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A SINGULAR DISCLOSURE REQUIREMENT IS NECESSARY FOR PATENT LAW

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The Court of Appeals for the Federal Circuit's recent jurisprudence on 35 U.S.C. § 112 has selectively and severely curtailed innovation in the fields of pharmaceuticals and biotechnology. Specifically, the Federal Circuit's shifting position on 35 U.S.C. § 112 and their evolving jurisprudence to combine expanding the application and scope of the written description requirement with a separate, heightened standard for enabling claims directed to innovation in a genus of therapeutic antibodies, or a genus of compounds having functional limitations, has caused havoc in the biopharmaceutical industry. Federal Circuit jurisprudence on how to interpret the disclosure requirements of the 35 U.S.C. § 112 contravenes the statute and Supreme Court precedent by mandating two separate disclosure requirements in place of one, namely that patent applications not only "enable" but also separately "describe" inventions. This recently developed and reactively evolving judge made approach raises the bar exceedingly high for obtaining any

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meaningful patent protection for new biomedical discoveries, goes against many decades of patent practice, and is proving to be a powerful impediment to the investment necessary for developing new and lifesaving medicines. This article examines patent law's current disclosure requirements to highlight a failing judicial trajectory and proposes a return to a single 35 U.S.C. § 112(a) standard. By doing so, the great shock that has singled out and disrupted the biopharmaceutical industry will be removed and the law can once again encourage, in a technology-neutral manner, the private sector to innovate in all fields of endeavor, including encouraging the biopharmaceutical industry to develop new lifesaving medicines and treatments.

I. INTRODUCTION

Patents provide inventors with the right to exclude others for a time, from making, selling or using their discoveries.[1] Stemming from this financial incentive, the public benefits from the development and commercialization of new technologies.[2] Moreover, society as a whole benefits because the inventor is expected to "reveal to the public the substance of his discovery" so that the public

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

[2] Richard Nelson & Roberto Mazzoleni, *Economic Theories About the Costs and Benefits of Patents*, NATIONAL RESEARCH COUNCIL (1996).

is "enabled without restriction to practice it and profit by its use." This *quid pro quo* of using patents to provide an incentive for the development of new technologies is foremost visible in the pharmaceutical and biotechnology industries.[3]

Pharmaceutical and biotechnology industries rely on a stable patent system when innovating and expect robust and predictable patent protection for their biomedical innovations to support their commercialization strategies. Innovators in this industry represent a large market in the U.S.[4] A novel scientific finding requires billions of dollars to advance to the marketplace as a product[5] and a reliance on a particular type of patent law claim, a genus claim, is at the heart of this investment decision in these medical fields to develop and bring to market groundbreaking pharmaceuticals and therapeutics.

Yet, many of the patents that cover the key revenue generating products of pharmaceutical and biotechnology companies are now invalid under current law. The reason for this stark reality is that the Federal Circuit has in recent years taken an increasingly rigid position when applying patent disclosure laws (hereinafter "§ 112(a)") to genus claims. In practice, the Federal Circuit's recent jurisprudence, aimed at relegating genus claims to be a near worthless tool of the patent practitioner's toolbox, has made it exceptionally difficult to obtain any meaningful patent protection to cover key small molecule pharmaceuticals and antibodies that make up a crucial component of the pharmaceutical and biotechnology industries, respectively. Prominent scholars have gone as far as declaring genus claims as "dead."[6]

Innovative companies in the pharmaceutical and biotechnology industries are highly sensitive to and protective of the patent portfolios they manage because the value of their companies generally depends on the scope and strength of their owned or exclusively licensed patent portfolios. Patent claims mark the boundaries

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[3] Diego Giugni & Valter Giugni, *Intellectual Property: A Powerful Tool to Develop Biotech Research*, MICROB BIOTECHNOLOGY, 493, 493–506 (2010).

[4] Lu, Ruei-Min, Hwang, Yu-Chyi, Liu, I-Ju, *et al.*, *Development of Therapeutic Antibodies for the Treatment of Diseases*, J. BIOMED. SCI. 27, 1 (2020). As well as pharmaceuticals, a large percentage of global drug sales now include biologics such as antibodies. Use of antibodies has grown exponentially since the U.S. Food and Drug Administration (FDA) approved the first monoclonal antibody in 1986. They 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.

[5] Olivier J Wouters, Martin McKee, Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market*, 844, 844-853 (2020); *see also* 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%*, 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 [https://perma.cc/PP6V-4HHH]; *see also* Joseph A. DiMasi, Henry G Crabowsi, Ronald W. Hansen, *Innovation in the pharmaceutical industry: New estimates of R&D costs,* Journal of Health Economics, vol. 47, 20–33 (2016).

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

of a patent owner's rights, and the scope of these rights is thus dependent upon the breadth of the patent claims. That is, the broader the patent claim, the greater the scope of the subject matter being claimed. When drafting patent claims, practitioners typically attempt to capture "classes" of embodiments of the invention instead of narrow specific embodiments of their discovery. The reason for this strategy is to avoid any potential infringer or competitor from easily designing around narrow specific embodiments of a claim to avoid infringement. Yet, in practical terms, the outcome is just as unwanted if patent claims are drafted too broadly to capture more than the inventor has invented. In such a scenario, the patent claim is not commensurate with what is disclosed and taught in the patent application, and this can result in the patent claim being rendered invalid and unenforceable.

Thus, it is of utmost importance that patent claims be drafted to reflect the teachings of the disclosure. If too narrowly drafted, they can be easily designed around by would-be infringers; and if drafted too broadly, they can be rendered void and invalid for not being fully supported by the patent application's disclosure. In practice, when assessing claim scope, it matters little whether one is attempting to obtain a patent before the U.S. Patent and Trademark Office or litigating in courts to enforce a patent or defend against accusations of patent infringement. Patent savvy practitioners, scholars and judges are increasingly sensitized to situations where patent claims attempt to capture more than the inventor has taught and disclosed in the patent application.

Generally, the broader the scope or breadth of a patent claim, the greater the amount of disclosure in the patent application that would be necessary to support a monopoly being granted by the government for the broad claim the inventor is seeking as her invention. The key doctrines in patent law governing how much or how little disclosure to include in patent applications are the doctrines of enablement and written description. These two taskmasters determine which patent claims are valid and supported by the disclosures in the patent application and which patent claims are void for being too broad and not commensurate enough to reflect that which the inventor has actually taught and disclosed.[7]

The statutory foundation for determining how much disclosure to include in a patent application can be found in § 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 mode contemplated by the inventor of carrying out his invention*."

[7] 35 U.S.C. § 112(a) (2018).

With this statutory framework as a foundation, it has been left for the courts to pin down the statute's meaning, namely how much and what type of disclosure is necessary to satisfy the requirements of this statute for obtaining a patent. Thus, the contours of this disclosure requirement for a patent application is at the heart of the inquiry. The Supreme Court has outlined 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."[8] In interpreting the statute, appellate courts developed two related, yet separate, doctrines of "enablement" and "written description." The disclosure requirement is a short paragraph,[9] and yet it has initiated intense debate and disagreement between judges on the Federal Circuit and District Courts, practitioners, and scholars alike. The issue remains how these two patent disclosure requirements interplay and whether the statute in fact requires a single or dual disclosure requirement for patentability.[10]

In this paper, I focus on § 112(a), otherwise referred to as the Patent Act's disclosure requirements, and highlight *seriatim* the reasons why the current enablement and written description laws embedded within it are broken, and how they particularly and selectively target and are damaging to the biopharmaceutical industry. The article ends by offering options for correcting the law's direction.

Despite its deep statutory foundation, enablement as a doctrine was born in more recent Federal Circuit decisions that interpreted the statute. However, that Federal Circuit is split on how this patent disclosure statute should be interpreted and applied. For example, should a single embodiment of an invention be enough to enable the full scope of a patent claim? In answering this question, one is faced with Federal Circuit decisions that squarely conflict with other Federal Circuit decisions on this same issue, namely that disclosing one mode satisfies enablement with other decisions indicating that it would not. In particular, 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,[11] 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.[12] As such, the statutory

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

[9] 35 U.S.C. § 112(a) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.")

[10] *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) (Chief Judge Rader dissenting).

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

[12] Automotive Technologies International, Inc. v. BMW of North America, Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007); Liebel-Flarsheim Co. v. Medrad Inc., 481 F.3d 1371, 1378–79 (Fed. Cir. 2007).

enablement requirement is being interpreted in conflicting ways by the Federal Circuit.

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."[13] Current enablement laws require patent applications to show "full scope" enablement. In the biopharmaceutical arts, this is translated into a requirement to identify every species that falls within a genus claim. Although that appears reasonable at first sight, it is unreasonable in practice because it mandates identifying every species in a genus even if there could be thousands of related species and screening and testing them would be "largely routine."[14] Therefore, in practice, we see enablement being used as a blunt tool to invalidate biopharmaceutical genus claims "as a matter of law" because the claimed genus "would require synthesizing and screening" thousands of compounds for the desired effects.[15] This is a misguided approach, and selectively harms the biopharmaceutical industry. In particular, the current eagerness to identify every species that falls within a genus and thereby identifying the boundaries of the patent claim to demonstrate what the Federal Circuit calls "full scope" enablement is misguided. This is especially so 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. As will be developed *infra* in Parts IV-VI, this approach to enablement targets certain industries more than others and is untenable.

Enablement laws aside, the Federal Circuit is also split on how the written description requirement should be applied. Should this requirement be used to police priority as first intended,[16] or to assess if the inventor "possessed" the claimed invention upon filing? These different interpretations have provided for very different outcomes.

While the enablement doctrine has deep roots in U.S. law dating back at least to 1832,[17] the written description doctrine is a relative newcomer dating back to case law from the 1970s. 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.[18] While this doctrine had this

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[13] Jason Romrell, *Biting off More Than You Can Chew: The New Law of Enablement*, 23 BERKLEY TECH. L.J. 139, 139–160 (2008).

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

[15] *Id.*

[16] Patent applications can claim priority to earlier filed patent applications. There are certain rules for claiming priority to an earlier filed application, one of which is that you cannot introduce new matter in the later filed patent application and still seek to claim priority to the earlier filed application.

[17] 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 . . . .").

[18] Jason Romrell, *supra* note 13.

limited and useful scope in the 1970s, the Federal Circuit greatly expanded the scope of this doctrine in *Lilly* in 1997 and this written description requirement has since been increasingly used as a sharp tool to invalidate patent claims. In particular, the Federal Circuit began using written description as a doctrine to prevent overreaching claims[19] and to prevent patentees from attempting to claim features of their invention that they did not possess when the patent application was filed.[20] The current written description requirement demands inventors show they "had possession of the claimed subject matter," including the infringing embodiment, "as of the filing date."[21] However, "possession" is not a statutory requirement, but a judicial doctrine.[22] As will be developed *infra* in Parts V and VI, this interpretation of written description is problematic and requires a new approach.

This deviation from the statutory text, as well as older case law from both the Supreme Court and also the Federal Circuit's own decisions, on both enablement and written description, has predictably had a negative effect in practice. In particular, the biopharmaceutical industry has been hit hard, much more so than other industries. In effect, the recent heightened requirements for satisfying the enablement and written description requirements of § 112(a) have now made it all but impossible to obtain genus claims that are critical for protecting innovation in pharmaceuticals and biologics.

Genus claims can fall within the scope of patent law's disclosure 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."[23] To determine whether a specification satisfies the disclosure requirement is a fact-intensive inquiry and is for the jury to decide.[24] The appellate courts' desire to stop broad claims to nascent, not fully developed inventions is valid. However, the statute itself addresses this concern by allowing factfinders to determine, given the amount of teaching in the patent application, whether a patent claim's breadth is warranted. For example, in a pharmaceutical patent application, when a claim is made in a patent application to a genus of compounds, it is for the jury to decide whether such

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

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

[21] *Ariad*, 598 F.3d at 1351; *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).

[22] "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways." *Manual of Patent Examining Procedures* § 2163.02 (10th ed. 2020). "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*, 935 F.2d at 1563–64).

[23] 35 U.S.C. § 112(a).

[24] Battin v. Taggert, 58 U.S. 74, 85 (1854).

a claim would satisfy § 112(a) by assessing whether an ordinary skilled artisan would appreciate the structural characteristics and could easily identify the relevant compounds falling within that genus.

As developed further in Part III, the core of pharmaceutical and biotechnology patent law practice is dependent on claim drafting strategies focusing on genus claims. A stable and predictable patent system is necessary, including predictability in key patent law principals such as genus claims, to entice innovators to invest the large financial and time demands required for drug discovery and bringing medications to market. Genus claims and the biopharmaceutical industry aside, a broader and fundamental problem with the Federal Circuit's separate requirements for written description and enablement is that neither of these two new Federal Circuit approaches for interpreting enablement 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.

