No. 20-1758

IN THE
United States Court of Appeals for the Federal Circuit

JUNO THERAPEUTICS, INC., SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,
Plaintiffs-Appellees,
v.
KITE PHARMA, INC.,
Defendant-Appellant.

On Appeal from the United States District Court
for the Central District of California
No. 2:17-cv-07639-PSG-KS
Hon. Philip S. Gutierrez

RESPONSE OF APPELLANT KITE PHARMA, INC. TO APPELLEES' COMBINED PETITION FOR REHEARING AND REHEARING EN BANC

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number	20-1758
Short Case Caption	Juno Therapeutics, Inc. v. Kite Pharma, Inc.
Filing Party/Entity	Kite Pharma, Inc.

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Date: **12/29/2021**

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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
Kite Pharma, Inc.		Gilead Sciences, Inc.

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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).

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INTRODUCTION

Eleven years ago, the en banc Court found the separate written-description requirement so clear and well established that it directed disgruntled patentees to Congress to air future grievances: "If the law of written description is to be changed … such a decision would require good reason and would rest with Congress." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010). Instead of making a change, Congress ratified *Ariad* when it revisited § 112 in the America Invents Act without altering the written-description requirement. Nonetheless, Juno returns to the en banc Court and asks it to reconsider *Ariad*.

Yet, Juno offers no new reasons to drastically change the status quo. Without so much as acknowledging stare decisis or Congress's ratification of *Ariad*, Juno rehashes the same arguments about text, precedent, and policy that the en banc Court thoroughly considered and rejected. And Juno's concerns about protection for biologic discoveries are unfounded. The written-description requirement promotes biologic innovation by preventing patentees from impeding research by claiming vast exclusionary rights based on limited discovery in this

unpredictable field. This Court's post-*Ariad* cases confirm that inventors can secure valid functional genus claims in the pharmaceutical space. What they may not do is stifle innovation by foreclosing research into a broad and varied functionally defined genus merely by discovering a few non-representative species, as the inventors did here.

Beyond this settled question, Juno also raises a case-specific question about whether the panel overlooked evidence—hardly fodder for en banc review. And in any event, the panel did consider Juno's evidence and properly found it legally irrelevant. The Court should deny Juno's petition.

BACKGROUND

Even now, chimeric antigen receptor T-cell ("CAR-T") therapy is a groundbreaking form of immunotherapy. It was even more so two decades ago, at the '190 patent's 2002 priority date, which a named inventor called "the birth of the CAR-T field." Op. 3 (citing Appx32976). It took 15 more years for CAR-T research to advance sufficiently to secure FDA-approval for the first treatment. Appx33161. And even at

the time of trial, in 2019, Kite's YESCARTA® was one of only two approved therapies. *See* Kite Br. 16-17.

CAR-T therapy reprograms a patient's own T-cells to fight disease. The therapy entails harvesting the patient's T-cells, sending them to a company like Kite, which inserts new genetic material into the cells and makes more of them, and then re-infusing them into the patient. The new genes instruct the cell to grow a new receptor—a chimeric antigen receptor, or "CAR." The receptor identifies and binds to a specific spot—called an "antigen"—on the surface of an enemy cell, such as a cancer cell. Once bound, the CAR yields an immune response that both attacks the enemy cell and produces more T-cells to join the battle. Op. 2-3; Appx32908-32914.

Each claim of Juno's '190 patent recites "[a] nucleic acid polymer encoding a chimeric T cell receptor"—that is, a chain of genetic material with instructions for manufacturing the CAR. Op. 4; Appx282 25:29-38; Appx32913-32914. The genetic material encodes a CAR with three parts: (1) "a zeta chain portion comprising the intracellular domain of human CD3 ζ"—a known T-cell activating protein; (2) a specified "costimulatory signaling region"—also from a known protein—which

causes the T-cell to multiply; and (3) "a binding element that specifically interacts with a selected target." Appx282 25:29-38.

The panel's decision, and Juno's petition, focuses on this third component: the critical "binding element" that allows the CAR to attach to a particular antigen and thus become activated. In the asserted claims, the "binding element" is a "single chain antibody," also known as an "scFv." An scFv is made from the highly unpredictable "variable" portions of an antibody (specifically, linking together portions of the variable regions of the heavy and light chains). Op. 3-4; Kite Br. 7-8; Appx2643-2644; Appx33674-33676. Illustrating the claims' overbreadth, two of the asserted claims encompass CARs with any scFv binding to *any* antigen, including antigens not yet identified. Op. 8-9; Appx282 25:41-42, 26:35-36. The other two encompass any scFv binding to CD19, an antigen prevalent on the surface of certain cancer cells. Op. 4; Appx282 25:45-46, 26:40-41.

