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APPENDIX A

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

2020-1758

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

Decided: August 26, 2021

MORGAN CHU, Irell & Manella LLP, Los Angeles, CA, argued for plaintiffs-appellees. Also represented by ALAN J. HEINRICH, ELIZABETH C. TUAN; GREGORY A. CASTANIAS, JENNIFER L. SWIZE, Jones Day, Washington, DC; LISA LYNN FURBY, Chicago, IL; ANDREA WEISS JEFFRIES, Los Angeles, CA; MATTHEW J. RUBENSTEIN, Minneapolis, MN.

E. JOSHUA ROSENKRANZ, Orrick, Herrington & Sutcliffe LLP, New York, NY, argued for defendant-appellant. Also represented by MELANIE L.

BOSTWICK, ROBBIE MANHAS, JEREMY PETERMAN, Washington, DC; GEOFFREY DONOVAN BIEGLER, Fish & Richardson, San Diego, CA; TED G. DANE, PETER GRATZINGER, ADAM R. LAWTON, GARTH VINCENT, JEFFREY I. WEINBERGER, Munger, Tolles & Olson LLP, Los Angeles, CA.

Before MOORE, *Chief Judge*,
PROST and O'MALLEY, *Circuit Judges*.

MOORE, *Chief Judge*.

Kite Pharma, Inc. appeals a final judgment of the United States District Court for the Central District of California that (1) claims 3, 5, 9, and 11 of U.S. Patent No. 7,446,190 are not invalid for lack of written description or enablement, (2) the '190 patent's certificate of correction is not invalid, and (3) Juno Therapeutics, Inc., and Sloan Kettering Institute for Cancer Research (collectively, Juno) were entitled to $1,200,322,551.50 in damages. *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, No. 2:17-cv-07639-PSG-KS, (C.D. Cal. April 8, 2020), ECF 728. Because we conclude that the jury verdict regarding written description is not supported by substantial evidence, we reverse.

BACKGROUND

T cells are white blood cells that contribute to the body's immune response. J.A. 32906–07. They have naturally occurring receptors on their surfaces that facilitate their attack on target cells (such as cancer cells) by recognizing and binding an antigen, i.e., a structure on a target cell's surface. J.A. 32907–08.

Chimeric antigen receptor (CAR) T-cell therapy involves isolating a patient's T cells; reprogramming

those T cells to produce a specific, targeted receptor (a CAR) on each T cell's surface; and infusing the patient with the reprogrammed cells. J.A. 32913; '190 patent at 2:31–36, 7:24–33. The reprogramming involves introducing genetic material containing a nucleotide sequence encoding for a CAR into the T cell so that the cell produces the CAR on its surface. J.A. 32913; '190 patent at 1:30–34, 2:27–36. This CAR allows the T cell to recognize the specific antigen for which it was programmed. J.A. 32913; '190 patent at 2:27–36.

The '190 patent relates to a nucleic acid polymer encoding a three-part CAR for a T cell. It claims priority to a provisional application filed May 28, 2002, a time period that one of the inventors labeled as "the birth of the CAR-T field." J.A. 32976. The first portion of the three-part CAR is called the intracellular domain of the human CD3 ζ (zeta) chain. *See, e.g.*, '190 patent at 2:14–16, 4:12–17. It is a signaling domain that, when the T cell binds to an antigen, is activated to create an initial immune response. J.A. 103. The second portion is a costimulatory region comprising a specific amino acid sequence (SEQ ID NO:6) that is part of a naturally occurring T-cell protein called CD28. '190 patent at 2:16–17, 3:44–54. When activated, the costimulatory region creates a second signal to augment or prolong the immune response by, for example, directing the T cells to multiply. J.A. 103; J.A. 32912. The CD3-zeta portion and the costimulatory region combine to make a signaling element, or backbone, of the CAR. J.A. 32906; J.A. 32912–13. This combination of the CD3-zeta and costimulatory regions allows the T cells to not only kill target cells but also to divide into more T cells. J.A. 32913–14. The third and final portion of

the '190 patent's CAR is the binding element, which is the portion of the CAR that determines what target molecule or antigen the CAR can recognize and bind to. '190 patent at 4:34–45; J.A. 32912–13.

One type of binding element in the '190 patent is a single-chain antibody, i.e., a single-chain antibody variable fragment (scFv). '190 patent at 4:52–57; *see also* J.A. 32910. An scFv is made by taking two pieces of an antibody, one from the heavy chain of an antibody's variable region and one from the light chain of an antibody's variable region, and linking them together with a linker sequence. J.A. 32908–09; *see also* J.A. 2643–44; J.A. 103; '190 patent at 4:52–5:5. Each variable region has a unique amino acid sequence that can dictate whether and how an antibody, and thus an scFv, binds to a target. J.A. 2643; J.A. 103. The '190 patent discloses two scFvs. One of those scFvs is derived from the SJ25C1 antibody and binds CD19, a protein that appears on the surface of diffuse large B-cell lymphoma cells. '190 patent at 11:12–22; *see also* J.A. 58. The other disclosed scFv is derived from the J591 antibody and binds PSMA, a protein that appears on the surface of prostate cancer cells. '190 patent at 7:43–51, 8:5–10; *see also* J.A. 32967; J.A. 33945. The '190 patent does not disclose the amino acid sequence of either scFv.

Independent claim 1 of the '190 patent recites:

> 1. A nucleic acid polymer encoding a chimeric T cell receptor, said chimeric T cell receptor comprising
>
> (a) a zeta chain portion comprising the intracellular domain of human CD3 ζ chain,

> (b) a costimulatory signaling region, and
>
> (c) a binding element that specifically interacts with a selected target, wherein the costimulatory signaling region comprises the amino acid sequence encoded by SEQ ID NO:6.

Dependent claims 3 and 9 limit the claimed "binding element" to "a single chain antibody," i.e., an scFv. Claims 5 and 11, which depend from claims 3 and 9, respectively, further specify that the claimed scFv binds to CD19.

Kite's YESCARTA® is a "therapy in which a patient's T cells are engineered to express a [CAR] to target the antigen CD19, a protein expressed on the cell surface of B-cell lymphomas and leukemias, and redirect the T cells to kill cancer cells." J.A. 58; J.A. 384; Kite Br. 17. It is a treatment that uses a three-part CAR containing an scFv that binds the CD19 antigen, a CD3-zeta chain portion, and a costimulatory signaling region. J.A. 58; *see also* Kite Br. 11; J.A. 383–96 (Complaint).

Juno sued Kite, alleging infringement of various claims of the '190 patent through the use, sale, offer for sale, or importation of YESCARTA®. Kite filed counterclaims seeking declaratory judgments of noninfringement and invalidity of the '190 patent. After a two-week jury trial, the jury reached a verdict in Juno's favor, finding (1) Kite failed to prove the '190 patent's certificate of correction was invalid, (2) Kite failed to prove any of the asserted claims were invalid for lack of written description or enablement, (3) Juno proved Kite's infringement was willful, and (4) Juno

proved Kite owed damages amounting to a $585 million upfront payment and a 27.6% running royalty.

The parties then filed post-trial briefs. Kite moved for judgment as a matter of law (JMOL), arguing (a) the claims were not supported by a sufficient written description, (b) the claims were not enabled, (c) Juno's certificate of correction was invalid, (d) Kite acted in good faith such that it could not be found to be a willful infringer, and (e) Juno's damages expert should have been excluded. J.A. 57, 60. Juno, for its part, moved for entry of judgment on the verdict, prejudgment interest, enhanced damages, and for the court to set an ongoing royalty rate. J.A. 38. The district court denied Kite's motions for JMOL. J.A. 86. The district court granted-in-part Juno's motion, updating the jury's award to $778,343,501 to reflect updated YESCARTA® revenues through trial, awarding prejudgment interest, enhancing damages by 50%, and awarding a 27.6% running royalty. J.A. 56.

Kite appeals, arguing the district court erred in denying JMOL on each of the above issues that Kite raised in its post-trial briefing. We have jurisdiction under 28 U.S.C. § 1295(a)(1). Because we determine that the record does not contain substantial evidence that the patent contains written description support for the asserted claims, we hold the claims invalid and need not reach Kite's alternative arguments.

DISCUSSION

We review denial of a motion for JMOL under regional circuit law. *See Trs. of Boston Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1361 (Fed. Cir. 2018). The Ninth Circuit reviews a denial of JMOL de

novo, and reversal is appropriate when "the evidence, construed in the light most favorable to the nonmoving party, permits only one reasonable conclusion, and that conclusion is contrary to that of the jury." *White v. Ford Motor Co.*, 312 F.3d 998, 1010 (9th Cir. 2002).

I

A patent's specification "shall contain a written description of the invention." 35 U.S.C. § 112 ¶ 1.[1] "[T]he hallmark of written description is disclosure." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). A specification adequately describes an invention when it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* at 1351. "A 'mere wish or plan' for obtaining the claimed invention is not adequate written description." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011). What is required to meet the written description requirement "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005); *see also Ariad*, 598 F.3d at 1351.

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[1] Paragraph 1 of 35 U.S.C. § 112 was replaced with newly designated § 112(a) by section 4(c) of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, sec. 4, 125 Stat. 284, 296–97 (2011). Section 4(e) of the AIA makes those changes applicable "to any patent application that is filed on or after" September 16, 2012. *Id.* Because the applications resulting in the patent at issue in this case was filed before that date, we refer to the pre-AIA version of § 112.

As we explained in *Ariad*, "[f]or generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" 598 F.3d at 1351 (citing *Capon*, 418 F.3d at 1359). For genus claims using functional language, like the binding function of the scFvs claimed here, the written description "must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus." *Ariad*, 598 F.3d at 1349. "The written description requirement [ ] ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function." *Id*. at 1352. Generally, a genus can be sufficiently disclosed by "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id*. at 1350. "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

Whether a patent complies with the written description requirement of § 112 ¶ 1 is a question of

fact, and "we review a jury's determinations of facts relating to compliance with the written description requirement for substantial evidence." *Ariad*, 598 F.3d at 1355 (quoting *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002)).

II

Kite argues that the asserted claims are invalid for failing to satisfy the written description requirement because the '190 patent discloses neither representative species nor common structural features of the claimed scFv genus to identify which scFvs would function as claimed. Kite argues that the claims cover an enormous number (millions of billions) of scFv candidates, only a fraction of which satisfy the functional binding limitation for any given target, and that the written description does not meet the written description requirement for this functional binding limitation. It also argues that the scFv field is unpredictable since an scFv's binding ability depends on a variety of factors.

Juno responds that scFvs were well-known (as was how to make them), that multiple scFvs for specific targets were well-known, that the '190 patent describes two working scFv embodiments that are representative of all scFvs, and that scFvs had been incorporated in CARs well before the '190 patent's priority date. It also argues that scFvs are interchangeable and have common structural features.

We agree with Kite that no reasonable jury could find the '190 patent's written description sufficiently demonstrates that the inventors possessed the full scope of the claimed invention. We hold that

substantial evidence does not support the jury's finding of adequate written description for any of the asserted claims.

A

The broadest asserted claims of the '190 patent, claims 3 and 9, recite that the scFv binding element "specifically interacts with a selected target." As the '190 patent explains, "[t]he target . . . can be *any target of clinical interest* to which it would be desirable to induce a T cell response." '190 patent at 4:36–39 (emphasis added). In other words, claims 3 and 9 broadly cover, as part of the claimed nucleic acid polymer encoding for the three-part CAR, *any* scFv for binding *any* target. But the '190 patent's written description fails to provide a representative sample of species within, or defining characteristics for, that expansive genus.

1

The '190 patent's written description contains scant details about which scFvs can bind which target antigens. The '190 patent discloses two example scFvs for binding two different targets: one derived from J591, which targets a PSMA antigen on prostate cancer cells, and another derived from SJ25C1, which targets CD19. J.A. 32922–23; J.A. 32967; J.A. 33945. The '190 patent contains no details about these scFv species beyond the alphanumeric designations J591 and SJ25C1 for a skilled artisan to determine how or whether they are representative of the entire claimed genus. Juno argues these two working embodiments are representative of all scFvs in the context of a CAR. The evidence does not support Juno's argument. The claims are directed to scFvs that bind to selected

targets. In claims 3 and 9 there is no limit as to the particular target. To satisfy the written description requirement, the patent needed to demonstrate to a skilled artisan that the inventors possessed and disclosed in their filing the particular species of scFvs that would bind to a representative number of targets. Kite demonstrated by clear and convincing evidence that this patent does not satisfy the written description requirement for the claims at issue and this record does not contain substantial evidence upon which a jury could have concluded otherwise. The disclosure of one scFv that binds to CD19 and one scFv that binds to a PSMA antigen on prostate cancer cells in the manner provided in this patent does not provide information sufficient to establish that a skilled artisan would understand how to identify the species of scFvs capable of binding to the limitless number of targets as the claims require.

Juno primarily relies on the testimony of its immunological expert, Dr. Brocker, but that testimony is far too general. Dr. Brocker testified that the two exemplary scFvs are representative "because [scFvs] all do the same thing. They bind to the antigen." J.A. 33945. Nothing about that testimony explains which scFvs will bind to which target or cures the '190 patent's deficient disclosure on this score. Without more in the disclosure, such as the characteristics of the exemplary scFvs that allow them to bind to particular targets or nucleotide sequences, the mere fact that scFvs in general bind does not demonstrate that the inventors were in possession of the claimed invention.

This is not to say, however, that a patentee must in all circumstances disclose the nucleotide or amino

acid sequence of the claimed scFvs to satisfy the written description requirement when such sequences are already known in the prior art. *See Capon*, 418 F.3d at 1360–61 (holding it was error for the Board of Patent Appeals and Interferences to require "recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field"). But the written description must lead a person of ordinary skill in the art to understand that the inventors possessed the entire scope of the claimed invention. *Ariad*, 598 F.3d at 1353–54 ("[T]he purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." (internal quotation marks omitted)). Dr. Sadelain, one of the '190 patent's inventors, testified that, at the time he filed his patent application, he had used only the SJ25C1-derived scFv and J591-derived scFv. J.A. 32965–67. Yet the '190 patent claims any scFv on its CAR that binds to any target, without disclosing details about which scFvs bind to which target. It is not fatal that the amino acid sequences of these two scFvs were not disclosed as long as the patent provided other means of identifying which scFvs would bind to which targets, such as common structural characteristics or shared traits. But this patent provides nothing to indicate that the inventors possessed the full scope of the genus that they chose to claim. Thus, the '190 patent's disclosure does not demonstrate the inventors possessed the entire class of possible scFvs that bind to various selected targets.

