Appeal No. 2021-1070

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff-Appellee,

v.

ACCORD HEALTHCARE INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., EMCURE PHARMACEUTICALS, HERITAGE PHARMACEUTICALS INC., GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS LIMITED, HETERO USA INC., HETERO LABS LIMITED UNIT-V, HETERO LABS LIMITED, MYLAN PHARMACEUTICALS, INC., PRINSTON PHARMACEUTICAL INC., STRIDES GLOBAL PHARMA PRIVATE LIMITED, STRIDES PHARMA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., ZYDUS PHARMACEUTICALS (USA) INC., CADILA HEALTHCARE LIMITED, APOTEX INC., APOTEX CORP., SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICAL INDUSTRIES INC., SUN PHARMA GLOBAL FZE,

Defendants,

HEC PHARM CO., LTD., HEC PHARM USA INC.,

Defendants-Appellants.

Appeal from the United States District Court for the District of Delaware
No. 1:18-cv-01043-KAJ, Honorable Kent A. Jordan, Circuit Judge

APPELLEE'S RESPONSE TO PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number:	2021-1070
Short Case Caption:	Novartis Pharmaceuticals v. Accord Healthcare Inc.
Filing Party/Entity:	Novartis Pharmaceuticals Corporation

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. Please enter only one item per box; attach additional pages as needed and check the relevant box. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: **3/4/2022** **Signature:** ***/s/ Jane M. Love, Ph.D.***
Name: **Jane M. Love, Ph.D.**

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☐ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Novartis Pharmaceuticals Corporation	Novartis AG	Novartis AG

☐ Additional pages attached

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

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5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☐ None/Not Applicable ☐ Additional pages attached

Novartis Pharmaceuticals Corp. v. Handa Neuroscience, LLC et al., Case No. 1:21-cv-00645 (D. Del.)	*Novartis Pharmaceuticals Corp. v. Handa Neuroscience, LLC et al.*, Case No. 5:21-cv-03397 (N.D. Cal.)	

6. **Organizational Victims and Bankruptcy Cases**. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

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INTRODUCTION

HEC challenges this Court's deferential review of the district court's finding of fact that a skilled person would read the specification of the patent-in-suit to support a particular claim limitation. Applying settled law on the written description requirement, the panel agreed that silence in the specification alone would not support a "negative" limitation. Op.17. The panel decision is based not on silence, but on the district court's finding—after a full trial on the issue—that a person of skill would read this specification as *not* silent. That finding was fully supported by the record, and certainly not clearly erroneous.

Nothing here departs from existing law or otherwise breaks new ground. The panel decision is limited to the particular patent and facts in this case and presents no "precedent-setting question[] of exceptional importance." Fed. Cir. R. 35(b)(2). Negative claim limitations do not involve a novel legal or factual issue. The panel recognized that there is no "heightened standard for negative claim limitations" (Op.13 (quoting *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1356 (Fed. Cir. 2015))), and that "[t]he mere absence of a positive recitation," alone, is insufficient to support a negative limitation (Op.17 (quoting MPEP § 2173.05(i))).

As in all written description disputes, what matters here is the perspective of "those skilled in the art." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). As the district court found—and the panel

affirmed—a person of skill would read this specification to describe the claimed administration of a drug without a loading dose. Indeed, the testimony on that issue was unrebutted at trial—HEC's expert declined to testify about the specification's key passage supporting the claims. Appx23117 (539:11–21).

The petition suggests merely that the panel improperly applied the established law in reviewing the district court's findings of fact. But under the clear-error standard, "a district court judge who has presided over, and listened to, the entire proceeding has a comparatively greater opportunity to gain the necessary familiarity . . . than an appeals court judge who must read a written transcript or perhaps just those portions referenced by the parties." Op.23 (quoting *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 327 (2015)). The panel properly applied that standard here in refusing to substitute its own judgment for the district court's factual findings.

To be sure, this was a 2–1 decision. But the division between the majority and dissent concerns, at bottom, whether the district court properly credited the trial evidence, including unrebutted expert testimony about how a person of skill would read this particular specification. That does not warrant rehearing, much less en banc review.