One of the many challenges of CAR-T therapy is finding the right scFv *and* getting it to work in a CAR. Even for one specific target antigen (including CD19), it is undisputed that there can be "millions of billions" of different scFvs that are potential candidates for inclusion in

a CAR. Appx33687-33688. The precise amino acid sequence used to make each part of the scFv will determine its unique three-dimensional shape and its ability to interact with other molecules—which dictate its binding ability. Appx33675-33676; Appx2643. Even today, there is no way to predict whether an scFv will have the necessary binding capability. Appx35643; *see* Appx33687-33688.

Notwithstanding the breadth of its claims, the '190 patent offers virtually no guidance on which scFvs will work in the claimed CARs. The specification uses codenames for two scFvs, neither of which Kite used. One binds to CD19, and the other binds to a different antigen. It provides no information about their structure, much less their specific amino acid sequences. Op. 9; Appx32967. It says nothing about why these scFvs bind to those antigens. And it offers no information on how a person of ordinary skill could recognize which scFvs would perform that critical binding function in the claimed CAR. Op. 9. The specification mentions a methodology—known as the "Orlandi method"—for how to *produce* scFvs from already-existing mouse antibodies. Appx271 4:57-63; Appx36185. But Orlandi does not teach

how to predict which scFvs will bind to a given target such as CD19, much less in a CAR.

Constructing the right CAR is but the first step in developing a CAR-T therapy. To produce its successful YESCARTA® therapy, Kite had to overcome numerous clinical, logistical, and manufacturing challenges. *See* Kite Br. 9-10. YESCARTA® has dramatically improved outcomes for patients suffering from lymphoma.

Juno tried and failed to do the same. Juno abandoned a product that practiced the '190 patent after the FDA twice halted clinical trials due to patient deaths. *See* Appx33143, Appx33152-33155. Juno's current CAR-T therapy—not even approved until 2021—does not practice the '190 patent. Appx33104; Appx33137-33139; Appx33141-33142. The only use Juno ever got out of the '190 patent was to sue Kite. A jury that was not instructed on this Court's *Ariad* test found the patent valid and infringed, Appx139; Appx34035-34036, yielding a judgment of $1.2 billion.

A unanimous panel of this Court followed numerous precedents properly applying *Ariad* to hold the asserted claims invalid for lack of written description.

REASONS FOR DENYING THE PETITION

I. The Petition Presents No Sound Reason For Reconsidering The Long-Settled Written-Description Requirement.

A. Juno ignores the high bar of stare decisis.

This Court should reject the petition out of hand based on a foundational defect: Juno fails to discuss stare decisis and the extraordinarily high bar it must meet to justify reconsidering a recent en banc ruling issued by a 9-2 majority. That omission is particularly disqualifying because stare decisis has special force here along four dimensions.

First, stare decisis is especially "weighty" when directed at an en banc decision. *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305, 1316 (Fed. Cir. 2013).

Second, the doctrine is at its "acme" for a precedent, like *Ariad*, involving "property and contract rights." *Payne v. Tennessee*, 501 U.S. 808, 828 (1991). The Supreme Court has admonished that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). Juno fails to acknowledge the countless investments and decisions that businesses

have made in reliance on a written-description rule that has been in place for decades, even before *Ariad*.

Third, "*stare decisis* has special force" for questions of statutory interpretation since "Congress remains free to alter what [courts] have done." *Watson v. United States*, 552 U.S. 74, 82 (2007) (internal quotation marks omitted).

Fourth, in *Ariad* itself, this Court concluded that "*stare decisis* impel[led]" it to uphold the written-description requirement, and that any future change must come from Congress. *Ariad*, 598 F.3d at 1347.

Congress has declined the invitation. Shortly after *Ariad*, Congress revamped the Patent Act. Congress materially amended § 112 with regard to the "best mode" requirement, which appears in the same sentence as the written-description requirement. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 15, 125 Stat. 284, 328 (2011). But Congress did not touch the written-description requirement or otherwise suggest discomfort with *Ariad*.

B. This Court rejected all of Juno's arguments in *Ariad*.

Instead of offering a compelling reason for overruling *Ariad*, Juno recycles the same arguments this Court already rejected.

