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Enablement for Genus Claims: A Bifurcated Approach

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INTRODUCTION

Amgen Inc. v. Sanofi is one of the most watched intellectual property law cases before the Supreme Court in 2023, and the Court decided the case without much controversy among the justices.

[1] At dispute are some antibody claims from two patents owned by Amgen for regulating blood cholesterol and treating heart disease.[2] A lot is at stake. Antibodies constitute a $145 billion annual market—an amount projected to almost double by 2026.[3] Three dozen amicus briefs were filed, including by big pharma companies, patent law associations, intellectual property law professors, and world-renowned scientists including a Nobel laureate.[4] High Tech Inventors Alliance, "a consortium of some of the world's most innovative technology companies" such as Amazon, Google, and Microsoft, also weighed in on this antibody patent case.[5]

It has been almost 100 years since the Court last addressed sufficiency of patent disclosure.[6] The Court granted certiorari to consider the question in *Amgen*:

> Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "*to reach the full scope* of claimed embodiments" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "time and effort," Pet. App. 14a.[7]

Amgen, the patentee, argued that the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit), the court with exclusive appellate jurisdiction over patent cases, had applied an enablement standard in a way not

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1. The Court handed down a unanimous opinion less than two months after the oral arguments. *See* Amgen Inc. v. Sanofi, SCOTUSBLOG, https://www.scotusblog.com/case-files/cases/amgen-inc-v-sanofi-2/ (last accessed July 27, 2023) [https://perma.cc/BGW3-QVRQ]. For a brief recap of the case's two journeys to the Federal Circuit, *see Dennis Crouch, Functional Claim "Raises the Bar for Enablement,"* PATENTLY-O (Feb. 16, 2021), https://patentlyo.com/patent/2021/02/functional-limitations-enablement.html [https://perma.cc/GG8T-YRAQ]; Jason Rantanen, *Rethinking enablement: Court grants cert in* Amgen v. Sanofi, PATENTLY-O (Nov. 6, 2022), . https://patentlyo.com/patent/2022/11/rethinking-enablement-grants.html [https://perma.cc/4P36-YNWZ].

2. Amgen Inc. v. Sanofi (*Amgen III*), 987 F.3d 1080, 1082–83 (Fed. Cir. 2021).

3. Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J 994, 994 (2023) [hereinafter *Paradox*].

4. *See* Amgen Inc. v. Sanofi, *supra* note 1.

5. Brief for High Tech Inventors Alliance and the Computer & Communications Industry Association as Amici Curiae in Support of Neither Party, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757) [hereinafter Brief for HTIA] (worrying the Court's ruling in this case may harm innovation and competition in other industries as well).

6. *See* Amgen Inc. v. Sanofi (*Amgen IV*), 598 U.S. 594, 605–06.

7. Brief for Petitioners at i, Amgen v. Sanofi, 598 U.S. 594 (2023) (No. 21-757) (emphasis in original).

warranted by the statutory text.[8] Amgen was not alone. Scholars have also argued that in recently years, the Federal Circuit has been imposing the heightened enablement requirement to strike down genus claims left and right.[9]

The Supreme Court decided that Amgen claimed more than it enabled.[10] It analogized the case at hand with its precedent that invalidated patents for lack of enablement.[11] Although the Court was clear that Amgen may not "monopolize an entire class of things defined by their function,"[12] the opinion fell short of guiding lower courts on how to address enablement in the days to come.

This paper focuses on the debate surrounding enablement with respect to genus claims. Genus claims cover multiple, related embodiments, or species, of an invention. For example, a claim covering a specific chemical is a species claim, whereas a claim covering a group of similar chemicals is a genus claim. By offering broad scope, genus claims are important to patent protection. Genus claims, however, are not limitless. Enablement is a limitation on genus claims: the accompanying patent document must enable a skilled artisan to make and use the invention.[13]

Part I begins with the patent bargain, the central policy objective behind the U.S. patent system. In the patent bargain, a patentee is incentivized by a limited monopoly for their invention, and in exchange, the patentee must disclose the invention to the public through the patent. The rest of Part I introduces some key concepts in U.S. patent law, including claims (defining the scope of protection), a person having ordinary skill in the art (or PHOSITA, a term of art referring to a skilled artisan in the field of the invention), and two patentability requirements, enablement and written description.

Part II discusses the genus claims and the policy issues they implicate, an apparent split in the enablement jurisprudence, and whether there has been a doctrinal drift to a higher enablement bar. While genus claims are conducive to effective patent protection, they also cause concerns because they are often unduly broad and would undermine the patent bargain and preempt future innovations. To this end, single-embodiment enablement and full-scope enablement both police the breadth of genus claims, although they appear to contradict each other. Furthermore, even though a judgment of

8. *Id.* at 1.

9. Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 4 (2021) [hereinafter *Genus Claim*].

10. *Amgen IV*, 598 U.S. at 613–14.

11. *Id.* at 613 ("Much as Morse sought to claim all telegraphic forms of communication, Sawyer and Man sought to claim all fibrous and textile materials for incandescence, and Perkins sought to claim all starch glues that work as well as animal glue for wood veneering, Amgen seeks to claim 'sovereignty over [an] entire kingdom' of antibodies.").

12. *Id.*

13. *See* 35 U.S.C. § 112(a).

enablement depends on specific facts of a case, e.g., the technical field, the invention, and the parties' arguments, it often suffers from courts' inconsistent applications of the law, illustrated by a comparison of two antibody patent cases.

In Part III, I propose a bifurcated approach to evaluate the enablement of genus claims. This approach recognizes two different types of genus claims, one containing structural limitations (and maybe also functional limitations) and the other containing only functional limitations, like the ones in Amgen's patents. To functional genus claims, means-plus-function (MPF) claiming applies, which limits a functional claim to the particular means of implementation (i.e., structure, material, or acts) in the patent disclosure and the equivalents of the disclosed means.[14] Under this approach, a patentee is allowed to claim an invention based on functionality, but not the function regardless of implementation.

For structural genus claims, the inoperative embodiments doctrine applies. Accordingly, a claim does not fail for nonenablement simply because some of the covered embodiments are not operative or screening of candidates is necessary. Instead, a patent challenger carries the burden to demonstrate that it is not reasonably likely that a skilled artisan—by following the patent disclosure—can reach operative embodiments of the invention across the full scope without undue experimentation.

I. BACKGROUND

The U.S. patent system supports a patent bargain with two important goals: to incentivize innovations by awarding patents and to enforce disclosure in exchange for patents. Patent claims are probably the most important part of a patent document; they delineate the scope of protection sought by or awarded to a patentee. Whether an invention is patentable is evaluated from the perspective of a PHOSITA. Furthermore, among the multiple patentability requirements, two are especially pertinent to this paper—enablement and written description. Both focus on the sufficiency of patent disclosure.

A. The Patent Bargain

The U.S. patent system is essentially a quid pro quo between the patentee and the society.[15] The patentee gets a monopoly for a limited period of time to recoup investment in the invention, while the society gets the

14. *See id.* § 112(f).

15. *See*, *e.g.*, Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.").

benefits of the invention as well as the disclosure about the invention.[16] The disclosure not only adds to the public's knowledge storehouse and guarantees that the public will get complete possession of the invention once the patent expires, but it also allows others to improve or design around the invention.[17] Disclosure, however, is widely seen as a secondary goal of the patent system; the primary goal is to incentivize innovation.[18]

"Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention . . . ."[19] Accordingly, maintaining the delicate balance between the interest in motivating innovation and the interest in avoiding unnecessary stifling of innovation has been a feature of the federal patent laws since their inception.[20]

To receive a patent, one must file a patent application with the U.S. Patent and Trademark Office (USPTO),[21] which will issue the patent after determining that the patent application satisfies all patentability requirements. The patentability requirements are patentable subject matter,[22] novelty,[23] nonobviousness,[24] utility,[25] enablement,[26] written description,[27] and claim definiteness[28] These requirements ensure the monopoly granted is deserved and a patentee upholds their end of the bargain. Among these, enablement and written description, safeguard the sufficiency of a patent disclosure.

After a patent is issued, its validity can be challenged either in the Patent Trial and Appeal Board (PTAB), an administrative tribunal within the USPTO, or federal district courts.[29] The only appellate court that has jurisdiction over patent cases is the Federal Circuit, which was created in 1982.[30] As a result, appeals from the PTAB go directly to the Federal Circuit without

16. *Genus Claim*, *supra* note 9, at 6–7.

17. *Id.* at 7.

18. Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts,* 56 UCLA L. REV. 127, 161 (2008) [hereinafter *Heightened Enablement*].

19. Mayo Collaborative Servs. v. Prometheus Lab'ys., Inc., 566 U.S. 66, 92 (2012).

20. *Pfaff*, 525 U.S. at 63.

21. JONATHAN S. MASUR & LISA LARRIMORE OUELLETTE, PATENT LAW: CASES, PROBLEMS, AND MATERIALS 13 (3st ed. 2023).

22. 35 U.S.C. § 101 (naming four statutory categories of invention: process, machine, manufacture, and composition of matter).

23. *Id.* § 102 (requiring an invention to be novel, or not anticipated, over a piece of prior art—an earlier reference).