Relying upon witness testimony, Juno argues that because scFvs, in general, were known, the two scFvs in the '190 patent are representative. *See, e.g.*, J.A. 32909 (Dr. Sadelain testifying that scFvs were not new in the field, and that they "had been around since the [1980s]"); J.A. 33209 (Kite's founder, Dr. Belldegrun, agreeing that "scientists knew about the scFvs that could be used with CARs going back to the 1980s"); J.A. 33932 (Juno's expert, Dr. Brocker, testifying that scFvs "were in the field for more than a decade, nearly 15 years" at the time of Dr. Sadelain's invention); J.A. 33939–40 (Dr. Brocker testifying that people knew how to make scFvs and "several of them had been described"). To satisfy written description, however, the inventors needed to convey that they possessed the claimed invention, which encompasses all scFvs, known and unknown, as part of the claimed CAR that bind to a selected target. Even accepting that scFvs were known and that they were known to bind, the specification provides no means of distinguishing which scFvs will bind to which targets. *See Eli Lilly*, 119 F.3d at 1568 ("A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." (quoting *Fiers*, 984 F.2d at 1171)). Accordingly, testimony that scFvs were generally known in the field is insufficient to satisfy the written description requirement for the '190 patent's claims requiring scFvs that bind to a selected target.

Juno relies heavily on our decision in *Capon*, arguing that we already determined that "scFvs were

well-known CAR components that did not need to be detailed in CAR patents' specifications to satisfy Section 112." Juno Br. 27. Our *Capon* decision neither made the determination Juno alleges nor determined that the inventors there satisfied the written description requirement. Instead, we vacated the Board's decision for imposing too high a standard to satisfy the written description requirement, and remanded for the Board to consider the evidence and determine whether the specification adequately supported the claims at issue. *Capon*, 418 F.3d at 1358–61; *see also id.* at 1358 ("The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization."). Also, more was known in the prior art in *Capon* than here, particularly when the inventors here used only two scFvs as of the '190 patent's priority date out of the vast number of possibilities. *See id.* at 1355, 1358; J.A. 32965–67. *Capon* does not support Juno's arguments regarding its exceedingly broad functional claim limitations.[2]

2

In addition to lacking representative species, the '190 patent does not disclose structural features common to the members of the genus to support that the inventors possessed the claimed invention. *See*

[2] We agree with Juno that a patent specification need not redescribe known prior art concepts. Juno Br. 28 (citing *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1064 (Fed. Cir. 2020)). The problem with the '190 patent is that, although there were some scFvs known to bind some targets, the claims cover a vast number of possible scFvs and an undetermined number of targets about which much was *not* known in the prior art.

Ariad, 598 F.3d at 1350. Juno argues that the '190 patent satisfies the written description requirement because scFvs are interchangeable, with a similar, common structure. It relies on Dr. Brocker's testimony that scFvs have "known structural commonalities, similarities." J.A. 33926. He explained that scFvs have the same general, common structure consisting of a variable region derived from the light chain of an antibody and a variable region derived from the heavy chain of an antibody, where these two portions are connected with a linker. J.A. 33936–38. These general assertions of structural commonalities, in the context of the technology in this case, are insufficient.

It is undisputed that scFvs generally have a common structure, as described by Dr. Brocker. But, as Dr. Brocker acknowledged, an scFv with the same general common structure but with a different amino acid sequence would recognize a different antigen. J.A. 33938. Dr. Brocker also testified that all scFvs have a common structure, regardless of whether they bind. J.A. 33959. The '190 patent not only fails to disclose structural features common to scFvs capable of binding specific targets, it also fails to disclose a way to distinguish those scFvs capable of binding from scFvs *in*capable of binding those targets. The '190 patent provides no amino acid sequences or other distinguishing characteristics of the scFvs that bind. Simply put, the '190 patent claims a "problem to be solved while claiming all solutions to it . . . cover[ing] any compound later actually invented and determined to fall within the claim's functional boundaries," *Ariad*, 598 F.3d at 1353, which fails to satisfy the written description requirement.

We have previously held similar claims invalid based on lack of written description. In *Idenix*, we held invalid claims that required nucleosides effective against hepatitis C virus, and the patent merely provided "lists or examples of supposedly effective nucleosides, but [did] not explain what makes them effective, or why." *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019). Without this explanation, "a [person of ordinary skill] is deprived of any meaningful guidance into what compounds beyond the examples and formulas, if any, would provide the same result." *Id.* Similarly, in *AbbVie*, we concluded that substantial evidence supported the jury's verdict of inadequate written description when the patents described one species of structurally similar antibodies derived from only one lead antibody but the asserted claims covered "every fully human IL-12 [targeted] antibody that would achieve a desired result" without an indication about an established correlation between the structure and the claimed function. *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301–02 (Fed. Cir. 2014).[3] As in these two cases, the '190 patent does

[3] Juno also relies on *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629 (E.D. Tex. 2017), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018). In that case, there were hundreds of known PDE5 inhibitors, the type of compound at issue, and the patent identified the compounds by chemical name and structural drawings. *Id.* at 645–46. The compounds also shared a common physical structure to fit the active site of the PDE5 enzyme to inhibit its activity, and the evidence supported that a skilled artisan "could make modifications to increase potency and selectivity." *Id.* at 652–53. The '190 patent, in contrast, does not disclose any amino acid sequences or structures to

not provide meaningful guidance about which scFv will bind which target.

Claims 3 and 9 broadly claim all scFvs, as part of the claimed CAR, that bind to any target. But the written description of the '190 patent discloses only two scFv examples and provides no details regarding the characteristics, sequences, or structures that would allow a person of ordinary skill in the art to determine which scFvs will bind to which target. That scFvs in general were well-known or have the same general structure does not cure that deficiency. Thus, substantial evidence does not support the jury's finding that the '190 patent conveys, to a skilled artisan, that the inventors possessed the broad genus of scFvs as recited in claims 3 and 9.

B

Claims 5 and 11, which are limited to scFvs that bind CD19 (a specific target), likewise find no written description support in the '190 patent. And again, Juno's general testimony about general scFv structure does not provide substantial evidence regarding the claims containing the functional limitation that covers all scFvs that bind to CD19.

Kite argues that there were "four or five" CD19-specific scFvs "arguably known in the art" at the priority date of the '190 patent. Kite Br. 35. Kite argues that the universe of possible sequences for scFvs is in the range of "millions of billions." *Id.* at 26.

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distinguish scFvs that bind to selected targets from those that do not, and the modifications of the sequence can change the binding ability. Juno also does not dispute that very few CD19-specific scFvs were known as of the priority date. *See* § II.B below.

Given the vast number of possible scFvs, the lack of detail in the '190 patent regarding the scFv sequences, and the few scFvs known in the art to bind CD19, Kite argues substantial evidence does not support that the '190 patent discloses species representative of the claimed genus.

Juno does not dispute Kite's characterizations regarding either the number of known CD19 scFvs at the priority date of the '190 patent or the universe of possible scFvs. Instead, it cites Dr. Brocker's general testimony that "there were several known" CD19 scFvs and publications "which have demonstrated that it's possible to make these single-chain Fvs that can bind to CD19." J.A. 33942. Juno also acknowledges that the '190 patent discloses only one CD19-specific scFv (the SJ25C1-derived scFv), but argues that a second CD19-specific scFv, the one used in YESCARTA®, was known by 1997. Juno Br. 24.

Substantial evidence does not support the jury's finding that the '190 patent disclosed sufficient information to show the inventors possessed the claimed genus of functional CD19-specific scFvs as part of their claimed CAR. The '190 patent provides no details about any CD19-specific scFv, such as an exemplary amino acid sequence, a shape, or general characteristics that would allow this target-specific scFv to bind. Instead, it provides only an alphanumeric designation, SJ25C1, as the source for the CD19-specific scFv. Without more guidance, in a vast field of possible CD19-specific scFvs with so few of them known, no reasonable jury could find the inventors satisfied the written description requirement.

Juno's reliance on a combination of expert and inventor testimony does not provide the required support. Dr. Brocker's testimony that "there were several [CD19 scFvs] known" at the priority date and that it was "possible to make these single-chain Fvs that can bind CD19," J.A. 33942, at most demonstrates a small number of CD19-specific scFvs were known and others were possible, albeit undiscovered. Indeed, Dr. Sadelain admitted that the SJ25C1-derived scFv was the only CD19-specific scFv he used at the time he filed his patent application. J.A. 32965. And Juno's reliance on only one more CD19-specific scFv, the one used in YESCARTA®, further demonstrates that the number of known CD19-specific scFvs at the time was small. Juno again relies on Dr. Brocker, who testified that he was not "aware of any *functional* CD19 scFv that has not been shown to work with Dr. Sadelain's CAR backbone." J.A. 33943–44 (emphasis added). But that testimony presupposes an scFv already known to be functional; one that was known to bind to CD19. Such circular reasoning does not support that the inventors possessed the full scope of possible CD19-specific scFvs, particularly when the genus of possibilities is expansive with only four or five CD19 scFv species known at the time. Finally, Juno relies on Dr. Sadelain's testimony that, since he filed his patent application, he has "placed multiple scFvs" on the CAR backbone, "probably up to 30 [CD19-specific scFvs] by now." J.A. 32923.[4] But we assess whether

[4] Fifteen years after the '190 patent's priority date, individuals from Juno published an article, J.A. 37426–34, in which they discussed having screened over a billion human scFv sequences

the written description requirement is satisfied as of the filing date of the patent application. *Ariad*, 598 F.3d at 1351. Dr. Sadelain's testimony about post-priority date developments, therefore, is irrelevant to the inquiry before us. *See id.* at 1355 (post-priority date evidence "legally irrelevant to the question of whether" the disclosure conveyed possession at the time of filing).

Juno's further arguments that it would not matter to a person of ordinary skill (1) that scFvs may be highly diverse in the abstract, (2) that "millions of billions" of scFvs would need to be made and tested to ascertain their binding properties, or (3) that a skilled artisan could not predict before testing whether an scFv would bind, Juno Br. 28–29, are contrary to our precedent. In *Ariad*, we explained 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." 598 F.3d at 1351. Some factors to consider when evaluating the adequacy of the disclosure include "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Id.* (alteration in original) (citing *Capon*, 418 F.3d at 1359). Contrary to Juno's argument, the diversity of the functional scFv genus, the unpredictability of an scFv's binding ability, and that the prior art had, at most, five CD19-specific scFvs as

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to arrive at only 60 that "displayed elevated binding to CD19-expressing cells," J.A. 37427–28.

of the priority date are all relevant to the written description inquiry.

We likewise reject Juno's argument that our decision in *Ariad* is "irrelevant" because the claims at issue here do not involve method claims reciting a "newly-identified cellular function or mechanism of action." Juno Br. 25. Juno relies on its expert's testimony that Dr. Sadelain invented the backbone, not scFvs. J.A. 33932; *see also* J.A. 33934 (Dr. Brocker testifying that scFvs were "not part of this invention. The real invention was the backbone."). But the '190 patent's claims are not limited to just the claimed backbone; they also include the functional scFv for binding the target. As we explained in *Boston Scientific Corp. v. Johnson & Johnson*, "[t]he test for written description is the same whether the claim is to a novel compound or a novel combination of known elements. The test is the same whether the claim element is essential or auxiliary to the invention." 647 F.3d 1353, 1365 (Fed. Cir. 2011). The '190 patent inventors, therefore, needed to provide a sufficient disclosure that "reasonably conveys to those skilled in the art that the inventor[s] had possession of the claimed subject matter as of the filing date," *Ariad*, 598 F.3d at 1351, including for the claimed functional binding element.

While it is true that scFvs in general were known, and even known to bind, the record demonstrates that, for even the narrowest claims at issue, the realm of possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most). The '190 patent, however, provides no details about which scFvs bind to CD19 in a way that distinguishes them from scFvs that do not bind to

CD19. Without this guidance, under our controlling *Ariad* decision, no reasonable jury could find the '190 patent satisfies the written description requirement.

CONCLUSION

Substantial evidence does not support the jury's verdict in Juno's favor on the issue of written description. For the claimed functional scFv genus, the '190 patent does not disclose representative species or common structural features to allow a person of ordinary skill in the art to distinguish between scFvs that achieve the claimed function and those that do not. Accordingly, we reverse.

REVERSED

COSTS

Costs to Kite.

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

JUNO THERAPEUTICS, INC., MEMORIAL SLOAN KETTERING CANCER CENTER, AND SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. KITE PHARMA, INC., Defendant.	 Case No. 2:17-cv-07639-PSG-KSx **[~~PROPOSED~~] FINAL JUDGMENT** Hon. Philip S. Gutierrez Courtroom 6A
AND RELATED COUNTERCLAIMS	

This action came on for jury trial on December 3, 2019, in Courtroom 10C of the above-entitled Court, the Honorable District Court Judge S. James Otero presiding. On December 13, 2019, the jury returned a unanimous verdict in favor of Plaintiffs Juno Therapeutics, Inc., and Sloan Kettering Institute for Cancer Research ("Plaintiffs"), and against Defendant Kite Pharma, Inc. ("Kite"). Dkt. No. 593 (redacted version); Dkt. No. 594 (sealed version). The Court has now considered and resolved each side's consolidated post-trial motions.

NOW THEREFORE, IT IS ORDERED, ADJUDGED, AND DECREED THAT JUDGMENT IS HEREBY ENTERED IN THIS MATTER AS FOLLOWS:

1. Kite has infringed claims 3, 5, 9, and 11 of United States Patent No. 7,446,190 ("the '190 Patent") since October 18, 2017, by making, selling, and/or offering to sell Yescarta® in the United States.

2. Kite's infringement of claims 3, 5, 9, and 11 of the '190 Patent has been willful.

3. Claims 3, 5, 9, and 11 of the '190 Patent are not invalid for lack of enablement or written description.

4. The '190 Patent's Certificate of Correction is not invalid.

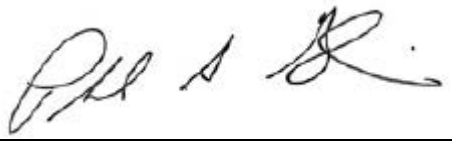
5. Judgment is entered against Kite on its counterclaims of non-infringement and invalidity.

6. Plaintiffs shall recover: (1) $778,343,501 on the jury verdict, comprising (a) a $585,000,000 upfront payment; and (b) $193,343,501, calculated as a 27.6% running royalty on each of (i) Kite's net revenues from sales of Yescarta® from October 18, 2017 through September 30, 2019, which were $603,650,765; and (ii) Kite's net revenues from sales of Yescarta® from October 1, 2019 to December 12, 2019, which were $96,869,167; (2) pre-judgment interest on the jury's verdict in the amount of $32,807,300, and (3) enhanced damages of $389,171,750.50.