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."[25] The Federal Circuit flouts this statutory text to split enablement and written description into two separate requirements. This approach to interpreting § 112(a) has resulted in the court judicially creating the court's new "possession" standard and further still its own various sub-tests for written description. Moreover, the court's interpretation of this patent disclosure statute has also simultaneously shifted the enablement inquiry from the well-grounded "undue experimentation" factors to one that requires patentees to now make and test all of the species within a genus and highlight which species works and which do not. This approach by the Federal Circuit is a fundamental shift and a negative one on balance.

Innovators in the pharmaceutical and biotechnology industries are left with few options if they wish to adhere to the Federal Circuit's current jurisprudence on § 112(a). As is developed in Part IV, these biomedical innovators cannot claim the

[25] 35 U.S.C. § 112(a); *see also*, *e.g.*, Patent Act of Feb. 21, 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."

full breadth of their invention if they are deemed to have disclosed too few species in their application because that would violate both the new genus-targeting rigid, numbers-focused "full scope" enablement rule and the separate written description's "possession" requirement. Conversely, it would be foolish for them to claim too narrowly as that only invites competitors to easily design around groundbreaking discoveries and take advantage by making minor changes to the claims to create another species of the same kind of drug to achieve the same clinical benefit. Pushing the biomedical industry into a very difficult corner, this new jurisprudence on § 112(a) is damaging certain industries much more so than others.[26] This also highlights why a new approach to patent disclosure laws is necessary—one that unifies the two separate yet interrelated patent disclosure requirements, enablement and written description, into one requirement that is supported by the statute, Supreme Court precedent and the Federal Circuit's own one line of prior cases.

Innovative pharmaceutical and biotechnology companies are currently being disincentivized from performing groundbreaking research by the Federal Circuit's recent jurisprudence on § 112(a), and this jurisprudence is also welcome news for those companies whose model is to copy the innovators. The practical ramification of this change of direction by the Federal Circuit will be felt in practice, as innovative biomedical companies will turn their back on innovating in some key sectors, including biotechnology, because their key inventions are suddenly unable to receive the patent protection they used to receive. Innovators cannot be content to receive patent claims to narrow embodiments of their inventions because such claims would be easy to design around by copycats who have not spent the time, effort, and dollars to perform the necessary research that led to the initial discovery. This will cost patients dearly in practice, as innovative pharmaceutical and biotechnology companies will pivot to focus their research and inventive efforts to established biological pathways and not take risks venturing into the unknown. The effect of this trajectory is that potential new targets and therapeutics will likely decline industry-wide for the foreseeable future to patients' detriment.

In Part II, I begin by discussing the legislative history of § 112(a), namely patent law's disclosure requirement, and how appellate courts have interpreted this statute over time. The article then introduces genus claims in Part III and highlights how critical this type of claim is for commercializing key products from the pharmaceutical and biotechnology industries. In Part IV, this article analyzes the Federal Circuit's current position concerning genus claims to show how their present rigid position is not technology-neutral and has made it exceedingly difficult to obtain valuable patent protection for drugs and biologics within the

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

pharmaceutical and biotechnology industries, respectively.[27] Part V of this paper focuses on unraveling the written description requirement from the enablement requirement.

Part VI of this article advocates for alternatives to the Federal Circuit's presently rigid approach to § 112(a). Namely, the currently rigid approach is highly problematic because genus claims that cover many species fail both the enablement requirement because they do not satisfy "full scope" enablement, and the separate written description because the patent application is not able to show "possession" of all the species. Instead of this dual requirement that is proving fraught with problems in practice, one option to fix § 112(a) is to treat it as having a singular requirement—a written description that enables—and evaluate compliance with the statute on a case by case, context-specific and flexible manner.

II. LEGISLATIVE HISTORY OF PATENT DISCLOSURE LAWS

Patent applications are required to "describe" the invention being claimed. This requirement has been a stalwart part of patent law, stemming from the language of the first Patent Acts of 1790 and 1793 to the present day.[28] For example, both the Patent Acts of 1793 and 1952[29] require "a written description of the invention"[30] and that it be "in such full, clear and exact terms . . . to enable."[31] Moreover, similar to 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."[32]

However, unlike current law, the Patent Act of 1793 required that the written description distinguish the invention from the prior art.[33] Although the requirement to have "a written description of the invention" was maintained in the Patent Act of 1836, the requirement for the written description 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] This language was kept

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

[28] Today, this is codified in 35 U.S.C. § 112, which 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" (emphasis added).

[29] The Patent Act of 1952, as amended, is current law.

[30] 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" (emphasis added).

[31] *Compare* Patent Act of 1790 and Patent Act of 1793 *with* Patent Act of 1952.

[32] Patent Act of 1793, ch. 11, § 3, 1 Stat. 318, 321-322 (emphasis added).

[33] *Compare* Patent Act of 1790 and Patent Act of 1793 *with* Patent Act of 1952.

[34] Patent Act of 1836.

intact in subsequent Patent Acts, including the Patent Acts of 1870 and 1952.[35] Presently, the written description requirement is codified in § 112(a),[36] with § 112(b) requiring clarity in claim language.[37] Under current law, patent claims outline the parameters of the invention and distinguish it from the prior art, and the patent application's specification is used to enable a person having ordinary skill in the art (hereinafter "PHOSITA") to make and use the claimed invention.[38]

A. Appellate Courts' Interpretation of Patent Disclosure Laws

Patents have been required to *describe* the invention, dating back to the first patent statute of 1790.[39] Although the Patent Act has been amended several times since 1790, this "written description" requirement was left intact,[40] albeit its role became less significant once "claims" were introduced as a statutory requirement for patent applications.[41]

Judicial interpretation of the current § 112(a), mandates that written description and enablement be viewed as two separate requirements.[42] Although it is at best unclear why one would interpret the one sentence of the statute as requiring two separate and yet closely overlapping requirements, there remains nevertheless the idea that written description makes sure an inventor had "possession" of her invention upon filing of the patent application,[43] and the enablement requirement

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

[38] *Id.* "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) (stating an ordinary skilled artisan "thinks along the line of conventional wisdom"); KSR, 550 U.S. at 420 (stating an ordinary skilled artisan is "a person of ordinary creativity, not an automaton.").

[39] Patent Act of 1790, ch. 7, §§ 1–7, and ch. 7, § 2, 1 Stat. 109, 110–11 (repealed 1793) (requiring patentee to deliver specification *describing* invention to Secretary of State) (emphasis added).

[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."); Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119 ("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.

[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 also* Patent Act of 1870, ch. 230, § 26, 16 Stat. 198.

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

[43] *Manual of Patent Examining Procedure* § 2163 (2021) [hereinafter MPEP].

ensures that sufficient disclosure is provided in the patent application such that a PHOSITA could practice the invention without having to perform "undue experimentation."[44]

In a key decision from 1988, the Federal Circuit provided "illustrative, not mandatory"[45] guidance for determining whether "undue experimentation" is necessary.[46] 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 these factors an ordinary skilled artisan could practice "the full scope" of the invention by having the patent specification show "how to make and use the full scope of the claimed invention without undue experimentation."[48] Some experimentation is permissible, so long as it is not "undue."[49]

This enablement doctrine has been a feature of patent law long before the Federal Circuit was formed in the U.S., dating as far back as 1832.[50] However, even with over 180 years of statutory foundation, the actual doctrine of enablement was developed by judicial interpretation of the statute. Interestingly, Federal Circuit decisions are split on this issue of enablement, with appellate decisions recognizing disclosure of one mode of an invention as being sufficient to satisfy the enablement requirement and yet other decisions requiring "full scope" of the claim to be enabled. For example, one line of Federal Circuit cases adheres to the principle that "the enablement requirement is met if the description enables *any* mode of making and using the invention."[51] That is, disclosing one mode of an invention is

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[44] *Id.* at § 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) (2012). 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.

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

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

[50] *Grant*, 31 U.S. at 241–42 ("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.").

[51] *See* Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1359–61 (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); 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").

sufficient. And yet, another line of Federal Circuit cases stands for the opposite—that is, disclosing a single mode fails to enable an invention's "full scope."[52] Moreover, as is discussed separately *infra* Parts V and VI, another related hot topic concerns what level of disclosure is enough to satisfy the related yet separate written description requirement.

Engel Indus., Inc. is one of the early "one mode" line of enablement decisions, standing for the proposition that *any* mode of making and using an invention satisfies the enablement requirement.[53] In line with this theme, other cases have highlighted that it is not necessary to disclose test results of every species encompassed by the patent claims. For example, in *In re Angstadt*[54] the patent application was directed to a method of catalytically oxidizing alkyl aromatic hydrocarbons to form a mixture comprising the corresponding hydroperoxides.[55] The examiner rejected this patent claim, alleging that a PHOSITA would have had to perform "undue experimentation" to figure out which catalysts would produce the desired hydroperoxides.[56] However, the court reversed the U.S. Patent and Trade Office ("USPTO"), holding that patent applications are not required to "disclose a test with every species covered by a claim" because the specification would then need to contain thousands of examples which would be "a prohibitive number of actual experiments."[57] This analysis was later clarified, focusing on what experimentation would be "undue," by the other seminal and oft cited case of *In re Wands.*[58]

However, in direct contrast to its own "one mode" enablement law precedent, the Federal Circuit has recently embraced "full scope" enablement, rejecting single embodiments as failing the enablement requirement. *Automotive Technologies v. BMW* is an example of this latter approach focusing on enabling the "full scope" of the patent claim. There, the court decided that it would not be enough to just provide

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[52] 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).

[53] *Engel*, 946 F.2d at 1533; *see also In re* Glass, 492 F.2d 1228, 1233 (C.C.P.A. 1974) ("Nonenablement is failure to disclose any mode.").

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

[55] *Id.* at 499.

[56] *Id*. at 501.

[57] *Id.* at 502.

[58] *In re* Wands, 858 F.2d at 737 (in order to determine what is "undue," this decision listed a number of factors to consider, 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.

one example of practicing the invention,[59] 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."[60] The court also rejected the disclosure of one embodiment as satisfying the enablement requirement in *Liebel-Flarsheim v. Medrad*,[61] citing another decision to indicate 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*."[62] Moreover, this "full scope" enablement approach was supported by referencing an older case that also rejected single embodiments as failing the enablement requirement.[63]

This split in the Federal Circuit's own decisions between the "one mode" and "full scope" enablement line of cases is best placed in context by reviewing Supreme Court decisions that have interpreted the relevant statute. *Morse v. O'Reilly* is one of the older Supreme Court cases on point and is best known. Morse, the inventor for the telegraph, sued O'Reilly for infringing his patent.[64] The Supreme Court found the patent claim invalid because Morse had indicated he did not wish to limit his invention to the specification and claims,[65] with Chief Justice Taney explaining "this claim can derive no aid from the specification filed. It is outside of it, and the patentee claims beyond it."[66] And yet, two Supreme Court decisions that followed *Morse* came to a different conclusion, with both decisions indicating patent claims *are* valid and adequately supported by a single disclosed mode for carrying out the method.[67]

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[59] 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.

[60] *Auto. Techs.*, 501 F.3d at 1285.

[61] 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.

[62] AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (emphasis added).

[63] *In re* Wright, 999 F.2d at 1561 ("[T]he applicant's specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention.").

[64] O'Reilly v. Morse, 56 U.S. 62, 68 (1853).

[65] *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.") (emphasis added).

[66] *Id.* at 119–20.

[67] Tilghman v. Proctor, 102 U.S. 707, 728–79 (1880) ("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 . . . . 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 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."); Dolbear

Although in *The Telephone Cases*, Alexander Graham Bell's broad patent claim was held valid,[68] the Supreme Court addressing a patent for the light bulb in *Incandescent Lamp* found the claim invalid as too broad given the disclosure.[69] As such, similar to the split in the Federal Circuit's interpretation of the statute as discussed *supra*, the Supreme Court's own decisions appear to show a split on how much disclosure is necessary to enable a claim, albeit this has been interestingly reconciled recently by using an implicit doctrine.[70]

Setting aside enablement and turning to the written description requirement, it is interesting to note that this latter requirement for patent applications was first developed in case law in the 1970s.[71] However, the Federal Circuit changed this area of settled law in the 1990s to impose a new court-created written description standard.[72] Beginning in the 1990s, the Federal Circuit sought to stop patent claims being broadened during prosecution to capture more than what was disclosed in the patent application upon filing. As such, patent applications were required to "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."[73]

Evans v. Eaton is one of the first Supreme Court decisions on written description.[74] Here, the Supreme Court interpreted the Patent Act of 1793 and invalidated a patent directed to an improved hopperboy because no distinct improvement was disclosed in the patent application and, therefore, the application was deemed not to satisfy the written description requirement.[75] According to the Supreme Court in *Evans*, the written description was necessary to stop inventors from obtaining patents that are "broader than the invention."[76] In *Le Roy v. Tatham*, another decision that came several decades after *Evans*, the Supreme Court again recognized that patent applications require a written description "of the invention, and of the manner and process of making and using it" such that it is "in such full,

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v. Am. Bell Tel. Co. (*The Telephone Cases*), 126 U.S. 1, 536 (1888) ("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.")