Juno starts with the text of § 112(a), asserting that the "language is straightforward" and "requires only that the specification describe the invention in sufficient detail to enable skilled artisans to make and use it." Pet. 8. That is precisely how the losing party in *Ariad* parsed the statute. 598 F.3d at 1343. And this Court rejected the assertion in a detailed textual analysis. *Id.* at 1344-45. The Court explained that the sentence is naturally read to "contain[] two separate description requirements: a 'written description [i] of the invention, and [ii] of the manner and process of making and using [the invention']." *Id.* at 1344. The Court rejected Juno's proposed interpretation because it would make "a portion of the statute … surplusage." *Id.* at 1344-45. Juno offers no response.

Ariad also observed that courts had interpreted earlier versions of the patent statute to contain a written-description requirement, and Congress "adopt[ed] that interpretation" when it "recodified this language in the 1952 Act" without change. 598 F.3d at 1344-45 (quoting *Forest Grove Sch. Dist. v. T.A.*, 557 U.S. 230, 239-40 (2009)). Tellingly, Juno ignores that part of the analysis, which, as discussed

above (at 8), has only gotten stronger with further congressional attention to the same provision after *Ariad*.

Ariad also disposed of Juno's arguments regarding Supreme Court precedent. Pet. 10. *Ariad* concluded that the Supreme Court too "recogniz[es] a written description requirement separate from an enablement requirement." 598 F.3d at 1345-47 (discussing *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938); *Festo*, 535 U.S. at 736). Juno cites nothing that contradicts this view. None of the Supreme Court cases it cites (Pet. 10-11) rejected a separate written-description requirement. Juno's lead authority held that the inventor "did *describe* accurately, and with admirable clearness, his process." *The Telephone Cases*, 126 U.S. 1, 535 (1888) (emphasis added). Another case did not involve the precursor to § 112 at all. *See United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933) (assignment). And the third held the claims at issue were not enabled without casting any doubt on the written-description requirement. *Universal Oil Prods. Co. v. Globe Oil & Refin. Co.*, 322 U.S. 471, 487 (1944). In repeatedly denying cert. petitions seeking to overrule *Ariad*, the Supreme Court has given no indication

that it believes the en banc decision flouted its precedents. *See Idenix v. Gilead*, 141 S. Ct. 1234 (2021); *Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019); *Janssen Biotech, Inc. v. Abbott Labs.*, 565 U.S. 1197 (2012); *see also Chiron Corp. v. Genentech, Inc.*, 543 U.S. 1050 (2005); *Univ. of Rochester v. G.D. Searle & Co.*, 543 U.S. 1015 (2004).

Juno similarly misdescribes the regional circuit cases from before this Court's creation—all of which were available to the *Ariad* Court. *See* Pet. 11. In two of those cases, the courts applied the written-description requirement and held patents *invalid* because they failed to describe and disclose the full scope of the invention. *Donner v. Am. Sheet & Tin Plate Co.*, 165 F. 199, 206 (3d Cir. 1908); *Philip A. Hunt Co. v. Mallinckrodt Chem. Works*, 177 F.2d 583, 585-86 (2d Cir. 1949). The third analyzed only enablement, that is, the "'how to make' requirement of paragraph one of" § 112; it did not suggest that this was all § 112 required. *Ill. Tool Works, Inc. v. Foster Grant Co.*, 547 F.2d 1300, 1309 (7th Cir. 1976).

C. Juno's meritless policy arguments provide no basis to reconsider the written-description requirement.

Juno asserts that a written-description requirement is bad for innovation in the context of "pharmaceutical inventions, … especially biologics." Pet. 3; *see* Pet. 12-15. Juno does not explain how such policy concerns could overcome the statutory language and other indicia of congressional intent. Nor does it explain how such policy concerns for one specific field could justify overriding the written-description requirement in all contexts, as it advocates. And Juno ignores the countervailing concern this Court has repeatedly expressed, that overbroad functional claiming threatens innovation.

Regardless, Juno's argument about biologics is also not new. *Ariad* emphasized that the sort of problems with expansive claiming on display in Juno's patent are "*particularly acute* in the biological arts." 598 F.3d at 1353 (emphasis added). It condemned claims that purport to cover "any compound later … invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention." *Id.* *Ariad* weighed the same policy arguments and adhered to the view that innovation is best

served if "the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time." *Id.* at 1353-54 (finding "no evidence of any discernable impact on the pace of innovation" caused by written-description requirement). It explained at length how a relaxed written-description standard would "impose costs on downstream research, discouraging later invention," and that the "right balance" was achieved by instead "giving the incentive to actual invention and not 'attempt[s] to preempt the future before it has arrived.'" *Id.* at 1353.

