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WRITTEN DESCRIPTION & ENABLEMENT: HOW THEY MIGHT CHANGE

THURSDAY, OCTOBER 13, 2022

~ TABLE OF CONTENTS ~

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Written Description & Enablement: How They Might Change

AIPLA CLE Webinar
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12:30 pm – 2:00 pm Eastern

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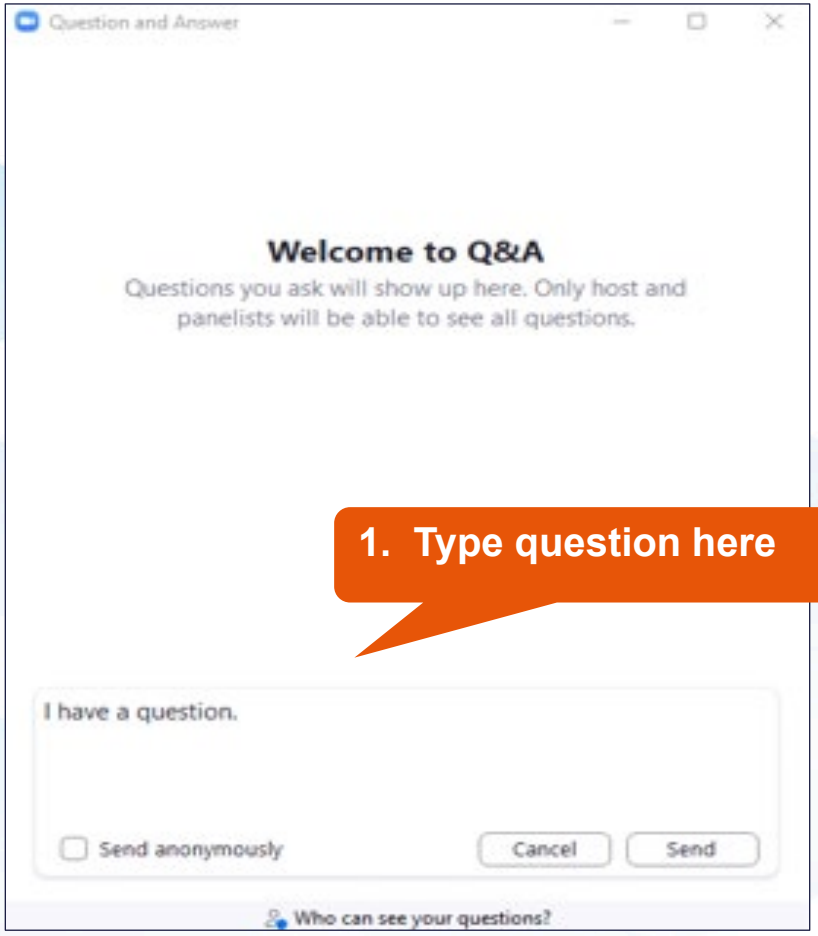

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Written Description & Enablement: What Could Change?

Tammy J. Terry, Partner, Osha Bergman Watanabe & Burton LLP

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Oct. 13, 2022

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35 U.S.C. § 112(a)

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.

Three Requirements

- Written Description
- Enablement
- Best Mode

Written Description

- Specification must allow a person of ordinary skill in the art to recognize that the inventor invented what is now claimed

Enablement

- Inventor must describe the invention in such a way that would allow others skilled in the art to make and use the invention.
- Public needs to be in general possession of the invention claimed in the patent.
- Objective inquiry: whether those of ordinary skill in the art would be enabled to practice the invention.

Best Mode

- Inventor must disclose best mode of invention, if one exists.
- AIA effect on failure to disclose best mode defense

Potential SCOTUS Review

1. *Amgen v. Sanofi*, 987 F. 3d 1080 (Fed. Cir. 2021)
2. *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021)
3. *Biogen Int'l GmbH v. Mylan Pharms., Inc.*, 18 F.4th 1333 (Fed. Cir. 2021)

District Court

- Amgen filed suit in 2014 based on patents for Repatha, a cholesterol medication
- Infringement of certain claims stipulated
- Invalidity tried to jury (Spring 2016)
- JMOL of nonobviousness and no willful infringement
- Jury verdict – patents not invalid due to lack of enablement and written description

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

Federal Circuit & District Court

- Sanofi appealed
- Federal Circuit remanded for new trial on written description and enablement
- Invalidity tried to jury (again)
- Jury verdict – patents not invalid due to lack of enablement and written description
- JMOL denied for lack of written description; granted for lack of enablement

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

Federal Circuit (Again)

- Amgen appealed
- Federal Circuit affirmed on lack of enablement
- Consideration of
  - *Wands* factors
  - Other Federal Circuit precedent

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

Federal Circuit (Again)

- Proving that a claim is invalid for lack of enablement requires showing by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without "undue experimentation."
- *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988)

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

Wands Factors

To determine if "undue experimentation" is needed, courts consider:

1. the quantity of experimentation necessary;
2. the amount of direction or guidance presented;
3. the presence or absence of working examples;
4. the nature of the invention;
5. the state of the prior art;
6. the relative skill of those in the art;
7. the predictability or unpredictability of the art; and
8. the breadth of the claims.