[68] *The Telephone Cases*, 126 U.S. 1, 539 (1888).

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

[70] Jason Rantanen, *The Doctrinal Structure of Patent Law's Enablement Requirement*, 69 VAND. L. REV. 1679 (2019) (conceptually viewed as two elements implicit in every enablement determination—the articulation of the target to be enabled as well as nature of enablement disputes as challenges.).

[71] *Id.*

[72] 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).

[73] *Vas-Cath*, 935 F.2d at 1560 ("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' . . . .").

[74] Evans v. Eaton, 20 U.S. 356 (1822).

[75] *Id.*

[76] *Id.*

clear, concise, and exact terms as to enable" an ordinary skilled artisan to practice the invention.[77] That is, § 112(a) was interpreted as requiring a written description that enables.

More recently, in a case where the patent application disclosed a general chemical structure with multiple variables, the Federal Circuit's predecessor found a claim to a single compound invalid for failing the written description requirement.[78] Here, this general disclosure in the patent application could yield "half a million potential compounds," according to the court. As such, the disclosure does "not constitute support for" a claim to one particular compound unless further disclosures are included to guide an ordinary skilled artisan to pick one particular compound over many others.[79] For the first time, the court used written description separate from enablement to disallow the addition of new matter to patent applications during prosecution in order to "prevent applicants from using the amendment process to update their disclosures . . . ."[80]

Other decisions interpreted this decision outside of the narrow context of determining priority and date of invention. These latter cases created an additional requirement of having patent applications include a written description of the invention and demonstrate that the inventor "was in possession of the invention" as of the filing date.[81] Later in the same decade, in *Lilly*, the Federal Circuit wholeheartedly embraced this requirement outside of the narrow context of priority determinations, holding a patent claim invalid for failing the written description requirement because the inventor did not show "possession" of his invention.[82]

Lilly was followed by other decisions that adopted the new approach to written description. However, many judges, scholars and practitioners disagree with this new approach.[83] For example, the former Chief Judge of the Federal Circuit considered *Lilly* to be the first time the written description was used "as a general disclosure doctrine in place of enablement."[84] In Judge Rader's view, using written description outside of the narrow context of policing against addition of new matter during prosecution elevated this written description requirement to "an effective super enablement standard."[85]

In *Ariad v Lilly,*[86] the court addressed the key question of whether the first paragraph of § 112 requires a single requirement, namely a written description that

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[77] Le Roy v. Tatham, 63 U.S. 132, 136–39 (1860).
[78] *In re* Ruschig, 379 F.2d at 990 (C.C.P.A. 1967).
[79] *Id.*
[80] *Id.*
[81] *Vas-Cath*, 935 F.2d at 1563–1564.
[82] *Regents*, 119 F.3d at 1569 (Fed. Cir. 1997).
[83] *See*, *e.g.*, *Ariad*, 598 F.3d at 1367 (Fed. Cir. 2010) (Linn, J. and Rader, J., dissenting-in-part).
[84] *Regents*, 119 F.3d at 976 (Rader, J., dissenting); *Enzo Biochem.*, 323 F.3d at 979–80.
[85] *Enzo Biochem.*, 323 F.3d at 979–81.
[86] *Ariad*, 598 F.3d at 1336.

enables one of skill in the art to make and use the claimed invention; or a double requirement, namely, a written description separate and apart from the enablement requirement. Here, the claim was to a method of regulating gene expression using the transcription factor NF-κB.[87] The court held 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.[88] Over vigorous dissents,[89] the Federal Circuit sat *en banc* and reaffirmed that written description and enablement are distinct requirements, with each requiring assessment under different standards. In *Ariad*, the court also rejected 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.[90]

There is debate amongst judges, scholars, and practitioners alike on whether enablement and written description ought to be separate requirements.[91] It is noteworthy that the statute itself does not mandate patent applications to comply with separate requirements for written description and enablement. Instead, the statue requires a written description of the invention that enables the claimed invention.[92] Since the written description requirement is a judge-made doctrine with no statutory foundation, the Federal Circuit has developed, and several times revised, subtests to determine if a patent application complies with the court's new "possession" requirement for written description.[93] And yet, as is developed further *infra* in Parts IV and V, even the latest version of this requirement has fundamental problems, highlighted in particular when it is applied to the pharmaceutical and biotechnology industries.[94]

Patent law's disclosure requirement remains unclear and unpredictable, with stakeholders unsure of the ever-changing contours of the varying sub-tests. In particular, stakeholders in the pharmaceutical and biotechnology industries are at times left clueless on how many or what type of species to include in patent applications in order to satisfy the requirements of § 112(a) for claiming a genus.

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[87] *Id.*

[88] *Id.* at 1350.

[89] Judges Rader and Linn dissented.

[90] *Ariad*, 598 F.3d at 1352.

[91] 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).

[92] 35 U.S.C. § 112(a) ("The specification shall contain *a written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms *as to enable any person skilled in the art* to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.") (emphasis added).

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

[94] *See infra* Part IV.

III. INNOVATION IN PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES DEPENDS ON THE VIABILITY OF GENUS CLAIMS

Although the Patent Act is "a technology-neutral statute,"[95] by creating non-statutory requirements to patentability, such as showing "possession" and its related sub-tests to satisfy written description,[96] judges have inadvertently created a technology-specific application of the statute. For example, patent law's recent disclosure requirement paradigm has, in practice, accounted for technology-targeted obstacles to patenting innovation within the pharmaceutical and biotechnology industries—an obstacle that would be "inconceivable in other industries."[97]

The cost of developing a new drug and bringing it to the marketplace is $2-3 billion and less than about 10% of drug development actually results in a drug reaching the marketplace.[98] As such, with hundreds of billions of dollars being spent on developing drugs in the past decade, innovators in this space demand and require a predictable patent system to protect their investments in bringing novel therapeutics to market to satisfy society's growing medical needs. One of the important tools by which innovators seek to commercialize their innovative technologies within this biomedical field is a particular type of patent claim that enables innovators to claim a group of related molecules, or "genus."[99] These genus patent claims are relied upon heavily by the pharmaceutical and biotechnology industries and are a central mechanism by which these vital industries protect their key investments in newly developed products. Unsurprisingly, fewer companies would take on the huge risk of expending billions over the course of decades to develop new pharmaceuticals or biologics if patent protection that such genus claims provide is eroded.[100] Sadly, unless the Federal Circuit changes course and significantly modifies its recent § 112(a) jurisprudence, the practical reality will likely be that truly innovative companies will react to this new landscape by curtailing and refocusing their research and new drug development strategies, which will stagnate this sector for years to come.

The ultimate end result of innovation in the pharmaceutical and biotechnological industries is typically a new small molecule drug or biologic appearing in the marketplace and satisfying society's need for new medical therapeutics. Genus patent claims play a key role in patent portfolio management strategies that enable innovators to bring such new therapeutics to market. For

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

[96] This has been referred to as "super enablement" by prominent judges.

[97] D. Burk & M. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1653–1654 (2003); and C. Nard & J. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1664 (2007).

[98] Joseph DiMasi *et al.*, *supra* note 5.

[99] *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.").

[100] Giugni & Giugni, *supra* note 3.

example, when an inventor or group of inventors discover a particular chemical has a defined narrow use (*e.g.*, a particular chemical structure works to treat leukemia), the inventors wish to capitalize on their discovery by claiming not only that one chemical entity they discovered to be efficacious but also all related chemical structures that might perform the same function. The related chemical structures that fall under the same umbrella form a genus. That is, whenever there is a discovery of one "species" of a chemical that is shown to work, the inventors will typically aim to protect more than just that one species. Patent attorneys work with inventors and carefully draft genus claims to capture a broader claim to structurally similar compounds (*i.e.*, one that encompasses many species within that genus).

Genus claims were granted by the USPTO and upheld in courts,[101] and were otherwise a key tool within a patent attorney's toolbox when drafting applications directed to new pharmaceuticals and biologics. However, as a direct result of changes in how the Federal Circuit is now interpreting § 112(a), the strategy of using genus claims to protect biomedical innovation has all but disappeared and with it any prospect of obtaining meaningful patent protection of a genus claim. Some prominent scholars recently have gone as far as declaring genus claims "dead".[102]

IV. CURRENT PATENT DISCLOSURE REQUIREMENTS FOR GENUS CLAIMS IMPACT DEVELOPMENT OF NEW DRUGS AND BIOLOGICS

The process of developing a new drug or biologic can take decades and cost billions of dollars.[103] For the innovative biopharmaceutical company, the risk of pursuing such a long and expensive path comes with no guarantees of success. To develop a drug or biologic, a great deal of research and development is necessary. For example, the process to develop a new chemical (small molecule) drug to treat high blood pressure takes years and typically generates a large group of chemically related compounds that the inventors believe would be active and efficacious. In a competitive marketplace and as part of their patent filing strategy that aims to obtain meaningful patent coverage on such groundbreaking and painstaking new discoveries, biopharmaceutical companies regularly file patent applications that claim a large genus of compounds. They do so because to do otherwise would leave the door open for third parties or competitors to design around very narrow embodiments of a particular species of chemical and make and sell very similar compounds without infringing the innovator's patent.

The mechanism by which such large groups of similar compounds are protected after long painstaking research is by use of the genus claim. This type of patent claim prohibits any third party from unfairly taking advantage of the innovator's

[101] So long as the specification included enough information that a person of ordinary skill in the art could practice the invention without undue experimentation (the enablement requirement of 35 U.S.C. § 112(a)).

[102] Karshtedt et al., *supra* note 6.

[103] *Id.*

time and expense spent to develop the technology by easily designing around a very narrow embodiment that would otherwise fall within the genus of similar compounds. And yet if the law allowed too broad a genus claim, the patent would cover large sways of compounds and the unwanted specter of others being estopped from developing follow-on technologies in that chemical field would be the unwanted reality. As such, although few would argue against the validity of genus claims *in toto*, the key question is what level of disclosure is necessary to support such claims.

A. Current Enablement Law for Genus Claims is Untenable

Statutory construction is required to "start where the statute does."[104] The statute at the center of this piece is 35 U.S.C. § 112(a) of the Patent Act, 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 make and use the same...."[105] (emphasis added).

Patent claims represent the boundary of intellectual property that an inventor desires to capture as her invention.[106] The enablement requirement has historically functioned to make sure the patent application teaches a PHOSITA how to make and use the invention the patentee claims as her invention, without undue experimentation.[107] In order to provide some guidance on how to determine if any "undue" experimentation would be necessary, the Federal Circuit has provided "illustrative, not mandatory"[108] guidance 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.[109]

For example, in *Wands*, the technology related to the *in vitro* production of antibodies that could bind to the hepatitis B virus.[110] To practice this invention, the PHOSITA would need to isolate and clone hybridoma cells, culture them and test them for their desired function. This appeared to require much experimentation by the ordinary skilled artisan, some of which could be "undue." However, the court

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

[105] 35 U.S.C. § 112(a) (2018).

[106] *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.").

[107] MPEP § 2164 (2021).

[108] *Amgen v. Chugai*, 927 F.2d at 1213.

[109] *In re* Wands, 858 F.2d at 737.