7. As provided in 28 U.S.C. § 1961, Plaintiffs shall also recover post-judgment interest on all amounts listed in paragraph 6 above, at a rate of 0.15%, compounded annually, from the date of this Judgment until the Judgment is paid.

8. Kite shall pay Plaintiffs a running royalty of 27.6% of its net revenues for Yescarta® and any other therapy using the same infringing CAR from December 13, 2019 to the expiration date of the '190 Patent, August 28, 2024. Kite shall disclose its net revenues for Yescarta® and any other therapy using the same infringing CAR to Plaintiffs by the second Monday following the end of each quarter and wire Plaintiffs a corresponding royalty payment by that same date. Further, within ten (10) days of entry of this Judgment, the parties shall submit to the Court proposed terms for inspection and reporting procedures regarding the therapies and revenues subject to the ongoing royalties awarded in this paragraph.

Dated: April 8, 2020



HONORABLE PHILIP S. GUTIERREZ
UNITED STATES DISTRICT JUDGE

APPENDIX C

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

UNDER SEAL

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CASE NO.:	**DATE:**
2:17-cv-07639 SJO-KS	**March 24, 2020**

Title: **Juno Therapeutics, Inc., et al. v. Kite Pharma, Inc.**

PRESENT:	**THE HONORABLE S. JAMES OTERO, UNITED STATES DISTRICT JUDGE**
Victor Paul Cruz	Not Present
Courtroom Clerk	Court Reporter
COUNSEL PRESENT FOR PLAINTIFFS:	**COUNSEL PRESENT FOR DEFENDANTS:**
Not Present	Not Present

PROCEEDINGS (in chambers): ORDER RE: DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW PURSUANT TO FED. R. CIV. P. 50(B) AND/OR A NEW TRIAL PURSUANT TO FED. R. CIV. P. 59 [ECF No. 659]

[Portions of the parties' briefing filed in support of and in opposition to the motion ruled upon in this Order were filed under seal. The parties are expected to file a joint report within five days of this ruling proposing redactions of any confidential material. If the parties fail to file a joint report, this Order will be publicly issued as-is.]

This matter comes before the Court on Defendant Kite Pharma, Inc.'s ("Defendant" or "Kite") Motion for Judgment as a Matter of Law Pursuant to Fed. R. Civ. P. 50(b) and/or a New Trial Pursuant to Fed. R. Civ. P. 59 ("JMOL") filed on January 21, 2020. (JMOL, ECF No. 659.[1]) Plaintiffs Juno Therapeutics, Inc. ("Juno") and Sloan Kettering Institute for Cancer Research ("SKI") (collectively, "Plaintiffs") filed their Opposition to Defendant's Motion for Judgment as a Matter of Law and/or a New Trial ("Opposition" or "Opp.") on February 10, 2020. (Opp., ECF Nos. 673.[2]) Defendant filed its Reply in Support of a Motion for Judgment as a Matter of Law Pursuant to Fed. R. Civ. P. 50(b) and/or a New Trial Pursuant to Fed. R. Civ. P. 59 ("Reply") on February 24, 2020. (Reply, ECF

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[1] Defendant subsequently filed a Corrected Memorandum in support of its JMOL on February 20, 2020, which the Court has considered in this Order. (ECF No. 692.) Unless otherwise noted, all citations to Defendant's JMOL refer to the Corrected Memorandum, ECF No. 692.

[2] Plaintiffs subsequently filed a Corrected Opposition to Defendant's JMOL on February 10, 2020, which the Court has considered in this Order. (ECF No. 683.) Unless otherwise noted, all citations to Plaintiffs' Opposition refer to the Corrected Opposition, ECF No. 683.

No. 699.[3]) In setting the post-trial briefing schedule, the Court indicated that it would take the matter under submission following the filing of reply motions. (Order, ECF No. 639 at 5; *see also* Fed. R. Civ. P. 78(b).) For the following reasons, the Court **DENIES** Defendant's Motion for Judgment as a Matter of Law Pursuant to Fed. R. Civ. P. 50(b) and/or a New Trial Pursuant to Fed. R. Civ. P. 59 [ECF No. 659].

I. BACKGROUND

This is a patent infringement action involving U.S. Patent No. 7,446,190 ("the '190 Patent"), titled "Nucleic Acids Encoding Chimeric T Cell Receptors." The '190 Patent issued on November 4, 2008 and incorporates a provisional application filed on May 28, 2002. ('190 Patent Caption.) The claimed invention provides "nucleic acid polymer encoding [] chimeric TCR's [T Cell Receptors] . . . ." ('190 Patent, col. 2:11–14.) The chimeric TCRs encoded by the claimed invention "combine, in a single chimeric species, the intracellular domain of CD3 ζ-chain ("zeta chain portion"), a signaling region from a costimulatory protein such as CD28 with a binding element that specifically interacts with a selected target." ('190 Patent, col. 2:14–18.) These TCRs are designed to "specifically interact[] with a cellular marker associated with target cells," resulting in the stimulation of a T cell immune response to the target cells. ('190 Patent, col. 2:30–36.)

Plaintiffs initiated this action on October 18, 2017, alleging that Defendant infringes the '190 Patent

[3] Unless otherwise noted, all citations to Defendant's Reply refer to the sealed Reply, at ECF No. 709.

through the use, sale, offer for sale, or importation of one of Defendant's immunotherapy treatments, YESCARTA®. YESCARTA® is described as a "therapy in which a patient's T cells are engineered to express a chimeric antigen receptor (CAR) to target the antigen CD19, a protein expressed on the cell surface of B-cell lymphomas and leukemias, and redirect the T cells to kill cancer cells." (Second Amended Complaint ("SAC") ¶ 18, ECF No. 484.) Plaintiffs assert that YESCARTA® infringes the '190 Patent by utilizing nucleic acid polymers encoding chimeric TCRs within the scope of the '190 Patent claims. (SAC ¶ 26.) Defendant, in turn, filed counterclaims seeking declaratory judgments of non-infringement and invalidity of the '190 Patent. (*See generally*, Answer to SAC and Counterclaims, ECF No. 617.)

On October 9, 2018, the Court issued the Claim Construction Order construing, *inter alia*, the following claim term:

Claim Term	Court's Construction
"the amino acid sequence encoded by SEQ ID NO:6"	**Before the Certificate of Correction:** Amino Acids 113–220 of CD28 (starting with lysine (K)) **After the Certificate of Correction:** Amino Acids 114–220 of CD28 (starting with isoleucine (I))

(Claim Construction Order, ECF No. 100.) In relevant part, the Court's Claim Construction Order was based upon the following: (1) Applicants filed Provisional Application No. 60/383,872 and incorporated a journal article identifying "nucleotides 336–660 of CD28"; (2) Applicants subsequently filed a non-provisional patent application incorporating the same language and defining SEQ ID NO:6 in accordance with this description; (3) following approval by the patent examiner, applicants filed a Request for Continuing Examination ("RCE") noting an error in the presentation of SEQ ID NO:6 and requesting removal of the first four nucleotides, such that the first codon corresponds to isoleucine, amino acid 114 of CD28, rather than lysine, amino acid 113; (4) the Patent and Trademark Office ("PTO") rejected the amended listing as damaged or unreadable; (5) the applicants provided a new copy again reflecting the changes to the presentation of SEQ ID NO:6; (6) the PTO again rejected the filing, for failure to comply with PTO formatting requirements; (7) the applicants for the third time filed an amended sequence listing, however the listing did not reflect the changes to SEQ ID NO:6; (8) the '190 Patent initially issued without the amendments contained in the RCE; (9) in mid-2013, the patentees requested, and the PTO granted, a CoC that altered the definition of SEQ ID NO:6 from the sequence beginning with nucleotide 336 (encoding amino acid 113) of the CD28 protein to the sequence beginning with nucleotide 340 (encoding amino acid 114) of the CD28 protein. (*Id.*)

On December 13, 2019, the jury entered a unanimous verdict in favor of Plaintiffs, finding: (1) Defendant had not proven by clear and convincing evidence that

the Certificate of Correction was invalid, (2) Defendant had not proven by clear and convincing evidence that any of claims 3, 5, 9, and 11 of the '190 Patent was invalid for lack of enablement or written description, (3) Plaintiffs proved by a preponderance of the evidence that Defendant's infringement of the corrected claims of the '190 Patent was willful, and (4) Plaintiffs proved by a preponderance of the evidence the damages owed were a $585,000,000 upfront payment, and 27.6% running royalty. (Jury Verdict, ECF No. 594.)

Following the jury's return of the verdict, the Court set a post-trial briefing schedule for both parties and deferred entry of judgment. (Order, ECF No. 639.)

II. LEGAL STANDARDS

A. Judgment as a Matter of Law

The Federal Rules of Civil Procedure provide for the issuance of judgment as a matter of law upon a motion "made at any time before the case is submitted to the jury." Fed. R. Civ. P. 50(a)(2). The Rules further provide that "[i]f the court does not grant a motion for judgment as a matter of law under Rule 50(a), the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion." Fed. R. Civ. P. 50(b). Moreover, "[n]o later than 28 days after the entry of judgment—or if the motion addresses a jury issue not decided by a verdict, no later than 28 days after the jury was discharged—the movant may file a **renewed** motion for judgment as a matter of law and may include an alternative or joint request for a new trial under Rule 59." Fed. R. Civ. P. 50(b) (emphasis added).

"A Rule 50(b) motion for judgment as a matter of law is not a freestanding motion. Rather, it is a renewed Rule 50(a) motion." *E.E.O.C. v. Go Daddy Software, Inc.*, 581 F.3d 951, 961 (9th Cir. 2009). Thus, "[u]nder Rule 50, a party must make a Rule 50(a) motion for judgment as a matter of law before a case is submitted to the jury," and "[i]f the judge denies or defers ruling on the motion, and if the jury then returns a verdict against the moving party, the party may renew its motion under Rule 50(b)." *Id.* "Because it is a renewed motion, a proper post-verdict Rule 50(b) motion is limited to the grounds asserted in the pre-deliberation Rule 50(a) motion." *Id.* "Thus, a party cannot properly 'raise arguments in its post-trial motion for judgment as a matter of law under Rule 50(b) that it did not raise in its preverdict Rule 50(a) motion.'" *Id.* (citing *Freund v. Nycomed Amersham*, 347 F.3d 752, 761 (9th Cir. 2003)). Notwithstanding this requirement, "Rule 50(b) 'may be satisfied by an ambiguous or inartfully made motion' under Rule 50(a)." *Id.* (citing *Reeves v. Teuscher*, 881 F.2d 1495, 1498 (9th Cir. 1989)).

A district court can grant a Rule 50 motion for judgment as a matter of law only if "there is no legally sufficient basis for a reasonable jury to find for that party on that issue." *Jorgensen v. Cassiday*, 320 F.3d 906, 917 (9th Cir.2003) (quoting *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 149 (2000)). "In entertaining a motion for judgment as a matter of law, the court may not make credibility determinations or weigh the evidence." *Krechman v. Cty. of Riverside*, 723 F.3d 1104, 1110 (9th Cir. 2013) (citations omitted). The evidence must be viewed "in the light most favorable to the non-moving party, and all

reasonable inferences are drawn in that party's favor." *El-Hakem v. BJY Inc.*, 415 F.3d 1068, 1072 (9th Cir. 2005).

B. New Trial

Rule 59(a) provides that "[t]he court may, on motion, grant a new trial on all or some of the issues . . . after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). "Unlike with a Rule 50 determination, the district court, in considering a Rule 59 motion for new trial, is not required to view the trial evidence in the light most favorable to the verdict. Instead, the district court can weigh the evidence and assess the credibility of the witnesses." *Experience Hendrix L.L.C. v. Hendrixlicensing.com Ltd.*, 762 F.3d 829, 842 (9th Cir. 2014) (citing *Kode v. Carlson*, 596 F.3d 608, 612 (9th Cir. 2010) (per curiam)). "However, a district court may not grant a new trial simply because it would have arrived at a different verdict." *Silver Sage Partners, Ltd. v. City of Desert Hot Springs*, 251 F.3d 814, 819 (9th Cir. 2001) (citing *United States v. 4.0 Acres of Land*, 175 F.3d 1133, 1139 (9th Cir. 1999)). A new trial is appropriate under Fed. R. Civ. P. 59 "only if the jury verdict is contrary to the clear weight of the evidence." *DSPT Int'l, Inc. v. Nahum*, 624 F.3d 1213, 1218 (9th Cir. 2010).

III. DISCUSSION

Defendant moves for judgment as a matter of law on: (A) its written description defense; (B) its enablement defense; (C) its defense that the CoC is invalid; (D) its good-faith defense to willfulness; and (E) the opinion of Plaintiffs' damages expert, Dr. Ryan Sullivan.

Defendant also: (F) moves for a new trial based on: (1) the verdict form; (2) Dr. Sullivan's testimony; (3) large figures; (4) the written description instruction; (5) Plaintiffs' IPR statements; (6) Plaintiffs' introduction of certain evidence; (7) the time limit; and (8) cumulative prejudice. Each ground is addressed below.

A. Written Description

Defendant argues that the '190 Patent claims are invalid for lack of written description as a matter of law. (JMOL 2 (citing *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350–51 (Fed. Cir. 2010) (*en banc*) (holding adequate description of a genus requires disclosure of either: (1) a representative number of species falling within the genus, or (2) structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus)).) Defendant further argues that the '190 Patent claims a broad genus that covers an enormous number of functionally-identified CAR constructs. (JMOL 3.) Defendant further argues that the CAR-T field was new and unpredictable when the '190 Patent was filed, and remains unpredictable even today. (JMOL 4.) Similarly, the use of single chain variable fragments ("scFvs") in CARs was also unpredictable. (*Id.*) Because the '190 Patent claims a broad genus, and because the CAR-T field was new and unpredictable, the written description does not satisfy the two-part test presented in *Ariad*. (*Id.*) Specifically, the specification does not adequately describe the two CARs disclosed as examples because it does not disclose a DNA or amino acid sequence, and for one example, does not disclose the amino acid sequence of the scFv. (JMOL 5.) Moreover, even

looking outside the specification (which would be improper), no published materials would permit a person of ordinary skill in the art ("POSITA") to identify the scFvs. (*Id.*) Additionally, the two CARs disclosed as examples, even if they were adequately disclosed, would not be representative of the billions of CAR constructs claimed in the '190 Patent. (JMOL 6.) For example, in *AbbVie*, the Federal Circuit determined that there was no evidence demonstrating any antibody described in the patent was structurally similar to the accused product (which was a member of the claimed genus). (JMOL 7 (citing *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014)).) Similar to *AbbVie*, the scFvs disclosed in the '190 Patent are not representative of the claimed genus, because YESCARTA® and other species encompassed within the genus are structurally and functionally different. (JMOL 8.) Nor does the specification disclose common structural features sufficient to allow a POSITA to visualize or recognize members of the genus. (JMOL 8–9.) Plaintiffs' expert Dr. Brocker's testimony to the contrary was insufficient. He testified only to common structural features (such testimony is insufficient under the law), and he applied the wrong legal standard (first by assuming the scFv portion was not part of the claimed invention, and by conflating the written description and enablement requirements). (JMOL 9–10.)