Federal Circuit Decision

- For claims that include functional requirements, enablement inquiry can focus on the breadth of the functional requirements, particularly where predictability in the results and guidance from the specification fall short.
- Court emphasized importance of considering the quantity of experimentation required to make and use the full scope of the claim, and not just the limited number of embodiments disclosed in the patent.

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

Federal Circuit Decision

- Breadth of functional limitations + narrowness of disclosed examples and guidance → no reasonable jury could conclude that anything but "substantial time and effort" would be required to reach the full scope of claimed embodiments.
- Affirmed the district court's finding that the claims were not enabled because undue experimentation would be required to practice the full scope of the claims.

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

Amgen's Petition to Supreme Court

- Question of enablement for judge or jury?
- Does enablement require a person of ordinary skill in the art to "reach the full scope" of the invention?

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

Sanofi's Response

- Patent validity has long been a question of law with factual underpinnings and courts have always retained right to rule on factual issues when evidence is lacking.
- Enablement requirement is clear that a patentee has not sufficiently enabled an invention if the patent describes how to make and use only part of the invention

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

What could change if SCOTUS grants cert?

- Clarity on question of who can decide enablement – could change the way these cases are tried
- Clarity on whether "full scope" of claimed invention needs to be enabled – could affect how patents are drafted

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

What if SCOTUS does not grant cert?

- Potential conflict with prior Federal Circuit precedent that established that claim coverage of some inoperative embodiments would not necessarily invalidate a claim for lack of enablement?
- Does *Amgen* effectively shift the burden of proving enablement to the patentee by requiring the patentee to show that the full breadth of the claims are enabled without the challenger needing to identify a particular embodiment that was not enabled?

District Court

- Juno filed suit over Kite's brand-named cancer therapy drug, YESCARTA®
- Patent was directed to cancer therapy involving single-chain antibody variable fragments (scFv) that are supposed to bind to certain targets that appear on surface of certain types of cancer cells
- Jury found patents not invalid and willfully infringed
- JMOL for failure to meet written description requirement denied

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

Federal Circuit

- Patent found invalid due to lack of written description
- Court recognized claims as genus claims with functional limitations
- Specific considerations applicable to genus claims with functional limitations

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

Federal Circuit

- Factors that apply when considering written description sufficiency for genus claims:
  - existing knowledge in the particular field,
  - extent and content of the prior art,
  - maturity of the science or technology, and
  - predictability of the aspect at issue

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

Federal Circuit

- Written description for genus claims with functional limitations "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."

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

Federal Circuit

- Written description for genus claims with functional limitations "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."
- Chemical genus claims require specification to include "a precise definition, such as by structure, formula, or chemical name" sufficient to distinguish claimed subject matter from other materials.

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

Federal Circuit Decision

- Patent's written description contained "scant details about which scFvs can bind which target antigens"
- Only two example scFvs for binding two targets
- No other details beyond alphanumeric designations for a POSA to determine how or whether scFv species are representative of entire claimed genus
- Insufficient evidence that the two working embodiments were representative of genus

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

Juno's Petition to Supreme Court

- Federal Circuit has created a new standard, which demands that the written description of the invention "demonstrate the inventor's 'possession' of 'the full scope of the claimed invention,' including all 'known and unknown' variations of each component," a standard that is often "impossible to meet."
- According to Juno, the decision contradicts the statute, Supreme Court precedent, and other precedent

Kite's Response

- 50 years of precedent has held that § 112's "written description" requirement is distinct from the enablement requirement, and written description was clearly not met in this case
- "Although there are millions of billions of possibilities for [the '190 patent's claimed function of its ability to bind to a particular structure], only an uncertain fraction would make the protein bind as claimed, and the patent discloses nothing that would allow scientists to predict which possibilities would."
- Case is poor vehicle for Supreme Court Review

What could change if SCOTUS grants cert?

- Clarity on question of written description sufficiency for generic claims with functional limitations, particularly for biologics patents

Amgen v. Sanofi, 987 F. 3d 1080 (Fed. Cir. 2021)

What if SCOTUS does not grant cert?

- More careful attention to drafting generic claims with functional language
- More attention providing specific guidance in a specification on how representative examples in a genus are actually representative.

District Court

- Mylan notified FDA of intent to release generic version of Biogen's Tecfidera®, a dimethyl fumarate (DMF) product for the treatment of multiple sclerosis
- Biogen filed multi-patent infringement suit, one patent became focal point
- Bench trial – sole issue was whether Biogen's 514 patent was invalid for failure to meet written description requirement.

Biogen Int'l GmbH v. Mylan Pharms., Inc., 18 F.4th 1333 (Fed. Cir. 2021)

District Court

Claim 1 of the '514 patent:

A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of

(a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and

(b) one or more pharmaceutically acceptable excipients, wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.

