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EVISCERATING PATENT SCOPE

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ABSTRACT

The scope of patent claims directed to inventions in the field of pharmaceuticals and biotechnology has been stumped by the Court of Appeals for the Federal Circuit's recent jurisprudence on 35 U.S.C. § 112. Specifically, the application of a heightened test for enablement of claims to a genus of compounds with functional limitations or a genus of therapeutic antibodies, coupled with an increasingly broader application of the written description doctrine, has resulted in considerable uncertainty in the biopharmaceutical industry. The Federal Circuit's shift in interpreting 35 U.S.C. § 112 contravenes the statute and Supreme Court precedent by splitting the singular standard of § 112(a) into two separate requirements, namely "enablement" and "written description", and by going a step further to treat enablement as a question of law when no such distinction was ever envisaged by Congress or held by the Supreme Court. This judicially created approach in recent years has set aside over a century of patent practice to now make it exceedingly difficult to obtain meaningful patent protection for biopharmaceutical innovations and as a result has impeded investment and progress for developing lifesaving treatments. This article examines this legal scheme and highlights why changes to current patent disclosure laws and a return to a single 35 U.S.C. § 112(a) standard is necessary to avoid disrupting and inhibiting future innovation in the essential fields of pharmaceuticals and biotechnology.

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I. INTRODUCTION

A stable patent system is at the heart of how companies in the pharmaceutical and biotechnology industries innovate. These companies use patent law, and in particular genus claims, to make measured judgments when investing to develop and bring to market groundbreaking pharmaceuticals and therapeutics. Billions of dollars are necessary to move a novel scientific finding forward to the point of bringing a product to market.[1] Meanwhile, the market for such therapeutics is steadily expanding. For example, as well as pharmaceuticals, a large percentage of global drug sales now include biologics such as antibodies. Pharmaceuticals aside, these antibodies have become the dominant class of new drugs being developed to date, with estimates that the market for therapeutic antibodies will reach $300 billion by 2025.[2]

With such a large market for pharmaceuticals and biologics in the U.S., innovators expect robust and predictable patent protection to support their commercialization strategies. However, based on the Federal Circuit's increasingly rigid position when applying certain patent disclosure laws (referred to herein as Section 112(a)) to genus claims, the stark reality is that many of the existing antibody and pharmaceutical patents are invalid under current law. Moreover, it is presently all but impossible to obtain meaningful patent protection to cover pharmaceuticals and antibodies because the recent interpretation of patent disclosure laws by the Federal Circuit has all but killed off genus claims.[3]

Patents promote progress and innovation by financially incentivizing inventors to innovate by providing them exclusive rights to their discoveries.[4] The public benefits from this system because new technologies are created and

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[1] Olivier J Wouters, Martin McKee, & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323(9) J. AM. MED. ASS'N 844, 849 (2020); *see* Thomas Sullivan, *A Tough Road: Cost To Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%*, POLICY & MED. (Mar. 21, 2019), https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html.

[2] Ruei-Mein Lu, et al., *Development of Therapeutic Antibodies for the Treatment of Diseases*, 1 J BIOMED SCI 27, 1 (2020).

[3] Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 4 (2021).

[4] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576–80, 1676 (2003).

commercialized as a direct result of this financial incentive. This basic *quid pro quo* of patent law advances the interests of society. In exchange for an inventor "revealing to the public the substance of his discovery" so that the public is "enabled without restriction to practice it and profit by its use,"[5] the inventor is provided a period of exclusivity to stop others from making, using or selling the invention.[6] The law is therefore used to incentivize innovation by restricting certain activities for a limited period of time in the hopes that this will benefit all of society at a later date.

Thus, patents are central to incentivizing the commercialization of new technologies and this is foremost visible in the pharmaceutical and biotechnology industries.[7] Generally, the value of innovative pharmaceutical and biotechnology companies is dependent upon the scope of the patent portfolios they own. The scope of a patent in turn is tied to the breadth of the patent claims it contains, with the articulation of such patent claims demarcating the boundaries of the patent owner's rights.[8] Because patent claims are critical to capturing the intellectual property the inventor considers as her invention, the process of drafting them typically involves attempting to capture "classes" of items as opposed to narrow specific embodiments of the discovery. By way of extension, if the scope of the patent claim is narrow, the claims can be easily designed around to not be infringed. This outcome can be just as bad where a patent claim is drafted too broadly and is not commensurate with what is taught in the application. As a result, whether attempting to obtain a U.S. patent at the U.S. Patent and Trademark Office or during patent litigation in courts, examiners and judges are attuned to patent claims that attempt to capture more than the inventor has described and taught in the patent application for any given invention.

The scope or breadth of patent claims determine what exactly the inventor is claiming as her invention. Traditionally, the broader the scope of the claim, the more disclosure one would be expected to provide to support such a monopoly to a broad claim in a patent. In this context, the doctrines of enablement and written description in patent law have been key taskmasters to reflect which patent claims are valid and supported by relevant disclosures and which fail for being overly broad and not reflective of the inventor's disclosure.[9]

The statutory foundation for determining how much disclosure to include in a patent application can be found in 35 U.S.C. § 112(a), which 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

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[5] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989).

[6] Universal Oil Prods. Co. v. Globe Oil & Refining Co., 322 U.S. 471, 484 (1944).

[7] Diego Giugni & Valter Giugni, *Intellectual Property: a Powerful Tool to Develop Biotech Research*, 3(5) J. MICROB BIOTECHNOL. 493, 498–501 (2010).

[8] *In re* Warmerdam, 33 F.3d 1354, 1360 (Fed. Cir. 1994) ("It is the claims which define the metes and bounds of the invention entitled to the protection of the patent system.").

[9] *Id.*

> mode contemplated by the inventor of carrying out his invention.

Although there is a well-established statutory framework focusing on the contours of disclosure required when a patent application is filed, it has been left to the courts to demarcate the statute's meaning as to how much and what type of disclosure is necessary to satisfy this requirement to patentability. In so doing and in the context of the Supreme Court's statement that "[t]he object of the statute is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent,"[10] appellate courts have interpreted the statute and developed two related, yet separate, doctrines of "enablement" and "written description". However, although the statute at the center of this disclosure requirement is a short paragraph,[11] it has sparked intense debate and disagreement between judges on the Federal Circuit and District Courts, practitioners and scholars alike on how these two patent disclosure requirements interplay with each other, ought to be interpreted and whether the statute requires a single requirement or a dual disclosure requirement for patentability.[12]

In this paper, I focus on both the enablement and written description doctrines of 35 U.S.C. § 112(a) and seriatim highlight the reasons why the current law pertaining to enablement and written description is broken and damaging to the biopharmaceutical industry. The article ends by offering suggestions for correcting the law's direction.

It is evident from separate lines of judicial interpretations that there is a split in how different Federal Circuit opinions pronounce how the statute ought to be applied. For example, should a single embodiment of an invention be enough to enable the full scope of a patent claim? Interestingly, despite its deep statutory foundation, the enablement doctrine interpreting the statute was born in judicial opinions from the Federal Circuit. Yet, while one line of Federal Circuit cases finds the enablement requirement is satisfied if the description enables *any* mode of making and using the invention,[13] another line of decisions finds the opposite, namely, that the enablement requirement is only satisfied if the specification enables the full scope of the claims.[14] These interpretations squarely conflict with each other, as the former rule states that disclosing one mode satisfies enablement whereas the latter states that it does not.

A second example of this split within the Federal Circuit concerns how should one apply the separate written description requirement: to police priority as first intended or to assess if the inventor "possessed" the claimed invention upon filing.

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[10] Schriber-Schroth Co. v. Cleveland Tr. Co., 305 U.S. 47, 57 (1938).

[11] 35 U.S.C. § 112(a) (2022) ("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.").

[12] *See* Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344, 1361–67 (Fed. Cir. 2010) (Rader, J. dissenting in part).

[13] Bernard Chao, *Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule*, 2009 STAN. TECH. L. REV. 3, 7 (2009).

[14] Automotive Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1284 (Fed. Cir. 2007); Liebel-Flarsheim Co. v. Medrad Inc., 481 F.3d 1371, 1379–80 (Fed. Cir. 2007).

Unlike the enablement doctrine that has deep roots in U.S. law dating back at least to 1832,[15] the written description doctrine is a relative newcomer dating back to case law from the 1970s. And yet, written description only became a significant issue after the late 1990s when the Federal Circuit used this doctrine to prevent overreaching claims[16] and to stop patentees from attempting to claim features of their invention that they did not have possession of when the patent application was filed.[17] As such, whereas the enablement requirement "helps ensure that a person of ordinary skill in the art will be able to practice the full scope of the invention,"[18] the written description requirement's role has predominantly been to prevent a patentee from claiming more than the patentee *possessed* when the patent application was filed.[19]

In this paper, I first discuss the legislative history of 35 U.S.C. § 112(a) and how appellate courts have interpreted the statute over time. Next, this article introduces genus claims and highlights how critical this type of claim is for developing meaningful patent protection in the pharmaceutical and biotechnology industries. In part III, the Federal Circuit's current position concerning genus claims is analyzed to show how their present rigid position has made it exceedingly difficult to obtain valuable patent protection for drugs and biologics within the pharmaceutical and biotechnology industries, respectively.[20] In part IV, the paper discusses how this recent jurisprudence has negatively targeted these essential industries much more so than, for example, the mechanical or electrical industries.

As the plain statutory text of 35 U.S.C. § 112(a) shows, genus claims can fall within the scope of this statute, so long as the claim includes a written description 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."[21] This fact-intensive inquiry of whether a specification satisfies the disclosure requirement is for the jury to decide.[22] As such, it is for the jury to decide whether a claim to a genus of compounds, for example, satisfies § 112(a) by assessing whether an ordinary skilled artisan would appreciate the relevant structural characteristics and could easily identify the relevant compounds. The concern of the court – to stop broad claims to nascent, not fully developed inventions – is valid. However, the statute addresses this concern by allowing factfinders to ultimately decide whether a patent claim's breadth is warranted given the level of teaching in the patent application.

As discussed *infra* in part III, use of genus claiming strategies is at the heart of pharmaceutical and biotechnology patent law practice. A stable and predictable patent system is necessary, including predictability in key patent law principals such as genus claims, to entice the incredibly large financial, time and management

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[15] Grant v. Raymond, 31 U.S. (1 Pet.) 218, 241–42 (1832) ("The public yields nothing which it has not agreed to yield; it receives all which it has contracted to receive. The full benefit of the discovery . . .").

[16] Where a patentee can use amendments to the claims to capture more than what is described in the patent application.

[17] Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

[18] Otherwise referred to as policing priority.

[19] Jason Romrell, *Biting off More Than You Can Chew: The New Law of Enablement*, 23 BERKELEY TECH. L.J. 139, 143–44 (2008).

[20] Genus claims refer to claims that embody a number of separate species that make up the genus.

[21] 35 U.S.C. § 112(a) (2022).

[22] Battin v. Taggert, 58 U.S. (17 How.) 74, 85 (1854).

demands for developing a discovery in the medical arts and bringing it to market. If, as the Federal Circuit has done presently, rigid laws are used to in effect kill off the chances of obtaining any meaningful patent coverage using genus claims for pharmaceuticals and biologics, then it will likely have a deleterious effect on society by inhibiting advances in new drug discovery and development and ultimately patient access to new medicines.

As is developed further *infra* in parts IV–VI, recent Federal Circuit jurisprudence has deviated from statutory text and replaced having jury involvement on a case-by-case manner to instead provide for judicially-created rigid rules that not only have no statutory foundation, but are also not supported by Supreme Court precedent. Perhaps most importantly, in practice, the recent heightened requirements for § 112(a) has now made it all but impossible to obtain genus claims on pharmaceuticals and biologics. The creation of the written description doctrine by the courts in the 1970s had a narrow and useful limited scope, however, ever since the *Lilly* decision in 1997, the scope of this doctrine has grown and been increasingly used as a sharp tool to invalidate patent claims. In particular, the written description requirement now demands that inventors show they "had possession of the claimed subject matter," including the infringing embodiment, "as of the filing date."[23] And yet, "possession" is not a statutory requirement, but a judicial doctrine.[24] As will be developed *infra* in part V and VI, this approach to written description has much room for improvement.

Similarly, the enablement requirement is also being misinterpreted by the Federal Circuit. To comply with the enablement requirement, the current law requires "full scope" enablement by identifying every covered species that is encompassed by a genus claim even if there could be thousands of related species and screening and testing them would be "largely routine." Current enablement laws invalidate such genus claims "as a matter of law" because the claimed genus "would require synthesizing and screening" thousands of compounds for the desired effects.[25] This current fascination with identifying the boundaries of the patent claim by identifying every species that falls within a genus to demonstrate what the Federal Circuit calls "full scope" enablement is misguided. This is especially so, given identifying every species of a genus has no practical effect on the ability of an ordinary skilled artisan to make and test an operable species. As will be developed *infra* in parts IV–VI, this approach to enablement has much room for improvement.

On a more general level and separate to the focus on genus claims, another problem with the Federal Circuit's separate written description and enablement requirements is that neither of these two new approaches for interpreting enablement

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[23] Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*); *see also* Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014) (referring to "two separate and independent requirements" of written description and enablement).

[24] "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways." U.S. PAT. & TRADEMARK OFFICE, U.S. DEPT. OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURES § 2163.02 (10th ed. 2020) [hereinafter "MPEP"]. "To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed." (citing Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991)).

[25] Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1385–86 (Fed. Cir. 2013).

and separately written description have any foundation in the statutory text of § 112(a) and moreover conflict with Supreme Court precedent generally and on genus claims specifically.

35 U.S.C. § 112 mandates that patent applications must "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 make and use the same."[26] Instead of adhering to this statutory text, the Federal Circuit's decision to flout statutory text and split enablement and written description into two separate requirements has resulted in the court following-up and judicially creating the court's new "possession" standard and various sub-tests for written description, plus simultaneously shifting the enablement inquiry from the well-grounded "undue experimentation" factors to a requirement for patentees to now make and test all of the species within a genus and highlight which species works and which does not. This is a fundamental shift in approach.[27]

Part IV of this article highlights how the Federal Circuit's current jurisprudence on § 112(a) is causing havoc in the pharmaceutical and biotechnology industries. Innovators in this space are dammed if they do and dammed if they don't. Namely, they cannot claim the full scope of their invention because that would violate both the new genus-targeting rigid, numbers-focused "full scope" enablement rule and the separate written description's "possession" requirement if too few species are disclosed. Yet, innovators also cannot claim narrowly as that would enable competitors to design around narrow claims and take advantage by making minor changes to claims to create similarly efficacious pharmaceuticals that achieve the same outcome. It is for this reason that § 112 is eviscerating patent scope in certain industries much more so than others.[28]

In some respects, the Federal Circuit's recent jurisprudence on § 112(a) is not only punishing innovators in the pharmaceutical and biotechnology sector, but also

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[26] 35 U.S.C. § 112(a) (2022); *see e.g.*, Patent Act 1793, ch. 11, § 3, 1 Stat. 318, 321–22; *see also*, Patent Act of 1790, ch. 7, § 2, 1 Stat. 109, 110 (repealed 1793):

> 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.