24. *Id.* § 103 (requiring an invention to be nonobvious over two or more pieces of prior art).

25. *Id.* §§ 101 and 112 (requiring an invention to be useful).

26. *Id.* § 112(a) (requiring claims to be commensurate in scope with the specification).

27. *Id.*

28. *Id.* § 112(b) (requiring claims to be sufficiently definite).

29. MASUR & OUELLETTE, *supra* note 21, at 16.

30. *Id.*

having to pass through the district courts.[31] But it was different before. The predecessor to the Federal Circuit was the Court of Customs and Patent Appeals (CCPA), which received appeals from the Board of Patent Appeals and Interferences (BPAI), the predecessor to the PTAB, while regional circuits heard other patent cases.[32]

B. Claims

A patent claim is "the portion of the patent document that defines the scope of the patentee's rights."[33] Infringement occurs when an alleged infringer makes, uses, sells, or imports a good or process covered by a patent claim.[34]

The role of claims—to set the outer boundaries of the exclusory right conferred by the patent—supports the patent bargain. They inform the public of what is protected by the patent and allow others to invent around the claimed invention.[35] In the meantime, a patent's claim(s) cannot be unduly broad; they must be supported by the specification, a written description of the invention and of the manner and process of making and using the invention.[36] This is enforced by the enablement and written description requirements.[37]

Despite their essential role, patent claims did not always exist. Early patents were defined by what the patentee built and not by its claims.[38] Today, claims are found at the end of the patent document.[39] They must be written by following certain rules, e.g., each claim can be only one sentence no matter how awkward it would read.[40]

Claims can be independent or dependent. An independent claim stands on its own, whereas a dependent claim refers back to and further limits another claim. Generally, a claim contains three parts: (1) the preamble identifying the category of the invention, (2) a transitional phrase (can be open-

31. *Id.*

32. *Id.*

33. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996).

34. MASUR & OUELLETTE, *supra* note 21, at 332.

35. Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 369 (1938) ("The limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.").

36. 35 U.S.C. § 112(a).

37. Sean B. Seymore, *Patenting Around Failure*, 166 U. PA. L. REV. 1139, 1150 (2018) [hereinafter *Around Failure*].

38. Mark A. Lemley, *Software Patents and the Return of Functional Claiming,* 2013 WIS. L. REV. 905, 910 (2013) [hereinafter *Software Patents*].

39. *Genus Claim*, *supra* note 9, at 5; *see also* 35 U.S.C. § 112(b) ("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.").

40. Gene Guinn, *Understanding Patent Claims*, IPWATCHDOG (July 12, 2014, 8:00 AM), https://ipwatchdog.com/2014/07/12/understanding-patent-claims/id=50349/ [https://perma.cc/SJK7-DYYV].

ended or closed), and (3) the body that set forth claim elements and how they exist in relationship to one another.[41]

C. PHOSITA

The shorthand "PHOSITA" stands for "Person Having Ordinary Skill in the Art." The concept of PHOSITA is indispensable to patent law: multiple patentability requirements are evaluated from the perspective of a PHOSITA—what the PHOSITA would know at the time of filing.[42] For example, obviousness analysis under Section 103 asks whether the PHOSITA would have been motivated to create the invention and would have had a reasonable expectation of success; enablement analysis under Section 112(a) asks how much information the patentee must disclose to enable the PHOSITA to make and use the invention without undue experimentation.[43]

Related to the concept of PHOSITA is the predictability of the technical field the PHOSITA is in. Traditional engineering fields, such as mechanical and electrical engineering, are deemed predictable arts, where engineers use well-understood applied technologies to develop new products and processes.[44] On the other hand, unpredictable arts include chemistry, pharmaceuticals, and biotechnology because the underlying scientific principles are not fully understood.[45]

Although the statutory patentability requirements are the same regardless of the art, patent law developed at a time when inventions primarily involved engineering-related devices and processes—the predictable arts.[46] But unpredictable arts are different. As the law evolves, scholars have observed technology-specific applications of the patentability requirements.[47] If the PHOSITA in a field knows a lot, an invention is more likely to be found obvious, and the patent does not need as many details to enable the PHOSITA.[48] By contrast, if the field is unpredictable, then the PHOSITA knows very little, and it is easier to show nonobviousness and nonenablement.[49]

41. *Patent Claim Format and Types of Claims*, WORLD INTELL. PROP. ORG. (last accessed Mar. 10, 2023), https://www.wipo.int/edocs/mdocs/aspac/en/wipo_ip_phl_16/wipo_ip_phl_16_t5.pdf [https://perma.cc/3VYA-XXNY]. Here, I use "claim element" and "claim limitation" interchangeably.