District Court

- Specification of the '514 patent:
  - Recites a range of effective doses of DMF
  - Includes range of "from about 480 mg to about 720 mg per day"
- DMF480 limitation was not in any of the claims in the parent applications, but was included in a preliminary amendment filed with the application that matured into the '514 patent

District Court

- Issue at trial: did the original specification of the parent to the 514 patent sufficiently disclose "possession" of DMF480 limitation to treat MS
- District court:
  - Court did not find Biogen's expert credible on the issue
  - Court credited Mylan's expert
  - Court found claims of '514 patent invalid due to failing to meet written description requirement

Federal Circuit

- Relied heavily on district court's factual findings
  - Specification only explicitly mentioned DMF480 dose once
  - The single reference to was "part of a wide DMF-dosage range and not listed as an independent therapeutic efficacious dose."
  - The single paragraph in the specification with dosing information included a wide range of other doses, including doses a skilled artisan would expect to be ineffective and a doses well above the therapeutically effective range

Federal Circuit

- Federal Circuit found important that the specification focused on drug discovery and basic research rather than the therapeutic effectiveness of DMF480 as a dose to treat MS.
- Federal Circuit also found important the district court's reliance on Mylan's discrediting of Biogen's expert.
- Federal Circuit concluded district court did not err in finding '514 patent claims invalid.
- Biogen sought rehearing *en banc*; denied.

Biogen's Petition to Supreme Court

- Biogen argues the Federal Circuit improperly held that § 112 requires proof that an invention is effective.
- Biogen's sole issue in its petition:
  - Is 35 U.S.C. § 112's requirement that a patent specification "contain a written description of the invention" met when the specification describes the invention, or must the specification also disclose data that demonstrates the claimed invention is "effective" and emphasize the claimed invention by singling it out and describing it more than once?

Biogen's Petition (cont'd)

- Federal Circuit's decision contradicts the language and purpose of § 112 and longstanding precedent
- Federal Circuit decision threatens innovation
- The fact that the Federal Circuit itself has been so divided in this case shows that future decisions will be panel-dependent and unpredictable unless the Supreme Court weighs in

Mylan's Response

- Federal Circuit decision is supported by extensive evidence and consistent with well-settled law
- It is Biogen's approach that would threaten innovation and Biogen has "manufacture[d] an 'internal division' within the Federal Circuit."

What could change if SCOTUS grants cert?

- Clarity on question of how much description really is enough
- Clarity on question relating to efficacy

What if SCOTUS does not grant cert?

- More repetition in patent specifications?
- More description for unclaimed embodiments?
- Less description of unclaimed embodiments (to avoid distraction)?
- More patents invalidated due to lack of written description?

Concluding Remarks

- Written description and enablement requirements can play a major role in patent infringement cases
- Expert credibility matters
- Evidence collection and presentation strategy on these issues must start early

Questions?

Thank you

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Written Description & Enablement: How They Might Change

By Tammy Terry and James Kurka

AIPLA Online Webinar Series

October 13, 2022

INTRODUCTION

Most patent litigation cases do not hinge on questions of whether the patents-in-suit meet written description or enablement requirements. As a result, these issues do not often reach the Supreme Court of the United States. That may soon change. Companies in three unrelated cases are asking the Supreme Court to weigh in on various issues involving written description and enablement. This paper explores the written description and enablement requirements and how they could change.

BACKGROUND OF WRITTEN DESCRIPTION & ENABLEMENT REQUIREMENTS

A patent application must describe the invention with sufficient particularity that those skilled in the art will be able to make, use, and understand the inventor's invention. This is captured in 35 U.S.C. § 112(a), which provides what are known as the enablement, best mode, and written description requirements.

35 U.S.C. § 112(a)[1] states:

> 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.

The enablement requirement requires the inventor to describe the invention in such a way that would allow others skilled in the art to make and use the invention. The idea is that the public needs to be in general possession of the invention that is claimed in the patent. The inquiry into whether enablement is sufficient is an objective one of whether those of ordinary skill in the art would be enabled to practice the invention.

The best mode requirement requires the inventor to disclose the preferred way of carrying out the invention at the time the patent application is filed. This inquiry, unlike the enablement inquiry, is subjective and looks to the state of mind of the inventor.

Although patent applicants are still required to disclose the best mode of the invention, if one actually exists, the enactment of the America Invents Act (AIA) did away with litigants being able to use failure to disclose best mode as a way to invalidate a patent claim. For that reason, best mode issues no longer see the light of day in patent litigation.

[1] Prior to the enactment of the America Invents Act, which made certain amendments to this and other statutes, 35 U.S.C. §112(a) was known as §112 ¶ 1.

The written description requirement, however, is also found in 35 U.S.C. § 112(a) and is a separate and distinct requirement that can still be used to invalidate a patent.[2] Written description requires that the specification allow a person of ordinary skill in the art to recognize that the inventor invented what is now claimed.[3]

RECENT CASES SEEKING SUPREME COURT REVIEW

Three written description and enablement cases are up for potential review by the United States Supreme Court, based on petitions filed within the past year. These cases help highlight some of the struggle litigants and courts face in having a firm understanding of what it takes to meet the written description and enablement requirements. Each case is discussed below with a brief background, explanation of the issues reached at the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), discussion of arguments litigants are making to the United States Supreme Court, and how Supreme Court review may impact patent prosecutors and litigants alike.