[110] *Id.*

found that the patent application provided significant guidance and "the experiments involve[d] repetition of known or commonly used techniques."[111] This coupled with the fact that the level of skill in this field is high and the techniques were well known resulted in the court ruling that the application is enabled and the experimentation necessary to practice the invention would not be "undue."[112]

As such, after *Wands* and its progeny, the specification is enabled only if upon balancing of the *Wands* factors, a PHOSITA could make and use the invention without undue experimentation.[113] This rubric became widely accepted and follow-on decisions reiterated its core principle that "to enable any person skilled in the art" means "without requiring undue experimentation."[114] That is, the patent application must provide enough information such that an ordinary skilled artisan could practice the invention without having to perform "undue experimentation."[115]

Inventors in the fields of pharmaceuticals and biotechnology often face a different set of obstacles than those in other industries. For example, an invention in these biomedical fields can include the discovery of a compound that inhibits colon cancer growth. This discovery usually leads to the inventors seeking to protect a family of related compounds that has the same effect of inhibiting colon cancer. This follow-on discovery is typically routine as the inventors work to identify any other member of the genus of related compounds that can produce the same effect. When seeking patent protection on such a discovery, it is commonplace to seek to obtain a broad patent claim that covers the full family of related compounds that have the same effect. 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"[116]—is a crucial aspect of how innovation in the pharmaceutical and biotechnology fields is protected. Within this biomedical field, the structure of such genus claims 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.[117]

Courts had long recognized the validity of genus claims, especially those found in pharmaceutical and biotechnology patents. Yet, the Federal Circuit's decisions are now split when it comes to enablement of genus claims. While one line of cases recognizes disclosure of one mode of an invention as being sufficient to satisfy the enablement requirement, others require "full scope" of the claim to be enabled. The Court of Customs and Patent Appeals ("CCPA"), for example, found it untenable

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[111] *Id.*; *see also Johns Hopkins,* 152 F.3d at 1360 ("Routine experimentation does not constitute undue experimentation . . . .").

[112] *In re* Wands, 858 F.2d at 737.

[113] *Id.*

[114] Invitrogen Corp. v. Clontech Laboratories, Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005); 35 U.S.C. § 112 (2006).

[115] MPEP § 2164 (2021).

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

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

to require patentees to draft "a patent application or applications with thousands of examples," as well as "disclosure of thousands of catalysts along with information as to whether each exhibits catalytic behavior."[118] The justification was that this "would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments."[119] As discussed *supra*, the *Wands* decision made a similar point, and focused the inquiry on whether a PHOSITA could make and use the disclosed invention without having to conduct "undue experimentation."[120]This in turn depended on determining what would be a reasonable amount of experimentation to comply with the enablement requirement.[121] Indeed, a "considerable amount of experimentation" is permissible and compatible with complying with the enablement requirement, if it is "'merely routine,' or the specification provides 'a reasonable amount of guidance.'"[122]

This established enablement law, however, has been drastically changed by the Federal Circuit's own recent decisions. This new direction not only goes against Supreme Court precedent, but also the Federal Circuit's own prior decisions related to genus claims. As required by § 112(a) statute, the focus had correctly been on whether an ordinary skilled artisan, in view of the patent applications disclosure, would need to perform "undue experimentation" to make and use the chemical species within the genus.[123] This past jurisprudence is now rejected. Instead, the Federal Circuit's focus is on whether patent applications point out which species in the genus will work. This change in approach is fatal for pharmaceutical and biotechnology patents because genus claims can cover thousands of related species, and patent applications have not been required to disclose every species. This change in approach harms innovation in the essential fields of pharmaceuticals and biotechnology and will significantly inhibit development of new lifesaving treatments by true innovators in this industry.

B. Current Enablement Law Conflicts with Supreme Court Jurisprudence

As a preliminary matter, the statute requires patent applications to 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

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[118] *In re* Angstadt, 537 F.2d at 502.

[119] *Id.*

[120] *Wyeth*, 720 F.3d at 1385–86; Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004).

[121] *See ALZA*, 603 F.3d at 940 ("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*, 707 F.3d at 1336 ("A reasonable amount of routine experimentation does not violate the enablement requirement.").

[122] *Wyeth*, 720 F.3d at 1385–86 (the 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).

[123] *Id.*

same,"[124] and the Supreme Court has interpreted this to be the "the right of the jury to determine."[125] And yet, beginning in 1983, the Federal Circuit began to treat enablement as a question of law for the court to decide.[126] The vital importance of this determination in such fact-sensitive, case-by-case, inquiry is examined *infra* in Part VI(b); however, it is worth introducing this as a preliminary matter and another example of how the Federal Circuit's jurisprudence on patent disclosure laws has evolved to conflict with Supreme Court precedent.

The key problem with respect to the current patent disclosure laws is that the Federal Circuit has judicially invented rules that have no statutory basis and their recent implementation is selectively harming innovation in the biomedical industry.[127] In particular, the current rigid jurisprudence is routinely applied to invalidate genus claims—patent claims that are crucial for the pharmaceutical and biotechnology industries.[128] The Federal Circuit's recent aversion to genus claims has led scholars to declare such claims as dead[129] and contradicts confirmation by the Supreme Court that genus claims are viable so long as the patentee can show some "common quality" between members of a genus.[130]

The Supreme Court has long recognized the importance of allowing inventors to claim more broadly than the narrow embodiments of their invention because otherwise a patent would be a "hollow and useless thing."[131] Genus claims allow inventors to claim by disclosing shared structural features common within the genus. Such claims have long been held valid by the Supreme Court, recognizing that to do otherwise would allow copycats to take advantage of innovators' research and development and make minor changes to bypass patent infringement.[132] Famously, Alexander Graham Bell's genus patent claim for the telephone was also upheld by the Supreme Court, with the court 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."[133] The Court found Bell had "described, with sufficient precision to enable one of ordinary skill in such matters to make the invention."[134] Thomas Edison, however, had his patent invalidated by the Supreme

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[124] *See* 35 U.S.C. § 112(a).

[125] *Battin*, 58 U.S. at 85.

[126] Raytheon Co. v. Roper Corp., 724 F.2d 951, 960 n.6 (Fed. Cir. 1983).

[127] *Id.*

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

[129] *See* Karshtedt et al., *supra* note 6. *See also* Shahrokh Falati, *Eviscerating Patent Scope*, 21 UIC REV. INTELL. PROP. L. 121 (2022).

[130] Corona Cord Tire Co. v. Dovan Chem. Corp., 276 U.S. 358, 385 (1928).

[131] Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950).

[132] Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 437 (1902); *see also* Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 419–22 (1908).

[133] *The Telephone Cases*, 126 U.S. at 536.

[134] *Id.* at 535.

Court on disclosure grounds because he had made a limited discovery to one embodiment for a light bulb filament and yet the patent claim was much broader.[135]

The Supreme Court has also made it clear that the vast scope of functional patent claims make them unacceptable.[136] Moreover, patent claims that simply lack any support in the patent application also are unacceptable because they do not allow an ordinary skilled artisan to practice the invention.[137] Indeed, the Supreme Court requires patent applications "*describe* the invention in… terms *as to enable* any person skilled in the art … to make and use the same."[138] The Supreme Court interprets the statute as requiring inventors provide a written description that enables a PHOSITA to make and use the invention—a singular requirement. Moreover, with this context, it is noteworthy that the Supreme Court has suggested that the sole purpose of § 112(a) is enablement.[139] Yet, although the statute and the Supreme Court, including in *The Telephone Cases*, indicate § 112(a) has just one disclosure requirement, the Federal Circuit has interpreted § 112(a) as requiring two separate disclosure requirements. Interestingly, the Federal Circuit's main position on § 112(a) was articulated in *Ariad* as requiring these two separate standards;[140] however, neither of the two Supreme Court cases on which *Ariad* relied fully support the Federal Circuit's own analysis in *Ariad*.[141]

Notably, the Supreme Court has never articulated anything near the Federal Circuit's current position on genus claims—that a well-defined and supported genus claim fails the enablement requirement unless that patent application teaches ordinary skilled artisans to make and test all of the species encompassed by the

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[135] *See* Incandescent Lamp Patent, 159 U.S. 465, 477 (1895).

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

[137] Tyler v. Boston, 74 U.S. 327, 330 (1868).

[138] *Markman*, 517 U.S. at 373 (emphasis added).

[139] 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).

[140] Namely, the two separate requirements of written description and enablement.

[141] In *Ariad*, the Federal Circuit relied on two U.S. Supreme Court cases—Evans v. Eaton, 16 U.S. 454 (1818) 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, however, neither of these cases fully support the court's analysis in *Ariad*. Specifically, in Evans v. Eaton, the Supreme Court invalidated a patent directed to an improved hopperboy because no distinct improvement was disclosed in the patent application and, therefore, the application was deemed not to satisfy the written description requirement. According to the Supreme Court in Evans, the written description was necessary to stop inventors from obtaining patents that are "broader than the invention." Put in the context that patent applications had no claims when Evans was decided, the decision does not align itself with the idea that §112(a) contains anything other than a basic description that enables the invention. Schriber-Schroth also does not support the Federal Circuit's position, as exemplified by the two dissenting judges in Ariad recognizing that Schriber-Schroth was solely about priority. In Schriber-Schroth, the Supreme Court held that a patent application "cannot be broadened by amendment so as to embrace an invention not described in the application as filed." This is essentially reciting the prohibition for adding new matter to patent applications – this prohibition would later be codified in 35 U.S.C. § 132. See also Ariad, 598 F.3d at 1363 (Rader, J., dissenting in part) (Schriber-Schroth thus stands only for "the unremarkable proposition that an applicant cannot add new matter to an original disclosure.").

genus. Rather, § 112(a) of the Patent Act recites a clear statutory requirement to and with which Supreme Court decisions have adhered and aligned themselves. Yet, the Federal Circuit's current evolving and increasingly rigid position regarding disclosure requirements of genus claims render them incompatible with the statute and Supreme Court precedent. As such, as is discussed in Part VI, much akin to the Supreme Court's decisions in *KSR*[142] and *Bilski*[143], in order to correct the Federal Circuit's rigid tests, the Supreme Court's intervention is needed to correct patent disclosure law's presently rigid requirements.

C. Current Patent Disclosure Requirements Impose Industry-Specific Barriers to Patentability

The Patent Act is intended to be technology-neutral, meaning the law should apply in the same manner irrespective of the field of invention.[144] However, the Federal Circuit's recent interpretation of patent law's disclosure requirements is negatively affecting the pharmaceutical and biotechnology industries to a greater extent than other industries.[145] One key reason for this technology-specific effect of the law is that genus claims are an important part of biomedical patent applications[146] and yet they are much less prevalent and generally not relied upon for protecting inventions in other industries.

Patent law's established disclosure requirements have in recent years been used by the Federal Circuit to attack genus claims and make them near impossible to obtain for inventions in the biomedical field. Based on the crucial nature of this type of claim to this industry, unsurprisingly, this major shift in approach by the Federal Circuit has created significant obstacles for innovators to recoup their investments and in turn dampened follow-on innovation. In particular, whereas established case law focused on whether patent applications "enable" a person of ordinary skill in the art to "make and use" the disclosed invention without "undue experimentation,"[147] it is now necessary, after a major change in approach, to enable the "full scope" of the claim. The practical significance of this is that every species of a genus in a patent application must now be enabled.[148] This entirely new approach to enablement by the Federal Circuit is "a categorical shift in thinking away from teaching the PHOSITA and towards a precise delineation of the boundaries of the claim."[149] These judicially created rules lack any basis in statutory

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

[143] Bilski v. Kappos, 561 U.S. 593, 604 (2010) (". . . is not the sole test.").

[144] The Patent Act of 1952, Public Law 593, 82nd Congress, 2nd Session, Chapter 950, 66 Stat. 792.

[145] Burk & Lemley, *Biotechnology's Uncertainty Principle*, *supra* note 27, at 706–08.

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

[147] As the 35 U.S.C. § 112(a) statute requires; *see also In re* Wands, 858 F.2d at 736.

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

[149] Karshtedt et al., *supra* note 6, at 31.

text and Supreme Court precedent, and seriously threaten innovation in the pharmaceutical and biotechnology fields.

Within the field of pharmaceuticals and biotechnology, the law now requires patent applications to exhaustively catalog all embodiments that fall within a genus, even if they are closely overlapping. However, this approach negatively targets the biomedical industry and is not a standard that is applied in the same way in other fields of art such as software.[150] Indeed, scholars have previously noted that courts apply a higher standard when assessing compliance with the written description and enablement requirement in the biomedical fields than in other fields of art.[151] Chemistry and biology are "unpredictable" fields and therefore more disclosure is generally required in the patent application[152] than in other applications which are directed to "predictable" fields of art such as in the mechanical and electrical fields.[153] This contrast in how the enablement and written description requirements are applied is also seen when comparing the biomedical fields with inventions in the software and business methods fields of art.[154] For example, unlike the biomedical fields, these latter fields of art rarely face situations where a claim can cover tens of thousands of species.

For "unpredictable" fields, such as pharmaceuticals and biotechnology, the Federal Circuit has opined that "a description of one species will ordinarily be insufficient to lay claim to the genus."[155] The main culprit for this heightened written description standard being applied to biotechnology is the Federal Circuit's decision in *Regents of the University of California v. Eli Lilly & Co.*[156] Scholars and practitioners alike agree that *Lilly* highlighted how lopsided and technology-specific the practical application of the Federal Circuit's patent disclosure standard

[150] Burk & Lemley, *Is Patent Law Technology-Specific?*, *supra* note 26, at 1183–84 .