42. *Genus Claim*, *supra* note 9, at 54.

43. *Id.*

44. *Heightened Enablement*, *supra* note 18, at 136–39.

45. *Id.*

46. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1155, 1159 (2002) [hereinafter *Technology-Specific*].

47. *Id.* at 1156.

48. *Genus Claim*, *supra* note 9, at 54–55.

49. *Id.*

In short, the PHOSITA in patent law is like the reasonable person in tort law. The level of skill imputed to the PHOSITA changes with the field and affects patentability analysis in both prosecution and litigation.[50]

D. Enablement

The enablement requirement is embedded in Section 112(a) of the Patent Act:

> 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.[51]

Enablement, like the other patentability requirements, enforces the patent bargain. It requires a patentee to uphold their end of the deal—to furnish a disclosure sufficient to teach the PHOSITA how to make and use the claimed invention without undue experimentation.[52]Enablement is evaluated at the time of filing.

Since patent law does not require an inventor to prove enablement, the issue of enablement only comes up when challenged, either at the Office or in litigation.[53] Furthermore, since a patent is presumed valid and a patent challenger bears the burden of establishing its invalidity,[54] a patentee only has to defeat a nonenablement challenge, but not demonstrate full-scope enablement.[55]

"To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'"[56] But what is "undue experimentation," a term that does not appear in the statute? "The key word is 'undue,' not 'experimentation.'"[57] In contrast to undue experimentation is "sufficiently routine" experimentation that the PHOSITA would reasonably be expected to carry out.[58] And "a considerable amount of experimentation is permissible, if it is merely

50. *See*, *e.g.*, *Technology-Specific*, *supra* note 46, at 1156.

51. 35 U.S.C. § 112(a) (emphasis added). The language is nearly identical to Section 112, ¶ 1 of the Patent Act of 1952.

52. *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

53. Jason Rantanen, *The Doctrinal Structure of Patent Law's Enablement Requirement,* 69 VANDERBILT L.R. 1679, 1703 (2016) [hereinafter *Doctrinal Structure*].

54. 35 U.S.C. § 282(a).

55. *Doctrinal Structure*, *supra* note 53, at 1703.

56. *Amgen III*, 987 F.3d 1080, 1084 (Fed. Cir. 2021).

57. *In re* Angstadt, 537 F.2d 498, 504 (C.C.P.A. 1976).

58. *Amgen III*, 987 F.3d at 1085.

routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed."[59]

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations."[60] The Federal Circuit set forth the relevant factors in *In re Wands*—the *Wands* factors—including (1) the amount of direction or guidance presented in the disclosure, (2) the existence of working examples, (3) the nature of the invention, (4) the predictability or unpredictability of the art, (5) the PHOSITA's level of skill, (6) the state of the prior art (preexisting knowledge and technology already available to the public), (7) the breadth of the claims, and (8) the amount of experimentation necessary to practice the claimed invention.[61] These *Wands* factors have become the go-to standard for the enablement inquiry.[62]

As with the other patentability requirements, the enablement inquiry relies on the skills of the PHOSITA to fill in the gap left open by the specification.[63] Even in the unpredictable arts, where it often takes trial and error for the PHOSITA to make and use the invention, the specification does not need to "describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art."[64]

E. Written Description

Written description is an independent patentability requirement, albeit related to the enablement requirement. Both requirements deal with sufficiency of patent disclosure and are found in the same statute provision, which provides: "The specification shall contain a *written description* of the invention . . . ."[65] The written description inquiry focuses on whether the specification contains sufficient details to allow the PHOSITA to reasonably conclude that the patentee "actually invented" the claimed subject matter.[66] The adequacy of the written disclosure supporting "generic claims" is evaluated by considering factors such as "the existing knowledge in the particular field,

59. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (quoting *In re* Jackson, 217 USPQ 804, 807 (Bd. App. 1982)).

60. *Id.*

61. *Id.*

62. *Amgen III*, 987 F.3d at 1085.

63. *See Wands*, 858 F.2d at 735 ("A patent need not disclose what is well known in the art.").

64. *AK Steel Corp. v. Sollac,* 344 F.3d 1234, 1244 (Fed. Cir. 2003).

65. 35 U.S.C. § 112(a) (emphasis added).