Case 1: *Amgen v. Sanofi*, 987 F. 3d 1080 (Fed. Cir. 2021)

1. Brief Background

The first case, *Amgen v. Sanofi*, involved Amgen's patents on Repatha, a cholesterol medication, and boasted a robust procedural history involving two trials and two visits to the Court of Appeals for the Federal Circuit before being postured for potential Supreme Court review. The case began when Amgen filed a patent infringement lawsuit based on several patents asserted against Sanofi and others in 2014. Amgen and Sanofi stipulated to infringement of certain claims and tried validity issues to a jury in the Spring of 2016. At trial, the district court granted judgment as a matter of law of nonobviousness and of no willful infringement. Then the jury concluded at the end of trial that the patents were not invalid due to lack of enablement and written description.

Sanofi appealed to the Federal Circuit, which reversed and remanded for a new trial on issues relating to Sanofi's defenses that the patents lack written description and enablement due to what the Federal Circuit found were errors by the district court in its related evidentiary rulings and jury instructions.

The parties then tried the issues of written description and enablement to the jury on remand and the jury again found the patents were not invalid due to lack of enablement and written description. Sanofi moved for judgment as a matter of law on these defenses, and, although the district court denied the motion for lack of written description, the court granted the motion for lack of enablement, finding Amgen's patent invalid. The district court also conditionally denied Sanofi's alternative motion for a new trial.

Amgen appealed to the Federal Circuit.

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[2] *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010)
[3] *Id*. at 1351.

2. What Happened at the Federal Circuit

On Appeal, the Federal Circuit found affirmed the district court's invalidity finding on the basis of lack of enablement. Proving that a claim is invalid for lack of enablement requires showing by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988). Determining whether "undue experimentation" is needed involves the following factual considerations that have become known as the "*Wands* factors":

(1) the quantity of experimentation necessary;
(2) the amount of direction or guidance presented;
(3) the presence or absence of working examples;
(4) the nature of the invention;
(5) the state of the prior art;
(6) the relative skill of those in the art;
(7) the predictability or unpredictability of the art; and
(8) the breadth of the claims.

Courts may consider these factors after a patent challenger has presented evidence that some experimentation is needed to practice the patented claim. Considering these factors, the court can determine whether the amount of experimentation is either undue, which suggests invalidity, or routine enough that a person of ordinary skill in the art would reasonably be expected to carry it out. *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d at 1188 (quoting *Wands*, 858 F.2d at 737). A specification is not required to "describe how to make and use every possible variant of the claimed invention"; however, it must reasonably enable the scope of a claimed range if a range is claimed.

On appeal to the Federal Circuit, Amgen argued the claims at issue were enabled because undue experimentation was not required to obtain antibodies fully within the scope of the claims. Amgen relied on expert testimony that a person of skill in the art can follow a roadmap using anchor antibodies and use well-known screening techniques described in the specification to make all antibodies within the scope of the claims. According to Amgen, the district court failed to recognize that Sanofi could not identify a single antibody that could not be made by following the teachings in the specification and improperly focused on the effort required to discover and make every embodiment of the claims. Amgen argued that the embodiments in the patent are structurally representative for purposes of fulfilling the written description requirement, which is sufficient to indicate a structure/function correlation that establishes enablement.

Sanofi argued the district court properly found the claims were not enabled because the claims are characterized mostly by functional limitations and cover a vast scope that could not be practiced without undue experimentation. According to Sanofi, because there are millions of antibody candidates within the scope of the claims and antibody generation is unpredictable, the specification's guidance was insufficient to allow those of ordinary skill to practice the full scope of the claims without substantial trial and error. Sanofi argued that Amgen focused on the wrong issue. That rather than focus on the number of antibodies actually known to satisfy the claims,

Federal Circuit case law requires examining the number of candidates that must be made and tested to determine whether they satisfy the claimed function.

The Federal Circuit ultimately agreed with Sanofi, beginning by considering the "go to" case for enablement, the *Wands* case. Like this case, *Wands* also involved claims relating to antibody technology. In *Wands*, the UPTO Board of Patent Appeals and Interferences found that undue experimentation would be required to make the claimed antibodies used in the claimed methods because production of certain antibodies was "unpredictable and unreliable." The Federal Circuit found that the specification in *Wands* adequately taught using hybridoma technology to produce the necessary claimed antibodies, and there was no evidence suggesting that there would be too many antibodies to screen from the perspective of a person of ordinary skill in the art, resulting in undue experimentation. Thus, the Federal Circuit held that the specification in *Wants* fully enabled the claimed invention.