[27] 35. U.S.C. § 112(a) (2022).

[28] Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RSRV. L. REV. 691, 706 (2004); Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1184 (2002).

providing rewards for the copycats. Creative innovators in this biomedical industry will turn their back on the patent system if their key inventions are suddenly not able to get the protection that they used to. Protection for narrow species does not adequately reward the innovator and allows copycats to make minor changes and bypass infringement without having to go through the difficult, expensive, and time-consuming innovation process. The long-term cost of this will be net negative for patients, as innovative pharmaceutical and biotechnology companies will pivot to target established biological pathways and targets rather than venture into new horizons. The result: potential new targets and therapeutics for patients will decline industry wide.

To fix § 112, part VI of this article proposes alternatives to the Federal Circuit's presently applied rigid approach to § 112(a), namely where genus claims that cover many species fail both the enablement requirement because they do not satisfy "full scope" enablement, and also fail the separate written description because the patent application is not able to show "possession" of the species upon filing. Instead of this current approach, one option to fix this problem would be to treat § 112(a) as having a singular requirement – a written description that enables – and make determinations on violations or compliance of the statute on a case by case, context-specific and flexible manner.

II. LEGISLATIVE HISTORY OF 35 U.S.C. § 112(A)

The requirement that a patent application "describe" the invention is nothing new. Indeed, this requirement has carried through from the language of the first Patent Acts of 1790 and 1793 to today.[29] For example, similar in language to the current law, the Patent Act of 1793 provided that the inventor: "shall deliver *a written description* of the 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 to make, compound, and use the same."[30] Other similarities in the statutory language between the Patent Act of 1793 and current law concerning how an invention should be "described" and enabled also exist. For example, similar to the Patent Act of 1952, the Patent Act of 1793 requires "a written description of the invention"[31] and that it be "in such full, clear and exact terms . . . and to enable."[32]

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[29] Today, this is codified in 35 U.S.C. § 112. 35 U.S.C. 112(a) provides:

> 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.

Id. (emphasis added) (2022).

[30] The Patent Act of 1793, ch. 11, §3, 1 Stat. 318, 321–22 (emphasis added).

[31] While the Patent Act of 1793 mentions "shall *deliver* a written description", the Patent Act of 1952 requires that patent application "shall *contain* a written description." Patent Act of 1952, ch. 11, § 112, 66 Stat. 792, 798 (emphasis added).

[32] *See* The Patent Acts of 1790 and 1793, *supra* note 26.

However, this 200+ year old Patent Act, unlike current law, required that the written description distinguish the invention from the prior art.[33] Although the requirement to have "a written description of the invention . . . in such full, clear and exact terms" was maintained in the Patent Act of 1836, the requirement for the written description be used to distinguish the invention from the prior art was removed in 1836 and instead "claims" that clearly identify the invention were introduced and became a requirement.[34] Subsequent Patent Acts, including the Patent Act of 1870, kept this language intact.[35] The same language was also used in the Patent Act of 1952 and today, the written description requirement is codified in 35 U.S.C. § 112(a),[36] with 35 U.S.C. § 112(b) requiring clarity in claim language.[37] Thus, under current law, the patent claims aim to distinguish the invention from the prior art, and the specification of the patent application is used to enable one of skill in the art to make and use the claimed invention.[38]

A. Appellate Courts' Interpretation of 35 U.S.C. § 112(a)

The first patent statute was passed in 1790 in the U.S., and it included the requirement that patent application *describe* the invention.[39] Since then and over the last 230+ years, the Patent Act has been amended a number of times, however, this "written description" requirement was left intact,[40] albeit its role became less

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[33] *See id*.

[34] The Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119.

[35] The Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201.

[36] *Id.*

[37] Requires that the claims "particularly point out and distinctly claim the subject matter" the inventor "regards as the invention." 35 U.S.C. 112(b) provides that "[t]he 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(b) (2022).

[38] *Id.*

[39] Patent Act of 1790, ch. 7, §§ 1–7, 1 Stat. 109, 110–11 (repealed 1793) (emphasis added) (requiring patentee to deliver specification *describing* invention to Secretary of State).

[40] Patent Act of 1793, ch. 11, § 3, 1 Stat. 318, 321–22:

> Every inventor, before he can receive a patent 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;
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> Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119:
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> He shall deliver a written description of his invention or discover, 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;

Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201; Patent Act of 1952, ch. 950, 66 Stat. 752.

significant once having "claims" in a patent application became a statutory requirement.[41]

Written description and enablement are two separate requirements under current patent laws in the U.S.[42] Although there is great overlap between these two doctrines and the justification of having two such closely overlapping requirements stemming from the same sentence of the statute is at best unclear, there remains nevertheless the idea that written description and enablement serve different purposes. Namely, while written description aims to make sure an inventor had "possession" of her invention upon filing of the patent application,[43] the enablement requirement aims to ensure that sufficient disclosure is provided in the patent application such that an ordinary skilled artisan could practice the invention without having to perform "undue experimentation."[44]

The Federal Circuit has provided "illustrative, not mandatory"[45] guidance for determining if any experimentation is "undue"[46] and this includes assessing various factors, such as (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the application as filed.[47] Under this rubric, the specification is found to be enabled only if upon balancing of these factors an ordinary skilled artisan could make and use the invention without undue experimentation.[48] This enablement requirement allows an ordinary skilled artisan to practice "the full scope" of the invention and to do so, the specification of the patent must teach that person "how to make and use the full scope of the claimed invention without undue experimentation."[49] Some experimentation is permissible, so long as it is not "undue."[50]

Enablement has a 200+ year old statutory foundation, however, the actual doctrine of enablement was developed by the courts and their judicial interpretation of the statute. This doctrine has been a feature of patent law in the U.S. since 1832, if not before.[51] The written description as a requirement for patent applications,

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[41] Markman v. Westview Instruments, 517 U.S. 370, 379 (1996) ("Claim practice did not achieve statutory recognition until the passage of the Act of 1836 and did not become a statutory requirement until 1870."); *see* Patent Act of 1870, ch. 230, § 26, 16 Stat. 198.

[42] Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

[43] MPEP, *supra* note 24, § 2163.

[44] MPEP, *supra* note 24, § 2164.

[45] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991).

[46] Patent applications must "contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112(a) (2022). It is noteworthy that the term "undue experimentation" does not appear in the statute, however, "it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation." *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

[47] *In re Wands*, 858 F.2d at 737 (Fed. Cir. 1988).

[48] *Id.*

[49] *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

[50] Sean B. Seymore, *Patenting Around Failure*, 166 U. PA. L. REV. 1139, 1165–73 (2018); *see* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986).

[51] Grant v. Raymond, 31 U.S. 218, 241–42 (1832) ("The public yields nothing which it has not agreed to yield; it receives all which it has contracted to receive. The full benefit of the discovery.").

however, was first developed in case law from the 1970s.[52] Beginning in the 1990s, the Federal Circuit changed this area of settled law to instead impose a new court-created written description standard.[53] During this period, the Federal Circuit desired to stop the amending of patent claims during prosecution to capture broader scope than what was disclosed in the specification upon filing of the patent application. To do so, the Federal Circuit started requiring patent applications "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, that the patentee was in *possession* of the invention."[54]

Judges, scholars, and practitioners alike have argued against having separate requirements for enablement and written description.[55] Indeed, there is nothing in the statute that would indicate patent specifications must include separate requirements for written description and enablement. Instead, the statue requires a written description of the invention that enables the claimed invention.[56] Since written description is a relatively new doctrine that has been developed by the courts and one which lacks any statutory foundation, the Federal Circuit has developed, and several times revised, subtests for assessing compliance with the court's new "possession" requirement for written description. And yet, as is developed further *infra* in parts III–V, the latest version of this requirement has fundamental problems with it, especially as it relates to its application within the pharmaceutical and biotechnology industries.[57] This evolving nature in how this judge-made law is being applied is causing great uncertainty and instability to the detriment of society as a whole.[58]

Turning to enablement, there is a history of a split between appellate decisions that recognize disclosure of one mode of an invention as being sufficient to satisfy the enablement requirement and other decisions that require "full scope" of the claim to be enabled. For example, the theme in one line of Federal Circuit cases is that "the enablement requirement is met if the description enables *any* mode of making and

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[52] *Id.*

[53] Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 979–80 (Fed. Cir. 2002).

[54] Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991) ("To the uninitiated, it may seem anomalous that the first paragraph of 35 U.S.C. § 112 has been interpreted as requiring a separate 'description of the invention.'").

[55] Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 62–69 (2000).

[56] 35 U.S.C. § 112(a) (2022):

> 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.

(emphasis added).

[57] *See* discussion in part IV, *infra*.

[58] The Federal Circuit recently created several "possession" sub-tests, which they later modified or rescinded.

using the invention."[59] That is, disclosure of one mode is sufficient. And yet, another line of Federal Circuit cases stands for the opposite – that disclosure of a single mode fails to enable an invention's "full scope."[60] Moreover, as is discussed separately in parts IV and V, the level of disclosure required to satisfy the separate, yet related, written description requirement is also hotly debated amongst various stakeholders.

One of the early "one mode" line of enablement decisions is *Engel Industries, Inc.*, a decision that stands for the proposition that *any* mode of making and using an invention would satisfy the enablement requirement.[61] Other cases also highlighted that patentees are not expected to provide test results of every species encompassed by their patent claim. For example, in *In re Angstadt*, [62] the patentee claimed a method of catalytically oxidizing alkylaromatic hydrocarbons to form a mixture comprising the corresponding hydroperoxides.[63] The claim was rejected on the basis that an ordinary skilled artisan would not have known which catalysts would produce the desired hydroperoxides without performing undue experimentation.[64] However, the court reversed the USPTO, deciding that the patentee was not required to "disclose a test with every species covered by a claim" since that would require the specification to contain thousands of examples which would be "a prohibitive number of actual experiments."[65] This analysis was later clarified by the other seminal and often cited case of *In re Wands*.[66]

More recently and in direct contrast to its own "one mode" precedent, the Federal Circuit has embraced the "full scope" of the claim enablement doctrine. For example, in *Automotive Technologies v BMW*, the court decided that one embodiment of practicing the invention would not be enough,[67] stating that "disclosure of only mechanical side impact sensors does not permit one skilled in the art to make and use the invention as broadly as it was claimed, which includes electronic side impact sensors."[68] Similarly, in *Liebel-Flarsheim v. Medrad*, the court rejected the

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[59] *See* Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quoting Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991)) (holding claim to genus of antibodies enabled by disclosure of one cell line); Edwards Lifesciences AG v. CoreValve, Inc., 699 F.3d 1305, 1309 (Fed. Cir. 2012); and Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1338–39 (Fed. Cir. 2003) (enablement requirement satisfied if the description enables "any mode of making and using the invention"); *Johns Hopkins*, 152 F.3d at 1359.

[60] Auto. Techs. Intl, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007); *see also* ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 943 (Fed. Cir. 2010) (holding "full scope" of claims not enabled where one of two methods of drug delivery disclosed); Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999–1000 (Fed. Cir. 2008) (holding claim to games as failing the enablement requirement when movies also fell within claim's scope).

[61] Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991); *see also In re* Glass, 492 F.2d 1228, 1233 (C.C.P.A 1974) ("Nonenablement is failure to disclose any mode.").

[62] *In re* Angstadt, 537 F.2d 498, 501–02 (C.C.P.A. 1976) (rejecting an enablement challenge despite the need for experimentation).

[63] *Id.* at 499.

[64] *Id.* at 501.

[65] *Id.* at 502.

[66] *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

[67] *Auto. Techs.*, 501 F.3d at 1285. This case involved a claim to two embodiments, with only one of them being disclosed in the specification. The court found that failure to disclose both embodiments made the claim directed to both embodiments invalid.

[68] *Id.*

disclosure of one embodiment as satisfying the enablement requirement,[69] citing another decision for the proposition that "as part of the *quid pro quo* of the patent bargain, the applicant's specification must enable one of ordinary skill in the art to practice *the full scope of the claimed invention*."[70] Moreover, another older case was used as support for this "full scope" enablement of the invention, rejecting single embodiments as failing the enablement requirement.[71]

This concept of the scope of patent claims being "commensurate" with the teachings of the patent disclosure is also a feature that was developed as a doctrine in the 1970s and is routinely applied to date.[72] For example, in *Fisher*, the court opined that "the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."[73]

However, the split between the one mode and "full scope" enablement lines of Federal Circuit cases is best placed in context by reviewing Supreme Court decisions that have interpreted the relevant statute. Of the Supreme Court cases from the 19th century on point, *Morse v. O'Reilly* is best known. There, the inventor for the telegraph, Morse, sued O'Reilly for infringing his patent.[74] The Supreme Court invalided the claim because Morse indicated that he did not wish to limit his invention to the specification and claims.[75] Chief Justice Taney found the claim invalid, explaining "this claim can derive no aid from the specification filed. It is outside of it, and the patentee claims beyond it."[76] Two 19th century Supreme Court decisions that followed *Morse* both indicated that patent claims stand valid and adequately supported by a single disclosed mode for carrying out the method.[77] And yet, although Alexander Graham

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[69] Similar to the *Automotive Tech.* decision, this case involved a claim to two embodiments, with only one of them being disclosed in the specification. The patent claim was deemed invalid because the specification did not disclose both embodiments. Liebel-Flarsheim v. Medrad, 481 F.3d 1371, 1379–81 (Fed. Cir. 2007).

[70] *Id.* at 1380 (quoting AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003)) (emphasis added).

[71] *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993) ("the applicant's specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention.")

[72] *In re* Fisher, 427 F.2d 833, 837 (C.C.P.A. 1970).

[73] *Id.*

[74] O'Reilly v. Morse, 56 U.S. (17 How.) 62, 77 (1853).

[75] *Id.* Claim 8 of Morse's patent stated, "*I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims*; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, signs or letters, at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer." *Id.* (emphasis added).

[76] *Id.* at 119–20.

