶ 22-23. The plain language of the specification says “administration of glucocorticoids in connection with the **stimulation of the immune system of a patient by antibody therapies**” is totally unknown. Op. FoF ¶ 7. (Emphasis added). On its face, this statement is not limited to only bispecific T cell engagers but includes any “antibody therapy” as long as it “stimulates the immune system.” Even Dr. Lindhofer, when asked by the Court whether the “totally unknown” premise “excludes monospecific antibodies,” did not say it did. BTr. at 148:14-149:14 (Lindhofer) (failing to answer and offering instead an argument that rituximab had some immunosuppressive properties). The plain language, which includes monospecific antibodies, is consistent with the patent application as-filed under oath, which originally had claims that covered monospecific antibodies. Op. FoF ¶ 68; Lind. FoF ¶ 55. Lindis’s

reinterpreted meaning is not. The later amendment to limit claims to bispecific antibodies cannot change the plain language, correct the false statement or purge the misconduct. Op. FoF ¶ 58.

25. Lindis argues the Examiner “knew” the truth about the “totally unknown” premise, citing portions of the prosecution history of the ’421 Patent. Lind. FoF ¶¶ 55-57. But none of the discussed references disclose the fact that “premedication with gl[u]cocorticoids like dexamethasone was established successfully in clinics” with monospecific antibodies to minimize side effects, as disclosed in Huhn. Lind. FoF ¶¶ 55-59; Op. FoF ¶ 23. And, the Examiner did not “issue[] a 103 rejection based on this premise” (Lind. FoF ¶ 58), but on a combination of six references, none of which showed this “common practice” of premedication with glucocorticoids with monoclonal antibodies. JTX104 at 501-503. The Examiner was in the dark.

26. Lindis says that the Examiner could have known the truth from Rose. But Dr. Lindhofer included Rose in an information disclosure statement (“IDS”) filed only **after** the Notice of Allowance, buried among 20 other references. JTX104 at 439-442; Op. FoF ¶ 45. Dr. Lindhofer did not specifically point out Rose to the Examiner. In that IDS, the Examiner initialed references from the IDS that he considered. JTX104 at 8-9. The Examiner did not initial Rose. *Id.*

27. Dr. Lindhofer has offered a litany of excuses as to which he has been repeatedly impeached. Op. FoF ¶ 20. Those excuses cannot obfuscate his pattern of misrepresentations, omissions and false statements to the Patent Office and this Court. *Id.* ¶¶ 76-83. Alone, each are *but-for* and *per se* material and done with the specific intent to deceive. Together, this pattern of falsehoods and withholding is *per se* material and the only conclusion is an intent to deceive.

III. AMGEN’S PROPOSED CONCLUSIONS OF LAW

A. Amgen Has Proven *Per Se* and *But-For* Materiality on Multiple Grounds

1. The two false premises of invention are *per se* and *but-for* material.

1. The two false premises, submitted by signed oath, are both *per se* and *but-for*

material. It is undisputed that “[w]hen the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.” Op. CoL ¶ 4. It is also undisputed that “a misrepresentation in the specification amount[s] to an act of egregious conduct.” Op. FoF at ¶ 57 (Stoll); *Ring Plus Inc. v. Cingular Wireless Corp.*, 614 F.3d 1354, 1360-61 (Fed. Cir. 2010) (affirming that a misrepresentation in the specification was highly material, reiterating that “the law prohibits genuine misrepresentations of material fact”).

2. Lindis also does not dispute that the two premises are the “central [] idea” and “fundamental premise” of the invention and that misrepresentations as to what the invention is are *but-for* material. Op. CoL at ¶¶ 6-7; see *Purdue Pharma L.P. v. Endo Pharms Inc.*, 438 F.3d 1123, 1132-33 (Fed. Cir. 2006) (affirming materiality where applicant distinguished invention over prior art based on a “surprising discovery” and falsely suggested that supporting experimental data existed). Lindis does not dispute that the two premises of invention, as written, are false.

3. Lindis does not dispute that the EMA Assessment contradicts the “surprising finding.” The EMA found that dexamethasone “inhibited” tumor cell killing by Removab “at all tested concentrations.” Op. FoF ¶¶ 33, 36. Acting on these findings, the EMA recommended using only non-steroidal anti-inflammatories for patients. *Id.* ¶ 34.