In addition to *Wands*, the Federal Circuit also reviewed three other precedential cases on enablement that the district court relied on to support its conclusion that the asserted claims lack enablement. First there was *Wyeth & Cordis Corp. v. Abbott Laboratories*,[4] where the Federal Circuit held that claims covering methods of preventing restenosis with compounds having certain functionality requirements were invalid for lack of enablement. Then, in *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc*., the Federal Circuit found the claims-at-issue to be similar to those in *Wyeth* in that they required a particular structure and functionality, and the court held that the specification failed to teach a person of ordinary skill in the art whether the broad claims' many embodiments would exhibit the required functionality.[5] The Federal Circuit similarly found that the claims in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc*. had both structural and functional limitations, and that undue experimentation would have been required to synthesize and screen the billions of possible compounds because, due to the specification's lack of guidance across that full scope, finding functional compounds would be akin to finding a "needle in a haystack."[6]

The review of the case law led the Federal Circuit to conclude that when it comes to claims that include functional requirements, the enablement inquiry can be focused on the breadth of the functional requirements, particularly where predictability in the results and guidance from the specification fall short. The Federal Circuit emphasized the importance of considering the quantity of experimentation that would be required to make and use the full scope of the claim, and not just the limited number of embodiments disclosed in the patent. Pointing to a footnote in *McRO, Inc. v. Bandai Namco Games Am. Inc.*[7] for support, the court explained that when claims involve not only certain structural requirements but also require the performance of certain functions, then undue experimentation can include undue experimentation in identifying the compounds that satisfy the functional requirement from the many concretely identified compounds that meet the structural requirements.

[4] 720 F.3d 1380, 1385–86 (Fed. Cir. 2013).
[5] 928 F.3d 1340, 1345–48 (Fed. Cir. 2019).
[6] 941 F.3d 1149, 1160–63, 1165 (Fed. Cir. 2019).
[7] 959 F.3d 1091, 1100 n.2 (Fed. Cir. 2020).

Ultimately, the Federal Circuit found that the claims in Amgen's patent fell into this category of cases in which broad composition claims require not just a particular structure, but particular functionality, resulting in too many embodiments to identify without undue experimentation. After considering the *Wands* factors and how they applied to the challenged claims, the Federal Circuit affirmed the district court's finding that the claims were invalid due to lack of enablement. In particular, the Federal Circuit was persuaded that the only ways for those skilled in the art to discover undisclosed claimed embodiments would be either through a significant trial and error process, or by discovering antibodies by using the patent's disclosed randomization and screening roadmap, which the court concluded would result in experimentation that "would take a substantial amount of time and effort." Because of the breadth of the functional limitations, and the narrowness of the disclosed examples and guidance, the Federal Circuit concluded no reasonable jury could conclude that anything but "substantial time and effort" would be required to reach the full scope of claimed embodiments. Therefore, the court affirmed the district court's finding that the claims were not enabled because undue experimentation would be required to practice the full scope of the claims.[8]

In reaching its conclusion, the Federal Circuit was careful to explain that "We do not hold that the effort required to *exhaust* a genus is dispositive. It is appropriate, however, to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance."[9]

3. Amgen's Petition to the Supreme Court

In November 2021 Amgen filed a petition with the Supreme Court of the United States, asking the high court to weigh in on what Amgen argued was a wrong holding by the Federal Circuit. Front and center is the issue of whether the district court erred in making its findings of lack of enablement instead of leaving the question of enablement to the jury (which, in this case twice found the patents were properly enabled). According to Amgen, the Federal Circuit erred in holding that enablement is an issue for judges, as opposed to juries, as the Supreme Court in *Wood v. Underhill*[10] already determined that enablement was a "question of fact to be determined by the jury."[11] The second issue Amgen raises has to do with the Federal Circuit's interpretation of the enablement requirement itself—Amgen argues that the Federal Circuit wrongly held that the enablement requirement requires a person of ordinary skill in the art to "reach the full scope" of the invention.

In response, Sanofi has argued that patent validity has long been a question of law with underlying factual underpinnings and courts have always retained the right to make rulings on even purely factual issues when there is an insufficient evidentiary showing.[12] According to Sanofi, the Supreme Court in *Woods* explicitly stated that it would "undoubtedly" be the court's duty to declare a patent invalid "when the specification of a new composition of matter gives only

[8] Op. at 13-14.
[9] Op. at 13.
[10] 46 U.S. 1, 4 (1846).
[11] Brief for Petitioner, *Amgen v. Sanofi* (petition for cert. filed Nov. 18, 2021) (No. 21-757), at 20 and 6.
[12] Brief for Respondent, *Amgen v. Sanofi*, (petition for cert. filed Nov. 18, 2021) (No. 21-757), at 18-19.

the names of the substances which are to be mixed together, without stating any relative proportion."[13] Sanofi argues against the high court granting cert because the question was not briefed in the lower courts.[14]

In response to Amgen's second issue, Sanofi argues that the enablement requirement is clear that a patentee has not sufficiently enabled an invention if the patent describes how to make and use only part of the invention. Sanofi has also argued that Amgen should have raised the issue when the jury instructions in the district court cases included that enablement requires making and using the "full scope" of the claimed invention.[15]

4. What could change if the Supreme Court grants cert?

Although the "full scope of the claim" enablement standard as applied to functional claims is not entirely new for the Federal Circuit, the *Amgen* opinion appears to leave a potential conflict with prior Federal Circuit precedent that established that claim coverage of some inoperative embodiments would not necessarily invalidate a claim for lack of enablement.[16] The *Amgen* opinion also could effectively shift the burden of proving enablement to the patent holder by requiring the owner to show that the full breadth of the claims are enabled without the challenger needing to identify a particular embodiment that was not enabled.