Plaintiffs respond that Defendant cannot meet its burden of demonstrating the evidence overcoming the presumption of validity is clear and convincing, and undisputed. (Opp. 2.) The record demonstrates scFvs were an old and well-known component of CARs, and

the Federal Circuit has already determined scFvs (as a CAR component) were known as early as 1995. (*Id.* (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005)).) The '190 Patent discloses a novel combination of known elements—a binding element (*i.e.*, scFv), and signaling element (CD28 and zeta chain). (Opp. 3.) At the time the '190 Patent was filed, scFvs were routine and well-known in the CAR field (as demonstrated by papers, witness testimony, and expert witness testimony), thus the law states that the specification should preferably omit routine technology that is well known. (Opp. 4–6.) Specifically, CD19-specific scFvs were shown to be well known in the art, even by Defendant's own witnesses. (Opp. 6.) The '190 Patent additionally provides examples of scFvs that can be used with the invention, and real-world evidence shows that POSITAs did make the three-part CAR claimed in the '190 Patent. (Opp. 7.) Plaintiffs further respond that the Federal Circuit recognized in 1995 that scFvs were a well-known component of CARs, which Defendant itself relied upon to overcome a written description objection during prosecution. (Opp. 8–9 (citing *Capon*, 418 F.3d at 1439 and other authority).) Plaintiffs further respond that Defendant baldly mischaracterizes the '190 Patent's claims as functional genus claims by virtue of their scFv element, but the claims are composition claims reciting a three-part structure. (Opp. 9–10.) Plaintiffs further argue the *Ariad* test is inapplicable here because the test is relevant to novel compounds, not those known in the art. (Opp. 11–12.) Even if relevant, *Ariad* is satisfied because the patent discloses the CAR backbone, two scFvs successfully

used with the backbone, additional scFvs, and the CD19 scFv is representative of scFvs in the context of CARs. (Opp. 12.) Defendant's contention that the two examples are not representative is unpersuasive because the claims recite scFvs as part of a CAR, not any possible scFv chain. (Opp. 13.) Plaintiffs further argue that Defendant's argument that Dr. Brocker used the wrong test is forfeited, because it was not raised in Defendant's Rule 50(a) motion. (Opp. 14.) Even if procedurally proper, Defendant misrepresents Dr. Brocker's testimony—he actually testified that single-chain scFvs had been known and were separate from the Sadelain two-part backbone invention. (Opp. 14–15.)

Defendant replies that Dr. Sadelain only made and disclosed two CARs in the '190 Patent, and for those two CARs, the patent does not disclose the structure of the scFv portion. (Reply 1.) Plaintiffs suggest the scFv portion is not the crux of the invention, where the law states that written description is the same whether the claim is to a novel compound or a novel combination of known elements. (*Id.*) Plaintiffs cannot satisfy *Ariad* where the specification discloses only two incomplete examples, each claim covers an enormous number of CARs, the CARs are diverse, the field was new and unpredictable, the two disclosed examples are not representative, and the patent does not describe structural features common to scFvs targeting CD19. (Reply 2–6.) Defendant further replies that knowledge outside the patent cannot substitute for an adequate description of the claims, and *Capon* did not hold there was sufficient written description for the claimed CARs. (Reply 6–7.)

In order for Defendant to succeed on its JMOL, it must show that the *Ariad* test was satisfied by clear and convincing, undisputed evidence. *Ariad* holds that "a sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus. 598 F.3d at 1350 (citations omitted). *Ariad* further recognizes that the inquiry is a highly factual one that "will necessarily vary depending on the context," and 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." *Id.* at 1351. The '190 Patent claims a three-part CAR, where the two-part Sadelain backbone permitted T-cells to proliferate, permitting patients' immune systems to continue targeting tumor cells following a single treatment. The parties' written description dispute centers around the sufficiency of the written disclosure for the third piece of the CAR—a binding element, which is limited to scFvs in the asserted claims.

During trial, both parties presented conflicting evidence for scFvs for both *Ariad* factors. ***First***, Plaintiffs presented evidence and testimony that a representative number of species was disclosed. Plaintiffs highlighted the '190 Patent's disclosure of several scFvs (two directed to PSMA and CD19). Plaintiffs also presented testimony that scFvs were well-known in the art. *See UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 648 (E.D. Tex. 2017)

("[W]hen a genus is well understood in the art and not itself the invention but is instead a component of the claim, background knowledge may provide the necessary support for the claim."). Plaintiffs presented testimony and argument that scFvs had been made since at least 1988, and CARs utilized scFvs as binding elements beginning in the early 1990s. Plaintiffs' expert Dr. Brocker testified that a paper he authored in 1993 noted the interchangeability of scFvs in CAR design. A separate paper authored by Krause and Finney stated scFvs had been successfully used as the binding element in CARs in 1998. Plaintiffs further presented testimony that the '190 Patent disclosed the Orlandi method, which could be used as a "cookbook" to make any desired scFv. Plaintiffs further presented testimony that a dishwasher from Dr. Brocker's lab in fact used Orlandi's method to make an scFv that Dr. Brocker used in his research.

Second, Plaintiffs presented evidence and testimony that a POSITA would be able to recognize the members of the genus, based on the disclosure of structural features of scFvs. Plaintiffs presented evidence that the '190 Patent describes two specific scFvs that share common structural features. As discussed in the preceding paragraph, Plaintiffs also presented evidence that scFvs were well known in the art, including the common structural features they share. In light of the testimony presented, including the disclosures within the four corners of the patent, Defendant cannot satisfy its burden of showing the *Ariad* test elements were undisputed.

That Defendant disputes Plaintiffs' testimony and evidence, or presented its own conflicting evidence, is

not grounds for JMOL. *See Krechman*, 723 F.3d at 1110 (court may not make credibility determinations or weigh the evidence during JMOL).

Thus, the Court denies Defendant's JMOL on written description.

B. Enablement

Defendant argues the '190 Patent does not enable the full scope of the claims as a matter of law because the art was nascent and unpredictable, the claims' structural limitations cover an untold number (millions of billions) of constructs, only a subset of those constructs bind to a particular target (but the '190 Patent does not disclose which), and the effective constructs must be discovered via screening. (JMOL 11–13 (citing *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019)).) Regarding screening, Plaintiffs presented no testimony regarding the effort this would take in the 2002 timeframe. (JMOL 13.) Defendant's expert, Dr. Garcia testified that making and testing a single scFv could take months to more than a year. (*Id.*) Juno's efforts to create a human scFv for CD19 demonstrate the time and effort required, where Juno screened one billion scFvs to identify three candidates for use in a CAR. (*Id.*) Although Plaintiffs' expert Dr. Brocker testified that the synthesis and testing were so easy that a dishwasher could perform them, the mere fact that those steps were required for claims covering a large number of compounds in an unpredictable field demonstrates that the claims were not enabled. (JMOL 14.)

Plaintiffs respond that Defendant cannot demonstrate that it proved enablement by clear and convincing, undisputed evidence. (Opp. 15.) Specifically, Defendant did not dispute the '190 Patent explains how to make and test the two-part Sadelain backbone, it challenges the third element of scFvs, which were not a new and unpredictable field. (Opp. 15–16.) Dr. Brocker testified that making and testing scFvs was not more than standard laboratory procedure, and the Sadelain backbone has worked with every scFv with which it was tested. (Opp. 16.) Dr. Garcia's testimony to the contrary was generalized and rebutted by Dr. Brocker's testimony and other evidence. (Opp. 17.)

Defendant replies that Plaintiffs' argument addresses only whether a POSITA could make a single embodiment, but the correct legal inquiry is the level of experimentation required to practice the full claim scope. (Reply 8.) Defendant argues that Plaintiffs started with a pool of a billion scFvs to identify only 60 that bound to CD19, Plaintiffs have no evidence that functioning of scFvs in the CAR field was predictable in 2002, Plaintiffs point only to generic techniques to produce an scFv, Plaintiffs do not rebut Dr. Garcia's testimony that making and testing a single functional scFv for a CAR could make months, if not years, with a success rate of 25%, and Dr. Sadelain's testimony that he made up to 30 functional CARs with different scFvs after filing his patent did not disclose the time and effort (or failures) relating to those CARs. (Reply 8–9.)

The enablement inquiry turns on whether a POSITA would have to engage in undue experimentation to make and use the claimed invention. *In re Wands*, 858

F.2d 731, 737 (Fed. Cir. 1988). At trial, Plaintiffs presented evidence and testimony that a POSITA would not. Specifically, Plaintiffs presented testimony including that in 2002, scFvs were not a new and predictable field, that the steps to create an scFv were straightforward, that the Sadelain backbone has been successfully used with a number of scFvs, that Plaintiffs' expert did not know a single scFv that would not work with the Sadelain backbone. Defendant's arguments to the contrary were appropriate for cross-examination, not for JMOL. Drawing all inferences in Plaintiffs' favor, there was a legally sufficient basis for the jury's verdict.

Thus, the Court denies Defendant's JMOL for enablement.

C. CoC

Defendant argues that the CoC is invalid as a matter of law. Although the question of whether a clerical or typographical error (or how to correct the error) was clearly evident is a question of fact, judgment as a matter of law is warranted when the material facts are undisputed. (JMOL 14–15 (citing *Cent. Admixture Pharm. Servs., Inc. v. Advanced Cardiac Sols. P.C.*, 482 F.3d 1347 (Fed. Cir. 2007)).) Here, no reasonable juror could have found the CoC valid because a POSITA would not know which of two possible costimulatory sequences was claimed—amino acids 113–220 (originally-issued patent), or amino acids 114–220 (as amended by CoC). (JMOL 15.) Defendant argues none of the original claims, specification, or cited publications unambiguously point to disclosure of amino acids 114–220. (JMOL 15–16.) The specification lists both sequences and does not

disclose a clearly evident correction and clearly evident error. (JMOL 16–17.) The prosecution history is also ambiguous, because although the patentee submitted an updated sequence listing with the RCE, the scientific explanation provided by patentee for correcting the error did not indicate a clear error as to SEQ ID NO:6. (JMOL 17.) Specifically, there was no clear error because the sequence in SEQ ID NO:6 need not be divisible by three, the stop codon at the end of the sequence is irrelevant to whether the first encoded amino acid is correct, the RCE's sequence merely identified an inconsistency from original SEQ ID NO:6, the RCE's statement that the correction conformed to the construct used in the examples is incorrect because the specification still described one example as beginning with nucleotide 336 (corresponding to amino acid 113), not nucleotide 340 (corresponding to amino acid 114). (JMOL 17–19.) Patentee's submissions containing the disclosure of amino acids 114–220 were rejected for formal defects, until ultimately the 336–663 nucleotide listing was reintroduced. (JMOL 19–20.) Plaintiffs did not introduce evidence creating a genuine dispute of material fact, based on the foregoing. (JMOL 20.) Instead, Plaintiffs' evidence impermissibly relied on material outside the intrinsic record, such as Dr. Schuetz, a third party, who requested Dr. Sadelain's complete sequence (not disclosed in the patent) before determining the error, Plaintiffs' expert Dr. Quackenbush did not give import to disclosures unfavorable to his opinion that amino acids 114–220 were intended, Dr. Quackenbush's opinions contradicted the prosecution history, although Plaintiffs argued Dr. Sadelain only worked on CARs

beginning with amino acid 114 (not disclosed in the intrinsic record), an article that formed the basis for the patent filing contained inconsistencies (including disclosure of sequences starting with both 113 and 114). (JMOL 20–23.) The Court already rejected Plaintiffs' arguments during claim construction, and the relevant evidence at trial confirmed the Court's findings, thus the Court should enter JMOL that the CoC is invalid. (JMOL 23.)

Plaintiffs respond that there were material factual disputes for the jury to decide, and Plaintiffs presented the testimony of Dr. Quackenbush that a POSITA would have understood SEQ ID NO:6 to begin at amino acid 114 (based on the prosecution history, including the RCE). (Opp. 18.) Defendant cites no cases finding a CoC invalid where the prosecution history contains a request for the correction in the CoC. (Opp. 19.) Defendant likewise points to scattered references to nucleotides encoding amino acid 113 and an extraneous sequence beginning with lysine, but these references do not serve as clear and convincing evidence (nor is it undisputed) of the invalidity of the CoC, where Plaintiffs presented evidence and testimony to the contrary. (Opp. 20.) Specifically, Dr. Quackenbush explained that the RCE showed four extraneous nucleotides crossed out at the beginning of corrected SEQ ID NO:6, and further explained why the correction was necessary. (Opp. 20–21, 22–23.) Dr. Quackenbush further testified that the '190 Patent itself would have indicated to a POSITA the four initial nucleotides should be removed. (Opp. 21–22.) Moreover, Defendant's argument is forfeited, because it was not raised in its Rule 50(a) motion, and its arguments

regarding the correctness of the RCE are irrelevant to the CoC inquiry. (Opp. 23.) Plaintiffs further respond that Defendant's criticisms of Dr. Quackenbush (besides being improper because they were also not raised in their Rule 50(a) motion), were proper considerations for cross-examination, not JMOL. (Opp. 24–25.) Plaintiffs further respond to the criticisms by responding that Dr. Quackenbush did not ignore certain evidence, nor did he rely on extrinsic evidence. (Opp. 27.) Plaintiffs further respond that Dr. Schuetz's testimony that he discovered a mistake based on information outside the intrinsic record does not mean that Dr. Schuetz would not have identified an error based on the intrinsic record, Dr. Bot admitted he did not review the RCE or prosecution history in determining SEQ ID NO:6 began with amino acid 113, and Dr. Junghans' testimony that he made a CAR using amino acids 113–220 is irrelevant because he testified he had not read the '190 Patent, let alone the full intrinsic record at that point. (Opp. 27.)