[77] Tilghman v. Proctor, 102 U.S. 707, 728–30 (1880); Dolbear v. Am. Bell Tel. Co., 126 U.S. 1, 535 (1888). In *Tilghman*, the Court stated that:

> If the mode of applying the process is not obvious, then a description of a particular mode by which it may be applied is sufficient. There is, then, a description of the process and of one practical mode in which it may be applied. Perhaps the process is susceptible of being applied in many modes and by the use of many forms of apparatus. The inventor is not bound to describe them all in order to secure to himself the exclusive right to the process, if he is really its inventor or discoverer. But he must describe some particular mode, or some apparatus, by which the

Bell's broad patent claim was held valid,[78] the Supreme Court found the claim in the *Incandescent Lamp* to be invalid as too broad given the disclosure.[79] In some respects, much akin to the split in the Federal Circuit's interpretation of the statute, there appears to also be some form of a split in the Supreme Court's own decisions, albeit this has been interestingly reconciled by using an implicit doctrine.[80]

Courts have interpreted § 112 as requiring a written description that enables. In particular, requiring a written description "of the invention, and of the manner and process of making and using it" such that it is "in such full, clear, concise, and exact terms as to enable" an ordinary skilled artisan to practice the invention.[81]

On written description, one of the first Supreme Court decisions to interpret the Patent Act of 1793 is *Evans v. Eaton*.[82] Here, the Supreme Court invalided a patent directed to an improved hopperboy for failing to satisfy the written description requirement because no distinct improvement was disclosed.[83] In this 1822 decision, the Supreme Court opined that the written description was necessary so that patentees would not obtain patents that are "broader than their invention."[84] More recently, the Federal Circuit's predecessor found a claim to a single compound invalid for failing the written description requirement where the specification disclosed a general chemical structure with multiple variables.[85] Here, the court found that the general disclosure could yield "half a million possible compounds" and that this does "not constitute support for" a claim to one particular compound unless there is further disclosures to guide an ordinary skilled artisan to choose that particular compound over many other options.[86] This was the first time that the court had used written description separate from enablement in order to disallow new matter to be added during patent prosecution in order to prevent applicants from using the amendment process to update their disclosures.[87]

This case was later interpreted by others outside of the narrow context of determining priority and date of invention, with these latter cases creating an

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> process can be applied with at least some beneficial result, in order to show that it is capable of being exhibited and performed in actual experience.

Tilghman, 102 U.S. at 728–29. In *Dolbear*, the Court stated that:

> The law does not require that a discoverer or inventor, in order to get a patent for a process, must have succeeded in bringing his art to the highest degree of perfection; it is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation.

Dolbear, 126 U.S. at 536.

[78] *Dolbear*, 126 U.S.at 539.

[79] Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 472, 476–77 (1895).

[80] Jason Rantanen, *The Doctrinal Structure of Patent Law's Enablement Requirement*, 69 VAND. L. REV. 1679, 1705–07 (2019).

[81] Roy v. Tatham, 63 U.S. (1 Black) 132, 138–139 (1860).

[82] Evans v. Eaton, 20 U.S. (7 Wheat.) 356 (1822).

[83] *Id.* at 434.

[84] *Id.* at 431–32.

[85] *In re* Ruschig, 379 F.2d 990, 996 (C.C.P.A. 1967).

[86] *Id.* at 993.

[87] *Id.*

additional requirement above and beyond that stated in the statute, namely that patent applications must also have a written description of the invention and demonstrate that the inventor "was in possession of the invention" as of the filing date.[88] Indeed, the Federal Circuit embraced this requirement outside of the narrow context of priority determinations and in 1997, in *Lilly*, decided a patent claim is invalid on the basis that the inventor had not shown "possession" of his invention and therefore failed the written description requirement.[89] This decision and others that followed it were met with great skepticism by judges, scholars and practitioners alike.[90] For example, Judge Rader viewed the Federal Circuit's decision in *Lilly* to be the first time the written description was being used as a "general disclosure doctrine in place of enablement."[91] In his and other scholars' view, the use of the written description requirement outside of context of policing against new matter addition during prosecution has elevated the written description to "an effective super enablement standard."[92]

In *Ariad v. Lilly,*[93] the court decided the key question of whether the first paragraph of 35 U.S.C § 112 requires a written description that enables one of skill in the art to make and use the claimed invention (single requirement), or requires a written description separate and apart from the enablement requirement (double requirement). Over vigorous dissents,[94] the Federal Circuit sat *en banc* and the majority reaffirmed that written description and enablement are distinct requirements, and each is to be assessed under different standards. In *Ariad*, the claim was to a method for regulating gene expression using the transcription factor NF-kB.[95] The court held that the claims encompassed a genus of ways to obtain the desired outcome and yet the specification had not disclosed a representative number of species from within that claimed genus that could accomplish that desired result.[96] The court used this biomedical case to also reject the notion that the application of written description in this new way amounts to a "super enablement" standard being applied to pharmaceutical and biotechnology inventions.[97]

Thus, in this key case, the Federal Circuit, sitting *en banc*, reaffirmed its prior decision in *Lilly*, holding that that 35 U.S.C § 112 requires separate written description and enablement, with each having different standards.[98] Whereas the enablement requirement is grounded in statutory language, namely a "written description of the manner and process of making and using" the invention so that it is "full, clear, concise, and exact" as to enable ordinary skilled artisans to practice the invention, the written description requirement is a judge-made, non-statutory requirement that mandates

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[88] Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563–1564 (Fed. Cir. 1991).

[89] Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567–69 (Fed. Cir. 1997).

[90] *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1368 (Fed. Cir. 2010) (*en banc*) (Linn, J., dissenting); *Id.* at 1361–67 (Rader, J., dissenting in part).

[91] Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 979–80 (Fed. Cir. 2002); *Lilly*, 119 F.3d at 1566–67.

[92] *Enzo Biochem, Inc.*, 323 F.3d at 982.

[93] *Ariad*, 598 F.3d at 1366.

[94] *Id.* at 1361–67 (Rader, J. dissenting in part); *Id.* at 1368 (Linn, J., dissenting).

[95] *Id.* at 1351.

[96] *Id.* at 1350.

[97] *Id.* at 1352.

[98] *Id.*

patent applications convey "that the inventor *had possession* of the claimed subject matter as of the filing date."[99] Moreover, to apply its judicially-created "possession" standard, the Federal Circuit also created various sub-tests. For example, based on *Lilly*, for pharmaceutical genus claims, "a representative number of species within the genus" is required to show "possession" of the genus.[100] The *Ariad* decision endorsed *Lilly*'s sub-test and this broader extra-statutory new written description doctrine has since been used to invalidate many patents.[101]

The current law, therefore, has resulted in an unclear landscape where stakeholders are not certain of the contours of the varying sub-tests, particularly how many or what type of species are required to satisfy the requirements of 35 U.S.C § 112 for claiming a genus.

III. GENUS CLAIMS DRIVE INNOVATION IN PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES

The Patent Act is "a technology-neutral statute."[102] However, the non-statutory, judge-created "possession" requirement (a.k.a "super enablement") and its related sub-tests, in practice, have accounted for technology-targeted barriers to patentability. Namely, this standard has amounted to a unique obstacle for patenting innovation in the pharmaceutical and biotechnology sector – an obstacle that would be "inconceivable in other industries."[103]

As such, the scope of § 112(a) is being used by the Federal Circuit to erect barriers to patentability, especially in the essential fields of pharmaceuticals and biotechnology. In these biomedical fields, patent claims to a group of related molecules, or "genus," are used as key features of the commercialization process for these innovations.[104] Until recently and before the Federal Circuit changed course dramatically to limit use of genus claims, such claims to a genus of small molecules or, for example, large molecules such as antibodies, were allowed by the U.S. Patent and Trademark Office and upheld by courts for satisfying the enablement requirement.[105]

Genus claims are a fundamental feature of the patent landscape in the pharmaceutical and biotechnology industry and innovative companies within this industry rely on such claim drafting strategies in a predictable patent system to protect their investments in bringing novel therapeutics to market. It is estimated that less than 10% of drugs in development at a given time will ever reach the market, and the cost for doing so is between $2-3 billion for bringing one new drug to market.[106] It is, therefore, perhaps not surprising that in just the past decade, hundreds of billions of

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[99] *Id.* at 1344–45, 1351 (emphasis added).

[100] *Lilly*, 119 F.3d at 1568–1569.

[101] *See e.g.*, Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

[102] Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1327 (Fed. Cir. 2003).

[103] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1653–1654 (2003); Craig A. Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1664 (2007).

[104] *In re* Kalm, 378 F.2d 959, 963 (C.C.P.A. 1967) (indicating that in chemistry, "genus" means "a group of compounds closely related both in structure and in properties.").

[105] Alan L. Durham, *Patent Scope and Enablement in Rapidly Developing Arts*, 94 N.C. L. REV. 1101, 1109 (2015).

[106] Sullivan, *supra* note 1.

dollars have been spent on discovery and development of innovative compounds and therapeutics to satisfy society's growing medical needs.

Since genus claims are central to patent protection in these vital industries, forgoing strong patent protection that such claims provide will result in fewer companies ever taking on the considerable risk of expending monetary resources on developing such pharmaceuticals or biologics.[107] Sadly, if the Federal Circuit does not change course and continues to use its recent § 112(a) jurisprudence to disincentivize truly innovative companies, the practical reality is that new drug development will become stagnated and slow considerably in the decades ahead.

A. Genus Claims

A key mechanism by which companies in the pharmaceutical and biotechnology industries protect their innovation is by using genus claims as part of their patent portfolio management strategy. Often the discovery of a chemical that has a particular use enables the inventor, for example, to capitalize on the discovery by claiming not only that one chemical entity that was discovered but also all related chemical structures that would perform the same function. These related chemical structures form a genus. As such, patent lawyers' clients who have made a discovery of one "species" of a chemical will typically aim to protect more than just that species. These genus claims are carefully drafted to encompass a broader claim to structurally similar compounds (*i.e.* to capture many species within that genus). These genus claims that once were the stable feature of patent law have recently become all but worthless; so much so that prominent scholars have gone so far as recently saying that genus claims are dead.[108] As is discussed in part IV, genus claims should be reaffirmed as being viable under the Patent Act. To do otherwise, would be to upend the pharmaceutical and biotechnology industries' incentives to develop novel drugs and biologics and their ability to protect their innovation.

Until relatively recently, the U.S. Patent and Trademark Office allowed genus claims to issue and courts upheld their validity during litigation so long as the specification included enough information that a person of ordinary skill in the art could practice the invention without undue experimentation.[109] However, claiming a genus as a tool in patent law practice has all but disappeared as an option, directly because of changes in how the Federal Circuit is now interpreting 35 U.S.C. § 112(a). For example, presently, if a genus encompasses thousands of possible chemicals, the court will reject the genus claim as invalid, if it does not further detail the nature of each of those species to identify those that work for its intended purpose. This fundamental change in approach has been especially felt in the pharmaceutical and biotechnology industries.

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[107] Giugni & Giugni, *supra* note 7, at 493–506.

[108] Karshtedt et al., *supra* note 3, at 5.

[109] 35 U.S.C. § 112(a) (2022) (provision containing the enablement requirement).

IV. CURRENT 35 U.S.C. § 112(A) JURISPRUDENCE IS UNTENABLE AND HIGHLY DAMAGING FOR NEW DRUG AND BIOLOGICS DEVELOPMENT

New drug development is a process that takes sometimes decades and costs into the billions of dollars.[110] Innovative biopharma companies pursue this process with no guarantees of success. During this research and development process, the research can generate a large group of chemically related compounds that the inventors believe would be active against the target disease or condition. As part of the race to file a patent application before others on such a discovery, patentees often file patent applications with claims that encompass a large genus of compounds to obtain meaningful patent protection on their discovery.

Were it not for the ability to protect such painstaking research with genus patent claims, it would be easy for third parties to design around very narrow embodiments of a particular species and instead practice substantially similar compounds without infringing the innovator's patent and thereby unfairly take advantage of the innovator's time and expense spent to develop the technology. Conversely, it is self-evident to see that by allowing too broad a genus claim, a patent can then be used as a weapon to prevent others from researching and developing technology in that field. As such, although this tunes our attention to assess where the line gets drawn vis-à-vis the validity of genus claims, it is clear that the present status quo for genus claims is unpredictable and untenable and has cost and will cost the drug development industry dearly.

Viewed holistically with a broad lens, it is perhaps revealing to appreciate that many initiatives have been taken from U.S. patent law and been adopted by foreign countries and, in parallel, other harmonization efforts have occurred here in the U.S. with the recent America Invents Act to align U.S. patent law more in harmony with patent laws of other key industrialized countries.[111] However, as strange (or wise) as it may appear, other industrialized foreign nations have adopted many features of American patent laws and yet they have not adopted our patent *disclosure* laws. For example, while the Federal Circuit has pushed the U.S. into a corner and now requires rigid patent disclosure, the European Patent Office does not require patentees that claim, for example, a genus of antibodies "to provide evidence that an antibody has actually been produced if the target is susceptible to routine methods of antibody production."[112] Australia's Patents Act of 1990 was amended in 2012 to, in direct contrast to the U.S., align itself with the European Patent Office's view on enablement and sufficiency.[113] Lastly, similar to the European approach, in Canada "claims to an

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[110] *Id.*

[111] For example, changing U.S. patent law from a first to invent to first to file.

[112] Yifan Mao & Andrew Serafini, *Navigating Key Differences in Therapeutic Antibody Patent Protection Strategies Between the United States and Europe*, JDSUPRA (April 29, 2021), https://www.jdsupra.com/legalnews/navigating-key-differences-in-8802999/; Mathys & Squire, *Patenting antibodies* at the European Patent Office, MATHYS & SQUIRE (October 6, 2020) https://www.mathys-squire.com/insights-and-events/news/patenting-antibodies-at-the-european-patent-office/; Donald Zuhn et al., *News from Abroad: Antibodies in the European Patent Office*, PATENT DOCS (Dec. 20, 2016), https://www.patentdocs.org/2016/12/news-from-abroad-antibodies-in-the-european-patent-office-.html.

[113] Tony Shaw & Candace Wu, *Navigating Australian Antibody Patent Protection Strategies*, ALLENS LINKLATERS (Feb. 10, 2022), https://www.allens.com.au/insights-news/insights/2022/02/Antibody-patent-protection-in-Australia/.

antibody specific for a novel antigen can be obtained even in the absence of working examples if the antigen is sufficiently described."[114] In essence and as is discussed further *infra*, this is the holding of *Noelle* in the U.S. from not long ago,[115] which was later abandoned by the Federal Circuit. The Federal Circuit's abrupt change in course in its patent disclosure jurisprudence will have grave consequences for new pioneering pharmaceutical and biotechnology development in the U.S. and threatens to push creative companies to pursue groundbreaking research and development in other industrialized jurisdictions outside of the U.S., countries having more stable and predictable patent laws.