4. The Trion Report concludes the opposite of the surprising finding, ten times over. Op. FoF ¶ 22. Lindis argues that reading the Trion Report’s plain words is “semantics.” But, Dr. Lindhofer attested to the accuracy of those conclusions as written. *Id.* Lindis also argues the “surprising finding” actually “works (even if there is some inhibition)” based on Dr. Stroehlein’s testimony and Blincyto’s efficacy. Lind. CoL ¶ 18. But Dr. Stroehlein’s testimony did not address glucocorticoid’s effect on Removab activity; it was about Removab’s efficacy alone. JTr. at 1362:22-1363:11 (Stroehlein) (no mention of glucocorticoids). And Blincyto’s efficacy says

nothing about Removab's vulnerability to glucocorticoid inhibition, as the Trion Report explains.

5. Lindis argued repeatedly during prosecution that the expected result of combining immunosuppressive glucocorticoids with an immunostimulating antibody would be impairment of the antibody's activity. Based on the "surprising finding," Dr. Lindhofer claimed the "invention" was the absence of that expected impairment. Op. FoF ¶¶ 40-50. The contrary conclusions of the EMA Assessment and Trion Report show the basis of invention was false.

6. The "totally unknown" premise is also false. Lindis admits that the use of glucocorticoids with monoclonal antibodies to stimulate the immune system to kill target cells was long known. Lind. CoL ¶ 48. Lindis suggests the "totally unknown" premise could be accurate if limited to bispecific immunostimulatory antibodies which stimulate T cells, claiming that it must be read "in context." Lind. FoF ¶¶ 22-23. But the plain language is otherwise and includes monospecific antibodies. *See, e.g.*, BTr. at 225:8-22 (Soiffer). Thus, as written, the "totally unknown" premise is false.

7. Lindis tries to reinterpret the false premises to contort what was said into true statements. Lindis narrows the "antibody therapy" of the "totally unknown statement" by limiting it to "bispecific" antibodies and argues that was what was meant. Lind. FoF ¶ 23. And Lindis reinterprets the surprising finding to be "a certain amount of killing which is inhibited" but "killing is fine" which, apart from being nonsensical, is not what Dr. Lindhofer said in the patent, the prosecution, or the jury trial. *Id.* ¶ 61; JTX001 at 3:38-40; JTr. at 274:19-276:4. Inherent in the duty of candor is that the applicant means what they say. And these misrepresentations were repeated throughout the patent prosecution as reasons for allowance.

8. If the two false premises were mistakes of "semantics," as Lindis argues, Dr. Lindhofer should have corrected them in the decade of patent prosecution. The MPEP provides a

mechanism to do so, which would require Dr. Lindhofer to reveal to the Examiner the truth about what he meant. Op. FoF ¶ 12; BTr. at 29:3-9; 39:3-40:8 (Stoll). But, Dr. Lindhofer never made any attempt to do so. He relied upon the false premises to obtain the patents. Op. FoF ¶¶ 48-49, 59-60.

2. The Examiner’s actual reliance on the false premises to allow the claims establishes that the premises are but-for material.

9. It is undisputed the Examiner relied upon the two false premises to allow the claims. Op. FoF ¶¶ 39-50; Lind. FoF ¶¶ 55-57; Rep. FoF ¶¶ 6-10. Thus, they are but-for material because “the PTO would not have allowed the claim[s] but for the . . . misrepresentation[s].” *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 519 (Fed. Cir. 2012).

10. Lindis cites portions of the prosecution history never addressed in earlier briefing or at trial to imply the “totally unknown” premise was “totally known” to the Examiner. Lind. FoF ¶¶ 54-57. The Examiner’s statements indicate that he was not aware the “totally unknown” premise was false. Rep. FoF ¶ 7; Lind. FoF ¶ 57. Dr. Lindhofer never came clean, and the Examiner allowed the ’421 Patent claims, based on the reliance on this false premise. Rep. FoF ¶ 10.

3. The withheld information is but-for material because the Patent Office would have rejected the claims had it been disclosed.

a. The EMA Assessment is material.

11. The EMA Assessment concludes exactly the opposite of the “surprising finding.” Op. CoL ¶ 23; Op. FoF ¶¶ 33, 38, 82. Had the Examiner known this, he would not have allowed the claims. *Id.* ¶¶ 61, 66. This is but-for materiality. *See Therasense*, 649 F.3d at 1290-91; *Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1360 (Fed. Cir. 2014) (affirming inequitable conduct, noting that “[b]ased on the Examiner’s reasons for allowance, the district court concluded that the Examiner adopted [the inventor]’s repeated misrepresentations verbatim and would not have allowed the claims had he been aware [of the truth regarding prior art].”).