Defendant replies that a CoC is improper for broadening the scope of a claim, where SEQ ID NO:6 did not contain a correctable error. (Reply 9–10.) Defendant further replies that the claims specified that SEQ ID NO:6 began with amino acid 113. (Reply 10.) The RCE does not resolve any purported ambiguity because the RCE was superseded by the patent prosecutor filing substitute sequence listings showing SEQ ID NO:6 to begin with amino acid 113, a POSITA would not uncritically accept the statements in the RCE, and the RCE does not show the original sequence had a clearly evident error. (Reply 11–12.) Dr. Quackenbush's testimony

contradicts the intrinsic record and the Court's claim construction ruling. (Reply 12.) Defendant further replies that real-world evidence, such as MSK's failure to notice the error for four and a half years, Dr. Bot's and Dr. Junghan's interpretations as beginning with amino acid 113, and Dr. Schuetz's tainted testimony as a result of meeting with counsel, weighs against such a finding. (Reply 13.)

For Defendant to prevail on its JMOL finding the CoC invalid, Defendant must show there was no legally sufficient basis for a reasonable jury to find in its favor. *Jorgensen*, 320 F.3d at 917. "Invalidating a certificate of correction for impermissible broadening therefore requires proof of two elements: (1) the corrected claims are broader than the original claims; and (2) the presence of the clerical or typographical error, or how to correct that error, is not clearly evident to one of skill in the art." *Central Admixture Pharm. Servs., Inc. v. Adv. Cardiac Sols., P.C.*, 483 F.3d 1347, 1353 (Fed. Cir. 2007). The Court previously ruled on the first element when it determined that the CoC altered the starting amino acid encoded by SEQ ID NO:6. (*See* Markman Order, ECF No. 100, at 17 (starting at amino acid 113 before the CoC, amino acid 114 after the CoC).) The Court previously declined to rule on the second element when it denied Defendant's motion for summary judgment of noninfringement, finding that "a clear and genuine dispute of fact" existed regarding whether "the error and correction would have been clearly evident to a POSITA examining the record." (Summary Judgment Order, ECF No. 246, at 7.) At trial, both parties presented extensive testimony and evidence regarding the validity of the CoC. Now, in

order for Defendant to prevail on its JMOL, it must show that despite Plaintiffs' extensive testimony and evidence, there was no sufficient basis for the jury's finding.

The Court finds that Plaintiffs presented sufficient testimony on which a jury could base its determination. It is undisputed that during patent prosecution, Plaintiffs sought an RCE in which it stated that "an error occurred in the presentation of Seq. ID No. 6," and that "the amino acids of the CD28 Sequence (144–220 contained a typographical error and should have been 114–220)." (RCE, Sept. 4, 2007.) Plaintiffs also submitted an amended SEQ ID NO:6 crossing out the first four nucleotides.

~~caaa~~attgaa

(RCE, Sept. 4, 2007.) The amended listing, and subsequent attempted amendment were both rejected for improper formatting. The third attempt reverted back to the original SEQ ID NO:6. Plaintiffs' expert Dr. Quackenbush then testified that as a POSITA, he understood the intrinsic record (including the '190 Patent claims, specification, and prosecution history) to show the uncorrected SEQ ID NO:6 solely as a result of a mistaken file submission, and that the RCE's unambiguous correction clearly showed the amino acid sequence beginning at 114. (Tr. 1149:7–1152:10.) Dr. Quackenbush further testified that the RCE stated that the first codon is "att," which corresponds to a sequence starting at position 114. (Tr. 1151:8–18.) Although there was additional testimony and evidence supporting Plaintiffs' position, the Court finds that at least these specific

examples provide a basis for the jury to have concluded the CoC was valid.

Defendant raises a number of points as to the merits of Plaintiffs' arguments, such as various citations in the specification to a sequence beginning at the equivalent of amino acid 113, the ambiguity of the RCE and subsequent amended submissions, the inadequacy of testimony by Dr. Schuetz, the bias of Dr. Schuetz, Dr. Quackenbush's failure to properly consider certain aspects of the patent and the prosecution history, an article by Dr. Sadelain, Plaintiffs' failure to notice the error for four and a half years, and the conflicting testimony of Dr. Bot and Dr. Junghans. But in light of the totality of the testimony presented, the Court cannot determine that there did not exist a genuine issue of fact whether a POSITA would have recognized a clearly evident error and solution, based on the intrinsic record of the '190 Patent. *See Krechman*, 723 F.3d at 1110 ("In entertaining a motion for judgment as a matter of law, the court may not make credibility determinations or weigh the evidence."); *see also El-Hakem*, 415 F.3d at 1072 (holding the evidence must be viewed "in the light most favorable to the non-moving party, and all reasonable inferences are drawn in that party's favor.").

Thus, the Court denies Defendant's JMOL for a finding that the CoC is invalid.

D. Willfulness

Defendant argues Plaintiffs failed to show Defendant launched YESCARTA® without doubts about its validity or any notion of a defense. (JMOL 24.) Plaintiffs argued Defendant failed to present

witnesses stating they did not believe Defendant infringed, but Defendant was not permitted to present such witnesses because it asserted privilege. (*Id.*) Plaintiffs also focused on communications between Dr. Sadelain with Dr. Rosenberg (a physician at the National Cancer Institute), Dr. Belldegrun's communications with Dr. Dash, and Defendant's filing of an IPR in 2015. (*Id.*) However, these events took place years before Gilead acquired Defendant and decided to launch YESCARTA®. (*Id.*) When sued, Defendant promptly raised the defenses it raised at trial, and no evidence at trial suggested Defendant lacked a good-faith belief in its defenses. (*Id.*)

Plaintiffs respond that Defendant cannot show no reasonable jury could have concluded Defendant's infringement was willful. (Opp. 28.) Defendant cannot do this where Plaintiffs introduced evidence that Defendant knew its collaborators copied the Sadelein backbone, tried to license the '190 Patent unsuccessfully, tried to invalidate the '190 Patent unsuccessfully, and then to commercialize YESCARTA® anyway. (*Id.*) The law considers conduct pre-dating infringement as a factor. (Opp. 28–29.) Dr. Bot's excluded homology analysis was excluded because it was superseded by other events, including advice of counsel and Defendant's licensing and IPR attempts, which rendered the evidence irrelevant, or at the very least, prejudicial. (Opp. 29.) The Court precluded no other percipient witness testimony. (*Id.*) On Defendant's litigation defenses, Defendant forfeited this argument by not raising it in its Rule 50(a) motion, but even if not, proof of an objectively reasonable litigation defense is no longer a defense to willful infringement. (Opp. 29–

30.) Even if it was, Defendant did not offer any evidence of actual reliance. (*Id.*)

Defendant replies that the following undisputed facts foreclose a finding of willful infringement: no infringing conduct before the launch, Gilead (not Drs. Belldegrun or Jakobovitz) decided to launch YESCARTA®, and Plaintiffs offered no evidence regarding Gilead's willful infringement. (Reply 13–14.) These facts do not support a finding of willful infringement because the inquiry focuses on the mind of the infringer at the time of infringement. (Reply 14.)

For Defendant to prevail of its JMOL finding no willful infringement, it must show that no reasonable jury could have concluded that Defendant acted despite a risk of infringement known or so obvious that it should have been known to the accused infringer. The conduct is required to be wanton, malicious, or in bad faith. *See SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295 (Fed. Cir. 2019) (clarifying the standard for willful infringement set forth in *Halo Elecs., Inc. v. Pulse Elecs, Inc.*, 136 S. Ct. 1923, 1932 (2016)). The infringer's state of mind is determined at the time of infringement, but conduct predating infringement may be relevant to determine the infringer's state of mind at the time of infringement. *Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1353–54 (Fed. Cir. 2018).

The Court finds that Plaintiffs presented sufficient evidence of willfulness that a reasonable jury could find in its favor. Plaintiffs presented evidence and testimony that Defendant knew that Dr. Rosenberg from National Cancer Institute ("NCI") copied

Dr. Sadelain's backbone, as demonstrated by Defendant's attempting to be the first to license and to invalidate the '190 Patent. Plaintiff's fact witness Dr. Dash testified that Dr. Belldegrun was so desperate to pursue a license to the '190 Patent that he appeared at her office, despite not having a meeting. Dr. Jakobovitz similarly testified that Dr. Belldegrun met with Plaintiffs in an attempt to license the '190 Patent. Plaintiffs further argued that Defendant's filing of the IPR against the '190 Patent demonstrated the importance of the '190 Patent to Defendant. In light of at least these examples of testimony and evidence, a reasonable jury could have entered a finding of willfulness.

Defendant's argument that it was precluded from introducing fact witness testimony relating to its belief of non-infringement does not change this outcome. Dr. Bot's homology analysis, performed in 2012, was excluded as having little relevance to the determination of willfulness in 2017, where Defendant subsequently obtained advice of counsel, attempted to license the '190 Patent, and filed an IPR against the '190 Patent. Thus, exclusion of Dr. Bot's testimony was not because Defendant claimed privilege over its advice of counsel. It was because Dr. Bot's analysis bore little relevance to the willfulness determination where it was superseded by other events, and what little relevance it did bear was outweighed by prejudice.

Finally, Defendant's argument that Gilead, not Defendant, was the one who decided to launch YESCARTA® does not provide a sufficient basis for finding that no reasonable jury could have determined Defendant willfully infringed YESCARTA®. The

testimony regarding Dr. Rosenberg, in addition to the testimony of Dr. Dash, Dr. Sadelain, Dr. Belldegrun, and Dr. Jakobovitz weighs in favor otherwise.

Thus, the Court denies Defendant's JMOL for a finding of no willful infringement.

E. Sullivan

Defendant argues Plaintiffs presented no legally or factually sufficient basis for damages, and the proper award is the opinion Defendant's damages expert, Dr. Mohan Rao, would have presented at trial but was precluded from doing so by the Court's *Daubert* Order. (JMOL 25.) Dr. Sullivan testified his opinion was based upon a license agreement ("MSK License") between Juno and Memorial Sloan Kettering[4] ("MSK"), which contained a royalty rate up to 7.25%, $6.9 million upfront payment, and potential milestone payments of $3.35 million through first approval. (JMOL 26.) Juno and MSK also entered into a Side Letter Agreement, which set a maximum stock appreciation success fee of $150 million. (*Id.*) Defendant argues Dr. Sullivan's use of the success fee was not tied to use of the '190 Patent, where the Side Letter Agreement reflected a broad collaboration between an academic institution and a startup. (JMOL 27.) Dr. Rao testified that success fees are based on a relationship with an extensive collaboration, not between two mature pharmaceutical companies. (*Id.*) Even if the success payment was proper, Dr. Sullivan did not explain what portion should be allocated to the '190 Patent.

[4] MSK was dismissed as a party, but the Court did not preclude Plaintiffs from arguing that MSK would have been present at a hypothetical negotiation.

(JMOL 27–28.) Moreover, the expected value of the success fee depended on the parties' expectations about Juno's future appreciation, and Juno's auditors assigned the success fee a de minimis value. (JMOL 28.) Dr. Sullivan improperly substituted the appreciation of Defendant's stock for Juno's stock, and improperly opined Defendant would have agreed to pay the stock success fee. (JMOL 29.) The evidence showed that Defendant's and YECARTA®'s value was driven by factors other than the patented construct, including clinical trials, manufacturing, lymphodepletion, physician outreach, and future therapies. (JMOL 29–30.) Defendant further argues the 27.6% running royalty does not apportion, where Dr. Sullivan did not value other essential inputs, such as manufacturing, business risks, or significant features. (JMOL 31.) Defendant further argues Dr. Sullivan's upward adjustments (markup from previous Novartis license, competitor adjustment) were illogical and unsupported, including for his adjustment to the success fee. (JMOL 31–33.) Dr. Sullivan's opinion departed from comparable licenses and rendered his opinion out of line with economic reality. (JMOL 33–34.)

Plaintiffs respond that Dr. Sullivan's analysis was proper, and Defendant continues to rely on its own interpretation of the MSK License to argue no reasonable jury could have found in Plaintiffs' favor. (Opp. 31–32.) The MSK License (via Side Letter) provided a $150 million payment based upon a multiple of initial equity value, and witnesses testified the success payment was important, intended to provide upside without increasing equity burden, and has actually been paid. (Opp. 31–32.)

Unlike the stock swap which was excluded by the Court, the success payment does not exchange Juno's shares for Kite's shares. (Opp. 33.) Apportionment was built into the comparable license framework, and even if not, Dr. Sullivan testified that the success payments would have been triggered solely off the $6.2 billion valuation for YESCARTA® at the time of the hypothetical negotiation. (*Id.*) Plaintiffs further respond that the Court already rejected Defendant's challenges to Dr. Sullivan's adjustments, and even if not, these challenges are inappropriate for a JMOL, which does not permit a challenge to the sufficiency of the evidence. (Opp. 34.) Moreover, the evidence at trial supported Dr. Sullivan's adjustments: (1) the first adjustment (hypothetical negotiation between competitors, not collaborators) uses a ratio, which was supported by the testimony of Dr. Dash and Dr. Belldegrun (Opp. 35); (2) the second adjustment (hypothetical negotiation on the eve of launch) accounted for the greater anticipated economic harm Juno expected due to Defendant being on the eve of launch, which was supported by the testimony of Dr. Dash, Dr. Dulac, Dr. Gilbert, Dr. Belldegrun, and Mr. Bishop (Opp. 35–36.) Plaintiffs further respond that the jury's damages award did not violate apportionment requirements, because apportionment is built into the comparable-license approach, and Defendant's authority addresses multi-component electronic devices or software programs, not biotechnology. (Opp. 36–37.) Although Defendant touted other components as drivers of value (lymphodepletion, manufacturing), Plaintiffs introduced contradicting evidence (lymphodepletion leading to higher toxicities, first-generation

manufacturing process), based on which the jury could have concluded these other components added little overall value to YESCARTA®. (Opp. 37–38.)

Defendant replies that the damages award is not apportioned because the '190 Patent is only one component of YESCARTA® therapy and does not account for a complex manufacturing process. (Reply 15.) The superiority of Juno's manufacturing and lymphodepletion regimen for JCAR017 is not relevant to whether Defendant's processes have contributed to demand. (*Id.*) Apportionment was not built into Dr. Sullivan's analysis, where he did not use the same license rate as comparable license agreements, and Plaintiffs presented no evidence that Defendant would have been willing to pay the success fee for a naked license to the '190 Patent. (Reply 16–17.) Moreover, there was no evidence tying the success fee to the '190 Patent, as the payments consistent of various other components. (Reply 17.) Defendant further replies that the success fee was improper because Dr. Rao's testimony that a success fee would not be part of a negotiation between two companies was unrebutted, the success fee was not apportioned to the '190 Patent, there was no evidence to support the appropriateness of transfer of the equity-based fee to a different company at a different time, and the 30-fold increase in Defendant's stock resulted from factors other than the '190 Patent. (Reply 18.) Defendant further replies that Dr. Sullivan's adjustments were unreliable because they resulted in Defendant paying five times as much as Novartis, Juno did not expect competing for a significant part of the patent term, and the adjustment to the success fee was unjustified. (Reply 18–19.)