If the *Amgen* opinion is left undisturbed, implications could be far-reaching, in that broad functional genus claims could become particularly vulnerable to enablement challenges. As Amgen warns in its brief to the Supreme Court, only time will tell how "devastating" the effect could be on innovation.[17]

As a practical matter, it would behoove patent prosecutors in the meantime to pay particular attention to the *Wands* factors when drafting patents, and in particular to provide as much direction as possible and to carefully select and describe embodiments in the specification. It would also be wise to include subgenus and species claims, just in case broader genus claims are invalidated. Meanwhile, litigators can expect enablement challenges for broad functional genus claims, increasing the need to pay attention to developing strategies and gathering necessary evidence early on to address the issues that will arise in such challenges.

Whether the Supreme Court weighs in on this issue has yet to be seen, particularly given that two other cases are currently vying for the High Court's attention, as discussed in more detail below. Most recently, the Solicitor General was invited to file a brief in April 2022, expressing the views of the United States. When that will occur has yet to be seen and whether the views of the United States will be similar to either Amgen's or Sanofi's views is also unknown as of the time of this article.

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[13] *Id.* at 22.
[14] *Id.* at 24-25.
[15] *Id.* at 30-31.
[16] *See Wyeth & Cordis v. Abbott Labs., 720 F.3d 1380, 1384 (Fed. Cir. 2013); Idenix Pharms. v. Gilead Scis., 941 F.3d 1149, 1154 (Fed. Cir. 2019); Crown Operations Int'l, Ltd. v. Solutia, 289 F.3d 1367, 1380 (Fed. Cir. 2002).*
[17] Brief for Petitioner at 3, 25.

Meanwhile, parties in two other cases have also questioned the Federal Circuit's approach to interpreting the enablement or written description requirement of Section 112.

Case 2: *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021)

1. Brief Background

In *Juno Therapeutics, Inc., v. Kite Pharma, Inc.,* the Federal Circuit invalidated various cancer therapy patents belonging to Juno Therapeutics, Inc., a Bristol-Myers Squibb company, wiping out Juno's $1.1 billion victory against Gilead Sciences' Kite Pharma Inc.

The case began when Juno sued Kite for patent infringement in the United States District Court for the Central District of California, alleging infringement of various claims of U.S. Patent No. 7,446,190 (the '190 patent) for Kite's use, sale, offer for sale, or importation of Kite's brand-named cancer therapy drug, YESCARTA®. Kite countersued for declaratory judgments of noninfringement and invalidity of the '190 patent.

Generally, the patent-at-issue was directed to cancer therapy involving single-chain antibody variable fragments (scFv) that are supposed to bind to certain targets that appear on the surface of certain types of cancer cells.

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.

A two-week jury trial resulted in a jury verdict in Juno's favor, finding the '190 patent not invalid and willfully infringed by Kite, with damages amounting to $585 million upfront payment and a 27.6% running royalty. In post-trial briefing, Kite moved for judgment as a matter of law (JMOL), arguing, among other things, that the '190 patent claims were invalid for failing to meet Section 112's written description requirement. Meanwhile, Juno moved for entry of judgment on the verdict, prejudgment interest, enhanced damages, and for the court to set an ongoing royalty rate. Denying Kite's motions for JMOL, the district court granted Juno's motion in part. The district court, among other things, updated the jury's award to $778,343,501 to reflect updated YESCARTA® revenues through trial, awarded prejudgment interest, enhanced damages by 50%, and awarded a 27.6% running royalty.

Kite appealed to the Federal Circuit, arguing the district court erred in denying JMOL on each of the issues that Kite raised in its post-trial briefing.

2. What Happened at the Federal Circuit

According to the Federal Circuit, the record did not contain substantial evidence that the '190 patent included sufficient written description support for the asserted claims. The Federal Circuit, therefore, invalidated all asserted claims and reversed the district court's decision.

The Federal Circuit began by reviewing the written description requirement of 35 U.S.C. § 112, which requires that a patent's specification "shall contain a written description of the invention." Quoting *Ariad*, the court emphasized that "the hallmark of written description is disclosure," and explained that 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."[18]

The Federal Circuit then analyzed the claims at issue, first recognizing them as genus claims, which have a number of factors that apply when analyzing the sufficiency of a patent specification's written description. These factors 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."[19] The Federal Circuit continued, recognizing that the claims-at-issue were not only generic, but were also genus claims with functional limitations, meaning that 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."[20] The point is that the patent specification must recite sufficient materials to accomplish the claimed functions. When it comes to chemical genus claims, the court explained that the patent's specification must include "'a precise definition, such as by structure, formula, or chemical name' of the claimed subject matter sufficient to distinguish it from other materials."[21]

Reviewing the jury's findings for substantial evidence, the Federal Circuit ultimately found that the '190 patent's written description contained "scant details about which scFvs can bind which target antigens," which ultimately led to the Federal Circuit's conclusion that the patent lacked sufficient written description. According to the Federal Circuit, the '190 patent discloses only two example scFvs for binding two different targets, but otherwise contains no details about the scFv species beyond their alphanumeric designations for a skilled artisan to determine how or whether they are representative of the entire claimed genus. The Federal Circuit found that the evidence did not support Juno's argument that these two working embodiments are representative of all scFvs in the context of the patent's particular biologic application. The court therefore found that Kite demonstrated by clear and convincing evidence that the patent did not satisfy the written description requirement and the record did not contain substantial evidence upon which a jury could have concluded otherwise.