Juno nonetheless contends that the en banc Court's standard for functional genus claims is "essentially impossible to meet" in the biologics context. Pet. 13. But Juno misreads this Court's cases to require inventors to characterize nearly every species in the genus in detail. Pet. 12-13. In truth, the cases require only "*representative*" species or structure. *Ariad*, 598 F.3d at 1350 (emphasis added). Section 112 "does not require 'a nucleotide-by-nucleotide recitation of the entire genus.'" *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1165 (Fed. Cir. 2019) (quoting *Ariad*, 598 F.3d at 1352); *see Pfizer Inc. v. Teva Pharms. USA, Inc.*, 555 F. App'x 961, 968 (Fed. Cir. 2014)

("written description does not require … possession of every species"); Op. 10. And the panel imposed no such requirement here.

Contrary to Juno's critique that the panel's approach was "rigid," Pet. 2, the panel required a *proportionate* disclosure. It followed *Ariad*'s holding that "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." Op. 18. The panel "agree[d] with Juno that a patent specification need not redescribe known prior art concepts." Op. 12 n.2. But the panel found the patent's paltry disclosure incommensurate with the massively broad genus "about which much was *not* known in the prior art" and undisputed evidence establishing that scFv binding in the context of a CAR was highly unpredictable. Op. 9, 12 n.2; *infra* Part II. The patent discloses only two scFv species used in CARs and "contains no details" about them. Op. 9. And of "millions of billions" of scFvs that could possibly target just *one* antigen—CD19—at most "four or five" were known at the time of the priority date. Op. 15 (quoting Kite Br. 26, 35).

By contrast, this Court has upheld broad functional genus claims where more was known and disclosed. *Ariad* itself favorably cited such cases. *Ariad*, 598 F.3d at 1352 (citing *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005)). And the panel specifically distinguished this case from the primary authority upholding functional genus claims that Juno relied on in its briefing. In that case, the claims covered a large functional genus of selective inhibitors of a specific enzyme (PDE5). *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 645 (E.D. Tex. 2017) (Bryson, J.), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018). The court found adequate written description where the specification disclosed "10 discrete compounds" and "two classes of compounds" that performed the claimed function; hundreds of others were known as of the priority date; and those known compounds had shared structural features that distinguished them from compounds outside the genus. *Id.* at 645, 652-53; *see* Op. 14 n.3. The record here contained no such evidence.

Juno also argues it is pointless to require disclosure of the scope of a genus because a scientist working in the lab "needs only a single scFv" to work. Pet. 14. In nearly all the precedents on which the panel relied,

the patentee also argued that there were known general methods of making the claimed invention. Crediting Juno's argument would eviscerate the written-description requirement and permit an inventor to claim a broad and unpredictable functional genus upon discovering only a single working species.

Finally, even if Juno's policy concern had any merit, its recourse is again with Congress. Congress has been responsive to valid subject-matter-specific concerns about the written-description requirement. For example, Congress passed the Plant Patent Act to address the concern that plant patents were "not amenable to the 'written description' requirement of the patent law." *Diamond v. Chakrabarty*, 447 U.S. 303, 312 (1980); 35 U.S.C. § 162. Congress has created no such carveout for biologics.

II. The Panel Did Not Overlook Evidence.

Juno also asks the full Court to decide whether "the panel ignored critical evidence" in applying the *Ariad* standard. Pet. 15. But the en banc Court does not sit to spot check a panel's record-specific determinations. And in any event, the panel considered Juno's evidence and properly found it insufficient.

Juno recites evidence purportedly "showing that artisans knew exactly how to make and use … scFv binders" for a desired target. Pet. 15-17. Far from ignoring this evidence, the panel acknowledged, and accepted, Juno's argument "that scFvs were known and that they were known to bind." Op. 11; *see also* Op. 8 ("Juno responds that scFvs were well-known (as was how to make them)."). The problem was that knowing how to make something generally—be it an scFv, an antibody, a chemical compound, or something else—says nothing about whether the patentee actually invented a full genus, with a claimed functionality.