Regarding the success payment, the Court already ruled that Dr. Sullivan's testimony regarding the $150 million success payment was permissible. Unlike the stock swap that the Court excluded, the success payment did not substitute the shares of one company for another. Instead, the success payment was based on Dr. Sullivan's opinion that the parties at the hypothetical negotiation would have agreed to the term based on the inclusion of the term to the MSK License (via the Side Letter), and based on the parties' consideration of the $6.2 billion valuation of YESCARTA®. That Defendant disagreed with the inclusion of the success payment was a theory presented to and, based on the verdict, rejected by the jury.

Regarding apportionment (of both the licensing rate and success payment), the Federal Circuit has held that apportionment is built into the comparable license framework. *Commonwealth Sci. & Indus. Research Org. v. Cisco Sys.*, 809 F.3d 1295, 1303 (Fed. Cir. 2015). However, even assuming not, Plaintiffs presented testimony and evidence regarding the importance of the '190 Patent to YESCARTA®, and to Defendant's overall business. Specifically, Defendant tried unsuccessfully, multiple times, to develop non-infringing alternatives. Defendant's own witnesses (for example, Dr. Komanduri) likewise testified to the importance of the '190 Patent's CAR construct to CAR-T therapy. That Defendant argued other factors contributed to the success of YESCARTA® does not as a matter of law render the conclusion that apportionment is required, especially where Plaintiffs introduced conflicting testimony regarding the importance of the '190 Patent to YESCARTA®.

Plaintiffs' damages testimony properly considered apportionment, and there was thus a legally sufficient basis for the damages award by the jury.

Regarding Dr. Sullivan's adjustments, the Court already previously rejected Defendant's argument that they were improper. Dr. Sullivan testified that he performed two adjustments, one to account for the fact that the MSK License involved parties who would want to collaborate, whereas the hypothetical negotiation involved two commercial competitors less likely to be agreeable. The second adjustment accounted for Plaintiffs allowing a commercial competitor to enter the marketplace with a competing product before them. The Court finds that the testimony at trial provided a legally sufficient basis for the jury to enter Plaintiffs' damages award, including enhancements.

Thus, the Court denies Defendant's JMOL regarding Dr. Sullivan.

F. New Trial

1. Verdict Form

Defendant argues that in closing argument, it used a version of the verdict form that specified the period for the upfront payment should extend through trial. (JMOL 36.) Defendant asked the jury to disregard Plaintiffs' damages requests, as Plaintiffs requested damages extending beyond trial. (JMOL 36–37.) When Plaintiffs pointed to the term of upfront payment reflected in the form, the Court stated Defendant's verdict form was different from the one the Court would provide to the jury, and the Court-provided verdict form did not include the limitation for the upfront payment through trial. (JMOL 37.)

Defendant argues it was prejudiced because it could not present a payment number for damages past trial, and its credibility was tarnished. (JMOL 37–38.)

Plaintiffs respond that Defendant knew or should have known that it was using an incorrect version of the verdict form. (Opp. 38.) The Court repeatedly denied Defendant's requests to: (1) limit Plaintiffs' evidence and testimony during trial regarding the upfront payment to the time period through trial, and (2) revise the verdict form to include language limiting the upfront payment through trial. (Opp. 38–39.) The Court at every turn denied Defendant's requests, and Defendant itself had received at least five versions of the verdict form omitting the language. (Opp. 39.) It was thus unreasonable for Defendant to believe that the Court, after consistently rejecting Defendant's request throughout trial and earlier versions of the verdict form, would have accepted Defendant's request in a later verdict form without any comment or explanation on the record. (*Id.*) As the Court stated on the record, Defendant used the verdict form without first clearing it with the Court, and the jury was provided with the verdict form that was approved by the Court on the record with both parties. (*Id.*) Moreover, Defendant witnessed Plaintiffs arguing from the correct verdict form (that was displayed on multiple monitors at Defendant's counsel's table), yet Defendant remained silent regarding the verdict form (it was Plaintiffs who pointed out Defendant's use of the wrong form). (Opp. 39–40.) Plaintiffs further respond that there was no prejudice, where the Court had consistently denied Defendant's requests to limit damages through trial, and Defendant's trial presentation never deviated from its view that the

upfront payment should be prorated. (Opp. 40.) Moreover, Defendant did present Dr. Rao's upfront payment that was not prorated—$88 million. (*Id.*)

Defendant replies that it used the form it received, which included language it had previously requested. (Reply 19.) The Court's rulings throughout trial did not reject Defendant's request to limit damages through trial. (*Id.*) The parties discussed changes with the Court on the morning of December 11, and the form distributed included the changes discussed that morning, as well as a change to the term of upfront payment. (Reply 20.) The Court also incorporated other changes without comment on the record, including two agreed-upon changes and the order of questions presented. (Reply 20.) Defendant was prejudiced because it did not suggest to the jury to use the $88 million upfront payment, although the figure was noted. (Reply 20–21.) Defendant also notes its credibility was harmed by criticizing Dr. Sullivan's upfront payment. (Reply 21.)

As a preliminary matter, the Court notes that it has already ruled upon Defendant's motion for a new trial based on the verdict form. First, the Court ruled on Defendant's oral motion for a mistrial on the record:

> Mr. Dane, you used the verdict form without clearing it first with the Court. So I just want to make sure that is clear. And this — the verdict form that is being given to the jury today is the verdict form that was initially approved . . . by the Court on the record.

(Tr. 1543:18–24.) Second, the Court provided further explanation in a written order following trial. (Order, ECF No. 584.) Specifically, the Court found the

motion for mistrial did not bear merit because: (1) the Court's ruling on the record was clear, (2) the verdict form provided to the jury was consistent with the Court's ruling, and (3) any error was not prejudicial to Defendant where its damages expert consistently argued damages should be limited through trial, and (4) removal of the express limitation of damages through trial did not preclude the jury from entering the award argued by Defendant's counsel. (Order, ECF No. 584, at 2–3.)

Nevertheless, the Court once again addresses Defendant's request. On December 10, 2019, the Court heard arguments from both parties regarding the proposed verdict form. One issue was whether Question 5a (regarding the upfront payment for damages) should include a note expressly limiting damages through the end of trial. Defendant, who argued throughout trial the upfront payment should be prorated through the end of trial, requested inclusion of the language. Plaintiffs, who argued throughout trial the upfront payment should not be pro-rated, opposed Defendant's request. The Court distributed an updated verdict form at the end of December 10, 2019, which did not include the limitation. On December 11, 2019, the Court noted Plaintiffs had submitted an updated jury verdict form. (Tr. 1321:13–14; *see also* ECF No. 554.) The form did not include the limitation. Each party made an unopposed request to the verdict form unrelated to the limitation. (Tr. 1321:14–1322:8 (requesting changes re party names and willful infringement).) The Court granted both modifications to Plaintiffs' updated jury verdict form. (Tr. 1322:9–12.) Plaintiffs' updated jury verdict form, including the two unopposed

modifications, was the form provided to the jury for deliberation.

In light of these facts, the Court finds that its ruling on the record was clear and unambiguous. Plaintiffs' updated jury verdict form, with the two unopposed modifications, was the final verdict form. Although there appears to be some confusion as to the potential distribution of a different version,[5] Defendant was at least on inquiry notice that what it believed to be the final verdict form was incorrect, because: (1) the Court permitted Dr. Sullivan to testify to an un-prorated upfront payment during trial, (2) the Court never granted Defendant's request to include the limitation on the record, (3) the Court's previous revisions to the verdict form without comment in the record were for non-substantive, unopposed, changes, (4) in addition to the two proposed forms provided by the Court on December 10, Plaintiffs sent an additional two proposed forms to Defendant, none of which included the limitation, (5) Defendant received Plaintiffs' updated jury verdict form (omitting the language) the morning of December 11, (6) Plaintiffs' updated verdict form had only two unopposed modifications incorporated on the record, (7) Defendant had the opportunity to see Plaintiffs utilize a different verdict form, (8) Defendant had a full day to verify the correct form because it received the form on December 11, but did not use it during its closing argument until December 12, and yet (9) as noted on the record,

[5] Plaintiffs state that contrary to Defendant's assertion, they never received an incorrect version of the verdict form prior to closing arguments. However, given Defendant's counsel's declarations, the Court assumes for purposes of this Order that Defendant received an incorrect version of the verdict form.

Defendant did not confirm the final verdict form with the Court before using it.

Moreover, Defendant was not prejudiced, where it presented the same damages theory throughout trial. Removal of the limitation did not preclude the jury from awarding Defendant a pro-rated upfront payment. Defendant referenced what its expert used as the full upfront payment ($88 million), so the jury was aware what amount they could award, if they agreed with Defendant. (Tr. 1502:17–23 ("For the upfront payment, he used the $88 million that potentially could have been paid over the whole term of the Novartis license . . . , and then he prorated it . . . . And that's proper to prorate it because of the limited period of damages.").); *see also Ruvalcaba v. City of Los Angeles*, 167 F.3d 514 (9th Cir. 1999) (relief warranted only where prejudice results). As to Defendant's argument that its credibility was tarnished, the Court notes that Defendant's counsel's arguments regarding the entirety of its damages case (including comparable license analysis, upfront payment, reasonable royalty, revisiting testimony of Dr. Sullivan and Dr. Rao) totaled 11 minutes, out of the 142 minutes Defendant argued.[6] Thus, Defendant's showing of the verdict form during a portion of the 11 minutes, out of 142 minutes of closing argument, was minimal. While the Court does not believe Defendant's use of the verdict form caused any

[6] The Court's records indicate Defendant's counsel's closing argument on December 11 spanned 1:59pm (Tr. 1417:15) – 3:29pm (Tr. 1465:7), and on December 12 spanned 8:45am (Tr. 1475:5) – 9:37am (Tr. 1506:1). Counsel's damages argument on December 12 spanned 9:26am (Tr. 1498:24) – 9:37am (Tr. 1506:1).

prejudice, any prejudice was minimal considering the minimal use of the form, when compared to the entirety of Defendant's closing argument.[7], [8]

Thus, the Court again denies Defendant's motion for a new trial based on the verdict form.

2. Sullivan's Testimony

Defendant argues Plaintiffs introduced testimony about future harms not disclosed in Dr. Sullivan's report. (JMOL 38.) Dr. Sullivan was limited to past damages (not future anticipated harm), as the Court had limited Dr. Sullivan to testifying that his upfront payment was for harms realized at the hypothetical negotiation, not any future anticipated harm. (JMOL 38–39.) Dr. Sullivan then testified the $585 million upfront payment necessarily applied through the term of the '190 Patent, thus his conflicting opinions about whether his proposed royalty fully compensates for future harms are irreconcilable and provide an improper basis for the jury's award. (JMOL 39–40.) Dr. Sullivan's testimony regarding his royalty compensating for future harms prejudiced Defendant, who would otherwise have presented testimony

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[7] The Court notes the jury, while sending notes on other issues, did not send a note requesting clarification regarding the jury verdict form.

[8] The Court notes its view that Defendant's use of the incorrect verdict form was minimal and no more prejudicial than other events during Defendant's closing, such as Defendant presenting a slide listing its own witness as a witness for Plaintiffs. (Tr. 1459:10–14 ("Oh, and I apologize, . . . there is an error on the slide. Dr. Schuetz was, of course, not a Juno witness, so I apologize for that. He was one of our witnesses, and that should not indicate that he was a Juno witness.").)

regarding anticipated non-infringing constructs. (JMOL 40.)

Plaintiffs respond that the Court already rejected Defendant's argument that Dr. Sullivan's testimony exceeded the scope of his expert report. (Opp. 41.) Plaintiffs further respond that Dr. Sullivan testified consistent with his opinion that the upfront payment is for harms realized at the hypothetical negotiation, not compensation for future harm. (*Id.*) Plaintiffs further respond that Dr. Sullivan did not give conflicting opinions on lost profits—Defendant conflated the hypothetical negotiation with post-trial relief. (*Id.*) Plaintiffs further respond that Defendant was not prejudiced by not presenting anticipated non-infringing constructs, because Defendant's non-infringing alternatives theory was so weak and speculative that Defendant withdrew its theory before trial. (Opp. 41–42.)

Defendant replies that Plaintiffs did not identify other opinions of Dr. Sullivan where he contradicted himself so as not to give confusing and self-contradictory testimony. (Reply 21.) Defendant further replies that it was prejudiced by not pursuing a theory regarding non-infringing alternatives which the parties would have expected to be available after the time of trial. (*Id.*)

The Court holds that for the reasons noted above (*see supra*, Section III.E), even under the standard for a motion for a new trial where the Court may "weigh the evidence and assess the credibility of the witnesses," the Court cannot conclude that the jury verdict is contrary to the clear weight of the evidence. The Court already ruled on Defendant's *Daubert* motion to

exclude certain testimony by Dr. Sullivan and found that his testimony was not inconsistent with his disclosed opinion that the upfront payment is for "harms realized at the hypothetical negotiation." (ECF No. 659 at 39.) To the extent Defendant argues it was prejudiced by its inability to develop and present non-infringing alternatives that would exist post-trial, Defendant: (1) was in possession of evidence of non-infringing alternatives post-trial (*see* DX2011c.8 (multi-generation forecast for 2020); *see also* DX0125c (clinical trials)), (2) to the extent Dr. Sullivan's testimony was inconsistent, Defendant never requested reopening discovery to develop its purported non-infringing alternatives theory, (3) it remains unclear to this Court why Defendant would require discovery of its ***own*** non-infringing alternatives, and (4) Defendant had the opportunity to address any inconsistency in Dr. Sullivan's damages theory in its opposition to Plaintiffs' post-trial briefing re damages. (*See* ECF Nos. 672-2, 693.)

For these reasons, the Court denies Defendant's motion for a new trial based on Dr. Sullivan's testimony.

3. Large Figures

Defendant argues Dr. Sullivan's testimony was tied to large figures (projected profits, YESCARTA® valuation, negative impact to Juno, upfront payment from separate agreement, and royalty rates for late-stage technologies). (JMOL 41.) Defendant argues these figures were not apportioned, highly speculative, not sufficiently similar, and should not have been permitted, even as a check on the reasonableness of a damages award. (JMOL 42.)