A. The Federal Circuit's Enablement Rule for Genus Claims is Broken

Statutory construction is required to "start where the statute does."[116] The relevant statute at the center of this piece, namely Section 112 of the current Patent Act, 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 of carrying out his invention.[117]

Historically, the key function of the enablement requirement has been to provide a specification that teaches a person having ordinary skill in the art (hereinafter "PHOSITA") how to make and use the invention without undue experimentation.[118] The Federal Circuit has provided "illustrative, not mandatory"[119] guidance on how to determine if any experimentation is "undue" by assessing various factors, including:

> (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the application as filed.[120]

Under this rubric, the specification is found to be enabled only if upon balancing of these factors a PHOSITA could make and use the invention without undue

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[114] Carmela De Luca & Anastassia Trifonova, *Patent Disclosure Requirements for Therapeutic Antibody Patents*, 27 EXPERT OPIN. THERAPUETIC PAT. 867, 869 (2017).

[115] Noelle v. Lederman, 355 F.3d 1343, 1349 (Fed. Cir. 2004).

[116] SAS Inst. Inc. v. Iancu, 138 S. Ct. 1348, 1355 (2018).

[117] 35 U.S.C. § 112(a) (2022) (emphasis added).

[118] MPEP, *supra* note 24, § 2164.

[119] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991).

[120] *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

experimentation.[121] As later decisions reiterated, and has been widely accepted, "to enable any person skilled in the art" means "without requiring undue experimentation."[122]

Inventions in the fields of pharmaceuticals and biotechnology typically are different in how they are developed when compared to inventions in other fields. For example, a discovery of a compound that has a positive effect on cancer cells leads typically to discovering a family of related compounds that has the same effect. As such, once the inventor makes such a discovery, it can be more routine work to decipher any other member of the family of related compounds that can produce the same effect. In practice, of course, the patentee would wish to capture a broad patent claim that would cover the full family of related compounds. Indeed, using such genus claims – i.e., claims that the Supreme Court outlined as "deal[ing] with a large class of substances and the range of treatment within the terms of the claims"[123] – is a crucial aspect of how innovation in the pharmaceutical and biotechnology fields is protected. The structure of such genus claims in the biomedical field will typically include certain "structural requirements" that all species falling within the scope of the genus have, as well as the "function" that the species can perform.[124]

The enablement doctrine is premised on requiring that patentees provide sufficient information in their patent application such that an ordinary skilled artisan could practice the invention without having to perform "undue experimentation."[125] Guidance has been provided for assessing what experimentation would be "undue" in the *Wands* factors.[126] In *In re Wands*, the technology related to the *in vitro* production of antibodies capable of identifying the hepatitis B virus.[127] An ordinary skilled artisan wishing to practice the invention would need to isolate and clone hybridoma cells, culture them and test them for their desired function. However, the court held that this level of experimentation would not be "undue" because it would be routine for a person of ordinary skill in the art.[128] The court reasoned that not only was the level of skill in this field of art high and techniques well known in the art, but also that the patent application had provided significant guidance so that it would not be "undue" because the experiments involve repetition of known or commonly used techniques.[129]

There is a history of a split between decisions from the Federal Circuit that recognize disclosure of one mode of an invention as being sufficient to satisfy the enablement requirement and other decisions that require "full scope" of the claim to be enabled. In the past, courts recognized the validity of genus claims, especially those found in pharmaceutical and biotechnology patents. For example, the Court of Customs and Patent Appeals ("CCPA") found it untenable to require patentees draft "a patent application or applications with thousands of examples," as well as

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[121] *Id.*

[122] Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005); 35 U.S.C. § 112 (2022).

[123] Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 271 (1916).

[124] McRO, Inc. v. Bandai Namco Games Am. Inc., 959 F.3d 1091, 1100 (Fed. Cir. 2020).

[125] MPEP, *supra* note 24, § 2164.

[126] *In re* Wands, 858 F. 2d 731, 737 (Fed. Cir. 1988).

[127] *Id.* at 734–35.

[128] *Id.* at 738.

[129] *Id.* at 736–38; *see also* Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1360 (Fed. Cir. 1998) ("Routine experimentation does not constitute undue experimentation.").

"disclosure of thousands of catalysts along with information as to whether each exhibits catalytic behavior."[130] The court reasoned that it "would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments."[131] As discussed *supra*, the court in *In re Wands* made a similar point to find the enablement requirement was satisfied where a person of ordinary skill in the art could make and use the disclosed invention.[132] The standard for the amount and kind of experimentation necessary is one of reasonableness. [133] That is, whether experimentation is "undue" depends on the degree of experimentation and the standard to assess that is to gauge what would be reasonable.[134] Indeed, a "considerable amount of experimentation" is allowed, if it is "'merely routine,' or the specification provides 'a reasonable amount of guidance.'"[135]

This established law for determining compliance with enablement laws has changed drastically of late. This new direction taken by the Federal Circuit goes against Supreme Court precedent as well as the Federal Circuit's own prior decisions related to genus claims. The focus had correctly been on whether the patent application teaches a person of ordinary skill in the art to make and use the chemical species within the genus, as required by § 112(a) statute, and without having to do any "undue experimentation."[136] And yet, recent jurisprudence on this issue now rejects such an approach and favors the enablement test to instead be whether the patent application points out which of all the species in the genus will work. This shift in approach to enablement is proving fatal for pharmaceutical and biotechnology patents because the genus claims can cover thousands of related species and the patent applications do not, understandably, disclose every species in the patent application. The Federal Circuit's present approach to enablement is flawed and harmful both to innovation in the essential fields of pharmaceuticals and biotechnology and for the development of new lifesaving treatments.

B. The Federal Circuit's Enablement Law Conflicts with Supreme Court Jurisprudence

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[130] *In re* Angstadt, 537 F.2d 498, 502 (C.C.P.A. 1976).

[131] *Id.*

[132] *In re* Wands, 858 F.2d 731, 738 (Fed. Cir. 1988).

[133] Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1385–86 (Fed. Cir. 2013); Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004).

[134] *See* ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) ("A 'reasonable' amount of routine experimentation" is allowed); *In re* Wands, 858 F.2d at 737 ("The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness"); Cephalon, Inc. v. Watson Pharms., Inc., 707 F.3d 1330, 1336 (Fed. Cir. 2013) ("A reasonable amount of routine experimentation does not violate the enablement requirement.").

[135] *Wyeth & Cordis Corp.*, 720 F.3d at 1385–86 (Fed. Cir. 2013):

> [T]he claim was to administering Rapamycin to prevent restenosis after a balloon angioplasty procedure. The specification disclosed only one species of Rapamycin, even though Rapamycin is genus of tens of thousands of compounds. Court held claim not enabled because ordinary skilled artisan would have to undertake time consuming testing to determine which of the thousands of Rapamycin compounds would work.

[136] *Id.*

The Supreme Court has long recognized that patentees must be permitted to claim more than just narrow embodiments of their invention because to do otherwise would make a patent a "hollow and useless thing."[137] As a preliminary matter, the statute requires that the specification of a patent application provide "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."[138] The Supreme court has interpreted this to be the "the right of the jury to determine."[139] And yet, the Federal Circuit, beginning in 1983, began to treat enablement as a question of law for the court to decide.[140] This question of law versus question of fact and why this is important in such a fact-sensitive case-by-case inquiry is further explored *infra* in part V(C), however, it is worth introducing this as a preliminary matter and just one example of how the Federal Circuit's jurisprudence on patent disclosure laws has evolved to conflict with Supreme Court precedent.

The main problem with the Federal Circuit's approach to a § 112(a) inquiry is that the court has effectively judicially invented rules that have no statutory basis and their recent implementation is causing disruption and having harmful effects on the biomedical industry.[141] The main reason is because this rigid jurisprudence is routinely being used to invalidate a type of claim format that is at the heart of pharmaceutical and biotechnology patent practice: the genus claim.[142] The Federal Circuit's shift in position comes in the face of clear support for genus claims from the Supreme Court. For example, the Supreme Court confirmed genus claims as a viable claiming option, so long as the patentee can show some "common quality" between members of a genus.[143] In these early cases, enablement of genus claims centered on whether the patent application sufficiently enabled an ordinary skilled artisan to "make and use" embodiments of the invention.

The Federal Circuit has in recent years made a drastic shift in position regarding their interpretation of a patent's disclosure requirements. Whereas the focus of the court used to be on whether a patent's disclosure enables a person of ordinary skill in the art to practice the invention without "undue experimentation,"[144] this has now evolved to become a test of how long it would take an ordinary skilled artisan to make and test all of the species within the claimed genus, irrespective of which aspects of that work would be routine work for the ordinary skilled artisan. The genus claim in the technological fields of pharmaceuticals and biotechnology can encompass thousands of species. In this context, the Federal Circuit has held that if identifying every species of a claimed genus would require making and testing thousands of compounds, the claim fails "as a matter of law."[145] In practice, the Federal Circuit's new numbers-based enablement requirement to identify every species in a genus is proving fatal for a swathe of genus claims in pharmaceutical and biotechnology

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[137] Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950).
[138] *See* 35 U.S.C. § 112(a) (2022).
[139] Battin v. Taggert, 58 U.S. (17 How.) 74, 85 (1854).
[140] Raytheon Co. v. Roper Corp., 724 F.2d 951, 960 n.6 (Fed. Cir. 1983).
[141] *Id.*
[142] Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1346 (Fed. Cir. 2013).
[143] Corona Cord Tire Co. v. Dovan Chem. Corp., 276 U.S. 358, 385 (1928).
[144] *Id.*
[145] Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1385–86 (Fed. Cir. 2013).

patents. This rigid position is untenable and goes against both the text of the statute and Supreme Court precedent.

The Supreme Court has long recognized the importance of using genus claims to protect inventions. Without such claims, copycats can take advantage of innovators' efforts to develop a technology without the threat of patent infringement by making minor changes of a particular embodiment claimed in the innovators' patent.[146] Famously, the Supreme Court upheld Alexander Graham Bell's genus patent claim for the telephone, holding "it is enough if [the patentee] describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation."[147] The Court further stated that Bell had "described, with sufficient precision to enable one of ordinary skill in such matters to make the invention."[148] However, in another case involving another famous inventor, Thomas Edison, the Supreme Court did not hesitate in holding a patent claim invalid for failing the Patent Act's disclosure requirement by claiming very broadly when in fact they had made a discovery limited to a certain embodiment for a light bulb filament.[149]

Other Supreme Court cases have made it clear that exclusively functional patent claims are not acceptable given the vast scope of such claims,[150] and neither are patent claims that simply lack any support or guidance in the patent specification to allow an ordinary skilled artisan to practice the disclosed invention.[151] Notably, although the Federal Circuit has interpreted § 112(a) as requiring two standards, both the statute and Supreme Court precedent, such as *The Telephone Cases*, indicate just one requirement.[152] According to the Supreme Court, the patent application must "*describe* the invention in such full, clear, concise, and exact terms *as to enable* any person skilled in the art to make and use the same."[153] Indeed, the statute requires inventors provide a written description that enables an ordinary skilled artisan to make and use the invention – a singular requirement. Further still, the Supreme Court has suggested that the only purpose of § 112(a) is enablement.[154]

Crucially, the Supreme Court has never indicated that a genus claim that is well-defined and supported fails the enablement requirement unless that patent application teaches ordinary skilled artisans to make and test all of the species within the claimed genus. As such, not only is there no support in § 112(a) of the Patent Act

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[146] Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 437 (1902); *see* Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 419–20 (1908).

[147] Dolbear v. Am. Bell. Tel. Co., 126 U.S. 1, 536 (1888).

[148] *Id.* at 535.

[149] Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 475–76 (1895).

[150] Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245, 256–58 (1928).

[151] Tyler v. City of Boston, 74 U.S. (7 Wall.) 327, 330 (1868).

[152] In *Ariad*, the Federal Circuit relied on two U.S. Supreme Court cases - *Evans v. Eaton,* 20 U.S. (7 Wheat) 356 (1822) and *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938) to hold that § 112(a) contains separate written-description and enablement requirements. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1346–47 (Fed. Cir. 2010). However, neither of these cases fully support the court's analysis in *Ariad*.

[153] Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996) (emphasis added).

[154] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 90 (2012); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001).

for the Federal Circuit's recent patent disclosure jurisprudence,[155] the Supreme Court's decisions align themselves with the statutory text of the Patent Act and therefore both are in conflict with the lower court's stance. Much akin to the Supreme Court's decisions in *KSR*[156] and *Bilski*[157] to correct Federal Circuit's rigid tests, as is discussed in part VI, a correction is needed for patent disclosure laws.

C. The Federal Circuit Imposes Industry-Specific Barriers to Patentability

The Patent Act was drafted to apply equally to all technologies, meaning the law would apply in the same manner irrespective of the invention and field of technology before it. However, recent changes in the way the Federal Circuit is interpreting the disclosure requirements of a patent is having a negative effect on the pharmaceutical and biotechnology industries more so than other industries.[158] One of the key reasons this is taking place is because of the prevalence for the use of genus claims in biomedical patent applications.

Genus claims are especially important and a key feature of patent practice in the pharmaceutical and biotechnology industries and function to protect and advance innovation in this technological field.[159] It takes years of effort and financial expenditure in research and development to conceive and bring to market groundbreaking inventions, especially one in the pharmaceutical or biotechnology fields. The Federal Circuit has in recent years interpreted patent disclosure requirements of the Patent Act to greatly increase the bar for obtaining patent protection of genus claims. This in turn has imposed hurdles for innovators to recoup their investments and in turn dampened follow-on innovation. In particular, whereas in the past courts assessed whether patent applications "enable" a person of ordinary skill in the art to "make and use" the disclosed invention without "undue experimentation,"[160] it is now necessary to enable the "full scope" of the claim. That is, every species of a genus must now be enabled.[161] In effect, this shift in how the Federal Circuit approaches enablement is "a categorical shift in thinking away from teaching the PHOSITA and towards a precise delineation of the boundaries of the claim."[162]

The field of pharmaceuticals and biotechnology is targeted by this shift in approach because the Federal Circuit now requires patent applications to exhaustively catalog all variates that fall within a genus, even if they are closely overlapping. However, this standard is not applied in the same way in other fields of art such as software.[163] This is not a controversial opinion, as many scholars have noted that when it comes to the enablement and written description standard, courts apply a higher

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[155] *See* Part IV(B), *supra*, for a discussion on the statutory interpretation of § 112(a) and the Federal Circuit's recent jurisprudence on point.

[156] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007) (holding that the Teaching, Suggestion, Motivation test not the sole test for determining obviousness).

[157] Bilski v. Kappos, 561 U.S. 593, 603 (2010) (". . . is not the sole test.").

[158] Burk & Lemley, *Biotechnology's Uncertainty Principle*, *supra* note 28, at 706.

[159] Sean B. Seymour, *Patenting the Unexplained*, 96 WASH. U. L. REV. 707, 729 (2019).

[160] As the 35 U.S.C. § 112(a) statute requires; *see In re* Wands, 858 F.2d 731, 735 (Fed. Cir. 1988).