66. *In re* Ruschig, 379 F.2d 990, 995 (C.C.P.A. 1967).

the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue."[67]

Enablement and written description requirements often stand or fall together, but not always so.[68] Indeed, one can "enable the practice of an invention as broadly as it is claimed, and still not describe that invention."[69] For example, a specification disclosing only compound A may enable the PHOSITA to make and use compounds B and C; but in the absence of any broadening language, compounds B and C have not been adequately described.[70] Conversely, a specification that adequately describes the claimed subject matter does not necessarily also enable the PHOSITA to make or use the claimed invention.[71]

Despite being separate requirements, written description and enablement serve the same policy objective—to protect the quid pro quo of the patent bargain, and specifically, to prevent overreaching of the claims by requiring the disclosure corresponds to the claims.[72] "[A] written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described."[73]

II. THE GENUS CLAIM PROBLEM

In this part, I will first introduce two types of genus claims and present arguments for and against genus claims. The biggest concern with genus claims is their breadth, which is often not supported by the accompanying patent disclosure. Enablement is a tool to guard against overbroad genus claims. But how many embodiments must a patent disclose to satisfy enablement? I will reconcile two facially opposite enablement doctrines, namely single-embodiment enablement and full-scope enablement. Next, despite an arguably heightened enablement standard, I will argue courts analyze enablement inconsistently, as can be seen in two antibody patent cases, *Wands* and *Amgen*.

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67. Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (modification in original).

68. *Id.* at 1352 ("Perhaps there is little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, including chemical and chemical-like inventions.")

69. *In re* DiLeone, 436 F.2d 1404, 1405 (C.C.P.A. 1971).

70. *See id.* at 1405 n.1.

71. *In re* Armbruster, 512 F.2d 676, 677 (C.C.P.A. 1975) ("Although appellant's specification describes the invention as broadly as it is claimed, thereby eliminating any issue concerning the description requirement, a specification which 'describes' does not necessarily also 'enable' one skilled in the art to make or use the claimed invention.").

72. *Genus Claim*, *supra* note 9, at 18.

73. *Ariad*, 598 F.3d at 1352 (modification in original).

A. Genus Claims

Genus claims provide broad scope of patent protection.[74] They can use either functional language or generic formulas to cover individual embodiments, or species, of the invention that share a common attribute or property.[75]

Accordingly, there are two types of genus claims: functional genus claims and structural genus claims.[76] For purposes of this paper, functional genus claims contain only functional limitations and no structural limitations, while structural genus claims may contain only structural limitations or a combination of both structural and functional limitations. Part III further discusses the differentiation of functional genus claims and structural genus claims.

One example of a structural genus claim comes from *Idenix Pharmaceuticals LLC v. Gilead Sciences, Inc.*, which related to hepatitis C treatment.[77] The broadest claim of the invalidated patent read: "A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β-D-2'-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof."[78] This claim contained a generic formula (β-D-2'-methyl-ribofuranosyl nucleoside) and covered potentially billions of nucleoside compounds, all having the structure of a five-carbon ring backbone, but modified with variable moieties.[79] Only some of these candidates would be effective in treating hepatitis C.[80]

By contrast, the antibody claims in *Amgen* are functional genus claims that define the antibody by the ability to bind to certain residues on the antigen PCSK9, a protein contributing to blood cholesterol levels and heart disease.[81] A representative claim reads: "An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369,

74. *Genus claim*, *supra* note 9, at 13.

75. *Id.* Interestingly, despite common references to genus claims and species claims, Professor Lefstin argued that there is no such thing as a species claim—all patent claims cover infinite variety of embodiments. Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement,* 23 BERKELEY TECH. L.J. 1141, 1168–74 (2008) (giving as an example a claim reciting "a chair with four legs"). Furthermore, most claims use "comprising," an open-ended transitional phrase that does not exclude additional, unnamed elements, making them genus claims. As a result of the open-ended transitional phrase, the use of the claimed elements, even with additional new elements, still leads to infringement. *Id.*

76. Note that a functional claim is different from a functional limitation. A functional limitation recites a feature of the invention by its function. A claim can have both functional and structural limitations.

77. 941 F.3d 1149, 1154 (Fed. Cir. 2019).

78. *Id.* at 1155.

79. *Id.* at 1155–56.

80. *Id.* at 1157.

81. 987 F.3d 1080, 1082–83 (Fed. Cir. 2021).

S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR."[82]

Both examples above are from unpredictable arts. Indeed, genus claims are prevalent in unpredictable arts: chemistry, pharmaceuticals, and biotechnology, which rely more heavily on patent protection than other industries.[83] In these fields, independent inventions and stacking of multiple patents are less common, and the pace of change is slower compared with other fields.[84] Furthermore, although both claims are genus claims, there is a distinction between the two. The latter claim is a purely functional claim, without any structural limitations.

Functional genus claims and structural genus claims are qualitatively different. A structural genus claim describes an invention with structural terms, so the invention is defined, at least partially, by what it is. By contrast, a functional genus claim defines an invention only by its function and covers all structures to achieve the function.[85] This difference lays the foundation for the bifurcated approach proposed in Part III.