Plaintiffs respond that the data points were highly relevant. As an initial matter, Defendant's failure to object to the admissibility of multiple data points to which it now objects, means it has waived its right to seek a new trial. (Opp. 42.) However, even if Defendant had not waived its right, each of the data points is relevant to the damages analysis. (Opp. 43.)

Defendant replies that it preserved its objections by moving *in limine* to preclude Plaintiffs from referring to high dollar figures Dr. Sullivan did not rely upon in his calculations. (Reply 21.) Plaintiffs then misrepresented to the jury large numbers as real anchors in the real world, skewing the jury's damages horizon. (Reply 22.) Defendant was also not permitted to introduce an estimated upfront payment between Juno and Celgene. (*Id.*)

As a threshold matter, Defendant failed to object to and receive a ruling on multiple figures it now disputes. *See* 11 Wright & Miller, Fed. Practice and Procedure § 2805 (3d ed. 2002) (stating a new trial will not be granted on issues not called to the court's attention, "unless the error was so fundamental that gross injustice would result"). True, Defendant filed a motion *in limine* to preclude generally testimony of "high dollar figures that Sullivan does not use in his calculations" (ECF No. 309 at 1, 12) (and the Court did in fact exclude all but one of the figures contained in the motion *in limine*) and filed objections "regarding projected or actual licensing figures that neither expert has relied upon," however these broad objections cannot satisfy the requirement for calling a court's attention to an inadmissible figure during live testimony.

Nevertheless, the Court determines on the merits that the figures presented by Plaintiffs do not warrant a new trial.

$7.1 billion projected profits through patent term. Although Defendant did not object to this figure during testimony, the Court determines that Gilead's projected profits for YESCARTA® through the term of the '190 Patent are a relevant consideration to the hypothetical negotiation, and specifically to what Plaintiffs would have considered paying. Defendant's argument that the figure should have been apportioned is an issue of fact appropriate for cross-examination, where Plaintiffs argued the '190 Patent was critical to YESCARTA®, and Defendant argued factors other than the '190 Patent contributed to the success of YESCARTA®.

$6.2 billion alleged value of YESCARTA®. The Court already rejected Defendant's motion *in limine* to exclude this figure, as it determined that Gilead's value assigned to YESCARTA® had a nexus to the accused product. (Order, ECF No. 473, at 9.) Furthermore, this figure is relevant as the value that Gilead attributed to YESCARTA®. Defendant's argument that the figure should have been apportioned is an issue of fact appropriate for cross-examination, where Plaintiffs argued the '190 Patent was critical to YESCARTA®, and Defendant argued factors other than the '190 Patent contributed to the success of YESCARTA®.

$1.3 billion projected annual negative impact to Juno. Although Defendant did not object to this figure during testimony, the Court determines that the negative annual revenue Juno anticipated from

Defendant's market entry as a result of its license to the '190 Patent is relevant to Dr. Sullivan's damages calculation and appropriate to consider under the law. *See Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1121 (S.D.N.Y. 1970) (considering "the anticipated amount of profits that the prospective licensor reasonably thinks he would lose as a result of licensing the patent").

$1 billion upfront payment from Celgene-Juno Agreement, 20–30% royalty rates for late-stage technologies. Defendant did not object to these figures during testimony, but the Court notes that even if Defendant had objected to and excluded these figures at trial, the jury verdict would not be rendered contrary to the clear weight of the remaining evidence.

Thus, the Court denies Defendant's motion for a new trial based on large figures.

4. Written Description Instruction

Defendant argues the written description jury instruction provided to the jury was flawed because it did not correctly cover the legal standard for written description of genus claims. (JMOL 43.) Although the Court followed a model instruction for written description, the instruction was inadequate because it referred to the invention in the singular, did not include the word genus, or explain that the specification must enable the full scope of the claims. The instruction also did not lay out the *Ariad* standard that "a sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the

genus so that one of skill in the art can visualize or recognize the members of the genus." (JMOL 44 (citing *Ariad*, 598 F.3d at 1350).) Defendant argues it presented clear and convincing evidence that the patent does not meet the legal standard for genus claims, but the jury was free to forgo the required analysis. (JMOL 45.)

Plaintiffs respond that Defendant cannot show, as it must, that the written description jury instruction was erroneous and prejudicial. (Opp. 44.) The instruction tracked the N.D. Cal. model patent instruction, updated in 2019. (*Id.*) There is no special instruction for what Defendant labels the *Ariad* standard, thus Defendant's objection amounts to nothing more than a complaint that the Court did not charge the jury in the particular way Defendant wanted. (*Id.*) 35 U.S.C. § 112(a) presents a single written description test, and *Ariad*'s discussion of genus claims makes clear that the description requirement does not demand any particular form of disclosure. (*Id.*) Defendant's proffered instruction would have confused the jury, where no witness ever discussed genus claims. (Opp. 45.) Defendant's objections regarding invention in the singular and omission of the term genus were likewise never raised, and the presented instruction clearly and correctly stated disclosure must show possession of the invention. (*Id.*)

Defendant replies that Plaintiffs mischaracterize the genus requirement, disclosed in *Ariad*. (Reply 22.) *Ariad* specifies what is required to show possession for a genus claim. (Reply 23.) Although the term genus was used only once, witnesses testified that the claims included millions of billions of different CARs. (*Id.*)

Defendant's use of the term genus only once was unsurprising, given the Court did not rule on jury instructions until after the close of the evidence. (*Id.*)

The Court finds that Defendant cannot demonstrate the written description instruction provided by the Court was erroneous and prejudicial. First, the instruction, from the N.D. Cal. Model Patent Instructions (last updated in Oct. 2019), was not erroneous where the written description instruction mirrored statutory requirements for written description. 35 U.S.C. § 112(a). The statute requires a written description of the invention so as to enable any person skilled in the art to make and use the same. (*Id.*) The instruction stated, *inter alia*, that "[a] patent claim is invalid if the patent does not contain an adequate written description of the claimed invention." (ECF No. 591, at Instruction No. 17.) Despite Defendant's assertion that the instruction should have set forth the specific requirements for a genus claim as set forth in *Ariad*, if true, Defendant offers no explanation for why the model instruction has not been modified in the nine years following *Ariad*'s issuance. Nor did Defendant present a model instruction from ***any*** authority for genus claims, instead drafting from scratch a two-part written description jury instruction, where the second part cherry-picked language from various decisions. (ECF No. 372, at 90–93.) Defendant's instruction was confusing, where the term "genus" was only used at trial once during Defendant's opening, and the jury did not hear the term referenced by any of the witnesses. Defendant's instruction was also argumentative and improper, for example because it used language improperly shifting the burden: "the

specification needs to show that the inventors had truly invented the claimed genus." (*Id.* at 91.) In light of these factors, the Court cannot conclude that providing Plaintiffs' instruction rather than Defendant's was erroneous.

Second, even if it was, the Court finds that Defendant cannot demonstrate the instruction was prejudicial. As *Ariad* states, the inquiry of whether a written description is sufficient is a question of fact that "will necessarily vary depending on the context," specifically "the nature and scope of the claims and . . . the complexity and predictability of the relevant technology." Both sides presented conflicting evidence regarding whether the three-part CAR structure, including the description of scFvs for use with the Sadelain backbone, was adequately described. Defendant had the opportunity to, and indeed did, argue that the claimed invention included millions and billions of potential scFvs, and that the patent did not contain an adequate written description describing which scFvs would create working CARs. If the jury agreed with Defendant's argument, based on the instruction provided to the jury, it could not have found the written description adequate. Based on this, Defendant cannot demonstrate the requisite prejudice warranting a new trial.[9]

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[9] The Court also notes that in its view, even if Defendant's two-part instruction had been read, the jury's finding of adequate written description would not have been in contravention of the clear weight of the evidence. (*See supra*, Section III.A.); *see also Ariad*, 598 F.3d at 1352 (stating in part that "written description and enablement often rise and fall together . . .").

Thus, the Court denies Defendant's motion for a new trial based on the written description jury instruction.

5. Plaintiffs' IPR Arguments

Defendant argues Plaintiffs misled the jury about the IPR for the '190 Patent when they questioned Dr. Belldegrun about the fact that none of the challenged claims was invalidated during IPR, and during closing arguments referenced Defendant having lost all challenges raised before the PTO. (JMOL 46.) The curative instructions could not dispel Plaintiffs' persistent misdirection. (JMOL 47.)

Plaintiffs respond that it was Defendant who offered the Final Written Decision ("FWD") from the IPR into evidence. (Opp. 46.) Once Defendant offered the patent prosecution history, including the FWD, into evidence, Plaintiffs were entitled to explain the FWD and place it in context. (*Id.*) Additionally, the IPR was relevant following Dr. Belldegrun's testimony that the '190 Patent was not important to Defendant. (*Id.*) Plaintiffs further respond that their IPR statements were accurate and proper, where they stated Defendant made arguments on a separate issue than the one the jury was asked to decide, three patent judges reviewed the IPR, and Defendant could have raised claim construction arguments on the SEQ ID NO:6 term. (Opp. 47.) Plaintiffs further respond Defendant was not prejudiced, where the Court provided a limiting instruction multiple times, and Defendant's counsel highlighted the instruction during closing argument. (*Id.*)

Defendant replies that Plaintiffs' misuse of the IPR was prejudicial where the Court admitted testimony regarding the filing of the IPR. (Reply 23.) Defendant

used the patent prosecution history only to cross-examine Dr. Sadelain regarding the CoC, and never mentioned anything related to the IPR. (Reply 23–24.) Plaintiffs' references to Defendant's CoC defense in the IPR were prejudicial and erroneous, and the curative instruction did not resolve the issue where the Court never specifically instructed the jury to disregard Plaintiffs' statements. (Reply 24.)

As a preliminary matter, the Court notes it already ruled on the record regarding Defendant's oral motion for a mistrial based on Plaintiffs' IPR arguments. During closing argument, counsel for Plaintiffs argued that "either party in an IPR proceeding can make arguments about claim construction . . . . [I]t's apparent that Kite made no argument before the three patent judges, who really know the technology and the law, that the '190 patent sequence for SEQ ID:6 started at 113." (Tr. 1532:1–8.) The Court subsequently issued a written Order:

> The Court understands Plaintiffs' argument to be that Defendant, while asserting some claim construction arguments during the IPR, did not ask PTAB to construe whether the sequence in claim 1 should start at 113 or 114. The Court is not persuaded that this comprises a misstatement of law. The Court already granted Defendant's request to instruct the jury during trial that a patent can only be challenged during IPR on grounds of anticipation or obviousness, not for a certificate of correction, inadequate written description, or enablement. The Court again included the instruction as Closing Instruction No. 15(a). Given the limited nature of Plaintiffs' remark during closing, the Court's

> multiple IPR instructions to the jury, and the Court's instruction to the jury that attorney argument is not evidence, the Court decides a mistrial is not appropriate.

(Order, ECF No. 584 at 3.)

Nevertheless, the Court again addresses Defendant's argument. Defendant made the decision to admit the entire prosecution history into evidence, including the FWD. If Defendant believed the FWD to be prejudicial, Defendant had the option of admitting an excerpted version of the prosecution history. Based on its failure to do so, Plaintiffs were entitled to utilize the FWD once admitted. The Court further notes that the IPR became relevant when Dr. Belldegrun testified that the '190 Patent was not important to Plaintiffs, as his testimony was contradicted by Defendant's decision to file the IPR to attempt to invalidate the '190 Patent. As the Court noted throughout trial, it did not view Plaintiffs' statements regarding the IPR as inaccurate, and moreover, the Court provided multiple limiting instructions regarding the IPR. The Court's view is thus that Plaintiffs' arguments did not misstate the law, the Court cured whatever prejudice may have resulted, and any prejudice was not so pervasive that a new trial is warranted.

Thus, the Court denies Defendant's motion for a new trial based on Plaintiffs' IPR arguments.

6. Good-Faith Evidence

Defendant argues that because it maintained privilege in this case, 35 U.S.C. § 298 precluded Plaintiffs from using Defendant's failure to present such advice to prove willful infringement. (JMOL 47.)

Defendant further argues it should have been permitted to offer Dr. Bot's homology analysis as non-attorney evidence of good faith. (*Id.*) Plaintiffs should not have been permitted to reference Defendant's lack of evidence, and Defendant should have been granted a curative instruction. (JMOL 47–48.)

Plaintiffs respond that Defendant, in its opening statement, promised the jury that Defendant had "very, very good reasons" for believing it did not infringe. (Opp. 48.) Plaintiffs' closing argument noted Defendant failed to fulfill its promise of showing those very, very good reasons. (*Id.*) Plaintiffs further respond Defendant was precluded from introducing Dr. Bot's homology analysis because it was outdated, irrelevant, and unfairly prejudicial, not because Defendant asserted privilege. (*Id.*) Plaintiffs further respond that their comment that Defendant presented no fact witness who reviewed the patent for non-infringement or invalidity did not violate 35 U.S.C. § 298 because Plaintiffs did not reference any failure to obtain advice from counsel, or choice to obtain advice of counsel but not present it. (Opp. 48–49.)

Defendant replies that Plaintiffs previously persuaded the Court that good faith evidence was inadmissible because Defendant elected to withhold the advice of counsel. (Reply 24–25.) Having been successful, Plaintiffs could not rely on the absence of such evidence at trial. (Reply 25.)

Regarding Dr. Bot's homology analysis, as noted above, the testimony was excluded for reasons other than Defendant's assertion of privilege. (*See supra*, Section III.D.) However, unlike for a JMOL, for a motion for new trial, the Court may weigh the

evidence to determine whether the jury verdict is contrary to the clear weight of the evidence. *DSPT Int'l*, 624 F.3d at 1218. Under this standard for a motion for a new trial, the Court finds that even if Dr. Bot's testimony had been permitted, the clear weight of the evidence would still support the jury's verdict.

Regarding Plaintiffs' reference to Defendant's lack of testimony of good-faith evidence, the Court finds that Plaintiffs' arguments were not improper, where Defendant promised during opening that it had very, very good reasons for believing it did not infringe. Given Defendant's statements, Plaintiffs were permitted to point out any purported failure by Defendant to satisfy its promise, particularly where the reference was to the lack of any fact witness, not advice of counsel.

Regarding the curative instruction, the Court notes it already ruled on Defendant's request on the record. (Tr. 1537:5–14.) Specifically, the Court stated that "the Court would conclude that it cannot be inferred from [Plaintiffs' counsel's] statements that he was suggesting to the jury that Kite should be found to have willfully infringed because it did not present advice of its lawyers that it had defenses under section 112 or 255." (*Id.*) Defendant's motion now does not change the Court's prior ruling.

For these reasons, the Court denies Defendant's motion for a new trial based on good-faith evidence.