12. Lindis argues—without reasoning or legal support—that the EMA Assessment “is

only relevant if it incorporated the Trion Report and its data.” Lind. CoL ¶ 30. If Lindis is arguing about an indicia of reliability, this is a report of the governing regulatory body. BTr. at 29:23-30:2 (Stoll); PTO Notice PTO-P-2021-0058, Fed. Reg. 87 45,764-65 (July 29, 2022) (discussing duty of candor, pointing out “conflicting statements” in submissions to the USPTO and FDA). Whether the EMA evaluated the Trion Report and/or other data, it concluded that Removab’s killing activity is inhibited by glucocorticoids, exactly the opposite of the “surprising finding.” Rep. FoF ¶ 3.²

13. Lindis’s sole remaining argument is that “the EMA Report does not include a request for premedication with glucocorticoids,” Lind. CoL at ¶ 73. This buttresses the fact that Dr. Lindhofer and Lindis’s predecessors had concluded that glucocorticoids impair cell killing, but argued the opposite to the Patent Office. Op. FoF ¶¶ 40-43. That the EMA identified the problem of how glucocorticoids inhibited Removab’s tumor killing, even though there was no request for premedication with glucocorticoids, highlights the seriousness of this finding. Rep. FoF ¶ 7.

b. The Trion Report is but-for material.

14. Lindis offers scattershot arguments that the Trion Report is not material. But it is undisputed the Trion Report concludes the opposite of the “surprising finding” at least 10 times. Lindis argues the Trion Report’s robust data “is pretty consistent” with one cherry-picked portion of the patent’s “quick and dirty” data. Lind. FoF ¶ 36. But the Trion Report, and the patent specification describing the data Lindis cites, reach the opposite conclusion. Rep. FoF ¶¶ 22-24.

15. Lindis cites the pre-*Therasense* decision in *Senju* to argue that the Trion Report’s conclusions contradicting the “surprising finding” are not material. In *Senju*, the defendant argued the plaintiff withheld studies relevant to two properties of the invention, but the court determined

² Lindis’s hearsay objection to testimony that the Trion Report was provided to the EMA is waived as untimely. Lind. FoF ¶¶ 42-49; *United States v. Carpenter*, 736 F.3d 619, 630 (1st Cir. 2013).

that one set of withheld data was unrelated to the patent properties, and the other set cumulative. *Senju Pharm. Co. v. Apotex Inc.*, 717 F. Supp. 2d 404, 431-32 (2010). Unlike *Senju*, Lindis does not dispute that the Trion Report's conclusions pertain to the "surprising finding." And the Trion Report is also not cumulative. *Infra* ¶ 31.

16. In a circular argument, Lindis says that because Examiner did not issue a Section 112 rejection, the Trion Report is not material to written description and enablement. Lind. CoL ¶ 19. But, the Examiner lacked the Trion Report's information to provide the basis of such a rejection. With the Trion Report, the Examiner would have rejected the claims. Op. FoF ¶¶ 62-67.

17. On enablement, Lindis says without citation that the Trion Report "shows the invention works at different dosage concentrations." Lind. CoL ¶ 43. Perhaps some work. But, this attorney argument cannot overcome the unchallenged expert testimony (and Report's conclusions) that showed it more often did not: the Report detailed that "glucocorticoid inhibition of Removab's tumor killing activity varied with the type of glucocorticoid, dexamethasone concentration, and Removab concentration." Op. FoF ¶¶ 66-67, 36. The broad issued claims encompass all concentrations, including those that do not "work" and are not enabled. Op. CoL ¶ 15.

18. Lindis misquotes the MPEP, arguing that there is no requirement that "the invention [must] work[] for a claim to be enabled." Lind. CoL ¶ 39. MPEP 2164.02(I) says only that "working examples" in the specification are not required. It does not say that an invention need not work; that is not the law. "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." *Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1349 (Fed. Cir. 2019). The Trion Report's differing results depending on different conditions indicates undue experimentation was needed to make a version of the invention that works, i.e., lack of enablement. Op. FoF ¶¶ 66-67.

c. Huhn is but-for material.