BACKGROUND

U.S. Patent 9,187,405 claims methods for treating relapsing-remitting multiple sclerosis (RRMS) with the drug fingolimod "at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen." Appx24741–24742. The specification describes an animal experiment showing that a dose roughly 60% lower than ever before thought possible could treat RRMS. This translated to the claimed 0.5 mg dose, as described in a human example. That section describes the use of "a daily dosage of 0.5 . . . mg" of fingolimod as a "treatment" for patients with RRMS, received "[i]nitially" for a period and continuing thereafter if tolerated and the disease does not progress. Appx24741. Novartis's Gilenya® RRMS medicine uses the 0.5 mg daily dose of fingolimod described and claimed in the 405 Patent.

In 2017, the Patent was challenged in an IPR. The Patent Office rejected all challenges, including an anticipation ground relying on an underlying theory of inadequate written description support for the absence of a loading dose. That decision was appealed, but all challengers either settled or were found by this Court to lack standing to appeal. *See Argentum Pharm. LLC v. Novartis Pharm. Corp.*, 956 F.3d 1374 (Fed. Cir. 2020). Simultaneously, Novartis asserted the Patent in Delaware District Court against more than 20 companies that had filed ANDAs for Gilenya. The district court (Chief Judge Stark) granted a preliminary injunction after

an in-person evidentiary hearing, finding that "defendants are not at all likely to prevail at trial" on their written description and anticipation challenges. Appx18858–18862.

After the preliminary injunction ruling and before trial, all defendants except HEC settled. Then, after a four-day bench trial, the district court rejected appellant HEC's written description argument. As relevant here, the district court found that a person of skill would read the specification to exclude an immediately preceding loading dose. Appx37. In addition, the court rejected HEC's anticipation challenge based on Kappos 2006, an abstract announcing an upcoming Phase III RRMS trial of 1.25 and 0.5 mg daily fingolimod. Appx38–42. HEC appealed solely on written description grounds, abandoning its anticipation challenge.

This Court affirmed the district court's decision. The panel majority (Judge O'Malley, joined by Judge Linn) held that "on this record, the district court did not clearly err in finding that a skilled artisan would read the 405 Patent's disclosure to describe the 'absent an immediately preceding loading dose' negative limitation." Op.24. The majority agreed that a negative limitation must be adequately described in the specification. Op.13–18. And it agreed that "silence alone is insufficient" and that "the mere absence of a positive recitation" is not enough. Op.17–18 (emphases omitted).

As the majority recognized, this Court has "repeatedly" rejected attempts like

HEC's to impose "heightened written description standards for negative limitations." Op.13–16. HEC's argument, the majority noted, "ignores a central tenet of our written description jurisprudence—that the disclosure must be read from the perspective of a person of skill in the art—as well as precedent stating that the disclosure need not describe a limitation *in haec verba*." Op.16–17 (citing cases). Ultimately, the majority held that "the district court correctly, and quite carefully, conducted 'an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art'" and that it "discern[ed] no clear error in the court's analysis or conclusions." Op.18–19.

The panel majority also agreed with the district court that rejecting HEC's written description challenge was consistent with rejecting HEC's anticipation challenge based on prior art reference Kappos 2006, a challenge HEC abandoned on appeal. Although HEC argued that Kappos 2006 and the 405 patent's disclosure were indistinguishable, "HEC's argument ignores the differences between the two district court findings and ignores the differences between the disclosures of Kappos 2006 and the '405 specification." Op.21.

Chief Judge Moore dissented, agreeing (at 3) that there is no heightened standard for negative limitations, but reading the specification (at 10) to be "entirely silent and ambivalent about loading doses."

ARGUMENT

The panel majority correctly applied deferential review to decide a narrow case- and patent-specific question of fact, concluding that the district court did not clearly err in finding written description support for the "absent an immediately preceding loading dose" limitation of the 405 Patent claims. Because the panel correctly applied well-settled law to the specific facts of this case, and its decision has little if any significance beyond the parties to this dispute, rehearing by the panel and the full court should be denied.

I. The Panel Applied Well-Settled Law and Broke No New Ground

HEC fails at the outset to identify a legal question of broad significance. The first question proposed in the petition is: "Does silence in the specification satisfy the written description requirement under 35 U.S.C. §112 for a negative claim limitation?" Pet. x. The panel answered that question with a resounding "no." It stated explicitly that its opinion did "not establish a new legal standard that silence is disclosure." Op.24. Instead, the panel correctly explained that "[w]hether a claim satisfies the written description requirement is a question of fact," not a question of law. Op.8. And the panel simply held that the district court did not clearly err in finding that the specification was not silent, but described the claimed limitation to a person of skill. Op.24.