[161] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021).

[162] Karshtedt et al., *supra* note 3, at 31.

[163] Burk & Lemley, *supra* note 28, at 1184.

standard in the biomedical fields than in other fields of art.[164] It is thought that the reason for this is because Chemistry and Biology are "unpredictable" fields and therefore more disclosure is required in the patent application[165] than in other applications which are directed to "predictable" fields of art such as mechanical and electrical.[166] If a field of art is deemed to be "unpredictable" by the Federal Circuit, "a description of one species will ordinarily be insufficient to lay claim to the genus."[167] The main culprit that practitioners, scholars and even judges on the Federal Circuit alike point to for suggesting a higher written description standard exists in biotechnology is the Federal Circuit's decision in *The Regents of the University of California v. Eli Lilly & Co.*[168]

It is also perhaps noteworthy to contrast this standard of enablement and written description as applied to the biomedical fields with the standard applied to inventions in the software and business methods fields of art.[169] The consensus is that when the Federal Circuit changed course in *Lilly*, it highlighted how lop-sided and technology-specific the practical application of this standard had become.[170] For example, Burke and Lemley best summed this up by noting that the heightened written description standard for biotechnology "would be inconceivable in other industries, such as software."[171] Indeed, there are empirical studies to show section 112 is not technology neutral.[172] However, other scholars have questioned whether the written description requirement after *Lilly* unfairly targets biotechnology more so than other fields.[173]

35 U.S.C. §112(a) has been interpreted recently by the Federal Circuit as requiring both a written description requirement and an enablement requirement,

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[164] Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 834 (1999); Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 137 (2008); Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 282–83 (2008); Burk & Lemley, *Is Patent Law Technology-Specific?*, *supra* note 28, at 1156; Burk & Lemley, *Biotechnology's Uncertainty Principle*, *supra* note 28, at 691 (The Federal Circuit "claims that the uncertain nature of the [bio]technology requires imposition of stringent patent enablement and written description requirements that are not applied to patents in other disciplines."); Burk & Lemley, *supra* note 103, at 1654.

[165] Chao, *supra* note 13, at 6–8.

[166] Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, *supra* note 164, at 137.

[167] Chiron Corp. v. Genentech, Inc., 269 F. Supp. 2d 1148, 1163 (E.D. Cal. 2002).

[168] Regents of the Univ. of Cal. v. Eli Lilly & Co., 19 F.3d 1559 (Fed. Cir. 1997); *see also* Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1314–24 (Fed. Cir. 2004) (Chief Judge Rader dissenting and including an appendix of scholarly articles that criticizes *Lilly* for its heightened standard).

[169] Margaret A. Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1240–41 (2000).

[170] Janis, *supra* note 55, at 86–88; Rai, *supra* note 164, at 834; Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 626–28 (1998).

[171] Burk & Lemley, *Is Patent Law Technology-Specific?*, *supra* note 28, at 1184; Burk & Lemley, *supra* note 103, at 1654; Burk & Lemley, *Biotechnology's Uncertainty Principle*, *supra* note 28, at 706.

[172] John R. Allison & Lisa L. Ouellette, *How Courts Adjudicate Patent Definiteness and Disclosure*, 65 DUKE L.J. 609, 621–23 (2016).

[173] Christopher M. Holman, *Is Lilly Written Description A Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1, 4–5 (2007); *see* Dennis Crouch, *An Empirical Study of the Role of the Written Description Requirement in Patent Examination*, 104 Nw. U. L. REV.. 1665, 1676–78 (2010).

each subject to different standards.[174] In this regard, the Federal Circuit's decision in *Lilly*[175] marked a turning point after which this dual disclosure requirement was established and found necessary for enforcing a patent.[176] It is noteworthy, therefore, that prior to the Federal Circuit's *en banc* decision in *Ariad* in 2010, *Lilly* was one of the most cited cases for showing that enablement and written description are two separate requirements.[177]

To comply with the written description requirement, the patent application must convey that the inventor had "possession" of the claimed invention upon filing of the patent application. Genus claims – claims that encompass multiple embodiments – raise the issue of written description and the Federal Circuit is nowadays focused on possession of the "full scope" of the claimed invention.[178] This usually involves providing a patent disclosure that includes "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.[179] However, the statute makes no mention of these heightened judge-made requirements. Moreover, if a genus is functionally-defined, this test is even more burdensome because structure cannot be derived from the patent claim language itself.

To further illustrate the Federal Circuit's current jurisprudence targeting biotechnology, one can focus monoclonal antibodies as a technology. Ever since 1986, when the first monoclonal antibody was approved by the Food and Drug Administration for use, therapeutic antibodies have risen to dominate as treatments for a variety of conditions.[180] The global market for antibody treatments was approximately $150 billion dollars in 2019 and is predicted to rise to $300 billion by 2025.[181] To protect such technology with meaningful patent claims is key for the companies developing these monoclonal therapeutics.

However, different tests have come and gone, including the "newly characterized antigen" test which was an exception to the written description rules at the USPTO as applied to antibody claims. This written description test allowed a party to disclose a newly characterized antigen and claim a genus of antibodies (possibly including thousands of species), so long as the production of such antibodies was routine. However, in *AbbVie*, the Federal Circuit cast aside the "newly characterized antigen" test for written description and highlighted that functionally defined genus claims are open to challenge for lack of written description support, especially if the technology is unpredictable. This is especially so if it is difficult to draw correlations between structure and function for the genus or to predict what is encompassed by the

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[174] *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1346 (Fed. Cir. 2010).

[175] *Id.*

[176] *Id.*

[177] *Id.* at 1366. (Rader, J., dissenting in part) (Linn, J., dissenting in part).

[178] Katie Albanese, *When Is Enough Enough? What Constitutes Adequate Written Description of a Genus*, 29 FED. CIR. B.J. 343, 358 (2020).

[179] *See Ariad Pharms., Inc.*, 598 F.3d at 1350.

[180] Monoclonal antibodies are big players on the biotechnology marketplace. As a current example, drug makers are pivoting to monoclonal antibody treatments for treating COVID-19. The US FDA granted Emergency Use Authorizations (EUAs) for three anti-SARS-CoV-2 monoclonal antibody products on December 16, 2021.

[181] Ruei-Min Lu et al., *Development of Therapeutic Antibodies for the Treatment of Diseases*, 27 J. OF BIOMEDICAL SCI. 1, 1 (2020).

functionally claimed genus.[182] This opened the gate and now antibody claims are frequently invalided on both written description and enablement grounds.

For example, in 2022, the court held functional claims, even in the presence of eleven working examples, lack enablement to an antibody that binds Factor IX, a protein important for blood clotting.[183] Similar as in *Amgen v. Sanofi*,[184] the court noted antibodies being "inherently unpredictable" and that the only way one could practice the invention would be by "trial-and-error; *i.e.*, by screening tens of thousands, if not millions, of candidate antibodies to determine whether they satisfy the limitations of the asserted claims."[185] As such, the recent decisions in *AbbVie,*[186] *Amgen,*[187] *and Baxalta*[188] are teaching innovators not to claim antibodies based solely on the target antigen, specific epitope, and/or function, with some scholars predicting that the scope of patent protection for therapeutic antibodies will get limited to just those that have been disclosed in the specification. However, as discussed in part VI, this need not be the case given the field of art is well developed concerning the structure and function. Once the inventor maps the variable region sequence and structure, she ought to be granted broader patent protection than just the specific narrow species of antibody disclosed.

This fundamental shift in the way the Federal Circuit is interpreting the statutory requirement is particularly problematic where pharmaceutical and biotechnological inventions are concerned. For example, claims to a genus of compounds or to therapeutic antibodies now are required to pass both a non-statutory "possession" standard for written description that requires the patent application disclose a "representative number of examples" of the genus; and separately a numbers-based rigid "full scope" enablement. This rigid formula may work in predictable arts such as mechanical and electrical, however, it is a bad fit and indeed harms innovation in the biomedical field. Indeed, this industry-specific barrier to patentability is not what Congress had in mind. Current jurisprudence concerning patent disclosure laws run contrary to statutory language and legislative intent and impose judicially-created additional requirements on patentees that, in practice, have evolved to target some industries more so than others.

V. WRITTEN DESCRIPTION AND ENABLEMENT: A RIDDLE, WRAPPED IN A MYSTERY

Patents are regarded as bargains between inventors and the government. The government provides exclusivity for a period of time, and the inventor in return

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[182] AbbVie Deutschland GMBH & Co., KG, v. Janssen. Biotech, Inc., 759 F.3d 1285, 1300–01 (Fed. Cir. 2014).

[183] Baxalta, Inc. v. Genentech, Inc., No. 1:17-cv-00509, 2022 U.S. Dist. LEXIS 26968, at *64–66 (D. Del. Jan. 13, 2022).

[184] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021).

[185] *Id.*

[186] AbbVie Deutschland GMBH & Co., KG, v. Janssen. Biotech, Inc., 759 F.3d 1285 (Fed. Cir. 2014).

[187] *Sanofi, Aventisub LLC*, 987 F.3d at 1086.

[188] Baxalta, Inc. v. Genentech, Inc., No. 1:17-cv-00509, 2022 U.S. Dist. LEXIS 26968 (D. Del. Jan. 13, 2022).

provides all details of her invention. To obtain a patent for a proposed invention, certain requirements must be satisfied, including that the idea be useful,[189] novel,[190] non-obvious,[191] and be fully disclosed.[192] The boundary of this disclosure requirement of a patent application has been debated by judges, scholars and practitioners alike. The details included in patent applications are critical in demonstrating how well claims are supported by the patent application (aka the specification). One of the fundamental issues has been whether the relevant statute of the Patent Act mandates enablement and written description to be treated as separate requirements. As stated in Section 112 of the current Patent Act, the statue 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 of carrying out his invention.[193]

As the structure of the one sentence that comprises this statute evidently shows, written description and enablement are textually linked together. Although the Federal Circuit has held enablement and written description to be two separate requirements, they overlap substantially and when claim scope is analyzed, they "usually rise and fall together."[194] It is important to point out that that the word "possession" does not appear in 35 U.S.C. § 112(a).[195] Moreover, the Supreme Court has never interpreted 35 U.S.C. § 112(a) as mandating separate written description and enablement requirements. Further still, the Federal Circuit itself did not treat enablement and written description as separate requirements until it decided *Lilly* in 1997[196] and solidified this view with the Court's *en banc Ariad* decision in 2010.[197]

Between 1952 when the last Patent Act was enacted and the Federal Circuit's 1997 decision in *Lilly*,[198] written description was used sparingly to police priority. That is, the notion of "possession" was used to determine if the specification provided sufficient support for the claims to demonstrate priority. "Possession" in this context was a narrow and easy to apply concept, focusing on whether the invention was described at a particular point in time.[199] With its *Lilly* decision in 1997, the Federal Circuit split the singular disclosure standard of the statute in two by vastly expanding the scope of "possession" that historically was narrowly applied to test for support for

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[189] 35 U.S.C. § 101 (2022).

[190] 35 U.S.C. § 102 (2022).

[191] 35 U.S.C. § 103 (2022).

[192] 35 U.S.C. § 112 (2022).

[193] 35 U.S.C. § 112(a) (2022) (emphasis added).

[194] LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991).

[195] The judge-created word "possession" is absent from the 35 U.S.C. § 112(a) statute for assessing compliance with the written description requirement, with all that is required being a written description that enables.

[196] Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568–69 (Fed. Cir. 1997).

[197] Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350–51 (Fed. Cir. 2010).

[198] Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

[199] Typically, at the time of filing of the patent application.

new or amended claim language to now be a separate and much broader requirement for the specification to meet under § 112. In 2010, the Federal Circuit confirmed in their *en banc Ariad* decision[200] that "possession" is a separate requirement and in an effort to apply this new principle, the Federal Circuit also came up with varying rigid subtests to implement it.[201]

The ill-conceived new and non-statutory "possession" requirement for demonstrating written description and its varying sub-tests aside, the Federal Circuit has also upended the doctrine of enablement as it applies to genus claims. Enablement of the "full scope" of genus claims has also recently been stringently applied when it comes to genus claims, such that the focus is now on providing a "representative number of species" even when this is contrary to the textually grounded inquiry. As the statute provides and as the Federal Circuit has itself in the past interpreted the statute, the focus ought to be on whether the patent application enables an ordinary skilled artisan to make and use the invention. The current focus on the outer perimeter of patent claims and by extension the identification of every species that falls within a genus to demonstrate what the Federal Circuit calls "full scope" enablement is misguided. Especially given that identifying every species of a genus has no practical effect on the ability of an ordinary skilled artisan to make and test an operable species.

35 U.S.C. § 112 requires that the specification of a patent "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 make and use the same."[202] The Federal Circuit has flouted this statutory text and split enablement and written description into two separate requirements.This recent change in position by the Federal Circuit has resulted in the court following-up and judicially creating the court's new "possession" standard and various sub-tests for written description, plus simultaneously shifting the enablement inquiry from the well-grounded "undue experimentation" factors to a requirement for patentees to make and test all the species within a genus and point out which works and which does not. This is a fundamental shift in approach.[203]

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[200] *Ariad*, 598 F.3d at 1351–52.

[201] These sub-tests are discussed in part V(A), *infra*.

[202] 35 U.S.C. § 112(a) (2022); *see e.g.*, Patent Act of 1793, ch. 11, § 3, 1 Stat. 318, 321–22; Patent Act of 1790, ch. 7, § 2, 1 Stat. 109, 110 (repealed 1793):

> 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.

[203] Patent Act of 1790, *supra* note 202, at ch. 7, § 2.

For enablement, the focus should be on how to make and use the invention without "undue experimentation." The various factors as discussed in the *In re Wands* factors ought to remain at the center of the inquiry, including for example, the nature of the invention, the predictability of the field of art, and the level of ordinary skill in the art. When a patent application is drafted, it is in effect directed to people having ordinary skill in that particular field of art ("PHOSITA").[204] That is, in situations where one must assess whether a particular patent application is drafted with disclosure that sufficiently enables a person to make and use what is taught, it is viewed from the eyes of this PHOSITA.[205] This standard for assessing enablement was supported by the statutory text, and Supreme Court and prior Federal Circuit decisions, however, the Federal Circuit has dramatically changed course on its enablement jurisprudence.

The Federal Circuit's new approach to enablement has become a rigid numbers-based test to assess if the patent application enables the "full scope" of its claims.[206] Instead of focusing on teaching an ordinary skilled artisan how to make and use the invention[207] and without conducting "undue experimentation,"[208] the new enablement test requires assessing how an ordinary skilled artisan can make and test every species encompassing a genus. Crucially, under this new scheme, it matters little how routine this new requirement of checking every species would be. Indeed, the Patent Act does not mandate any limitations on the number of species falling within a genus claim or require "full scope" enablement. This new court-created heightened enablement standard, as discussed in more detail *infra* in part V(B), lacks any statutory basis or Supreme Court precedent, and is hurting innovation in the biomedical industries more so than other industries.