19. There can be no question that, citing Huhn, the Trion Report states that use of glucocorticoid premedication with immunostimulating antibodies was “common practice” and “established in the clinic.” Op. CoL ¶ 12. Lindis argues that the examiner “totally knew” about this withheld information showing the common use of glucocorticoid premedication with monospecific antibodies, like Rituxan. Lind. CoL ¶ 48 (citing Lind. FoF ¶¶ 55-58).

20. But, the prosecution history excerpts in Lindis’s FoF ¶¶ 55-58 confirm the Examiner did not know that use of monospecific immunostimulatory antibodies “premedicat[ed] with gl[u]cocorticoids like dexamethasone was established successfully in clinics” to reduce cytokine-related side effects. Op. FoF ¶ 23. The prosecution history shows the opposite. Rep. FoF ¶ 7; Lind. FoF ¶ 57. Had Huhn been disclosed, the Examiner would have found the claims obvious.

4. The pattern of misrepresentations, omissions, and false statements is *per se* material.

21. Dr. Lindhofer engaged in the long pattern of misrepresentations, omissions, and false statements, starting with the false premises submitted in the application under oath, his continued reliance on them during prosecution, and the withholding of the three references. *See* Op. FoF ¶¶ 14-50. Lindis does not dispute such pattern of conduct would be *per se* material. *See Therasense*, 649 F.3d at 1292 (“affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit,” are *per se* material); *Ohio Willow*, 735 F.3d at 1351 (patent owner’s multiple “misrepresentations...[found] tantamount to [] filing of an unmistakably false affidavit.”).

5. The jury neither assessed nor decided materiality.

22. Lindis does not dispute that materiality is assessed without the presumption of validity, and courts “apply the preponderance of the evidence standard.” Op. CoL ¶ 17 (citing *Therasense*, 649 F.3d at 1291-92; *Ohio Willow*, 735 F.3d at 1345; *Aventis.*, 675 F.3d at 1334. Lindis

also admits the “legal standard is different” between proving invalidity and materiality. Lind. CoL ¶ 45. Citing *Natera, Inc. v. ArcherDX, Inc.*, 690 F. Supp. 3d 437, 448 n.5 (D. Del. 2023), Lindis argues that “[t]he jury’s factual findings regarding this same evidence is entitled to deference by this Court.” *Id. Natera*, however, held that “the court must defer to the jury’s findings on any **overlapping factual issues.**” 690 F. Supp. 3d at 448 n.5. The jury did not decide materiality.

B. Amgen Has Proven Dr. Lindhofer’s Specific Intent to Deceive the PTO.

1. Dr. Lindhofer made conscious decisions to assert the false premises and withhold the Trion Report, EMA Assessment, and Huhn.

23. Lindis does not dispute Dr. Lindhofer knew about (1) the EMA Assessment—while he initially tried to deny it, he later admitted that he was closely involved in it; (2) the Trion Report, because he signed it, attesting to its accuracy; and (3) the immunostimulatory antibody Rituxan’s use with glucocorticoid premedication in patients to reduce cytokines, as published in Huhn. Op. FoF ¶¶ 20, 23, 38, 75; JTr. at 265:11-25, 267:2-8 (Lindhofer); Op. CoL ¶ 22. Lindis also does not dispute that Dr. Lindhofer knew of his duty of candor and his duty to disclose. *Id.* ¶ 21.

2. Lindis does not dispute that Dr. Lindhofer had motivation to deceive.

24. Dr. Lindhofer admitted the motivation for his actions—he wanted broad claims to cover the industry to finance his business. Op. CoL ¶ 24. He acted on the broad claims he sought—contacting, through Ms. Brea-Krueger, over 100 companies, offering a license. *Id.*

3. Dr. Lindhofer has no credible explanation for the misrepresentations, omissions, and false statements.

25. **The False Premises.** Dr. Lindhofer offered no excuse for misrepresentations included under oath in the specification and repeatedly argued to the Examiner, and there is none.

26. **The EMA Assessment.** Lindis has offered no excuse for Dr. Lindhofer withholding the EMA Assessment. Unquestionably, it was relevant, as an independent assessment contrary to the surprising finding by Europe’s governing regulatory body for pharmaceuticals. Lindis does not

even try to argue it was cumulative. And, Lindis cannot dispute Dr. Lindhofer's inability to provide any explanation for withholding the EMA Assessment when asked by the Court. Op. FoF ¶ 79.