[151] 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 26, at 1156; Burk & Lemley, *Biotechnology's Uncertainty Principle*, *supra* note 26, at 691 ("The Federal Circuit claims that the uncertain nature of biotechnology requires imposition of stringent patent enablement and written description requirements that are not applied to patents in other disciplines."); Burk & Lemley, *supra* note 2, at 1654.

[152] Chao, *supra* note 11, at 6–8.

[153] Seymore, *Heightened Enablement in the Unpredictable Arts*, *supra* note 151, at 137.

[154] 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 (2000).

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

[156] *Regents*, 119 F.3d at 1569; *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).

had become.[157] Indeed, prominent scholars in this field even noted that the heightened written description standard for biotechnology "would be inconceivable in other industries, such as software."[158] Further still, recent empirical studies have also shown § 112(a) is not technology neutral.[159] However, it is noteworthy to point out that other scholars have questioned whether the *Lilly* decision unfairly targets biotechnology more so than other fields.[160]

The Federal Circuit's decision in *Lilly*[161] marked a turning point after which § 112(a) was interpreted as requiring a dual disclosure requirement, namely written description and enablement requirements, with each subject to different standards[162] and necessary for enforcing a patent.[163] The seminal turning point that *Lilly* represented is best captured by the fact that, prior to the Federal Circuit's follow-up *en banc* decision in *Ariad* in 2010, it was one of the most cited cases showing that enablement and written description are two separate requirements.[164]

To satisfy the Federal Circuit's current rigid patent disclosure scheme, patent applications must convey that the inventor had "possession" of the "full scope" of the claimed invention upon filing of the application.[165] As a result, patent applications with genus claims are 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.[166]

Yet, these non-statutory, judge-made, heightened requirements target the pharmaceutical and biotechnology industries disproportionately. This can be illustrated, for example, by focusing on monoclonal antibodies as biotechnology. Ever since the FDA approved their use some thirty-seven years ago, use of this

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[157] *See* Janis, *supra* note 91; Rai, *supra* note 151; Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998).

[158] Burk & Lemley, *supra* note 2; *see also* Burk & Lemley, *Is Patent Law Technology-Specific?*, *supra* note 26, at 1184; Burk & Lemley, *Biotechnology's Uncertainty Principle*, *supra* note 26, at 706.

[159] John R. Allison & Lisa L. Ouellette, *How Courts Adjudicate Patent Definiteness and Disclosure*, 65 DUKE L.J. 609, 644–69 (2016).

[160] 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, 88 (2007); *see also* 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).

[161] *Id.*

[162] *See Ariad*, 598 F.3d at 1344.

[163] *Id.* at 1351.

[164] *Id.* at 1566.

[165] Katie Albanese, *When Is Enough Enough? What Constitutes Adequate Written Description of a Genus*, 29 FED. CIR. BAR J. 343, 355 (2020).

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

form of treatment has risen exponentially for a variety of conditions[167] with the global market for antibody treatments expected to double to $300 billion by 2025.[168] Meaningful patent protection is a primary driver for biotechnology companies developing monoclonal therapeutics.

Different patent disclosure rules have evolved, including the "newly characterized antigen" test which was an exception to the written description rules as applied to antibody claims by the USPTO.[169] This written description test allowed a newly characterized antigen to be disclosed with a claim to a genus of antibodies (possibly including thousands of species), so long as the production of such antibodies was routine. The Federal Circuit, however, set aside this test in 2014 in its *AbbVie* decision and highlighted that functionally defined genus claims are highly vulnerable for lack of written description support, especially in unpredictable fields of art such as pharmaceuticals and biotechnology where it is difficult to draw correlations between structure and function for the genus or to predict what is encompassed by the functionally claimed genus.[170] *AbbVie* is now used to routinely invalidate antibody claims on both written description and enablement grounds.

As another recent example, the court in *Baxalta* held that functional claims to an antibody that binds the blood clotting Factor IX lacked enablement, even in the presence of eleven working examples.[171] As in *Amgen v. Sanofi*,[172] the court noted that antibody technology was "inherently unpredictable" and that practicing the invention would require "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."[173] These recent decisions in *AbbVie,*[174] *Amgen,*[175] and *Baxalta*[176] are encouraging innovators not to claim antibodies based solely on the target antigen, specific epitope, and/or function. Some scholars have gone as far to predict that patent protection for therapeutic antibodies will be limited to just those

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[167] 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.

[168] Ruei-Min Lu *et al.*, *Development of therapeutic antibodies for the treatment of diseases*, 27 J. BIOMEDICAL SCI. 1, 1 (2020).

[169] The newly characterized antigen test carved out an exception to allow written description support for a genus claim covering antibodies through the disclosure of a newly characterized antigen, if the production of such antibodies would be routine to a PHOSITA. See also, https://www.uspto.gov/sites/default/files/documents/amgen_22feb2018.pdf

[170] AbbVie Deutschland GMBH & Co., KG, v. Janssen. Biotech, Inc., 759 F.3d 1285, 1301 (Fed. Cir. 2014).

[171] Baxalta, Inc. v. Genentech, Inc., 579 F.Supp. 3d 595, 597 (D. Del. 2022).

[172] *Amgen v. Sanofi*, 987 F.3d at 1086.

[173] *Id.*

[174] *AbbVie*, 759 F.3d at 1301.

[175] *Amgen v. Sanofi*, 987 F.3d at 1086.

[176] *Baxalta*, 579 F.Supp. 3d at 597.

that have been disclosed in the patent application. However, as is discussed in Part VI, this approach is unnecessary given the field of art is well developed concerning the structure and function of antibodies, and that once the variable region sequence and structure are mapped by the inventor, broader patent protection ought to be granted than just the specific narrow species of antibody disclosed.

This fundamental shift in approach for interpreting patent law's statutory disclosure requirement is particularly problematic for pharmaceutical and biotechnological inventions.[177] As exemplified *supra*, claims to a genus of compounds or to therapeutic antibodies now must pass both a non-statutory "possession" standard for written description that requires patent applications disclose a "representative number of examples" of the genus; and separately a numbers-based rigid "full scope" enablement. This rigid new rubric may be of no concern in fields of art such as mechanical and electrical; however, it is fundamentally a bad fit and harms innovation in the biomedical field. Indeed, it is implausible to think Congress had this industry-specific barrier to patentability in mind when drafting the statute. Current jurisprudence concerning patent laws disclosure requirements runs afoul of statutory language and legislative intent and imposes judicially created additional requirements that, in practice, have transpired to target the biomedical industries more so than others. That is, this technology-targeted application of patent law's disclosure requirement to the detriment of one industry over that of others is an untenable situation requiring a correction.

V. UNRAVELLING THE WRITTEN DESCRIPTION INQUIRY FROM ENABLEMENT

An invention is patentable if certain requirements are met, including that the idea is useful,[178] novel,[179] non-obvious,[180] and fully disclosed.[181] The boundary of the disclosure requirement has been debated by judges, scholars and practitioners alike for the past two decades. That is, how much information about the invention must there be in the patent application? This information found in patent applications is critical for demonstrating how supported a patent claim is to an invention. In this context, one of the key issues has been whether the Patent Act mandates enablement and written description to be treated as separate requirements.

The Federal Circuit views enablement and written description as two separate requirements; however, their overlap is noteworthy, as is the fact that when patent claims are analyzed under the current two separate requirements model, enablement and written description "usually rise and fall together."[182] Indeed, the Supreme

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[177] Falati, *supra* note 129, at 138.
[178] 35 U.S.C. § 101.
[179] 35 U.S.C. § 102.
[180] 35 U.S.C. § 103.
[181] 35 U.S.C. § 112.
[182] LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005); *see also Vas-Cath*, 935 F.2d at 1561.

Court has never interpreted § 112(a) as mandating separate written description and enablement requirements. To illustrate this problem further still, the Federal Circuit itself did not treat enablement and written description as separate requirements until it decided *Lilly* in 1997,[183] and solidified this view with the Court's *en banc Ariad* decision in 2010.[184]

Within the context of the written description requirement, it is noteworthy that between the last Patent Act seventy years ago[185] and the Federal Circuit's 1997 decision in *Lilly*,[186] written description was used sparingly to police priority. That is, while appreciating that the word "possession" does not appear in § 112(a),[187] the notion of "possession" was used nevertheless in a very limited context to determine if the specification provided sufficient support for the claims to demonstrate priority. In this narrow context, "possession" was easy to apply and focused on whether the invention was described at a particular point in time.[188] With their *Lilly* decision in 1997, the Federal Circuit split the singular disclosure standard of the statute in two by vastly expanding the scope of the non-statutory term "possession." That is, while prior to 1997, this judge-made possession requirement of written description was narrowly applied to test for support for new or amended claim language, after 1997, this judge-made requirement grew in scope and resulted in a higher hurdle for the patent specification to meet under § 112. In 2010, in *Ariad*,[189] the Federal Circuit confirmed that "possession" is a separate requirement and, in an effort to make it work, the Federal Circuit also later came up with varying rigid sub-tests to implement it.[190] This ill-conceived new and non-statutory "possession" requirement for demonstrating written description and its varying new sub-tests aside, the Federal Circuit has in recent years also upended the other key doctrine within § 112(a), namely the doctrine of enablement as it applies to genus claims.

Within the context of the enablement requirement, "full scope" enablement of genus claims is now being stringently applied to assess if patent applications provide a "representative number of species" that fall within the genus claim, even when this is contrary to the textually grounded inquiry. Indeed, as the statute provides and as the Federal Circuit has itself in the past determined, the focus ought to be on whether patent applications enable an PHOSITA to make and use the invention. The current focus on the identification of every species that falls within a genus to demonstrate what the Federal Circuit calls "full scope" enablement is misguided, even if the idea of attempting to determine the outer perimeter of patent

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[183] *Regents*, 119 F.3d at 1569.

[184] *Ariad*, 598 F.3d at 1336 (Fed. Cir. 2010).

[185] Patent Act of 1952, 35 U.S.C. § 271.

[186] *Regents*, 119 F.3d at 1569.

[187] 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.

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

[189] *Ariad*, 598 F.3d at 1355.

[190] These sub-tests are discussed *infra* in Part V(b).

claims appears proper at first sight. This new approach is especially misguided, given that identifying every species of a genus has no practical effect on the ability of an PHOSITA to make and test an operable species.

A patent 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."[191] The Federal Circuit's interpretation of this statute splits enablement and written description into two separate requirements. This stance on patent law's disclosure requirement has resulted in the court going a step further to judicially create the new "possession" standard and various sub-tests for written description, and concurrently shift 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 what works and what does not. This is a seismic shift in approach.

This new approach to the enablement and written description requirements has now become a formidable obstacle to patent validity, especially in the pharmaceutical and biotechnology industries. As is developed further *infra*,[192] to compound this new approach to enablement that in effect nullifies genus claims, the Federal Circuit's treatment of enablement as a question of law is also surprising given the enablement inquiry is so fact-intensive and to treat it as a legal question runs against Supreme Court precedent.

A. The problem with "Full Scope" Enablement

There is no doubt that the Federal Circuit has drastically shifted their position recently on 35 U.S.C. §112(a)—housing patent law's disclosure requirement. Whereas, for many years, the focus of the enablement inquiry was whether a PHOSITA could practice the invention without "undue experimentation,"[193] this standard has now morphed to assess how long it would take an ordinary skilled artisan to make and test all of the species within the claimed genus, irrespective of what would be routine work for the ordinary skilled artisan. The Federal Circuit's

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[191] 35 U.S.C. § 112(a); *see also*, *e.g.*, Patent Act of Feb. 21, 1793, *supra* note 25; *see also*, Patent Act of 1790, *supra* note 25, "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."

[192] *See infra* Part VI.

[193] *Id.*

new approach to enablement considers this necessary to show enablement of the "full scope" of the patent claims.[194]

At first sight, this approach appears reasonable because it focuses on how a PHOSITA can review the patent application and make *all* the species that fall within a genus claim.[195] After all, when a patent application is drafted, the disclosure must sufficiently enable a PHOSITA to make and use what is taught, including all the species that fall within a genus appears reasonable.[196] However, that is not the statutory test. Indeed, this is the main problem of the current enablement jurisprudence, as articulated by the Federal Circuit. That is, the move away from the well-established "undue experimentation" factors that played a central role for determining a specification's compliance with the enablement requirement,[197] 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 to enable the "full scope" of the claims,[198] is a fundamental shift in approach.[199]

Interestingly, the Patent Act does not impose any limitations on how many species fall within a genus claim, or even mention this new judge-made "full scope" enablement. Indeed, the Federal Circuit has previously outlined that enablement does not require a PHOSITA to make and test every possible substitution to exclude hypothetical outliers that do not work.[200] According to the Federal Circuit, a patent application is "not required to provide a detailed recipe for preparing every conceivable . . . permutation[] of [a] compound."[201] For example, genus claims in pharmaceutical or biotechnology patents can have thousands of species within them, and yet such claims have been found enabled in view of patent disclosures that have not identified every species encompassed by a genus.[202] Surprisingly, however, under this new approach to enablement, it is of no concern how routine it would be to test every species within a genus.