7. Time Limit

Defendant argues it was prejudiced by insufficient time, where it was given only 11.7 hours to present evidence on a wide range of issues, and where it bore

the burden on three liability defenses. (JMOL 48.) Defendant argues the time limit forced it to drop or truncate the testimony of numerous witnesses and could not develop key aspects of its case. (JMOL 49.)

Plaintiffs respond that the Court imposed no rigid time limits, and Defendant was ultimately satisfied with its time. (Opp. 49.) The Court noted from the beginning that time limits were subject to adjustment during trial, and in fact expanded time to allow for interim summation (which neither party utilized). (*Id.*) Throughout trial, the Court noted its flexibility and willingness to add time. (Opp. 49–50.)

Defendant requested more than one time for additional time, and the Court denied those requests. (Reply 25.) Only on the last day of testimony did the Court allow Defendant extra time for cross-examination, which did not undo the prejudice of having to drop or truncate every witness in its case. (*Id.*)

As an initial matter, the Court has already considered and ruled upon Defendant's request for additional time. ***First***, the Court stated on the record, "I have always made it clear that the Court would reconsider in terms of the time. The defendant asked for 40 minutes. They were given an additional 40 minutes. The plaintiff asked for an additional 40 minutes, they were given 40 minutes. And there was no request for more time. So that should be clear in the record also." (Tr. 1314:22–1315:3.) ***Second***, following trial, the Court issued an Order noting that: (1) at the parties' Scheduling Conference in March 2018, the Court contemplated a five or six day trial, as only one patent was at issue (ECF No. 92 at 54); (2) after the

Scheduling Conference, the disputed issues narrowed significantly, as literal infringement and infringement under the doctrine of equivalents were no longer at issue; (3) at the parties' November 26, 2019 Pretrial Conference, the Court initially allotted 10 hours for each side for witness testimony; (4) at the parties' unopposed request, the Court expanded the time limit to 11 hours for each side to permit witness summation, "subject to adjustment" (Order, ECF No. 530, at 1); (5) after trial began, Defendant requested an extra forty minutes for witness testimony, which based on the stage of trial and stage of examination, the Court granted; and (6) Defendant did not utilize the full amount of its requested extension. (Order, ECF No. 584, at 2.) The Court further noted that for its closing argument, Defendant initially requested and was granted 1.5 hours, then requested and was granted 2 hours, then requested and was granted 2.25 hours, and still exceeded its time allotment. (*Id.*) Because the Court disclosed as early as eighteen months before trial the trial would be allotted five to six days,[10] the case subsequently narrowed, the Court adjusted the time limits for trial based on a demonstrated need, and Defendant did not utilize its full time on the record, the Court found Defendant was allotted sufficient time at trial.

Defendant's current arguments largely mirror its previous arguments. Nevertheless, the Court addresses them again. The Court's view is that the

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[10] In the Court's view, a six-day trial estimate, expecting 5.5 hours of witness testimony per day, would break down to one day for jury selection and opening statements, four days of witness testimony (11 hours per side), and one day for closing arguments.

scope of this patent case, although dealing with complex technology, was not large. There was one asserted patent, with essentially two asserted claims (four claims, broken into pairs, with limitations common to all four claims). This was an untraditional patent case in the sense that infringement (neither literal nor under the doctrine of equivalents) was at issue for trial. Nor were there common invalidity issues, such as invalidity or anticipation. The Court's view is that neither party bore a substantially heavier burden, where Plaintiffs bore the burden of introducing the technology, proving willful infringement, and proving damages in the amount of $752 million, and where Defendant bore the burden of proving the Certificate of Correction invalid and proving its written description and enablement defenses.[11]

Trial spanned eight days, during which the jury heard from 23 total witnesses,[12] twelve for Plaintiffs and eleven for Defendant. The Court repeatedly maintained flexibility and accommodated the parties where a need was demonstrated. For example, the Court permitted Defendant to put up two of its own witnesses out of order. Dr. Bot testified on December 5 in order to allow him to attend a conference, and Dr. Schuetz was permitted to testify on December 6, during the middle of Plaintiffs' expert's testimony. The Court further accommodated Defendant by keeping the jury late on December 5 for Dr. Bot to

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[11] The Court's view is that there was significant overlap between Defendant's written description and enablement defenses at trial.

[12] The testimony of five witnesses was by deposition designation.

complete his testimony. With regard to the time limit, the Court granted Defendant's request for time when Defendant demonstrated a need, for example by granting an extra forty minutes during a cross-examination when Defendant was nearing the end of its allotted time. The Court further granted Defendant's two requests to extend its time allotted for closing argument.

Defendant's argument that it was forced to drop or truncate the testimony of numerous witnesses due to its 11.7-hour allotment is not persuasive. Before trial, Defendant itself requested 12.5 hours of witness testimony (ECF No. 531, at 1), yet filed an order of proof on the evening before the last day of witness testimony containing nine pages of testimony and exhibits that it was supposedly precluded from presenting (ECF No. 543, at 2–10). The Court is doubtful that all of Defendant's arguments and exhibits could have been introduced in an additional 48 minutes. Nor is Defendant's authority persuasive. Defendant cites a "similarly meager 10-hour time allotment in a 'complex' copyright case" as grounds for a new trial, but the district court's time limit in that case has since been affirmed by the Ninth Circuit, sitting *en banc*. *Skidmore v. Led Zeppelin*, No. 16-56057, at 49–50 (9th Cir. 2020) (*en banc*) (finding trial time limit was not an abuse of discretion where the district court was "up front about the limits and then . . . flexible at counsel's request").

Thus, the Court denies Defendant's request for a new trial based on time limits.

8. Cumulative Prejudice

Defendant argues the cumulative prejudice of multiple errors requires the Court to grant a new trial. (JMOL 49.) Defendant alleges that misconduct and error pervaded the trial, and each error affected a central component of the case. (*Id.*) The errors were not harmless because the Federal Circuit has invalidated analogous antibody claims, Plaintiffs offered no new evidence demonstrating the CoC's error and correction were clearly evident, and Plaintiffs' damages vastly exceeded comparable licenses. (JMOL 49–50.)

Plaintiffs respond that all of their previous arguments address why there was no prejudice to Defendant, and thus why no errors could have accumulated. (Opp. 50.) Even if errors had occurred, they would have been harmless, especially given Defendant's new trial arguments largely address different legal issues and discrete evidentiary issues. (*Id.*)

Based on the Court's analysis above, and based on the Court's observations having presided over the entirety of trial, the Court finds that prejudice for each of Defendant's issues (if any exists) did not accumulate to a level such that the jury's verdict was against the clear weight of the evidence. *DSPT Int'l*, 624 F.3d at 1218.

IV. RULING

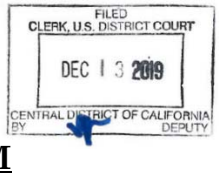
For the foregoing reasons, the Court **DENIES** Defendant's Motion for Judgment as a Matter of Law Pursuant to Fed. R. Civ. P. 50(b) and/or a New Trial Pursuant to Fed. R. Civ. P. 59 [ECF No. 659].

IT IS SO ORDERED.

APPENDIX D

Redated Copy

CV 17-07639 SJO



JURY VERDICT FORM

When answering the following questions and filling out this Verdict Form, please follow the directions provided throughout the form. Please refer to the Jury Instructions if you are unsure about the meaning or usage of any legal term that appears in the questions below.

We, the jury, unanimously agree to the answers to the following questions and return them as our verdict in this case:

I. CERTIFICATE OF CORRECTION

1. Has Kite proven by clear and convincing evidence that the Certificate of Correction is invalid?

Yes _____	No ✓
(in favor of Kite)	(in favor of Sloan Kettering and Juno)

II. VALIDITY OF ASSERTED PATENT CLAIMS

A. ENABLEMENT

2. Has Kite proven by clear and convincing evidence that the following claims of the '190 Patent are invalid because the specification of the '190 Patent does not adequately enable the claims?

"Yes" means the claim is not adequately enabled by the specification, and "No" means the claim is adequately enabled by the specification.

Asserted Patent Claims	Yes (in favor of Kite)	No (in favor of Sloan Kettering and Juno)
3, 9		✓
5, 11		✓

[continue to next page]

B. WRITTEN DESCRIPTION

3. Has Kite proven by clear and convincing evidence that the following claims of the '190 Patent are invalid because the specification of the '190 Patent does not contain an adequate written description of the claims?

"**Yes" means the claim does not contain adequate written description support in the specification, and "No" means the claim does contain adequate written description support in the specification.**

Asserted Patent Claims	Yes (in favor of Kite)	No (in favor of Sloan Kettering and Juno)
3, 9		✓
5, 11		✓

[continue to next page]

If you answered "no" to all of questions #1, #2, and #3, then answer the next two questions. Otherwise, you should not answer the next two questions.

III. WILLFUL INFRINGEMENT

4. Have Plaintiffs proven by a preponderance of the evidence that Kite's infringement of the corrected claims of the '190 Patent was willful?

Yes ✓	No _____
(in favor of Sloan Kettering and Juno)	(in favor of Kite)

IV. DAMAGES

5. What is the total amount of damages that you find Plaintiffs have proven by a preponderance of the evidence?

a. Upfront Payment (dollars): $585,000,000

and

b. Running Royalty (percentage): 27.6% (to be applied to Yescarta® revenues through trial)

END

Please review your selections above to confirm that they accurately reflect your unanimous determinations. Your Foreperson should then sign and date below, and notify the U.S. Marshal that you have reached a verdict. Your Foreperson should bring this form when the jury is brought back into the courtroom.

Dated: Dec. 13, 2019

By Jury Foreperson's Signature Redacted
Foreperson

APPENDIX E

NOTE: This order is nonprecedential

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

2020-1758

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

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MOORE, *Chief Judge*, NEWMAN, LOURIE, DYK, PROST, O'MALLEY, REYNA, TARANTO, CHEN, HUGHES, STOLL, and CUNNINGHAM, *Circuit Judges*.

PER CURIAM.

O R D E R

Juno Therapeutics and Sloan Kettering Institute for Cancer Research filed a combined petition for panel rehearing and rehearing en banc. City of Hope, Amgen Inc., Association of University Technology Managers, Albert Einstein College of Medicine, St. Jude Children's Research Hospital, Inc, and University of Texas MD Anderson Cancer Center requested leave to file briefs as amici curiae which the court granted. A response to the petition was invited by the court and filed by Kite Pharma, Inc. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on January 21, 2022.

FOR THE COURT

January 14, 2022
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

APPENDIX F

35 U.S.C. § 112
Specification

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

* * *

35 U.S.C. § 112 (Pre-AIA)
Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

* * *

Patent Act of 1870
41st Congress – 2nd Session
16 Stat. 198
July 8, 1870

CHAP. CCXXX.—*An Act to revise, consolidate, and amend the Statutes relating to Patents and Copyrights.*

* * *

SEC. 26. *And be it further enacted*, That before any inventor or discoverer shall receive a patent for his invention or discovery, he shall make application therefor, in writing, to the commissioner, and shall file in the patent office a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of a machine, he shall explain the principle thereof, and the best mode in which he has contemplated applying that principle so as to distinguish it from other inventions; and he shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery; and said specification and claim shall be signed by the inventor and attested by two witnesses.

* * *

Patent Act of 1836
24th Congress – 1st Session
5 Stat. 117
July 4, 1836

CHAP. CCCLVII.—An Act to promote the progress of useful arts, and to repeal all acts and parts of acts heretofore made for that purpose.

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SEC. 6. *And be it further enacted*, That any person or persons having discovered or invented any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter, not known or used by others before his or their discovery or invention thereof, and not, at the time of his application for a patent, in public use or on sale, with his consent or allowance, as the inventor or discoverer; and shall desire to obtain an exclusive property therein, may make application in writing to the Commissioner of Patents, expressing such desire, and the Commissioner, on due proceedings had, may grant a patent therefor. But before any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of any machine, he shall fully explain the principle and the several modes in which he has contemplated the

application of that principle or character by which it may be distinguished from other inventions; and shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery. He shall, furthermore, accompany the whole with a drawing, or drawings, and written references, where the nature of the case admits of drawings, or with specimens of ingredients, and of the composition of matter, sufficient in quantity for the purpose of experiment, where the invention or discovery is of a composition of matter; which descriptions and drawings, signed by the inventor and attested by two witnesses, shall be filed in the Patent Office; and he shall moreover furnish a model of his invention, in all cases which admit of a representation by model, of a convenient size to exhibit advantageously its several parts. The applicant shall also make oath or affirmation that he does verily believe that he is the original and first inventor or discoverer of the art, machine, composition, or improvement, for which he solicits a patent, and that he does not know or believe that the same was ever before known or used; and also of what country he is a citizen; which oath or affirmation may be made before any person authorized by law to administer oaths.

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Patent Act of 1793
2nd Congress – 2nd Session
1 Stat. 318
February 21, 1793

CHAP. XI.—An Act to promote the progress of useful Arts; and to repeal the act heretofore made for that purpose.

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SEC. 3. *And be it further enacted*, That every inventor, before he can receive a patent, shall swear or affirm that he does verily believe, that he is the true inventor or discoverer of the art, machine, or improvement, for which he solicits a patent, which oath or affirmation may be made before any person authorized to administer oaths, and shall deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same. And in the case of any machine, he shall fully explain the principle, and the several modes in which he has contemplated the application of that principle or character, by which it may be distinguished from other inventions; and he shall accompany the whole with drawings and written references, where the nature of the case admits of drawings, or with specimens of the ingredients, and of the composition of matter, sufficient in quantity for the purpose of experiment, where the invention is of a composition of matter; which description, signed by himself and

attested by two witnesses, shall be filed in the office of the Secretary of State, and certified copies thereof shall be competent evidence, in all courts, where any matter or thing, touching such patent-right, shall come in question. And such inventor shall, moreover, deliver a model of his machine, provided, the secretary shall deem such model to be necessary.

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Patent Act of 1790
1st Congress – 2nd Session
1 Stat. 109
April 10, 1790

CHAP. VII.—An Act to promote the progress of useful Arts.

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SEC. 2. *And be it further enacted*, That the grantee or grantees of each patent shall, at the time of granting the same, deliver to the Secretary of State a specification in writing, containing a description, accompanied with drafts or models, and explanations and models (if the nature of the invention or discovery will admit of a model) of the thing or things, by him or them invented or discovered, and described as aforesaid, in the said patents; which specification shall be so particular, and said models so exact, as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term; which specification shall be filed in the office of the said Secretary, and certified copies thereof, shall be competent evidence in all courts and before all jurisdictions, where any matter or thing, touching or concerning such patent, right, or privilege, shall come in question.

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