B. The Policy Issues Surrounding Genus Claims

Genus claims exist for good reasons. Most importantly, genus claims afford patentees protection from infringement by minor variations of the invention.[86] There is less incentive to apply for a patent if the inventor knows an infringer could easily get around it. Worse, inventors may have less incentive to invest time and money in innovations.[87] To illustrate this point, think about drug development, which, if successful, normally takes years and billions of dollars.[88] And keep in mind many more drug development

82. *Id.* at 1083.

83. *Genus Claim*, *supra* note 9, at 63–64.

84. *Id.* at 64.

85. *See* Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353 (Fed. Cir. 2010) ("Such claims merely recite a description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention.").

86. *Genus Claim*, *supra* note 9, at 3.

87. Consistent with the incentive objective of the patent bargain, in some cases, whether the invention was pioneering mattered. *Doctrinal Structure*, *supra* note 53, at 1696–97. Awarding pioneering inventions with broad claims incentivizes prompt, early disclosure. *In re* Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977). But this is probably not the prevailing view. *See*, *e.g.*, Bene v. Jeantet, 129 U.S. 683, 686 (1889) ("The broad construction claimed for this patent as a pioneer and foundation invention in the art of refining hair cannot extend the rights of the patentee beyond the compositions of matter and processes which, as stated in the patent, embody his real invention."). *See* Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1341 (Fed. Cir. 2003) (agreeing with the district court in not applying *Hogan*'s dicta—pioneering inventions "deserve broad claims to the broad concept"—to the enablement analysis).

88. *See* Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1324 (Fed. Cir. 2012) (noting "patents on life-saving material and processes" involved "large amounts of risky investment"); Brief for Petitioners, *supra* note 7, at 7, 40 (claiming investment of "more than $2.7 billion dollars" and "a decade of research bringing [the] invention to market"); Joseph A. DiMasi et al., *Innovation in the*

processes are terminated after expenditures of time and money but without a marketable product. To make it worthwhile to undertake the upfront risky investment, genus claims offer broad protection, which means more hurdles for the competitors and more opportunities for the patentee to recoup the costs of innovation.

Not surprisingly, genus claims are especially important for the unpredictable fields. Also, it can be a matter of pragmatism. For example, antibodies were traditionally claimed by the targets they bind to—the antigens. Indeed, antibodies were claimed by functional limitations because in the early days of antibody research, it was the only practical way.[89] Now this rationale is not valid anymore as science today allows for structurally defining antibodies.[90] However, the proponents for genus claims continue to emphasize the incentivizing function of genus claims with great force.[91]

Besides the necessity of genus claims, there are also serious policy concerns about their breadth. Oftentimes with genus claims, there is a mismatch between the disclosure and the claims: "If the genus is analogized to a plot of land, the disclosed species and guidance only abide in a corner of the genus."[92] The famous *Incandescent Lamp Case* exemplifies this mismatch. While the claim at issue broadly covered *every* "carbonized fibrous or textile material" as a filament for light bulbs, the patent specification only disclosed carbonized paper and wood carbon.[93]

When the breadth of a genus claim, in light of the accompanying disclosure, is not warranted, it runs against the disclosure objective of the patent bargain. For one, a patentee may define a genus based on improper generalization.[94] For another, genus claims may allow an inventor to get an early priority date in the absence of possession, also called gun jumping.[95]

Overbroad claiming may harm innovations by blocking future innovations in the field. Going back to the *Incandescent Lamp Case*, Thomas Edison made painstaking efforts to identify that a particular part of some "special bamboo" worked as a filament, but not over 6,000 vegetable growths.[96] The filament material Edison discovered—despite the time and efforts he

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Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. HEALTH ECON. 20, 20 (2016) (finding the average research and development cost per approved new drug brought to market was $2.59 billion dollars).

89. *Paradox*, *supra* note 3, at 1044.

90. *See id.*

91. *See*, e.g., *Amgen IV*, 598 U.S. 594, 616 (2023). The Supreme Court did not seem to be too worried. "If the Court had not [enforced the statutory enablement requirement according to its terms] in *Incandescent Lamp*, it might have been writing decisions like *Holland Furniture* in the dark."

92. *Amgen III*, 987 F.3d 1080, 1087 (internal quotation marks omitted) (quoting AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285, 1299–300 (Fed. Cir. 2014)).

93. Consol. Elec. Light Co. v. McKeesport Light Co. (*The Incandescent Lamp Case*), 159 U.S. 465, 468–69 (1895).

94. *Genus Claim*, *supra* note 9, at 59–60 (citing *The Incandescent Lamp Case* as an example).

95. *Id.* at 61–62. But this is more a written description problem.