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[194] *Amgen v. Sanofi*, 987 F.3d at 1086.

[195] 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 6.

[196] 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) (stating an ordinary skilled artisan "thinks along the line of conventional wisdom"); *KSR*, 550 U.S. at 420 (stating an ordinary skilled artisan is "a person of ordinary creativity").

[197] *Amgen v. Hoechst*, 314 F.3d at 1334 ("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 at 737).

[198] *Amgen v. Sanofi,* 987 F.3d at 1086.

[199] *Id.*

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

[201] Pfizer Inc. v. Teva Pharm. USA, Inc., 555 F. Appx. 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").

[202] *In re* Angstadt, 537 F.2d at 501–02.

This court-created heightened new enablement standard that attacks genus claims that cover "too large" a number of compounds lacks any statutory basis or Supreme Court precedent and is hurting innovation in the biomedical industries more so than other industries.[203] The proper inquiry ought to focus on teaching an ordinary skilled artisan how to make and use the invention[204] without "undue experimentation."[205]

Patent claims in pharmaceutical and biotechnology applications routinely include genus claims. These types of claims can encompass thousands of species, and thousands of issued patents have genus claims in them.[206] And yet, 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."[207] In practice and in light of this heightened enablement approach, a swathe of genus claims in pharmaceutical and biotechnology patents are rendered invalid and worthless based on this new numbers-based enablement requirement that mandates identification of every species within a genus.[208]

The enablement requirement should focus solely on how to make and use the invention without "undue experimentation." In *Wands*,[209] a genus claim covered the use of monoclonal antibodies in an immunoassay to detect a hepatitis B antigen. Although an extensive amount of experimentation was deemed necessary, the court held the claim *was* enabled because the specification included considerable direction, guidance, and working examples.

Wands established that the enablement requirement can be satisfied, even when extensive routine experimentation would be necessary to practice an invention. The *Wands* factors for determining what experimentation is "undue" ought to remain at the center of the present enablement 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. This standard for assessing enablement is supported by the statutory text, Supreme Court precedent, and Federal Circuit's own prior decisions; and avoids the undesirable technology-targeted effects of the Federal Circuit's new approach.

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[203] Many patent claims have been rendered invalid based on this recent change in the enablement jurisprudence by the Federal Circuit; *see*, *e.g.*, *Novozymes*, 723 F.3d at 1346.

[204] As the statute requires.

[205] Some experimentation is permissible and does not fail enablement; *see In re Wands* factors for assessing if experimentation would be "undue."

[206] Examples include patent claims to small molecules or to antibodies, including for example, U.S. Patent Nos.: 7,713,723 (patent claims to modified enzymes with improved function and stability); 6,914,128 and 7,504,485 (patent claims to fully human antibodies that bind to and neutralize the activity of human interleukin 12 (IL-12)); and 7,608,597 (patent claims to methods for treating Hepatitis C Virus using antiviral compounds).

[207] *Wyeth*, 720 F.3d at 1385–86.

[208] *Amgen v. Hoechst*, 314 F.3d at 1334 ("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).

[209] *Id.*

It is an error to redirect the enablement inquiry to the recent numbers-based test to evaluate "full scope" enablement that focuses on evaluating how a PHOSITA can make and test every species encompassing a genus no matter how routine a practice that would be, instead of the *Wands* analysis.[210]

The statute, § 112(a), clearly mandates 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 the contents of the patent application to be "commensurate in scope" with what the patent claims.[211] Should the patentee pursue broad patent claims, arguably a more valuable right, the law requires the patent application to provide sufficient support and to enable that wider claim scope.[212]

Past decisions of the Federal Circuit provide a roadmap of how the court views enablement and written description requirements. For example, *University of Rochester v. G.D. Searle & Co.*[213] involved pharmaceutical inhibitors of prostaglandin H synthase-2 ("PGHS-2" or "Cox-2"), an enzyme involved in the inflammatory response. The patent application was directed to methods for screening for inhibitors of cyclooxygenases 1 and 2 (Cox-1 and Cox-2), with the specification disclosing how to make cells that express these two enzymes as well as the assays used to screen for their inhibitors. The patent application included disclosure to permit an ordinary skilled artisan to identify compounds that could be used in the claimed methods, allowing a PHOSITA to not only derive the compounds using the disclosed methods, but also to perform the claimed methods.[214] However, the court held that since the specification did not actually disclose any compounds that could be used to practice the claimed methods, the patent claims were invalid.[215] The Federal Circuit upheld the invalidity finding, ruling that the patent application failed the written description requirement and that this is a separate requirement to enablement under § 112(a).[216]

The beginning of this numbers-focused enablement requirement can be traced to *Wyeth*.[217] In that case, the patent claims were to a "class of compounds" for treating restenosis (re-narrowing of blood vessels after an angioplasty procedure to open them). Only one species of the genus claim was disclosed in the patent application, and when the genus patent claim was enforced against a rival, during

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[210] *In re* Wands, 858 F. 2d at 737.

[211] *Amgen v. Chugai*, 927 F.2d at 1213 ("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.").

[212] *Dreamworks*, 516 F.3d at 999 ("A patentee who chooses broad claim language must make sure the broad claims are fully enabled.").

[213] *Univ. of Rochester*, 358 F.3d at 917.

[214] *Id.* at 919.

[215] *Id.*

[216] *Id.* at 927.

[217] *Wyeth*, 720 F.3d at 1380.

litigation, the Federal Circuit held the claim invalid for failing the enablement requirement.[218] A key question for the court was "whether having to synthesize and screen each of at least tens of thousands of candidate compounds" defeats enablement, and the court answered in the affirmative.[219] Another unusual feature of this decision was that the court found 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.[220]

This new jurisprudence on enablement continued, with the Federal Circuit recently building off their decision in *Wyeth* to overturn a jury verdict in *Idenix*—a decision from 2019 that effectively kills off the practice of genus claiming in biopharma patent practice.[221] Here, a divided panel held patent claims, directed to methods for treating Hepatitis C Virus ("HCV") by administering compounds, invalid for not complying with the enablement and written description requirements under § 112(a).[222] The Federal Circuit reasoned that the claims were directed to methods for treating HCV by administering certain compounds that covered "tens if not hundreds of thousands" of antiviral compounds, and yet the patent application failed to guide a PHOSITA to which of those compounds would work to treat HCV.[223] The court rejected Idenix's view that the four working examples were sufficient to satisfy the enablement requirement.[224] Instead, the court considered this field of art unpredictable and one that would not allow a PHOSITA to know which compounds would work to treat Hepatitis C.[225] The court also found the patent claims invalid on written description grounds because the inventors were not "in possession" of their claimed invention.[226] The Federal Circuit's reasoning in the recent *Idenix* decision was also based on their earlier *Wyeth* decision that held that a claim covering thousands of compounds was invalid for lack of enablement as a matter of law.[227]

Similarly, in *Amgen v. Sanofi*,[228] the Federal Circuit in 2021, invalidated Amgen's patents for lacking enablement. The district court had earlier granted a judgment as a matter of law to overturn a jury verdict that had found Amgen's patent claims as enabled and valid. Here, the claims were directed to a genus of monoclonal antibodies that bind proprotein convertase subtilisin-like kexin type 9 ("PCSK9") and block binding of PCSK9 to Low-Density Lipoprotein ("LDL")

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[218] *Id*. at 1385.
[219] *Id*. at 1385.
[220] *Id.*; Enzo Life Sci., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340, 1346 (Fed. Cir. 2019).
[221] Idenix Pharm. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1165 (Fed. Cir. 2019) *cert. denied*, 141 S. Ct. 1234 (2021).
[222] *Id.*
[223] *Id.* at 1161, 1164.
[224] *Id.* at 1161.
[225] *Id.* at 1164.
[226] *Id.* at 1165.
[227] *Id*. at 1162–63; *Wyeth*, 720 F.3d at 1380.
[228] *Amgen v. Sanofi*, 987 F.3d at 1080.

receptors. These patents cover Amgen's breakthrough medicine that lowers bad cholesterol to reduce the risk of heart attacks. The Federal Circuit drew similarities in the facts in *Amgen* to their cases in *Wyeth*,[229] *Enzo*,[230] and *Idenix*,[231] in which the claims at issue were drawn to small molecules instead of antibodies and had both structural and functional limitations with limited disclosure in the patent application that taught many embodiments of the broad claims. Here, the court held that the genus claims were broad and that practicing the full scope of the claims would require undue experimentation and "substantial time and effort"[232] given the unpredictability of antibody technology and limited examples provided in the patent application.

Moreover, in *Juno Therapeutics v. Kite Pharma*, [233] another decision from 2021, the Federal Circuit used written description to invalidate Sloan Kettering's Juno patent claims to a nucleic acid polymer (DNA/RNA) that encodes a "chimeric T cell receptor." 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.[234] The technology allows a patient's own immune system, T-Cells in particular, to be genetically modified to recognize and kill specific antigens—a revolutionary technology referred to as CAR T-Cell therapy. In *Juno*, the patent claims were directed to a "binding element that specifically interacts with a selected target" in the form of a single chain antibody. The claim was found invalid on written description grounds because the patent application failed to disclose the DNA sequence of such a binding element.[235] In particular, reversing the district court's decision, the Federal Circuit held 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*."[236] The majority were not persuaded that a PHOSITA would be able to recognize all the members of the genus given the two embodiments that fell within the genus that the patent application included.[237]

These recent cases confirm that functional claiming of a genus can meet the written description requirement only when the specification either explains structural features that are common between members of the species that fall within the genus so that a PHOSITA can practice the scope of the genus, or the

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[229] *Id*. at 1086.

[230] *Enzo Life Sci.*, 928 F.3d at 1345–48.

[231] *Id.*

[232] *Amgen v. Sanofi*, 987 F.3d at 1080.

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

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

[235] *Juno*, 10 F.4th at 1341–42.

[236] *Id*. at 1336 (emphasis added).

[237] *Id.* at 1342.

specification provides "a representative number of species" that fall within the scope of the genus.[238]

In practice, however, antibody patents have become very vulnerable to attack at a time when antibody drugs covering tens of billions of dollars in yearly sales constitute five of the top ten global best-selling drugs forecasts.[239] This has huge implications for patents covering a large genus of molecules in general, particularly if the genus claim recites functional limitations. This will affect tens of thousands of patents, including those covering financially lucrative drugs and allow competing copycats to enter the market. Interestingly, this notable shift in jurisprudence is very different to how European practice addresses this issue. There, it is typical to have broad patents to antibodies against a new epitope, and any follow-on application that claims particular sequences are generally rejected on inventive step/obviousness grounds based on the earlier patent's functional disclosures.[240]

B. The Rigid Sub-Tests for Written Description Impede Innovation of New Therapeutics

Written description functions firstly to provide adequate description of the invention to satisfy the aforementioned *quid pro quo* of the monopoly for disclosure bargain;[241] secondly to assure that the inventor "possessed" the claimed invention when the application was filed;[242] and thirdly to police against addition of new matter added that patent applications post filing.[243]

However, the Federal Circuit's current test for written description does not conform with the statutory text of § 112(a). In particular, the Federal Circuit rejected the statutory standard for "written description of the invention,"[244] and instead has created its own test centering on a finding of "whether the disclosure of the application relied upon reasonably conveys to those in the art that the *inventor had possession* of the claimed subject matter as of the filing date."[245] Yet, this test or "possession" standard appears nowhere in the statute, § 112(a). In a message likely intended for the Federal Circuit and arising from other parts of the Patent Act, the Supreme Court recently demanded "that courts should not read into the patent laws limitations and conditions which the legislature has not expressed."[246] However, not only has the Federal Circuit done just that, but in order to make their

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[238] *Id.*

[239] *Forecast of TOP 10 global best-selling drugs in 2021*, Echemi (Dec. 15, 2021), https://www.echemi.com/cms/132623.html.

[240] C. Germinario, S. Bertoli & P. Rampinelli et al., *Patentability of antibodies for therapeutic use in Europe*,36 NAT BIOTECHNOL 402, 402–405 (2018).