The Federal Circuit has judicially created rules that now make it exceedingly hard to obtain any meaningful patent protection of a genus claim. This new dramatic shift in approach to the enablement doctrine and concurrently the extra-statutory approach to the written description requirement has grown in scope and breadth and has now become a formidable obstacle to patent validity, especially in the pharmaceutical and biotechnology industries. As is developed further *infra*,[209] to compound this new interpretation of the enablement doctrine being used as a sharp sword to now routinely invalidate genus claims, the Federal Circuit's decision to view enablement as a question of law also is a topic deserving of attention given the enablement inquiry is so fact-intensive in nature and that the decision to treat it as a question of law runs against Supreme Court precedent.

The Federal Circuit has argued whether enablement and written description are separate requirements of the statute in prior decisions. For example, *University*

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[204] PHOSITA stands for "A Person Having Ordinary Skill in The Art."

[205] A "person of ordinary skill" is one of average skill in the relevant art. *See* Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985) (an ordinary skilled artisan "thinks along the line of conventional wisdom"); KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 420 (2007) (an ordinary skilled artisan is "a person of ordinary creativity, not an automaton.").

[206] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021).

[207] As the statute requires.

[208] Some experimentation is permissible and does not fail enablement; *see e.g., In re* Wands, 858 F.2d 731, 739 (Fed. Cir. 1988) (factors for assessing if experimentation would be "undue.").

[209] *See* part V(C), *infra*.

of Rochester v. G.D. Searle & Co.[210] involved pharmaceutical inhibitors for an enzyme that plays a key role in the inflammatory response, prostaglandin H synthase-2 ("PGHS-2" or "Cox-2"). The University of Rochester had filed patent applications directed to methods for screening for inhibitors of cyclooxygenases 1 and 2 (Cox-1 and Cox-2), and the specification disclosed how to make the cells that express Cox-1 and Cox-2 as well as the assays that can be used to screen for inhibitors of the two enzymes.

The court held that although the patent application included disclosure to permit an ordinary skilled artisan to identify compounds that could be used in the claimed methods,[211] the fact that the specification did not actually disclose any compounds that could be used to practice the claimed methods rendered the patent invalid.[212] On appeal, the Federal Circuit held the patent invalid for failing to satisfy the written description requirement, which the court interpreted to be a separate requirement to enablement under § 112.[213] And yet, although the patent was held invalid for failing to comply with the written description requirement, the patent application enabled an ordinary skilled artisan to not only derive the compounds using the disclosed methods, but also to perform the claimed methods.

This decision to interpret the first paragraph of § 112 as requiring a double requirement of enablement separate from written description has been especially devastating and harmful to patents within the pharmaceutical and biotechnology industries for reasons developed *infra*.[214] Even in more recent cases from the Federal Circuit, one can see the disagreement between judges on whether enablement and written description are separate requirements. For example, the disagreement between Judge Lourie and dissenting Judge Rader is demonstrated in their positions in *Enzo*.[215] To be clear, under such a dual standard favored by Judge Lourie and the majority, many pharmaceutical and biotechnology patents are invalid, whereas if the first paragraph of § 112 is interpreted to require inventors disclose and enable their invention (*i.e.* a single requirement, focusing on a written description that enables),[216] the patent in *Rochester* and many like it would survive such invalidity challenges.

The conflation of enablement and written description continues to this day, with some courts using the written description requirement to invalidate claims that are broader than the invention the applicant "possessed" upon filing, even if the claims were not amended during prosecution. Applied in this way, the written description requirement overlaps substantially with the enablement requirement. Recent cases have cemented the Federal Circuit's stance that a) the enablement and written description of the invention are two separate requirements;[217] b) to satisfy the enablement requirement of genus claims, a rigid numbers-based evaluation is needed to determine whether the patent application enables the "full

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[210] Univ. of Rochester v. GD Searle & Co., Inc., 358 F.3d 916, 918–20 (Fed. Cir. 2004).

[211] *Id.* at 919.

[212] *Id.*

[213] *Id.* at 927.

[214] *See* part V(A).

[215] Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002); *Id.* at 976 (Rader, J., dissenting).

[216] *Id.*

[217] Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010).

scope" of its claims (that is, evaluating how an ordinary skilled artisan can make and test every species encompassing a genus, no matter how routine a practice that would be);[218] and c) to satisfy the written description requirement, the application must show the judicially-created "possession" of the invention and this in turn depends on satisfying various court-created sub-tests, including the popular "representative number of species."[219] These judicially-created rules lack any basis in statutory text and Supreme Court precedent, and seriously threaten innovation in the pharmaceutical and biotechnology fields.

The *Idenix v. Gilead* decision is another recent example. Here, the Federal Circuit held patent claims to methods for treating Hepatitis C Virus ("HCV") by administering certain compounds as being invalid on both enablement and written description grounds, under 35 U.S.C. § 112.[220] The court held that the patent claims covered "tens if not hundreds of thousands" of antiviral compounds, and yet the patent application failed to provide guidance on which of those compounds would actually work to treat HCV.[221] Although Idenix argued that the patent application's four working examples were enough to comply with the enablement requirement,[222] the court rejected this argument and pointed out that the field of art was unpredictable and therefore an ordinary skilled artisan would not know which compounds would work for their intended purpose. The court also found that the inventors were not "in possession" of their claimed invention and therefore the patent was also held invalid based on its failure to comply with the written description requirement.

The reasoning behind this recent decision was also based on an earlier case in which the Federal Circuit similarly held that a claim covering thousands of compounds was invalid for lack of enablement as a matter of law.[223] Moreover, in August of 2021, the Federal Circuit found Sloan Kettering's Juno patent claims to a nucleic acid polymer (DNA/RNA) that encodes for a particular "chimeric T cell receptor" as being invalid for lack of written description.[224] This technology relates to the revolutionary CAR T-Cell therapy where a patient's own T-Cells are genetically modified so that they can then recognize and kill specific antigens. This technology, for which its two inventors were awarded the 2018 Nobel prize in Physiology or Medicine, culminated in the first personalized cellular therapy for cancer, treating blood cancers such as leukemia and lymphoma.[225] The patent claims are directed to coding for a "binding element that specifically interacts with a selected target" in the form of a single chain

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[218] Baxalta, Inc. v. Genentech, Inc., No. 1:17-cv-00509, 2022 U.S. Dist. LEXIS 26968, at *64–66 (D. Del. Jan. 13, 2022); Idenix Pharms. LLC v. Gilead Sci. Inc., 941 F.3d 1149, 1162 (Fed. Cir. 2019), *cert. denied*, 141 S. Ct. 1234 (2021); Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021); AbbVie Deutschland GMBH & Co., KG, v. Janssen. Biotech, Inc., 759 F.3d 1285, 1301 (Fed. Cir. 2014); Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1385–86 (Fed. Cir. 2013).

[219] Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1569 (Fed. Cir. 1997); *Ariad*, 598 F.3d at 1349.

[220] *Idenix Pharms*., 941 F.3d at 1162–63.

[221] *Id.* at 1164.

[222] *Id.* at 1161.

[223] *Wyeth*, 720 F.3d at 1386.

[224] Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1339–40 (Fed. Cir. 2021).

[225] Mary Caffrey, *Nobel Prize Recognizes Discoveries with T Cells in Immunotherapy*, AM. J. MANAGED CARE (Oct. 1, 2018), https://www.ajmc.com/view/nobel-prize-recognizes-discoveries-with-t-cells-in-immunotherapy.

antibody. Because the patent application failed to disclose the DNA sequence of such a binding element, the claim was found to lack written description.[226]

In this recent case, the Federal Circuit confirmed that the only time functional claiming of a genus can meet the written description requirement is where the specification either explains structural features that are common between members of the species that fall within the genus so that a person of ordinary skill in the art ("PHOSITA") can recognize the genus, or the specification provides "a representative number of species" that fall within the scope of the genus.[227] In this case, the Federal Circuit reversed the district court, holding 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*."[228] In particular, in *Juno*,[229] the court held that even if two embodiments were disclosed that fell within the scope of the genus, the specification failed to provide details about their commonality to allow a PHOSITA to recognize all the members of the genus.

Separate to these new requirements for enabling genus claims, the non-statutory written description doctrine has grown in scope and the contours of this separate requirement also remain unclear for genus claims. In particular, to comply with the written description requirement, the Federal Circuit demands that genus claims be articulated to show a "representative number of species" within that genus.[230] The Manual of Patent Examining Procedure ("MPEP") suggests that this showing then depends on whether an ordinary skilled artisan would recognize that the patentee was "in possession of the necessary common attributes or features possessed by the members of the genus"[231] and yet the MPEP also cautions patentees that individual support for each of the species within a genus is unpracticable and unnecessary.[232] To appreciate when a patentee is "in possession" of her invention depends on whether an ordinary skilled artisan would understand the patentee to be in possession of her invention. From a litigation perspective, disclosure of a single species in a patent application can render a patent claim to a genus invalid.[233]

These recent cases from the Federal Circuit, as well as requirements outlined in the U.S. Patent and Trademark Office's Manual of Patent Examining Procedure, make it clear that drafting viable genus claims is becoming exceedingly difficult to do. Namely, when a genus encompasses a large number of species, one is faced with the question of how best to comply with the now very stringent enablement laws for genus claims. This exceedingly high bar that has now been set for pharmaceutical and biotechnology companies has resulted in unintended consequences and is presently

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[226] *Id.*

[227] *Id.*

[228] *Juno Therapeutics, Inc.,* 10 F.4th at 1336 (emphasis added).

[229] *Id.*

[230] Amgen Inc. v. Sanofi, 872 F.3d 1367, 1373 (Fed. Cir. 2017) (To show possession, the court "requires a precise definition" of the invention, which for a genus claim, a patentee must disclose "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."); *see* Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1569 (Fed. Cir. 1997).

[231] MPEP, supra note 24, § 2163(II)(A)(3)(a)(i).

[232] MPEP, supra note 24, § 2163(II)(A)(3)(a)(ii).

[233] AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285, 1300 (Fed. Cir. 2014).

and will in the future impede biomedical innovation in the U.S. In particular, the hardening and rigid nature of the Federal Circuit's position on genus claims has consequences not only for protecting small molecule pharmaceuticals, as demonstrated by the *Idenix* case,[234] but also implicates biologics as demonstrated by the *Amgen* case,[235] since genus claims are routinely used when drafting claims to biologics (*e.g.* claims to a genus of antibodies). Yet, as is explored in part VI, there is hope for this impasse to play out in a meaningful way for all stakeholders.

A. The Rigid Written Description Sub-Tests are Untenable and Hinder Innovation of New Therapeutics

The written description's function is focused firstly on providing adequate description of the invention to satisfy the aforementioned *quid pro quo* where the government provides limited monopoly for a full description of the invention;[236] second to assure that the inventor "possessed" the claimed invention when the application was filed;[237] and third to police against addition of new matter being added that expands and is outside of the scope of the original patent filing.[238]

The Federal Circuit's "possession" standard runs afoul of the statutory text of 35 U.S.C. § 112(a). The court first rejected the statutory standard for "written description of the invention,"[239] and instead created its own test centering on a finding of "whether the disclosure of the application reasonably conveys that the *inventor had possession* of the claimed subject matter as of the filing date."[240] Interestingly, this test or possession standard appears nowhere in the statute, § 112(a). Within the field of patent law and in a message to the Federal Circuit, the Supreme Court recently demanded "that courts should not read into the patent laws limitations and conditions which the legislature has not expressed."[241] However, not only has the Federal Circuit done just that, but in order to interpret and apply their view of the statutory language, the Court has had to formulate and update their own judicially-created sub-tests as follow-on creations to their judicially-created, non-statutory extra requirement to demonstrate written description.

While the enablement doctrine has been developed by the courts and can be traced back to the early 1900s, its related close cousin – the written description requirement – is a relative newcomer that appeared over 140 years later.[242] The Patent Act of 1952 did not contain a "written description" requirement apart from enablement. Instead, the addition of "new matter" to pending patent applications was a parallel requirement and prohibited under 35 U.S.C. § 132. In the key *In re Ruschig* decision

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[234] *Id.*

[235] *Id.*

[236] *Id.*

[237] Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010).

[238] *Id.*

[239] 35 U.S.C. § 112(a) (2022) (emphasis added).

[240] *Ariad*, 598 F.3d at 1351.

[241] Bilski v. Kappos, 561 U.S. 593, 602 (2010).

[242] *In re* DiLeone, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971) ("Consider a case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.").

from the 1960s, the court for the first time created the link between prohibition against adding "new matter" to pending patent applications and the "written description" requirement.[243]

A claim to a genus that is in a nascent field in which there is little prior art to use to bridge gaps is susceptible to violating the written description requirement.[244] Moreover, the level of disclosure is key itself, as the Federal Circuit has held that describing only a single species usually violates the written description requirement.[245] In *Ariad*, the Federal Circuit made clear that when broad genus claims cannot rely on the prior art, the patent application should include either "structural features common to the members of the genus" or "a representative number of species" within the genus.[246]

Although focusing on providing a "representative number of species" sounds reasonable and can help as a focal starting point, it is not without problems as a subtest because, for example, it remains unclear how the "representative number" would be determined. This problem is also compounded by the fact that post *Ariad*, it remains unclear what the boundaries are for complying with the written description requirement, in large part because the guidance provided points to what is *not* required and not what *is*. For example, the written description of patent applications does not require examples,[247] recitation of known structure,[248] reduction to practice,[249] nor any particular form of disclosure.[250] As such, the Federal Circuit has not actually provided any positive guidance to patentees regarding what is required to satisfy the written description requirement. Indeed, a reasonable idea contemplated by some on the patent bar would be to eliminate the written description doctrine[251] and focus more on enablement and clarity sections of the Patent Act.[252]

Having created the non-statutory "possession" standard for written description, the Federal Circuit developed several sub-tests in an effort to apply and make sense of its non-statutory "possession" standard. For example, the

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[243] Prior to *In re* Ruschig, 379 F.2d 990 (C.C.P.A. 1967), not a single case from the C.C.P.A. had considered "written description" under 35 U.S.C. § 112, to be anything other than a modifier of the enablement requirement. *See e.g.*, Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991) ("With respect to the first paragraph of § 112 the severability of its 'written description' provision from its enablement ('make and use') provision was recognized . . . as early as *In re Ruschig*.").

[244] Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1125–27. *But see* Capon v. Eshhar, 418 F.3d 1349, 1358 (Fed. Cir. 2005) (reliance on prior art as prior art contained "extensive knowledge of the nucleotide structure").