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[18] Op. at 6, quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351, 1348 (Fed. Cir. 2010) (en banc).
[19] Op. at 7, quoting *Ariad*, 598 f.3d at 1351.
[20] *Id.*, citing *Ariad*, 598 F.3d at 1349.
[21] *Id.* quoting *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)).

3. Juno's Petition to the Supreme Court

In June 2022, Juno filed a petition for writ of certiorari with the United States Supreme Court. The issue, as framed by Juno, is whether the written description requirement is to be measured by the statutory standard of "in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the same," or, in Juno's words, "is it to be evaluated under the Federal Circuit's test, which demands that the 'written description of the invention' demonstrate the inventor's 'possession' of 'the full scope of the claimed invention,' including all 'known and unknown' variations of each component?" According to Juno, the Federal Circuit's decision contradicted the statute and Supreme Court precedent, as well as other circuit's interpretations. In its petition to the Supreme Court, Juno argued that the Federal Circuit wrongly held that Section 112 requires the patent show the inventor had "possession" of the invention, a standard Juno said is often "impossible to meet." Juno also argues that the Federal Circuit's erroneous interpretation threatens research an innovation, particularly in the life sciences.[22]

In response, Kite argues that precedent has held for over 50 years that § 112's requirement of a "written description" is distinct from the requirement to "enable any person skilled in the art to make and use the" invention, and that the written description was clearly not met in this case. In its brief in opposition, Kite argues that "Although there are millions of billions of possibilities for [the '190 patent's claimed function of its ability to bind to a particular structure], only an uncertain fraction would make the protein bind as claimed, and the patent discloses nothing that would allow scientists to predict which possibilities would." Kite has argued that Juno's points are meritless and that the case is a poor vehicle for Supreme Court review.

Briefing by the parties closed on August 24, 2022.

4. What could change if the Supreme Court grants cert?

Although the Federal Circuit did not rely on *Wands* in this case as they did in *Amgen v. Sanofi*, the issue is similar in that again the court faced generic claims with functional language. Here, the take home for patent prosecutors is that there needs to be careful attention to providing more specific guidance on how representative examples in a genus are actually representative. If the Supreme Court grants cert in this case, perhaps more light will be shed on how generic claims with functional language in biologics patents may need to change, or not. In the meantime, litigants should beware more written description challenges, particularly when it comes to generic claims with functional language.

[22] Brief for Petitioner, *Juno v. Kite* (petition for cert. filed Jun. 13, 2022) (No. 21-1566), at 2.

Case 3: *Biogen Int'l GmbH v. Mylan Pharms., Inc.*, 18 F.4th 1333 (Fed. Cir. 2021)

1. Brief Background

The third case of the year in which Section 112 is at the center of controversy was another pharmaceutical case, this one involving Biogen International Gmbh and Mylan Pharmaceuticals, Inc. In that case the Federal Circuit affirmed the invalidation of a Biogen patent covering the blockbuster multiple sclerosis drug Tecfidera®, due to the alleged failure to meet Section 112 written description requirement. In this case, Mylan had availed itself of the Hatch-Waxman Act ANDA procedures to alert the FDA of its plans to release a generic version of Biogen's brand name drug, Tecfidera®, a dimethyl fumarate (DMF) product for the treatment of multiple sclerosis. Biogen filed a multi-patent infringement suit in response, but only one patent (U.S. Patent No. 8,399,514 ("the '514 patent)) became the focal point for the trial and ensuing Federal Circuit appeal.

The claims at issue in Biogen's '514 patent recite a method of administering a therapeutically effective amount of about 480 mg of DMF per day to treat multiple sclerosis.

Claim 1 provides for:

> A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of
>
> (a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and
>
> (b) one or more pharmaceutically acceptable excipients, wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.

The specification of the '514 patent recites a range of effective doses of DMF, including "from about 480 mg to about 720 mg per day." Notably, the DMF480 limitation was not in any of the claims in the parent applications, but it was included in a preliminary amendment filed with the application that matured into the '514 patent.

At a bench trial, the sole issue was whether or not Biogen's '514 patent was invalid for failure to meet the written description requirement.

The issue was whether or not the original specification of the parent to the '514 patent sufficiently disclosed "possession" of the claimed therapeutically effective DMF480-dose limitation to treat MS. According to the district court, the specification did not sufficiently describe DMF480 as being therapeutically linked to MS treatment sufficient to meet the written description requirement. The district court did not find Biogen's expert credible on this issue and instead credited Mylan's testimony, and ultimately found the claims of the '514 patent invalid for failing to meet the written description requirement.