[241] *Id.*

[242] *Ariad*, 598 F.3d at 1349.

[243] *Id.* at 1348.

[244] 35 U.S.C. § 112(a) (emphasis added).

[245] *Ariad*, 598 F.3d at 1351 (emphasis added).

[246] *Bilski*, 561 U.S. at 602 (internal quotations omitted).

own test work properly in practice, the Court has also had to update their own judicially-created, non-statutory extra requirement by creating various sub-tests to demonstrate written description.

Written description as a doctrine appeared over 140 years after the enablement doctrine.[247] Indeed, 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. The use of the "written description" requirement to stop the addition of "new matter" to a pending patent application first appeared in *In re Ruschig* in the 1960s.[248]

The level of disclosure necessary to support a patent claim is at the heart of this question, with applications that describe only a single species typically running afoul of the written description requirement.[249] For example, based on *Lilly*,[250] for pharmaceutical genus claims, "a representative number of species within the genus" is necessary to show the required "possession" of the genus.[251] *Ariad* endorsed *Lilly*'s sub-test and this broader extra-statutory new written description test has since been used to invalidate many patents.[252] In particular, in *Ariad*, the Federal Circuit made clear that to comply with the written description requirement, 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.[253] That is, if a discovery is made in a nascent field and there is little prior art to bridge gaps, any genus claim to that technology would be vulnerable to a written description challenge.[254] Although it sounds reasonable to focus on including a "representative number of species" in patent applications, it remains unclear how the "representative number" would be determined. This also helps little that post *Ariad*, when it still remains unclear what one has to do to comply with the written description requirement, in

[247] *In re* DiLeon, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971) ("[C]onsider the 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.").

[248] Prior to *In re Ruschig*, not a single case from the CCPA had considered "written description" under 35 U.S.C. § 112, to be anything other than a modifier of the enablement requirement. *See Vas-Cath*, 935 F.2d at 1561 ("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*.").

[249] *Ariad*, 598 F.3d at 1349; 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. Assoc'd Reg'l & Univ. Pathologists, Inc., 642 F.3d 1031, 1037 (2011).

[250] *Regents*, 119 F.3d at 1568.

[251] *Id.* at 1568–1569.

[252] *See*, *e.g.*, *Novozymes*, 723 F.3d at 1346.

[253] *Ariad*, 595 F.3d at 1350, 1352.

[254] Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1125–27 (Fed. Cir. 2008); *but see Capon*, 418 F.3d at 1355 (reliance on prior art as prior art contained "extensive knowledge of the nucleotide structure").

large part because the Federal Circuit has focused its guidance on what is *not* required and not what *is*. For example, a written description of an invention in a patent application does not require examples,[255] recitation of known structure,[256] reduction to practice,[257] nor indeed any particular form of disclosure.[258] So mercurial and allusive is this written description requirement that the Federal Circuit has not actually provided any positive guidance to patentees on what *is* required to satisfy it, which alludes to Supreme Court Justice Stewart's declaration "I know it when I see it" when asked to pin down the allusive explanation of "hardcore pornography."[259] Given all the above, it is entirely possible and practical to eliminate the written description doctrine[260] and focus on enablement and clarity.[261]

To make the point for eliminating the written description requirement,[262] one can point to the fact that the Federal Circuit has recently developed several sub-tests in an effort to apply and make sense of its non-statutory "possession" standard. For example, the sub-tests for written description that were created include the "representative number of species," [263] the "structure-function," and the "common-structural-features" tests.[264] There has even been variation in these sub-tests depending on the type of technology—an unwelcome outcome given the contemplation for various variations of various subtests being created for different technologies when the statute is supposedly technology-neutral. For example, to determine if a patent application has complied with the written description requirement where a genus claim to biologics such as antibodies is involved, three variations of the sub-tests are used, including (i) the "fully characterized antigen" sub-test, (ii) the "common structural features" sub-test, and (iii) the "representative number of examples" sub-test, with this latter test currently the most favored.

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[255] *Ariad*, 598 F.3d at 1352.

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

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

[258] *Carnegie Mellon,* 541 F.3d at 1122.

[259] Jacobellis v. Ohio, 378 U.S. 184, 197 (1964) (Stewart, J., concurring).

[260] *Ariad*, 598 F.3d at 1361–67 (Rader, J., dissenting in part, criticizing the en banc majority's holding that § 112 contains two separate requirements for written-description and enablement); *see also* 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).

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

[262] See *infra* Part VI of this paper for a proposal of how this can be done, namely by collapsing the *In re* Wands factors for enablement with the *Cabon* factors for written description.

[263] *Amgen v. Sanofi*, 872 F.3d at 1373 (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."); s*ee also Regents*, 119 F.3d at 1569.

[264] *See Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112(a)*, https://www.uspto.gov/web/offices/pac/mpep/s2163.html

To establish "possession," the Federal Circuit mandates that the patent application must include a "precise definition" of the claimed invention "such as by structure, formula, chemical name, or physical properties."[265] As outlined in *Ariad*, for genus claims, 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."[266] However, even the Manual of Patent Examining Procedure ("MPEP") suggests that although the patent application can demonstrate the patentee was "in possession of the necessary common attributes or features possessed by the members of the genus,"[267] the MPEP also cautions patentees that individual support for each of the species within a genus is unnecessary.[268] Viewed differently and from a litigation perspective, it is noteworthy that disclosure of a single species in a patent application can render a patent claim to a genus invalid.[269]

The key takeaway and as further argument for eliminating the written description requirement, is that none of these "sub-tests" or "precise definitions" that the Federal Circuit has conjured, and mandates have any statutory basis in the text of § 112(a). Indeed, as outlined *supra* in Part II of this paper, the Federal Circuit's interpretation of the statute runs afoul of the statute, its legislative history, and also conflicts with Supreme Court precedent.[270] For example, in contrast to the Federal Circuit's position on written description, even when the patent claim encompassed "a large class of substances and the range of treatment within the terms of the claims,"[271] the Supreme Court has held such genus claims *are* valid and comply with § 112(a).

The Federal Circuit's dramatic change in position for interpreting the language of § 112(a), including these new written description requirement schemes, has created immense practical problems for stakeholders in the pharmaceutical and biotechnology industries and thereby hindering innovation in this field in recent years.[272] 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,[273] but also implicates biologics as demonstrated by the *Amgen* case,[274] since genus claims are routinely used when drafting claims to biologics (*e.g.*, claims to a genus of antibodies). Respectfully, this judicially created standard is not what the statute requires;

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[265] *Eli Lilly*, 119 F.3d at 1566.
[266] *Ariad*, 598 F.3d at 1350.
[267] MPEP § 2163(II)(A)(3)(a)(ii) (2023).
[268] *Id.*
[269] *Abbvie*, 759 F.3d at 1300.
[270] *See supra* Part II.
[271] *Minerals*, 242 U.S. at 271.
[272] *See*, *e.g.*, *Novozymes*, 723 F.3d at 1346.
[273] *Id.*
[274] *Id.*

instead, this new judge-made standard mandates patent applications disclose additional and different information from what is necessary for a PHOSITA to understand what the invention is and how to make and use it. In the next and final section, Part VI, a flexible and context-specific standard is proposed for interpreting § 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.

VI. OPTIONS FOR FIXING U.S. PATENT DISCLOSURE LAWS

Patent law's current disclosure requirements are not technology neutral. In particular, the Federal Circuit's current stance concerning patent law's disclosure requirements, namely their current rigid approach for interpreting § 112(a) of the Patent Act, has resulted in selective harm to the pharmaceutical and biotechnology industries. Recent cases have cemented the Federal Circuit's stance that a) the enablement and written description of the invention are two separate requirements;[275] 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 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);[276] 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."[277] Respectfully, this judicial trajectory is wrong.

To correct this judicial trajectory for patent law's disclosure requirements, one approach would be to interpret 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. That is, retreat from the newly paved path of treating enablement and written description as two highly overlapping yet separate requirements and instead view them as one requirement.

It is somewhat interesting to note that foreign countries have drawn from and adopted many initiatives from U.S. patent law. The opposite has also occurred, in which the U.S. used the recent America Invents Act to harmonize its own patent laws to be more in unison with patent laws of other key industrialized countries.[278] With this as backdrop, it is somewhat telling that although other industrialized foreign nations have adopted many features of American patent laws, they have not adopted our patent *disclosure* laws. For example, at the same time as the Federal Circuit's judicial trajectory now requires rigid patent disclosure, the European

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[275] *Ariad*, 598 F.3d at 1349.

[276] *Baxalta, Inc. v. Genentech, Inc.*, 1:17-cv-00509 (D. Del. Jan. 13, 2022); *Idenix*, 941 F.3d 1149; *Amgen v. Sanofi*, 987 F.3d at 1086; *AbbVie*, 759 F.3d at 1301; *Wyeth*, 720 F.3d at 1385–86.

[277] *Regents*, 119 F.3d at 1569; *Ariad*, 598 F.3d at 1350.

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

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."[279] Similarly, in direct contrast to the U.S., Australia's Patents Act of 1990 was amended in 2012 to align itself with the European Patent Office's view on enablement and sufficiency.[280] Further still, Canada also favors the European approach and not the rigid U.S. stance on patent disclosure laws. In Canada, "claims to an antibody specific for a novel antigen can be obtained even in the absence of working examples if the antigen is sufficiently described."[281] In essence and as is discussed further *supra*, this is the holding of the Federal Circuit's *Noelle* decision from 2004,[282] which unfortunately was later abandoned.[283]

Moreover, why is enablement treated as a question of law? It is noteworthy that the same sentence of the § 112(a) statute that mentions enablement also mentions the arguable highly overlapping written description requirement. Yet, enablement is treated as a question of law and written description is treated as a question of fact. The current atextual tests for enablement and written description should be set aside and instead a simpler approach should be embraced, one that would 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."[284]

This abrupt change in direction by the Federal Circuit vis-à-vis patent law's disclosure requirement will hurt biomedical innovators and have grave consequences for the potential development of new pioneering pharmaceuticals and biotechnology products. Creatively led, prudent biomedical companies will pursue

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[279] Yifan Mao & Andrew Serafini, *Navigating Key Differences in Therapeutic Antibody Patent Protection Strategies Between the United States and Europe* (April 29, 2021), https://www.jdsupra.com/legalnews/navigating-key-differences-in- 8802999/; Hazel Ford & Martin MacLean, *Patenting Antibodies at the European Patent Office*, (October 6, 2020), https://www.mathys-squire.com/insights-and-events/news/patenting-antibodies-at-the-european-patent-office/; News from Abroad: Antibodies in the European Patent Office, Patent Docs (2016), https://www.jdsupra.com/legalnews/news-from- abroad-antibodies-in-the-97737/.

[280] Tony Shaw and Candace Wu, *Navigating Australian Antibody Patent Protection Strategies* (February 1, 2022) https://www.allens.com.au/insights-news/insights/2022/02/Antibody-patent-protection-in-Australia/.

[281]Carmela De Luca & Anastassia Trifonova, *Patent Disclosure Requirements for Therapeutic Antibody Patents,* 27(8) EXPERT OP. ON THERAPEUTIC PATS. 867, 868.

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

[283] For analysis of patents related to antibodies, see also Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE LAW JOURNAL 994 (2023), University of Illinois College of Law Legal Studies Research Paper No. 22-26, Available at SSRN: https://ssrn.com/abstract=4032912 or http://dx.doi.org/10.2139/ssrn.4032912.

[284] 35 U.S.C. § 112(a).

their research and development in industrial jurisdictions outside the U.S. that have more stable and predictable patent laws--an undesirable policy outcome.

A. "Full Scope" Enablement Requires a Flexible Approach

The innovator is required, under § 112(a), to provide an enabling disclosure of the invention. When § 112 was enacted, Congress clearly mandated that the patent specification "enable any person skilled in the art to which it pertains" to "make and use the same." To comply with this enablement requirement, courts require that the patent disclosure be "commensurate in scope" with the subject matter that the patent claim is claiming as the inventor's property.[285] This concept of the breadth of patent claims being "commensurate" with what the patent application teaches is a feature that was developed as a doctrine in the 1970s and is routinely applied to date.[286] 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."[287] Indeed, if broad and arguably more valuable patent claims are pursued, sufficient disclosure is mandated by law to support and enable that wider claim breadth.[288]

The statutory foundation for the enablement requirement dates back over 200 years; however, it was developed more recently as a doctrine by judicial interpretation of the statute.[289] The Federal Circuit established and long used a rubric for assessing if a patent application is enabled. Under this rubric, the specification is found to be enabled only if upon balancing the *Wands* factors a PHOSITA could make and use the invention without undue experimentation,[290] with decisions after *Wands* consistently stating "enable" means replication "without requiring undue experimentation."[291] The *Wands* factors were routinely used to determine a patent application's compliance with the enablement requirement.[292] Under this long established framework, the enablement inquiry is correctly identified as case-specific inquiry, where an imposition of any bright-line rules is problematic.