Accordingly, this case is unsuited to rehearing because the panel *expressly agreed* with HEC and the dissent that "the '*mere absence* of a positive recitation' is not enough and 'silence *alone* is insufficient.'" Op.17. Following this Court's clear precedent that there is no "new and heightened standard for negative claim limitations" (*Inphi*, 805 F.3d at 1356; *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1348 (Fed. Cir. 2016)), the panel majority applied "the customary standard for the written description requirement" (Op.16). And under that standard, the panel concluded, the district court "did not clearly err in finding that a skilled artisan would read the 405 Patent's disclosure to describe the 'absent an immediately preceding loading dose' negative limitation." Op.24.

HEC does not and cannot disagree with any of the doctrinal bases for the majority decision. HEC now agrees that "negative claim limitations may be disclosed in many ways" (Pet. 10–11)—backing away from its argument to the panel that "the specification *must* 'describe[] a reason to exclude the relevant limitation'" (Open. Br. 41 (alteration in original; emphasis added)). Although it says that "[i]deally the specification should 'describe[] a reason to exclude the relevant limitation'" (Pet. 11 (quoting *Inphi*, 805 F.3d at 1355) (second alternation in original)), the word "ideally" does not appear in *Inphi* or any of this Court's precedent. And the MPEP provision on which HEC relies itself "provides for implicit written description." Op.18; *see*, *e.g.*, MPEP § 2163 ("newly added claims

or claim limitations must be supported in the specification through express, *implicit*, or inherent disclosure" (emphasis added)).

Applying this settled law, the district court's written description finding was not based on "silence" but on affirmative disclosures in the 405 Patent. Novartis's experts explained at trial how these disclosures conveyed the absence of a loading dose to a person of skill in the art. Appx26–27 ¶¶ 61–66; Appx22791–22793 (213:23–215:4); Appx23334–23335 (756:16–757:8); Appx23343–23344 (765:5–766:2); Appx23441–23442 (863:22–864:18). And that testimony was unrebutted: HEC did not submit *any* evidence regarding how a person of skill would read the pertinent human example, and neither HEC nor the dissent cites any such witness testimony. In other words, the district court did not establish any new legal standard; it simply found, based on the trial record in this case and unrebutted expert testimony about a person of skill's reading of this particular patent specification, that the specification disclosed the claimed limitation. *See Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1131 (Fed. Cir. 2018).

The panel explained that the key question under this Court's cases is "how a person of skill in the art would read the disclosure—not the exact words used." Op.18. And there is simply no requirement that a limitation be disclosed *in haec verba*. Op.17; *see also All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002) ("[T]he failure of the specification to specifically

mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented."). Moreover, "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002). The majority concluded—correctly—that the district court did not clearly err in finding written disclosure here, on the basis of a full trial record.

HEC's argument boils down to a request to create a "new rule that a limitation which is not expressly recited in the disclosure is never adequately described, regardless of how a skilled artisan would read that disclosure." Op.18. The panel correctly recognized that accepting HEC's argument would be *inconsistent* with this Court's precedent. Op.13, 18–19, 21. HEC does not ask for further review to overrule any of that precedent, and thus the petition itself concedes that the panel decision (and the district court's judgment) contain no legal error.

II. The Panel's Application of Clear-Error Review to Case-Specific Facts Warrants No Rehearing

HEC ultimately concedes that its dispute with the panel is factual, not legal: It seeks to relitigate the district court's factual findings and the majority's conclusion that those findings are not clearly erroneous. Pet. 14–17. But HEC cannot point to any points of law or fact that the panel "overlooked or misapprehended." Fed. R.

App. P. 40(a)(2). And mere disagreement over the panel's resolution of an inherently fact-specific question does not provide any basis for rehearing.