The panel concluded that Juno's evidence was insufficient, in light of the sheer breadth of the '190 patent and the unpredictability of scFvs in CARs. *See* Op. 10-11, 13, 16-17. As the panel explained, the claims at issue cover a vast universe of CARs with scFvs, known and unknown, that bind to a specific antigen (or more broadly to any antigen, known or unknown). Op. 10-11. But Juno's patent "fails to disclose a way to distinguish those scFvs capable of binding from scFvs *in*capable of binding" to target antigens. Op. 13. It does not even disclose how to make this distinction for the specific antigen, CD19, that is the subject

of the narrower asserted claims. Given the "diversity of the functional scFv genus, the unpredictability of an scFv's binding ability," and the fact that only a handful of CD19-specific scFvs were known, the patent's written description cannot support the claims, which "include the functional scFv for binding the target." Op. 18.

In light of this analysis, it did not matter whether the method was sufficiently easy that a technician who also worked as a lab dishwasher made an scFv. Pet. 17. The panel's point was that knowing how to make a particular species does not give an inventor the right to monopolize a vast genus unless the inventor provides a way to recognize which species are in the genus and which ones are not. Op. 9-12 & n.2. Even Juno acknowledges the ample precedent invalidating patents that "inadequately described [the inventions] because skilled artisans needed iterative 'trial and error' testing to identify which embodiments would actually perform the claimed newly discovered function." Pet. 18; *see* Op. 14; *Idenix*, 941 F.3d at 1164 (patent failed to provide "any meaningful guidance into what compounds" would provide the claimed result); *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301-02 (Fed. Cir. 2014) (patent claims covered every human

antibody that would "achieve a desired result" while disclosing only one functioning example).

Juno is wrong to distinguish all these cases on the ground that "[n]o trial-and-error testing was necessary here." Pet. 18. The panel correctly found the evidence undisputed on this point: Kite's expert explained—in uncontradicted testimony that Juno itself cites in its petition—that there is "no way to know" without testing which of the vast universe of scFvs candidates will perform the requisite function. Appx33680; *see* Appx33687-33688. Juno is wrong that the evidence showed "for any target antigen, the Orlandi method could be used to generate millions or billions of scFvs, each of which would be expected to work with [its] inventive backbone." Pet. 13. None of its citations say that. The uncontested testimony and documentary evidence established that "Orlandi … didn't work on many … antibodies" and was further limited to scFvs derived from mice. Appx33705; *see* Appx35640-35643; Appx36174; Appx36182; Appx36185. As of the priority date, it would take "six months to over a year" to make and test one scFv. Appx33681. Moreover, 15 years after the priority date, and with new technology, Juno tested *a billion* scFvs for binding to CD19—

identifying only 60 that did, of which only three were worth further investigation for inclusion in a CAR. Appx33705-33707.

Ultimately, Juno's argument about ignored evidence collapses into the specious assertion that "'Orlandi' does not appear even once" in the opinion. Pet. 17. The panel referred to Orlandi generically as a "publication[]" and cited testimony discussing it. Op. 16 (citing Appx33942). During oral argument, the panel also probed the Orlandi method and noted its limitations. *See, e.g.*, Oral Arg. 49:04-50:35 (Chief Judge Moore noting that Orlandi provided no information about how to identify antigens of interest, identify the universe of scFvs binding to a particular antigen, or predict binding); 53:38-59 (Judge Prost noting that prior art provided no guidance on making the human or humanized scFvs encompassed by the claims). As Chief Judge Moore put it, "the whole problem is, nobody knew which scFvs were going to bind to the antigen." Oral Arg. 59:09-15. Juno could not provide an answer to that problem at argument, and its petition does not even try.

Juno also cannot show that the panel ignored evidence here by citing evidence developed in *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). The panel explained *Capon* did not "determine[] that the

inventors there satisfied the written description requirement." Op. 12. It merely overturned the Board's categorical rule that written description requires disclosing a DNA sequence. *Id.*

The panel did not "overlook" anything. It simply applied this Court's established precedent to the record at hand and rejected Juno's attempt to monopolize a broad swath of genetic innovations when it had not yet discovered let alone described them.

CONCLUSION

This Court should deny Juno's request for rehearing.

Respectfully submitted,

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December 29, 2021

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on December 29, 2021.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 35(e), Fed. R. App. 35(b)(2)(A) and Fed. Cir. R. 35(e)(2). The brief contains 3,893 words, excluding parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2).

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