2. What Happened at the Federal Circuit

On Appeal, Biogen argued that the district court erred, in large part by having confused the issues of clinical efficacy and therapeutic effectiveness, but to no avail. The Federal Circuit, in a majority opinion written by Circuit Judge Reyan, found the district court did not err in finding the '514 patent claims invalid for lack of written description under 35 U.S.C. § 112. The Federal Circuit heavily relied on the district court's factual findings that the specification only explicitly mentioned a DMF480 dose once, and that the single reference to DMF480 was "part of a wide DMF-dosage range and not listed as an independent therapeutic efficacious dose." The single paragraph in the specification with dosing information included a wide range of other doses, including doses a skilled artisan would expect to be ineffective and a doses well above the therapeutically effective range.[23] The Federal Circuit found important that the specification focused on drug discovery and basic research rather than the therapeutic effectiveness of DMF480 as a dose to treat MS. The Federal Circuit also found important the district court's reliance on Mylan's discrediting of Biogen's expert.

Circuit Judge O'Malley wrote a dissenting opinion, criticizing the majority for appearing to reweigh the evidence rather than review the findings of the district court. O'Malley also thought the district court conflated therapeutic and clinical efficacy, which caused it to erroneously require clinical data in the specification, rather than a disclosure of therapeutic effects, which the specification included. The dissent also criticized the district court's application of "blaze mark" cases, which should not apply in this case, since the claim was not to a genus but to a species that was explicitly mentioned in the specification. And even if applied, the specification provides sufficient blaze marks. "How much brighter need a disclosure blaze?"

After the decision, Biogen sought rehearing *en banc*, which the Federal Circuit denied in a 6-3 vote. Biogen has since filed a petition seeking Supreme Court review.

3. Biogen's Petition to the Supreme Court

According to Biogen, the Federal Circuit improperly held that Section 112 requires proof that an invention is effective; a requirement Biogen argues has no basis in law. The sole issue Biogen raises in its petition for review to the Supreme Court is:

> Is 35 U.S.C. § 112's requirement that a patent specification "contain a written description of the invention" met when the specification describes the invention, or must the specification also disclose data that demonstrates the claimed invention is "effective" and emphasize the claimed invention by singling it out and describing it more than once?[24]

[23] Op. at 17–18.
[24] Brief for Petitioner, *Biogen v. Mylani* (petition for cert. filed Jun. 14, 2022) (No. 21-1567), at *i*.

Biogen has argued that the Federal Circuit's decision contradicts the language and purpose of Section 112 and longstanding precedent, and that the decision threatens innovation.[25] Biogen also argues that the fact that the Federal Circuit itself has been so divided in this particular case shows that future decisions will be panel-dependent and unpredictable unless the Supreme Court weighs in.[26]

Not surprisingly, Mylan argues that the Federal Circuit decision should be left undisturbed, that it is supported by extensive evidence and consistent with well-settled law.[27] Mylan also argues that it is Biogen's approach that would threaten innovation and that Biogen has "manufacture[d] an 'internal division' within the Federal Circuit."[28]

4. What could change if the Supreme Court grants cert?

If the Supreme Court does not take this case up on review, there could be some repercussions felt by patent prosecutors and litigants in the years to come. For example, to the extent the *Biogen* Federal Circuit decision may stand for the proposition that mentioning an embodiment once in a specification is insufficient to meet written description requirements, we may see patent specifications take on more repetition than they already have, out of fear of later invalidation. There may also be an increase in describing unclaimed embodiments, out of the same concern. Alternatively, out of concern that the description of unclaimed embodiments could distract from the description of claimed embodiments, practitioners could choose to avoid describing unclaimed embodiments altogether. To this point, the dissent in the denial of *en banc* review argued that the majority panel erroneously emphasized unclaimed disclosures in the specification. According to the dissent, the specification expressly described the claimed species, which made the disclosure sufficient for purposes of written description. Also, as the dissent in the denial of *en banc* review pointed out, there may be a blurring of the line between written description and enablement. Specifically, the dissent argued that "[b]y focusing on whether the patentee proved that 480 mg per day is an effective amount to treat multiple sclerosis—as distinct from whether the '514 patent specification discloses that 480 mg per day is an effective amount to treat multiple sclerosis—the panel majority and the district court erroneously imported operability considerations into the written description analysis." According to the dissent, the express statement in the specification that "480 mg per day is an effective amount" satisfied the written description requirement, notwithstanding the lack of any additional evidence or data in the patent that such a dose would actually be therapeutically effective.

The parties have completed the briefing process at the Supreme Court and as of August 31, 2022, the case has been distributed for conference of September 28, 2022.

[25] *Id.* 19 and 29.
[26] *Id.* 32-33.
[27] Brief for Respondent, *Biogen v. Mylani* (petition for cert. filed Jun. 14, 2022) (No. 21-1567), at 17.
[28] *Id.* at 28-30.

CONCLUSION

Although written description and enablement cases may not have historically received a lot of press in patent infringement cases, the tables may soon be turning. If the Supreme Court grants cert in any one of the three cases discussed in this article, the landscape for written description and enablement defenses may see some changes. For now, best practices suggest including more description in patent specifications than ever before, particularly in patents involving genus claims with functional limitations. Meanwhile litigants would be best served by preparing for more battles over written description and enablement issues, requiring earlier development of specific strategies and collection of evidence to deal with these issues.