The majority discussed the district court's findings in detail, and concluded that "the district court correctly, and quite carefully, conducted 'an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.'" Op.18–19 (quoting *Ariad*, 598 F.3d at 1351). For example, the district court found that the human example's "descri[ption of] giving a 'daily dosage of 0.5 . . . mg' fingolimod to treat RRMS, started 'initially' . . . tells a person of ordinary skill that on day 1, treatment begins with a daily dose of 0.5 mg, not a loading dose." Appx00026 ¶ 62. It found that a loading dose is a "higher-than-daily dose," and that on this record, "starting with a daily dose plainly implies that there is no loading dose." Appx00027 ¶ 63. Moreover, "[t]here was no recitation of a loading dose in the specification" (Appx00026 ¶ 61), "[t]he EAE example discloses a dosing regimen which does not involve a loading dose" (Appx00027 ¶ 64), and "[t]he Patent describes alternative dosing regimens, like 'intermittent dosing,' but does not describe loading doses" (Appx00027 ¶ 65).

After discussing the extensive evidence in the trial record, the majority stated that it was "not left with the 'definite and firm convention' that the district court made a mistake in coming to [its] conclusion. . . . To the contrary, the district court's conclusion appears wholly correct." Op.21. That is the essence of clear-error review.

And accordingly the second question presented by HEC's petition (Pet. xi) fails to present any issue, on this record, warranting further consideration by this Court.

A. The District Court Did Not Misquote the Specification

The linchpin of HEC's factual argument is the notion that the district court misquoted the specification in finding that the "Prophetic Trial describes giving a 'daily dosage of 0.5 . . . mg' fingolimod to treat RRMS, started 'initially' concluding that 'starting with a daily dose plainly implies that there is no loading dose." Pet. 15 (quoting Op.23; Appx00026 ¶ 62). This argument is new, and wrong.

In its opening panel brief HEC did not even mention the district court's finding at paragraph 62. *See* Resp. Br. 44 n.13 (explaining HEC's forfeiture). And in reply, HEC argued only that the testimony the district court cited for that finding supported HEC's argument—not that it misquoted the specification. *See* Reply Br. 4–5. The panel could not have overlooked or misapprehended a record-specific argument that HEC failed to present.

In any event, the district court misquoted nothing. The specification says that "20 patients with [RRMS] receive said compound at a daily dose of 0.5, 1.25, or 2.5 mg p.o." and that "[i]nitially patients receive treatment for 2 to 6 months." Appx24741 (11:8–14). Like the dissent, HEC "would find that the 'word "initially" is not modifying the daily dosage; it is modifying the initial length of treatment in this example.'" Op.23 (quoting Dissent 6–7). But as the panel explained, "if the 2–

6 month 'initial' dose does not differ in any way from the previously described daily doses, the language, used in context, must exclude a loading dose." *Id.*

The district court did not clearly err in crediting expert testimony that a person of skill would read the specification in precisely that way. The district court considered evidence that the language conveys that patients are "taking the dosing that's outlined in that first sentence continually for two to six months," which does not "involve a loading dose." Appx22791–22793. Thus, the word "initially" in context "tells a person of skill that on day 1, treatment begins with a daily dose of 0.5 mg, not a loading dose. If a loading dose were directed, the Patent would say that a loading dose should be administered 'initially.'" Appx00026 ¶ 62 (citation omitted). The district court was permitted to credit the expert testimony "to inform what is actually in the specification" and how a person of skill would understand its language. *Rivera v. ITC*, 857 F.3d 1315, 1322 (Fed. Cir. 2017).

Additionally, the district court found that HEC's physician witness was *not* qualified to testify about human trial design—a finding that HEC did not challenge on appeal. Appx23105–23106 (527:5–528:11); Appx23108–23110 (530:23–532:2). The witness accordingly refused to testify about the Patent's human example in which this disclosure is found. Appx23117 (539:11–21). With that failure of proof, HEC was (and is) left only with attorney argument about how to read the

specification. *See* Pet. 5, 15. The district court did not clearly err in crediting the unrebutted testimony of Novartis's experts, rather than HEC's counsel.

And even if the reading advanced by HEC were permissible, that would not mean that the district court clearly erred—much less justify rehearing. "'Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.'" *Nalpropion Pharms., Inc. v. Actavis Labs. FL, Inc.*, 934 F.3d 1344, 1348 (Fed. Cir. 2019). "Clear error review 'does not entitle this court to reverse the district court's finding simply because it would have decided the case differently.'" *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 967 (Fed. Cir. 2006). Rather, the Court "must uphold the trial court's determination if it is 'plausible in light of the entire record or where it chooses one of two permissible views of the evidence.'" *Id.* (quoting *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 874 (Fed. Cir. 1993)).