96. *The Incandescent Lamp Case*, 159 U.S. at 472–74.

invested—could be preempted as a carbonized fibrous or textile material if the claim covering "carbonized fibrous or textile material" were held valid, even though the patentee's bulb was no longer in use and had never been a commercial success.[97]

Functional genus claims are even more concerning. Still, with the light bulb filament example, a functional claim could potentially cover all kinds of material used as a filament in a light bulb.

In short, genus claims are intertwined with competing interests. Broad claims provide broad protection and more incentives to patentees; narrow claims leave room for competitive innovation, and the availability of choices benefits the public by lowering the prices of the innovations. A proper balance is needed.

The patent bargain has checks for genus claims; one such check is enablement. In the following, I turn to two doctrinal debates in enablement jurisprudence. The first debate surrounds an apparent split in case law: the single-embodiment enablement and full-scope enablement. The second debate concerns an alleged drift to a heightened enablement requirement.

C. The Doctrinal Debates

Due to the short statutory text foundation, the enablement doctrine is largely embodied in case law.[98] The claim must reasonably correlate to the scope of enablement,[99] the scope of enablement must be commensurate with the scope of the claims,[100] or the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation."[101]

Many papers address a split in the enablement doctrine.[102] Sometimes enablement of a single mode or embodiment of the claimed invention (i.e., single-embodiment enablement) is sufficient to meet the enablement requirement; at other times, enablement of the full scope (i.e., full-scope enablement) is necessary. But is there really a split in the enablement doctrine? After a closer examination, it is possible to reconcile these two standards.

97. *Id.* at 471.
98. *Doctrinal Structure*, *supra* note 53, at 1680–81.
99. *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).
100. *In re* Moore, 439 F.2d 1232, 1236 (C.C.P.A. 1971).
101. AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003).
102. *See*, *e.g.*, *Doctrinal Structure*, *supra* note 53, at 1681–82 (citing authorities).

1. Single-Embodiment Enablement

In one line of cases, a single embodiment or mode could be sufficient to enable a broad claim.[103] In a starting case for this line of precedent, the court stated that "[t]he enablement requirement is met if the description enables any mode of making and using the invention." [104] This statement seemed to derive from an even earlier case's "unremarkable proposition that a broad claim can be enabled by disclosure of a single embodiment when the art involved is one where the results are predictable."[105] In addition to the association with predictable arts, single-mode or single-embodiment enablement also appears to come up more in the context of process claims. If there are multiple ways to implement a process by using multiple forms of apparatus, an inventor needs to describe one particular way and apparatus, but not all of them.[106]

But even when single-embodiment enablement is sufficient, single-embodiment disclosure can still encounter a written description challenge. While acknowledging that disclosure of one species may be "sufficient written description support" for a claimed genus, in an unpredictable art, "disclosure of more species [may be] necessary to adequately show possession of the entire genus."[107] Furthermore, the Federal Circuit clarified that "while we did state . . . that the mechanical field was 'fairly predictable,' we did *not* hold that *all* inventions that may be characterized as 'mechanical' allow claiming a genus based on disclosure of a single species."[108]

2. Full-Scope Enablement

In an opposite line of cases, the specification must do more than enabling a single embodiment.[109] The specification must enable the full scope of the claimed invention,[110] although full-scope enablement does not mandate a specification that details "every conceivable permutation" of a claimed embodiment.[111] In *Wyeth v. Abbott Laboratories*, the claims covered methods for treating restenosis with rapamycin; the Federal Circuit invalidated

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103. *Id.* at 1681 (stating one line of Federal Circuit cases "says that one mode necessarily enables the claims" while acknowledging the confusion and imprecision surrounding the terms "mode" and "embodiment"); *See also* Sean B. Seymore, *The Enablement Pendulum Swings Back,* 6 NW. J. TECH. & INTELL. PROP. 278, 282 (2008) [hereinafter *Enablement Pendulum*].

104. *Doctrinal Structure*, *supra* note 53, at 1685 (quoting Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991)).

105. *Id.* at 1687; *see Enablement Pendulum*, *supra* note 103, at 282.

106. *Doctrinal Structure*, *supra* note 53, at 1692–93.

107. Synthes v. Spinal Kinetics, 734 F.3d 1332, 1344 (Fed. Cir. 2013) (internal quotation marks omitted) (quoting Bilstad v. Wakalopulos, 386 F.3d 1116, 1124–25 (Fed. Cir. 2004)).

108. *Id.* at 1345 (emphasis in original).

109. Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007) (rejecting the patentee's argument of single-embodiment enablement).