27. The case law is clear that intent to deceive can be inferred when an applicant withholds inconsistent positions taken before regulatory agencies for drug approval. *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1353-54 (Fed. Cir. 2021). Under the case law, Dr. Lindhofer's "central role" as to both the EMA approval process and patent prosecution, his possession of the EMA Assessment, his knowledge of the effect of glucocorticoids on Removab, and his arguments as to the "criticality" of the surprising finding, support an inference of intent. *Id.* at 1354 (inference of intent in withholding FDA filing when inventor had "knowledge" of the product, had "central roles in FDA approval and patent prosecution," and had argued criticality of property at issue).

28. Citing no legal precedent, Lindis contends that submitting the EMA Assessment in the prosecution of an unrelated application does not support intent. Lind. CoL ¶ 74. To the contrary, Dr. Lindhofer's submission of the EMA Assessment in an application where he thought it would be "helpful" one month before he argued the "surprising finding" as a basis for patentability in this case—despite knowing the EMA Assessment concluded the opposite—proves knowledge and intentional withholding. Rep. FoF ¶ 12; see *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co.*, 837 F. Supp. 1444, 1468 (N.D. Ind. 1992), (withholding material prior art submitted in earlier application indicative of intent), *aff'd*, 1993 WL 443814, 11 F.3d 1072 (Table) (Fed Cir. Nov. 2, 1993).

29. **The Trion Report.** Lindis abandons its previous excuses, now arguing the Trion Report is cumulative. Dr. Lindhofer's excuse about "total elimination of activity" is not a mere "elaboration" on his previous testimony as Lindis argues. Lind. CoL ¶ 62. Rather, it is the fifth

excuse offered by Dr. Lindhofer, many of which have already been discredited. Op. FoF ¶ 76.

30. Lindis's reinterpretation of the Trion Report based on its attorney argument of what Dr. Lindhofer meant by inhibition cannot make it cumulative. Lind CoL ¶ 61. Lindis disparages as "semantics" Amgen's reliance on the plain words of the Trion Report and the specification. *Id.* ¶¶ 61-62. But Lindis cannot dispute that using those same words and concepts, the Trion Report and specification come to opposite conclusions. Lind. CoL ¶¶ 22, 61-62. Dr. Lindhofer had every opportunity at trial to try to explain his falsehoods and withholding of the Report, but he offered only contradictory excuses and was repeatedly impeached. Op. FoF ¶ 76.

31. The Trion Report is not cumulative. Op. FoF ¶ 18; CoL ¶ 32. Lindis clings to one figure in the Trion Report, Figure 12, and argues that it is "pretty consistent" with the specification. Rep. FoF ¶ 36. But Lindis ignores the vast remainder of the Trion Report, including its ten conclusions contradicting the "surprising finding" premise and related statements in the specification and prosecution. Op. FoF ¶¶ 21-22. It ignores that the Trion Report presented unique data not in the patent: different testing and the effect of different glucocorticoids on antibody killing activity at different concentrations that would be used in patients. *Id.* ¶¶ 22-23. *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1240 n.16 (Fed. Cir. 2008) (withheld reference not cumulative when it "'refutes, or is inconsistent with' a position the applicant has taken in opposing an argument of unpatentability," and no other disclosed reference does so). Further, the Trion Report acknowledged that the use in Huhn was central to the idea of using glucocorticoids with Removab, contradicting the "totally unknown" premise. *Id.* ¶¶ 23-24. *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (withheld prior art "could not possibly be cumulative with respect to a feature not found in any disclosed prior art.").

32. Dr. Lindhofer's "cumulative" rationalization is unsupported by contemporaneous

evidence and inconsistent with the specification's plain language, prosecution history arguments, and his own testimony, which suggests he came up with this after hearing Mr. Stoll testify. BTr. at 137:11-18 (Lindhofer). *Aventis* rejected such post hoc rationalization. 675 F.3d at 1336.

33. In another excuse first raised post-trial, improperly relying on deposition testimony, Lindis argues Dr. Lindhofer did not “order” the Trion Report. Lind. FoF at 36. Dr. Lindhofer's jury trial testimony is that the Trion Report was conducted to confirm the “quick and dirty” testing that was reported in the patent. Rep. FoF ¶¶ 12, 17. Lindis cannot change that through briefing now.