[245] Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010); Capon v. Eshhar, 418 F.3d 1349, 1358 (Fed. Cir. 2005); Boston Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1366–67 (Fed. Cir. 2011); Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc., 642 F.3d 1031, 1037 (2011).

[246] *Ariad*, 595 F.3d at 1350.

[247] *Id.*at 1352.

[248] Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1367 (Fed. Cir. 2006).

[249] Streck, Inc. v. Rsch. & Diagnostic Sys., Inc., 665 F.3d 1269, 1285 (Fed. Cir. 2012).

[250] Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1122 (Fed. Cir. 2008).

[251] *Ariad*, 598 F.3d at 1361–67 (Rader, J., dissenting in part) (Judge Rader dissenting in part, criticizing the en banc majority's holding that § 112 contains two separate requirements for written-description and enablement); *see* Allen K. Yu, *The En Banc Federal Circuit's Written Description Requirement: Time for the Supreme Court to Reverse Again?*, 33 CARDOZO L. REV. 895, 964–66 (2012).

[252] Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 586–96 (2012).

"representative number of species" test, the "structure-function" test, and the "common-structural-features" test were created. These sub-tests have even varied depending on the technology; for example, the three sub-tests to assess if a patent application had complied with the written description of a genus claim to biologics such as antibodies, include (i) the "fully characterized antigen" sub-test, (ii) the "common structural features" sub-test, and (iii) the "representative number of examples" sub-test. However, the Federal Circuit's "possession" jurisprudence has evolved, and the "representative number of examples" sub-test is now the most favored.

As well as creating sub-tests in an attempt to apply the non-statutory "possession" test for written description, the Federal Circuit has held that to establish "possession," the patent application must include a "precise definition" of the claimed invention "such as by structure, formula, chemical name, or physical properties."[253] For genus claims, the court in *Ariad* goes on to state that this precise definition is required to include "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."[254]

The key takeaway, however, is that none of these subtests or precise definitions have any statutory basis in the text of § 112(a). Moreover, in direct contrast, the Supreme Court has previously held genus claims valid and in compliance with § 112(a) even when the patent claim encompassed "a large class of substances and the range of treatment within the terms of the claims."[255] It is for this reason that commentators have mentioned that these non-statutory requirements for showing "possession" impose heightened burdens on inventors, especially those in the biomedical field, not found under the statute.[256]

One problem with the Federal Circuit's recent 35 U.S.C. § 112(a) jurisprudence is some industries in which genus claiming strategies are prevalent have been unjustly targeted and negatively impacted by this change in law and the heightened new standard necessary to comply with the statute. For example, if the claim covers a genus of pharmaceutical compounds, "possession" may be demonstrated by disclosure of either "a representative number of species" within the scope of the claims or by showing "structural features common to the members of the genus."[257] This judicially-created standard is not what the statute requires; instead, this new judge-made standard requires patent applications to disclose additional and different information from what is necessary for a person of ordinary skill in the art to understand what the invention is and how to make and use it.

The Federal Circuit's interpretation of the statute runs afoul of the statute, its legislative history, and also conflicts with Supreme Court precedent.[258] The court's dramatic change in position for interpreting the language of § 112 and its current application of the "representative number of examples" sub-test for showing the court-created, extra-statutory "possession" requirement for

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[253] Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997).

[254] *Ariad*, 598 F.3d at 1350.

[255] Minerals Separation Ltd. v. Hyde, 242 U.S. 261, 271 (1916).

[256] Harold C. Wegner, *The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years*, 37 AKRON L. REV. 243 (2004).

[257] *Ariad*, 598 F.3d at 1350.

[258] *See* part II, *supra*.

demonstrating written description have created immense practical problems for stakeholders in the pharmaceutical and biotechnology industries and this has significantly hindered innovation in this field in recent years. In practice, the rigid and expansive written description doctrine has been too high a bar to meet and is viewed by many stakeholders in the pharmaceutical and biotechnology industry as a non-statutory, judge-created obstruction to fostering innovation of new therapeutics to meet patient needs.[259]

B. The Patent Act Does Not Require "Full Scope" Enablement

The Federal Circuit has not only flouted statutory text and added their own new "possession" standard for written description, but the court has also gone awry on the enablement requirement of this statute. That is, the Federal Circuit has of late adopted a rigid numbers-based test to evaluate "full scope" enablement that focuses on evaluating how an ordinary skilled artisan can make and test every species encompassing a genus no matter how routine a practice that would be, instead of focusing on whether any "undue" experimentation would be required to make and test the species.[260] This change in approach away from the well-established "undue experimentation" factors that the court had devised previously to a requirement for patentees to now make and test all of the species within a genus and highlight which species works and which does not, is a fundamental shift in approach.[261] This heightened enablement is a significant shift in approach which has devastated the pharmaceutical and biotechnology industries because of their unique reliance on genus claims.[262]

When Congress enacted 35 U.S.C. § 112, the statute clearly mandated that the patent specification "enable any person skilled in the art to which it pertains" to "make and use the same." To satisfy the enablement requirement, the courts require that the disclosure of the patent be "commensurate in scope" with what the patent claim is attempting to capture.[263] Indeed, if a patentee decides to pursue broad patent claims, arguably a more valuable right, the law requires that the disclosure be sufficient to support and enable that wider claim scope.[264]

The statutory foundation for the enablement requirement dates back over 200 years, and yet enablement as a doctrine was developed by judicial interpretation of the statute.[265] Under the rubric developed and long established by the courts, the

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[259] *See e.g.*, Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

[260] *In re* Wands, 858 F. 2d 731, 736 (Fed. Cir. 1988).

[261] Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003) ("The enablement requirement is satisfied if, given what they already know, the specification *teaches those in the art enough that they can make and use the invention*.") (emphasis added).

[262] It is also noteworthy that some noted scholars have recently commented that this approach towards enablement marks "a categorical shift in thinking away from teaching the PHOSITA and towards a precise delineation of the boundaries of the claim." Karshtedt et al., *supra* note 1, at 4. .

[263] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) ("What is necessary is that the applicant provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims.").

[264] Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008) ("A patentee who chooses broad claim language must make sure the broad claims are fully enabled.").

[265] *See* part II, *supra*.

specification is found to be enabled only if upon balancing of the *In re Wands* factors a PHOSITA could make and use the invention without undue experimentation.[266] As follow-on decisions highlighted, "to enable any person skilled in the art" means "without requiring undue experimentation."[267]

However, it is bad enough that the Federal Circuit's decision to flout statutory text and split enablement and written description into two separate requirements and the ensuing instability that resulted from this new judicially created "possession" standard for written description and its related various sub-tests, but the court has also gone significantly awry on the enablement requirement of this statute. For a long time prior to the recent dramatic shift in the Federal Circuit's jurisprudence on enablement, the well-established "undue experimentation" factors were used as a central feature for determining a specification's compliance with the enablement requirement.[268] This framework correctly identifies that the enablement analysis is case-specific and that any imposition of arbitrary bright-line rules cause problems.

However, the Federal Circuit's move away from the well-established "undue experimentation" factors to a requirement for patentees to now make and test all of the species within a genus and highlight which species works and which does not, is a fundamental shift in approach.[269] That is, the problem with the current enablement jurisprudence, as articulated by the Federal Circuit, is the fact that it has become a rigid numbers-based test to evaluate whether the patent application enables the "full scope" of its claims.[270] This test has evolved to incorrectly focus on evaluating how an ordinary skilled artisan can make and test every species encompassing a genus, no matter how routine a practice that would be. And yet, as the court has previously outlined, enablement does not require an ordinary skilled artisan to make and test every possible substitution to exclude hypothetical outliers that do not work.[271] Indeed, 35 U.S.C. § 112(a) of the Patent Act does not mandate any limitations on the number of species falling within a genus claim or require "full scope" enablement. This new court-created heightened enablement, as discussed in part III and IV, has devastated the pharmaceutical and biotechnology industries because it is an impossible requirement to meet for genus claims of any size in these biomedical industries.[272] This effective prohibition on genus claims that cover "too large" a number of compounds lacks any basis in statutory text of 35 U.S.C. § 112(a) or Supreme Court precedent.

The genesis of this numbers-focused enablement requirement can be found in *Wyeth*.[273] In that case, the patent claimed use of a "class of compounds" to treat restenosis (re-narrowing of blood vessel after angioplasty to open the blood vessel). The

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[266] *Id.*

[267] Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005); 35 U.S.C. § 112 (2022).

[268] Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003) ("The enablement requirement is satisfied if, given what they already know, the specification *teaches those in the art enough that they can make and use the invention"*) (emphasis added); *see also In re* Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991) (quoting *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)).

[269] *Id.*

[270] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021).

[271] Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984).

[272] Many patent claims have been rendered invalid based on this recent chance in the enablement jurisprudence by the Federal Circuit. *See e.g.*, Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

[273] Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1386 (Fed. Cir. 2013).

patent application disclosed only one species that was encompassed within the genus. During litigation to enforce the genus patent claim against a rival who had made a different species, the Federal Circuit held the claim invalid for failing the enablement requirement. The court considered key as to "whether having to synthesize and screen each of at least tens of thousands of candidate compounds" defeats enablement and answered in the affirmative.[274] What made the case even more unusual was the fact that the court held the claims non-enabled while "accept[ing] as true Wyeth's claims about the state of the art" and that one of ordinary skill could routinely screen candidate compounds for the desired effect.[275]

The Federal Circuit continued its recent jurisprudence on enablement and built off its decision in *Wyeth* and used the recent *Idenix* decision to effectively kill off and undermine the practice of genus claiming in biopharma patent practice. The Federal Circuit in *Idenix* drew on *Wyeth* and overturned a jury verdict that upheld the claims, affirming a district court's finding that the genus claims were not enabled as a matter of law.[276] Here, a divided panel held patent claims directed to methods for treating Hepatitis C Virus ("HCV") by administering compounds was invalid for failing both the enablement and the written description requirements under 35 U.S.C. § 112.[277] The court drew on its earlier *Wyeth* case, to find that the claims captured "tens if not hundreds of thousands" of compounds, and that the patent application provided minimal guidance on which compounds would work to treat HCV.[278] Even though the patent specification included four working examples, the court held that the claims failed the enablement requirement.

And yet, it is a mistake to think that the full-scope assessment depends on how long a person of ordinary skill in the art would take to make and test all the species encompassed by a genus. That is not the statutory test. Genus claims that have thousands of species within them, for example genus claims in pharmaceutical or biotechnology patents, have been found to be enabled in view of patent disclosures that have not identified every species encompassed by a genus.[279] As the Federal Circuit has outlined, a patent application is "not required to provide a detailed recipe for preparing every conceivable . . . or . . . permutations of that compound."[280] Indeed, in a well-established case, *In re Wands*,[281] the genus claim covered an immunoassay method using monoclonal antibodies directed to a hepatitis B antigen. Although an ordinary skilled artisan would have had to engage in extensive amount of experimentation, the court held the claim *was* enabled because the specification included considerable direction, guidance, and working examples. The enablement requirement was satisfied, even where extensive routine experimentation was needed to practice the invention.

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[274] *Id*. at 1385.

[275] *Id.*; Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (Fed. Cir. 2019).

[276] Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1165 (Fed. Cir. 2019).

[277] *Id.*

[278] *Id.* at 1164.

[279] *In re* Angstadt, 537 F.2d 498, 501–02 (C.C.P.A. 1976).

[280] Pfizer Inc. v. Teva Pharms. U.S.A., Inc., 555 F. App'x. 961, 967 (Fed. Cir. 2014) (a patent specification is not required to "describe how to make and use every possible variant"; "the artisan's knowledge of the prior art and routine experimentation can often fill gaps").

[281] *Id.*

A new Federal Circuit approach to § 112(a) is required that is a flexible and adaptable test, and not the current rigid rules that focus on "representative number of examples" sub-test for the written description's non-statutory "possession" requirement, and "full scope" enablement that requires every species within a genus to be made and tested. Since determinations on compliance with these § 112(a) requirements are fact-intensive, including determining the ordinary skilled person's knowledge, the amount of guidance provided by the patent application and the nature of the field of invention, it also is questionable at best why enablement is treated as a question of law whereas written description is treated as a question of fact. Having such rigid judicially-invented rules has unintended consequences, namely in this instance on the validity of vast number of valuable genus claims in pharmaceutical and biotechnology patents as district courts around the nation have been bound by the Federal Circuit's jurisprudence concerning § 112(a).

As is discussed in the next and final section, part VI, a flexible and context-specific standard is required to interpret § 112(a). To have the current rigid tests as outlined above be the *only* test for enablement, or the *only* test for written description, is wrong. Much like when the Supreme Court rejected the Federal Circuit's rigid "teaching, suggest, or motivation" test for obviousness,[282] and the rigid "machine or transformation" test for patent eligibility,[283] the Federal Circuit's current numbers-based enablement inquiry to determine "full scope" enablement, or the "representative number of examples" inquiry for written description, should be struck down as too rigid and extra-statutory and because these tests within the § 112(a) inquiry do not represent the *sole* tests. Rather, instead of striking down the current tests, the currently adopted tests can instead be regarded as merely providing "a useful and important clue,"[284] as provided for by the recent Supreme Court cases in *KSR* and *Bilski*.[285]

C. 35 U.S.C. § 112(a) Requires a Fact-Intensive Jury Inquiry

35 U.S.C. § 112(a) requires that the "written description" of a patent specification must include "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."[286] The Supreme Court has previously held that "it is the right of the jury to determine . . . whether the specifications . . . were so precise as to enable any person skilled in the art . . . to make the invention described."[287] A key reason for this being that fact-intensive determinations such as, whether an ordinary skilled artisan would appreciate the similarities between species within a genus claim typically involve question of fact for juries to decide.

The Federal Circuit decided for the first time in 1983, against Supreme Court precedent, that enablement is a question of law.[288] This has carried through and today enablement is a question of law for the court to decide. And yet, one cannot divorce

[282] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007).
[283] Bilski v. Kappos, 561 U.S. 593, 603 (2010).
[284] *Id.* at 604.
[285] *Id.*
[286] 35 U.S.C. § 112(a) (2022).
[287] Battin v. Taggert, 58 U.S. (17 How.) 74, 85 (1854).
[288] Raytheon Co. v. Roper Corp., 724 F.2d 951, 960 n.6 (Fed. Cir. 1983).

enablement determinations from inherently factual questions, including, critically, the knowledge of the ordinary skilled artisan in the relevant field of art, the nature and maturity of the field of the invention, and how much guidance the patent application provides. The enablement inquiry depends on determining if experimentation is "undue" and there is an eight-factor test that is used to assess if an ordinary skilled artisan would be required to perform "undue experimentation" in order to practice the invention.[289]

Even in the context of such intensive factual inquiries, the Federal Circuit's current view is that determining whether "undue experimentation" is required is a question of law.[290] However, these eight factors require expert testimony and weighing evidence related to the eight factors. Such analysis is typically a function reserved for the jury – i.e., a question of fact and not a question of law. In addition, it remains a puzzle as to why juries routinely resolve enablement issues when enablement is a question of law,[291] and if juries do make determinations on whether "undue experimentation" would be necessary, why are judges given the permit to discard juries' findings? That is, although the settled view has been that enablement is a fact issue according to Supreme Court precedent, the specter of having enablement be decided as a legal question means judges are able to set aside validity determinations and reweigh the facts.