As this case illustrates, "clear error review is 'particularly' important where patent law is at issue"; this is "'a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience.'" *Teva*, 574 U.S. at 327; *see also* Op.23. There is thus ample reason to defer to the district court's evaluation of expert testimony presented at trial, and not to substitute this Court's judgment for that of the district court.

B. The District Court Did Not Clearly Err with Respect to Kappos 2006

HEC also includes a one-paragraph argument that the district court clearly erred in finding that a person of skill would read the 405 Patent to exclude a loading dose but would not necessarily read a prior art abstract (Kappos 2006) to do so. Pet. 17. But HEC did not appeal the district court's finding of no anticipation based upon that abstract. To the extent this argument is even appropriate for consideration, HEC once again ignores the trial testimony and seeks to transform mere disagreement with the district court's factual findings into a legal dispute.

The panel explained that the district court credited expert testimony "that a person of skill in the art would not presume that the Kappos 2006 abstract was complete." Op.22. And it pointed to differences between the 405 Patent and Kappos 2006, including that the latter "nowhere says that the daily fingolimod [0.5 mg] dosage should be 'initially' administered." *Id.* Thus, "it was not clear error for the district court to find that a skilled artisan would read the specification as not including a loading dose and would read Kappos 2006 as silent on the presence or absence of a loading dose." *Id.*

HEC does not attempt to explain why these findings are clearly erroneous or even to cite contrary record evidence. Instead, HEC simply asserts that the panel "imports a new standard under which a POSA evaluates prior art references (particularly journal abstracts) differently than a patent." Pet. 17. The panel did no

such thing. It merely held that the district court did not clearly err in finding that a person of skill would interpret *this* prior art reference differently than *this* patent. In so doing, the panel did not "upend[] settled precedent" (*id.*), but properly refused to substitute its judgment for the findings of the district court.

III. HEC's Rehearing Petition Does Not Present Any Question of Exceptional Importance

HEC falls far short of establishing that the panel's actual opinion presents any question of exceptional importance justifying rehearing en banc. As to its first question (Pet. x), HEC asserts that the panel's opinion establishes "a separate disclosure requirement (i.e., no disclosure whatsoever) for negative claim limitations." Pet. 12–13. That hyperbole bears no resemblance to the panel's decision. The panel made clear that a negative limitation *must* be described in the specification. The unrebutted expert testimony presented at trial confirmed that a person skill would read *this* specification to disclose an invention excluding a loading dose. HEC could have attempted to present expert testimony rebutting that evidence, but failed to do so. As a factual matter, therefore, this is not a "no disclosure whatsoever" case, and the panel's opinion will not open the floodgates to undescribed negative claim limitations.

Recognizing this, HEC makes an even more transparent attempt to recast a factual dispute as a legal one. It contends the question is whether the court is bound to sustain particular factual findings "where those district court findings are based

solely on expert testimony that are contradicted by the intrinsic evidence and plain language of the specification." Pet. xi. That question is not presented here as a factual matter, because there is no contradiction between the expert testimony and the intrinsic record. Rather, the district court's findings are amply supported by the totality of the evidence presented at trial. Indeed, this case went to trial precisely so that the district court could make the factual finding whether the challenged limitation is supported by the specification.

HEC's petition asks for rehearing en banc solely to reconsider the application of clear-error review to factual findings, after a trial on the merits, about how a person of skill in the art would understand the disclosures of a particular patent where there is no contrary expert testimony. En banc review is not warranted.

CONCLUSION

The petition for rehearing should be denied.

Dated: March 4, 2022

Respectfully submitted,

By: */s/ Jane M. Love*
Jane M. Love, Ph.D.

Counsel for Appellee Novartis Pharmaceuticals Corporation

CERTIFICATE OF SERVICE

I, Jane M. Love, Ph.D., hereby certify that I caused the foregoing to be filed via the Court's CM/ECF system and served on counsel of record by electronic mail on March 4, 2022.

/s/ Jane M. Love
Jane M. Love, Ph.D.

CERTIFICATE OF COMPLIANCE

I, Jane M. Love, Ph.D., hereby certify that the foregoing response complies with the type-volume limitation of Federal Circuit Rule 35(e)(2) because it contains 3,761 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2). I further certify that the response complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a) because it was prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, 14-point.

/s/ Jane M. Love
Jane M. Love, Ph.D.