34. **Huhn.** In yet another newly minted excuse, Lindis argues there can be no intent because “Rose discloses the exact contents of Huhn.” Lind. CoL ¶ 75. It does not. Lind. FoF ¶ 67; BTr. at 239:1-240:10 (Soiffer) (Rose does not “teach everything that Huhn does . . .” “Huhn discloses the use clinically of corticosteroids, [] -- to reduce . . . cytokine-related side effects, whereas Rose does not address that at all”).

35. Moreover, burying Rose in an IDS along with 20 other references, submitted only after the notice of allowance, is evidence of intent. Lindis cites to *Molins* to incorrectly claim that “burying” a relevant reference in an IDS is not inequitable conduct. Lind. CoL ¶ 51. *Molins* held the opposite: “burying a particularly material reference in a prior art statement containing a multiplicity of other references *can be probative of bad faith.*” *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) (emphasis added). There, inequitable conduct was reversed only because the examiner initialed each reference, indicating he considered each. *Id.* Here, the Examiner did not initial Rose, although he initialed other references. Rep. FoF ¶ 25.

36. The Federal Circuit has consistently held that burying a reference to reduce the likelihood of examiner consideration indicates inequitable conduct. *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 480 F.3d 1129, 1137 (Fed. Cir. 2007) (submitting a “blizzard of paper,” alongside a

declaration minimizing the significance of the relevant art, was improper); *Golden Valley*, 837 F. Supp. at 1477, *aff'd*, 1993 U.S. App. LEXIS 28844 (“violation of the duty of candor” to “bury” pertinent art including within “disclosures of less relevant prior art references.”).

4. Lindis’s argument that Dr. Lindhofer made a mistake is another post hoc rationalization in its ever-changing narrative in this case.

37. Lindis argues that “[a]t best, Amgen demonstrated Dr. Lindhofer made a mistake or was negligent.” Lind. CoL ¶¶ 76-78. Lindis just says so; there is no evidence of mistake or negligence. Allowing applicants to obtain patents by passing off false statements and withheld information as mere “mistakes” would undermine the patent system. *See KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576 (Fed. Cir. 1985) (“There is no reprieve from the duty of square dealing and full disclosure . . . in dealings with the PTO.”); BTr. at 29:10-30:2 (Stoll) (Patent Office relies on applicants’ candor, because they have information the Examiner needs to properly assess the application, which may be unavailable to the Examiner).

5. The single most reasonable inference is intent to deceive.

38. It is undisputed that “[a]n inference of intent to deceive is appropriate where the applicant engages in ‘a pattern of lack of candor,’ including where the applicant repeatedly makes factual representations ‘contrary to the true information he had in his possession.’” *Regeneron*, 864 F.3d 1343, 1351 (Fed. Cir. 2017). Dr. Lindhofer relied upon falsehoods and omissions from the initial patent application filings, through prosecution, and through the jury trial. Op. CoL at ¶¶ 42-43. Intent to deceive is “the single most reasonable inference.” *Therasense*, 649 F.3d at 1290.

IV. CONCLUSION

39. Amgen has demonstrated by clear and convincing evidence that Dr. Lindhofer committed inequitable conduct in the prosecution of the Asserted Patents.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Melanie K. Sharp

PERKINS COIE LLP
Michael J. Wise
Joseph P. Hamilton
Lara J. Dueppen
Courtney M. Prochnow
1888 Century Park East
Suite 1700
Los Angeles, CA 90067-1721
(310) 788-9900

Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Stephanie N. Vangellow (No. 7277)
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
svangellow@ycst.com

Attorneys for Amgen Inc.

AMGEN INC.
Brian Kao
J. Drew Diamond
Blake Greene
Wendy A. Whiteford
Carolyn S. Wall
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
(805) 447-1000

O'MELVENY & MYERS LLP
Lisa B. Pensabene
Hassen Sayeed
Jing Ying (Amy) Zhao
1301 Avenue of the Americas
Suite 1700
New York, NY 10019
(212) 326-2000

Luann L. Simmons
Sorin G. Zaharia
Two Embarcadero Center
28th Floor
San Francisco, CA 94111
(415) 984-8700

AUTZ IP LLC
Lindsay H. Autz
115 Lampwick Lane
Fairfield, CT 06824
(203) 526-1307

Dated: April 16, 2025