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[285] *Amgen v. Chugai*, 927 F.2d at 1213 ("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.").

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

[287] *Id.* at 839.

[288] *Dreamworks*, 516 F.3d at 999 ("A patentee who chooses broad claim language must make sure the broad claims are fully enabled.").

[289] *See supra* Part II.

[290] *Id.*

[291] *Invitrogen*, 429 F.3d at 1070; 35 U.S.C. § 112.

[292] *Amgen v. Hoechst*, 314 F.3d at 1334 ("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 at 737).

However, the Federal Circuit fundamentally shifted its approach recently away from the well-established "undue experimentation" factors and 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.[293] That is, the Federal Circuit's recent jurisprudence on enablement is problematic because it has become a rigid numbers-based test to evaluate whether the patent application enables the "full scope" of its claims.[294] This new test is incorrect because it ignores how many species are within a genus and how routine it would be to make any particular species and instead focuses on how an ordinary skilled artisan can make and test every species encompassing a genus.

As the court itself has previously outlined before their major shift in approach, enablement does not require an ordinary skilled artisan to make and test every possible substitution to exclude hypothetical outliers that do not work.[295] Indeed, the statute does not mandate any limitations on the number of species falling within a genus claim or require "full scope" enablement. The new Federal Circuit's 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.[296] This severe curtailing of genus claims that cover "too large" a number of compounds lacks any basis in statutory text of § 112(a) or backing from Supreme Court precedent.

A new flexible and adaptable approach to § 112(a) is required. The Federal Circuit's current rigid rules are detrimentally affecting the biopharmaceutical industry because they mandate compliance with the "representative number of examples" sub-test for the written description's non-statutory "possession" requirement, and "full scope" enablement that mandates every species within a genus to be made, tested, and disclosed. In particular, the Federal Circuit's current rigid test for enablement cannot be the *sole* test, and similarly, the Federal Circuit's current "possession" subtest for written description cannot be the *sole* test for determining compliance. Similar to the Supreme Court's recent rejection of the Federal Circuit's rigid "teaching, suggest, or motivation" test for obviousness,[297] and the Federal Circuit's rigid "machine or transformation" test for patent eligibility,[298] the Federal Circuit's current numbers-based inquiry for enablement as well as the "representative number of examples" inquiry for written description should both be struck down as too rigid and not representing the sole tests for

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[293] *Id.*

[294] *Amgen v. Sanofi*, 987 F.3d at 1086; for a comparison to foreign jurisdictions on this issue, see also Sam Habein, *The United States Stands Alone: A Divergence in the Treatment of Genus Claims in Pharmaceutical Patents*, 22 UIC REV. INTELL. PROP. L. 97 (2022).

[295] *Atlas*, 750 F.2d at 1576.

[296] Many patent claims have been rendered invalid based on this recent chance in the enablement jurisprudence by the Federal Circuit; *see*, *e.g.*, *Novozymes*, 723 F.3d at 1346.

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

[298] *Bilski*, 561 U.S. at 603–04.

determining compliance with the Patent Act's disclosure requirement. Thus, there is a present need for a new and flexible approach to interpreting § 112(a).

B. A Fact-Intensive Jury Inquiry Required for Patent Disclosure Laws

The patent application's "written description" must include "such full, clear, concise, and exact terms as to enable any person skilled in the art to…make and use the same."[299] In *Battin v. Taggert*, the Supreme Court held that "it was 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."[300] Indeed, fact-intensive determinations typically involve questions of fact for juries to decide, such as whether an ordinary skilled artisan would appreciate the similarities between species within a genus claim.

In 1983, against Supreme Court precedent, the Federal Circuit decided for the first time that enablement is a question of law.[301] This has carried through to today, and yet one cannot divorce enablement determinations from inherently factual questions such as the knowledge of the ordinary skilled artisan in the relevant field, how much guidance the patent application provides, and the maturity of the field. Even in the context of such intensive factual inquiries, the Federal Circuit's current view is that determining if "undue experimentation" is required is a question of law.[302] However, the eight *Wands* factors for determining if "undue experimentation"[303] is necessary for practicing the invention require expert testimony and weighing evidence related to the eight factors. The jury typically makes such fact intensive assessments—*i.e.*, enablement should be a question of fact and not a question of law. Moreover, if enablement is a question of law, then why do juries routinely resolve enablement issues?[304] Further still, if juries make determinations on whether "undue experimentation" would be necessary, why are judges allowed to discard juries' findings? A cynic would note that having enablement be decided as a legal question allows judges to set aside validity determinations and reweigh the facts. To add even more mystique to these questions, it is eyebrow-raising that while the enablement requirement's close cousin—the "written description" requirement—from the very same sentence of § 112(a) is treated as a question of fact, the Federal Circuit has kept to its post 1983 framework of viewing enablement as a question of law.

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[299] *See* 35 U.S.C. § 112(a).

[300] *Battin*, 58 U.S. at 85.

[301] *Raytheon*, 724 F.2d at 960.

[302] Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1337 (Fed. Cir. 2005).

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

[304] AIPLA's Model Patent Jury Instructions, https://www.aipla.org/docs/default-source/default-document-library/2018-07-23-clean---aipla-model-patent-jury-instructions.pdf?sfvrsn=8664a8dd0 (last updated 2018).

Yet, it has long been recognized by the Supreme Court that enablement is a question of fact, that it is "the right of the jury to determine."[305] The Federal Circuit's post 1983 treatment of enablement as a question of law goes against Supreme Court precedent and has had a big impact by taking the jury's role and handing it to 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 by either the Supreme Court or by Congress, so that stability can return to patent laws, and the growth of innovation, especially in the biomedical field, can be fostered.

C. A Written Description that Enables – a Single Standard Necessary for Patent Disclosure Laws

The Federal Circuit has in the past created their own tests for interpreting different areas of patent law, only for the test to fall for being applied too narrowly and rigidly. For example, the Federal Circuit held the "teaching, suggestion, and motivation" (TSM) test as the only test for assessing obviousness of a patent application, only for the Supreme Court to overturn such a rigid, formulaic interpretation of § 103 obviousness law in *KSR.*[306] Although the Supreme Court did not significantly change the Federal Circuit's jurisprudence on obviousness, they did make a note to say that the TSM test should not be applied so rigidly and is not the *sole* test for obviousness.[307] In another recent Supreme Court case involving yet another aspect of patent law, § 101, the Court rejected the Federal Circuit's rigid "machine or transformation" test as the only test for determining patent eligibility in *Bilski*.[308] In both these instances, the Supreme Court showed a more flexible approach for assessing obviousness and subject matter eligibility than the rigid "only if" approach of the Federal Circuit. Having taken action to make § 101 and § 103 of the Patent Act more pliable and predictable, the Supreme Court ought to choose a ripe case to tackle § 112(a) to strike down in similar fashion the recent rigid approach that the Federal Circuit is pursuing.

A context-specific, flexible and multi-pronged approach is required to interpret § 112(a). As a guide, it is key to have in mind that the Supreme Court has recently emphasized adherence to the Patent Act's text, without adding any "rigid and mandatory formulas"[309] on top or any additional requirements that would be "inconsistent with the text and the statute's purpose and design."[310] The Supreme Court's two recent decisions nullified rigid patent laws. Language could be used from these two recent cases to, for example, indicate that the current § 112(a)

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[305] *Battin*, 58 U.S. at 85.

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

[307] *Id.*

[308] *Bilski*, 561 U.S. at 604 ("The machine-or-transformation test is not the sole test for patent eligibility.").

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

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

analysis is "a useful and important clue,"[311] but "not [as] the sole test."[312] Also, as the Supreme Court noted in *KSR*, even though disclosing working examples may provide helpful insight in some situations, "helpful insights . . . need not become rigid and mandatory formulas."[313] Adhering to this flexible and context-specific new approach to § 112(a) would bring much needed stability and calm to a key area of patent law that has come to have a negative impact on the biotech and pharmaceutical industries in particular.

Indeed, the above proposed approach was used for analyzing § 112(a) for both enablement and written description by the Federal Circuit prior to their recent detour. For example, such a flexible manner was used to recognize that "the 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge."[314] Therefore, for both written description and enablement analysis, factors such as 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 one dispositive. Crucially, upon further analysis, this kind of multi-pronged approach effectively subsumes written description and enablement into one and in natural fashion leads one to propose one test as required by the statute. But what would such a singular test look like?

The key *Wands* factors used to analyze enablement are highly instructive for any new flexible and context-specific multi-factor test. For example, *Wands* includes "presence of working examples" as a factor for determining enablement. Similarly, the "representative number of examples" sub-test from *Regents* and *Ariad* cases is used when determining compliance with the written description requirement. Such overlap is striking, with Judge Linn even commenting that the *Capon* factors for written description "mirror the *Wands* factors for enablement."[315] This comes as no great surprise, given how closely enablement and written description overlap in practice, and their common statutory roots in § 112(a).

A viable option for lawmakers would be to return patent law's disclosure requirements to the statutory text and Supreme Court precedent. This can be done by recognizing § 112(a) as a singular requirement, one for a written description of the invention and of the manner of making and using it. To interpret the statute as requiring a singular disclosure requirement, as is proposed here, aligns with both statutory language and the purpose of the disclosure requirement.[316] Indeed, a single requirement to evaluate the highly overlapping features of § 112(a), namely enablement and written description, is necessary. A new multi-pronged test could be created by combining the *Capon* factors for determining written description with the *Wands* factors for determining enablement to come up with a singular test that

[311] *Id.* at 604.
[312] *Id.*
[313] *KSR*, 550 U.S. at 401–402.
[314] *Capon*, 418 F.3d at 1358.
[315] *Ariad*, 598 F.3d at 1368 (Linn, J., dissenting).
[316] Evans v. Eaton, 20 U.S. 356, 433–34 (1822).

is both flexible and context-specific and one that focuses on how a PHOSITA views a disclosure and what types of experiments would be necessary to practice the invention.

As an example of how this would be applied in practice, 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. Such flexible tests could also factor in other tests, including the "representative number of examples" test, providing for a more nuanced and technology-neutral application of patent law's disclosure requirement in practice. In short, a flexible approach is required for complying with patent law's disclosure laws, especially for inventions grounded in Chemistry and Biology, because no rigid, one size fits all, rule works and "each case involving the issue of written description must be decided on its own facts".[318]

Moreover, it is interesting to note the disagreement between judges in recent Federal Circuit cases 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*.[319] On the one hand, under a dual standard of having two distinct requirements for enablement and written description with different tests for each that is favored by Judge Lourie and the majority, many pharmaceutical and biotechnology patents are invalid. On the other hand, if § 112(a) is viewed to require inventors disclose and enable their invention (*i.e.*, a single requirement, focusing on a written description that enables),[320] the patent in *Rochester* and many existing patents like it would survive such invalidity challenges.

Based on the recent *Amgen* and *Idenix* decisions,[321] it is clear that under this new jurisprudence broad functional genus claims are unlikely to succeed for the foreseeable future. The original *Amgen* panel's strong defense of their heightened enablement standard coupled with denying Amgen's rehearing request as "non-precedential" indicates the Federal Circuit is not in a mindset to change its position on their heightened enablement requirement anytime soon. Moreover, the fact that the Supreme Court recently denied Idenix's petition for *certiorari* also indicates that the courts are at present not willing to change the present status quo on § 112(a). Short of action from Congress and with no remedy forthcoming from the courts for

[317] *Noelle*, 355 F.3d at 1349.
[318] *Noelle*, 355 F.3d at 1349.
[319] *Enzo Biochem.*, 323 F.3d at 977.
[320] *Id.*
[321] Amgen, Inc. v. Sanofi, No. 2020-1074, 2021 U.S. App. LEXIS 18379 (Fed. Cir. 2021); *Idenix*, 941 F.3d at 1162.

the foreseeable future,[322] practitioners would be well advised to avoid functional genus claims and instead focus on describing small molecules in structural terms. If genus claims are included in patent applications with functional language, based on current § 112(a) jurisprudence, it is now advisable to include multiple specific examples in the patent application to support the scope of the patent claim.

[322] With the completion of this article, the Supreme Court granted certiorari in *Amgen v. Sanofi*, No. 21-757, agreeing to review the Federal Circuit's "full scope of the claimed embodiments" test for enablement. A decision is expected later in 2023.