The Supreme Court has long recognized enablement as a question of fact, stating that it is "the right of the jury to determine" whether a specification is sufficient to "enable any person skilled in the [art] . . . to make the [invention] described."[292] Moreover, it is noteworthy to mention that while the enablement requirement's close cousin - "written description" requirement - from the very same sentence of § 112 is treated as a question of fact, the Federal Circuit considers the enablement inquiry as a question of law. This position runs against the statute and Supreme Court precedent. Perhaps most importantly, in practice, this move has been felt and had a significant impact because the Federal Circuit effectively took the jury's role and handed it to the judges to decide, to the detriment of society and settled law. As such, for at least this additional reason, the enablement doctrine is ripe for correction, so that stability can return to patent laws and the growth of innovation, especially in the biomedical field, can be fostered.

VI. FIXING 35 U.S.C. § 112(a)

As outlined *supra*, the status of current laws concerning § 112 has not been technology-neutral. In particular, the pharmaceutical and biotechnology industries have been greatly harmed by the Federal Circuit's presently applied rigid approach to § 112(a), whereby genus claims that cover too many compounds fail the enablement requirement, and by requiring a separate written description to show the inventor was

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[289] *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) ("Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.").

[290] Warner-Lambert Co. v. Teva Pharms. U.S.A., Inc., 418 F.3d 1326, 1337 (Fed. Cir. 2005).

[291] AIPLA Model Patent Jury Instructions (2018), https://www.aipla.org/docs/default-source/default-document-library/2018-07-23-clean---aipla-model-patent-jury-instructions.pdf?sfvrsn=8664a8dd_0.

[292] Battin v. Taggert, 58 U.S. (17 How.) 74, 85 (1854).

"in possession" of the compounds upon patent filing. One approach to fix the problem with the current status quo concerning § 112 would be to treat the statute as requiring a singular requirement and make determinations on violations or compliance of the statute on a case by case, flexible and context-specific manner. Moreover, the Federal Circuit's labeling of enablement as a question of law has resulted in the court creating rigid tests without any statutory authority. It is noteworthy that enablement in the same sentence of the § 112(a) statute is treated as a question of law, whereas written description requirement from the same sentence is treated as a question of fact. Instead of embracing the current atextual tests for enablement and written description, a simpler approach would be to follow statutory language and ask the factfinder whether the patent application has described the invention and 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 to make and use the same."[293]

A. Flexible Approach Necessary For "Full Scope" Enablement

The boundary of intellectual property that an inventor desires to capture as her invention is listed in a patent's claims.[294] The U.S. Patent and Trademark Office and the courts have long been aware that an inventor's claims may attempt to capture more than the inventor has disclosed in the patent application. The statute, 35 U.S.C. § 112(a), of the Patent Act focuses on the disclosure requirements for a patent. In particular, when an innovator obtains a patent and with it the exclusivity to stop others from practicing the invention for a period of time, the innovator is required, under § 112(a), to provide an enabling disclosure of the invention.

When Congress enacted 35 U.S.C. § 112, the statute clearly mandated that the patent specification "enable any person skilled in the art to which it pertains" to "make and use the same." To satisfy the enablement requirement, the courts require that the disclosure of the patent be "commensurate in scope" with what the patent claim is attempting to capture.[295] Indeed, if a patentee decides to pursue broad patent claims, arguably a more valuable right, the law requires that the disclosure be sufficient to support and enable that wider claim scope.[296]

The statutory foundation for the enablement requirement dates back over 200 years, however, enablement as a doctrine was developed by judicial interpretation of the statute.[297] Under the rubric developed and long established by the courts, the specification is found to be enabled only if upon balancing of the *In re Wands* factors a PHOSITA could make and use the invention without undue experimentation.[298] This rubric became the accepted norm for assessing enablement, with decisions after *In re*

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[293] 35 U.S.C. §112(a) (2022).

[294] *In re* Warmerdam, 33 F.3d 1354, 1360 (Fed. Cir. 1994) ("It is the claims which define the metes and bounds of the invention entitled to the protection of the patent system.").

[295] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) ("What is necessary is that the applicant provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims.").

[296] Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008) ("A patentee who chooses broad claim language must make sure the broad claims are fully enabled.").

[297] *See* part II, *supra*.

[298] *Id.*

Wands consistently stating "to enable any person skilled in the art" means "without requiring undue experimentation."[299]

However, not only has the Federal Circuit flouted statutory text and split enablement and written description into two separate requirements and caused instability because of their new "possession" standard and various sub-tests for written description, but the court has also gone significantly awry on the now separate enablement requirement of this statute. Prior to the recent dramatic shift in the Federal Circuit's jurisprudence on enablement, the well-established "undue experimentation" factors were used as a central feature for determining a specification's compliance with the enablement requirement.[300] This framework correctly identifies that the enablement analysis is case-specific and that any imposition of arbitrary bright-line rules cause problems.

However, the Federal Circuit's move away from the well-established "undue experimentation" factors to a requirement for patentees to now make and test all of the species within a genus and highlight which species works and which does not, is a fundamental shift in approach.[301] That is, the problem with the current enablement jurisprudence, as articulated by the Federal Circuit, is the fact that it has become a rigid numbers-based test to evaluate whether the patent application enables the "full scope" of its claims.[302] This test has evolved to incorrectly focus on evaluating how an ordinary skilled artisan can make and test every species encompassing a genus, no matter how many species there are within the genus and how routine a practice that would be.

And yet, as the court has previously outlined, enablement does not require an ordinary skilled artisan to make and test every possible substitution to exclude hypothetical outliers that do not work.[303] Indeed, 35 U.S.C. § 112(a) of the Patent Act does not mandate any limitations on the number of species falling within a genus claim or require "full scope" enablement. This new court-created heightened enablement has devastated the pharmaceutical and biotechnology industries because it is an impossible requirement to meet for genus claims of any size in the biomedical industry.[304] This effective prohibition on genus claims that cover "too large" a number of compounds lacks any basis in statutory text of 35 U.S.C. § 112(a) or Supreme Court precedent.

A new Federal Circuit approach to § 112(a) is required, one that is a flexible and adaptable test. The current rigid rules are proving devastating to the biopharmaceutical industry because they focus on "representative number of examples" sub-test for the written description's non-statutory "possession"

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[299] Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005); 35 U.S.C. § 112 (2022).

[300] Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003) ("The enablement requirement is satisfied if, given what they already know, the specification *teaches those in the art enough that they can make and use the invention*") (emphasis added); *see In re* Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991) (quoting *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)).

[301] *Id.*

[302] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021).

[303] Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984).

[304] Many patent claims have been rendered invalid based on this recent chance in the enablement jurisprudence by the Federal Circuit. *See e.g.*, Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

requirement, and "full scope" enablement that requires every species within a genus to be made and tested. Since determinations on compliance with these § 112(a) requirements are fact-intensive, including determining the ordinary skilled person's knowledge, the amount of guidance provided by the patent application and the nature of the field of invention, having such rigid rules have unintended consequences, dooming genus claims of many high value biopharma patents as invalid. The current rigid tests cannot be the *sole* test for enablement, and similarly, the current "possession" subtest cannot be the *sole* test for written description. Much like when the Supreme Court rejected the Federal Circuit's rigid "teaching, suggest, or motivation" test for obviousness,[305] and the rigid "machine or transformation" test for patent eligibility,[306] the Federal Circuit's current numbers-based enablement inquiry as well as the "representative number of examples" inquiry for written description should be struck down as too rigid and because they do not represent the sole tests. Thus, there is present need for a new standard or interpreting § 112(a) of the Patent Act.

B. Returning to a Single Section 112(a) Standard – A Written Description that Enables

If history is any judge, we have seen the Federal Circuit create its own tests for interpreting other areas of patent law, only for the test to apply too narrowly and rigidly. For example, the "teaching, suggestion and motivation" (TSM) test became the only test for assessing obviousness of a patent application and the Supreme Court disagreed with such a rigid, formulaic interpretation of Section 103 obviousness law in *KSR*. Although the Court did not significantly change the Federal Circuit's jurisprudence on obviousness, they did make a note to say that the TSM test is not the sole test for obviousness and that the Federal Circuit was wrong to apply their own TSM test so rigidly.[307] In another recent Supreme Court case involving yet another aspect of patent law, Section 101, the Court rejected the Federal Circuit's rigid "machine or transformation" as the only test for determining patent eligibility in *Bilski*.[308] Having taken action to make Sections 101 and 103 of the Patent Act more predictable, giving both a more flexible test, the Supreme Court ought to tackle Section 112 to also strike down in similar fashion the rigid approach used to test for Section 112 compliance.

A flexible and context-specific standard is required to interpret § 112(a). As discussed *supra*, such a flexible approach to § 112 is key to bringing more predictability and calm to an area of patent law that is in flux to the detriment of many stakeholders in the biotech and pharmaceutical industries. The Federal Circuit's often used narrow and inflexible "representative number of examples" sub-test to determine compliance with the written description requirement is proving unworkable and, in practice, a test that has decidedly negatively targeted one industry over others.[309] Just as the Supreme Court did to change the rigid

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[305] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007).

[306] Bilski v. Kappos, 561 U.S. 593, 603 (2010).

[307] *Id.*

[308] *Id.* at 603 (". . . is not the sole test.").

[309] Scholars, practitioners and judges alike have previously remarked Biotechnology and Pharmaceutical industries as being targeted much more than other industries such as mechanical and electrical that are more "predictable."

stance of the Federal Circuit's position on their own devised obviousness laws in *KSR*, and also similar to the Supreme Court's stance to reject a rigid inquiry for determining patent eligible subject matter in *Bilski*, this current issue concerning § 112 is ripe to address by a future Supreme Court decision. The goal ought to be the creation of a flexible, multi-pronged, context-specific § 112(a) inquiry. It is perhaps indirectly noteworthy that the Supreme Court has recently emphasized adherence to the Patent Act's text, without adding any "rigid and mandatory formulas,"[310] or any additional requirements that would be "inconsistent with the text and the statute's purpose and design."[311]

What is clear is that the rigid application of the "representative number of examples" sub-test by the Federal Circuit as the only test for determining if a patent application has complied with the written description requirement is a mistake. Language could be taken from the Supreme Court's two recent decisions that aimed to nullify rigid patent law rules to, for example, indicate that the current test can help in the § 112 analysis as "a useful and important clue," but "not [as] the sole test."[312] Also, although disclosing working examples may provide a helpful insight in some situations, "helpful insights . . . need not become rigid and mandatory formulas" as the Supreme Court outlined.[313]

Prior to the Federal Circuit's recent detour on its § 112(a) jurisprudence, this approach was used for analyzing § 112(a) for both enablement and written description. In particular, a more holistic and flexible manner was used, for example, to recognize that "the 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge."[314] Here, the context of the nature of the technology, its maturity, predictability, the breadth of the claims and the level of skill of the ordinary person were all considered as important factors, with no factor being dispositive, for both written description and enablement. Under this multi-pronged analysis, the written description and enablement determinations are subsumed into one test as required by the statute.

The key factors used to analyze enablement, the *Wands* factors, include a similar list that aims to provide a context-specific multi factor test. For example, whereas "presence of working examples" factors into determining whether a patent claim is enabled under the *Wands* factors, the "representative number of examples" sub-test from *Regents* and *Ariad* cases is similarly used to determine whether a patent claim complies with the written description requirement. The overlap here is clear, with Judge Linn going as far as saying that the *Capon* factors for written description "mirror the *Wands* factors for enablement."[315] This comes as no great surprise, given that both enablement and written description have their roots in 35 U.S.C. § 112 and closely overlap each other in practice.

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[310] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007).

[311] *Bilski*, 561 U.S. at 603.

[312] *Id.* at 604.

[313] *KSR*, 550 U.S. at 419.

[314] Capon v. Eshhar, 418 F.3d 1349, 1358–59 (Fed. Cir. 2005).

[315] Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1368 (Fed. Cir. 2010) (Linn, J., dissenting).

An option for law makers to consider is to return to the statutory text and Supreme Court precedent by recognizing § 112(a) as a unitary requirement for a written description of the invention and of the manner of making and using it. This interpretation of the statute aligns with both the language of the statute and the purpose of the disclosure requirement.[316] A singular approach to assessing these two highly overlapping features of 35 U.S.C. § 112 is necessary, one test that ought to be created and applied in a flexible, multi-pronged, context-specific manner. This could perhaps take the form of collapsing the *Capon* factors for determining written description with the *Wands* factors for determining enablement to come up with a singular test that focuses on the kind of experimentation a PHOSITA would conduct in view of a particular disclosure. In the context of biotechnology and antibody-based therapeutics in particular, the Federal Circuit should return to its own decision in *Noelle* and integrate their "fully characterized antigen"[317] test as one of the possible routes patentees can use to comply with the written description requirement. This flexible approach would level the playing field for biotechnology and pharmaceutical innovations and such flexible tests could also factor in other tests, including the "representative number of examples" test.

The academic exercise of suggesting ways to fix 35 U.S.C. § 112(a) aside, recent decisions provide some guidance regarding the likelihood of any change in direction from the courts. Based on the *Amgen* and *Idenix* decisions from 2021,[318] one can extrapolate that broad functional genus claims are all but worthless for at least some time to come. The original Amgen panel's full throttle defense of their heightened enablement standard and denying Amgen's rehearing request as "non-precedential" indicates the Federal Circuit is unlikely to change its position on their heightened enablement bar in the near term. This coupled with the fact that *Idenix* petition for certiorari was also recently denied by the Supreme Court, also is indicative of no changes in law being forthcoming from the courts. Therefore, from a practical perspective, patentees would be well advised to avoid functional genus claims and instead focus on describing small molecules in structural terms. If functional language is used in genus claims, it is now advisable to provide multiple specific examples in the patent application to support the scope of the patent claim.

[316] Evans v. Eaton, 20 U.S. (7 Wheat) 356, 433–34 (1822).

[317] Noelle v. Lederman, 355 F.3d 1343, 1349 (Fed. Cir. 2004).

[318] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021); Idenix Pharms. LLC v. Gilead Sci. Inc., 941 F.3d 1149 (Fed. Cir. 2019), *cert. denied*, 141 S. Ct. 1234 (2021).