110. Trs. of Boston Univ. v. Everlight Elecs. Co., 896 F.3d 1357, 1364 (Fed. Cir. 2018) (collecting cases).

111. Pfizer Inc. v. Teva Pharms. USA, Inc., 555 Fed. Appx. 961, 967 (Fed. Cir. 2014).

the claims because it would have required undue experimentation to synthesize and test tens of thousands of candidates to determine which candidates exhibited the claimed functionality.[112] In *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*, the court held that the specification failed to teach the PHOSITA which structures would produce the claimed functional properties, even assuming the specification taught how to create the broad range of structures covered by the claims.[113] Similarly, in *Idenix*, the court found nonenablement because screening billions of nucleoside candidates to identify functional compounds with efficacy against hepatitis C virus would be akin to finding "a needle in a haystack."[114] It is worth noting that the claims in these three cases all pertained to unpredictable arts and all contained both structural and functional limitations and they were all struck down because the Federal Circuit decided that satisfying the functional limitation would take undue experimentation.[115]

The full-scope enablement requirement has also been imposed in cases from predictable arts. *Liebel-Flarsheim Co. v. Medrad, Inc.* involved a high-pressure medical injection system.[116] The Federal Circuit rejected the patentee's single-embodiment enablement argument and held that the patent did not enable an injector without a pressure jacket because the specification did not provide an enabling description of a jacketless injector, and it called a jacketless injector "expensive" and "impractical."[117] A few months later, in *Automotive Technologies International, Inc. v. BMW of North America, Inc.*, the court held that the disputed patent claiming automotive side impact crash sensors did not enable an electric sensor.[118] Next, in *Sitrick v. Dreamworks, LLC*, where the claimed invention concerned integrating a user's audio signal or video image into a preexisting video game or movie, integrating into movies was not enabled.[119] More recently, a patent relating to a semiconductor device was found invalid because it enabled only "five out of the six referenced permutations."[120] Once more, the Federal Circuit reiterated: "The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement."[121]

112. 720 F.3d 1380 (Fed. Cir. 2013).
113. 928 F.3d 1340 (Fed. Cir. 2019).
114. 941 F.3d 1149, 1162 (Fed. Cir. 2019).
115. *Amgen III*, 987 F.3d 1080, 1086–87 (Fed. Cir. 2021).
116. 481 F.3d 1371, 1373–74 (Fed. Cir. 2007).
117. *Id.* at 1379.
118. 501 F.3d 1274, 1276–77 (Fed. Cir. 2007).
119. 516 F.3d 993, 995, 1000–01 (Fed. Cir. 2008).
120. Trs. of Bos. Univ. v. Everlight Elecs. Co., 896 F.3d 1357, 1364 (Fed. Cir. 2018).
121. *Id.* (quoting Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195-96 (Fed. Cir. 1999)).

3. Reconciliation of Single-Embodiment Enablement and Full-Scope Enablement

In both lines of cases, the blackletter law is the same. Both doctrines serve the same goal: to ensure compliance with the enablement requirement. At least two theories have been advanced to reconcile single-embodiment enablement and full-scope enablement.

In one theory, Professor Rantanen argued that the two lines of cases emerged as a result of target articulation.[122] When enablement is challenged in courts, the underlying principle is simple: "for any given target, at least one way of making and using it must be taught, but at least one way of making and using every target must be taught."[123] If a patent challenger articulates only a single target that allegedly is not enabled by the patent at issue, then the case is a single-embodiment enablement case.[124] Alternatively, a patent challenger can articulate multiple targets; when they do so, each and every target must be enabled, giving rise to full-scope enablement cases.[125] For example, in *Automotive Technologies*, one target was mechanical side impact sensors, and the other one was electronic side impact sensors, and the latter target was not enabled.[126] As to how to determine targets, Professor Rantanen summarized that multiple targets tend to associate with a genus "viewed as being made up of identifiable" species and single target may be raised when the "genus is viewed as a set of common characteristics."[127] Furthermore, purely functional claims often give rise to multiple targets representing alternative structures providing the function.[128]

A more popular theory proposes that single-embodiment enablement and full-scope enablement are separate enablement standards courts apply to inventions in the predictable arts and unpredictable arts,[129] although the Federal Circuit denies so.[130] In applied sciences, a single embodiment may sufficiently enable the invention.[131] By contrast, in unpredictable arts, "where a slight variation in a method can yield an unpredictable result or may not work at all," single-embodiment enablement is not enough.[132] For example, in chemical art, "a single species can rarely, if ever, afford sufficient support

122. *Doctrinal Structure*, *supra* note 53, at 1704.

123. *Id.* at 1707 (emphasis omitted).

124. *See*, *e.g.*, Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1361 (Fed. Cir. 1998) (finding one way to produce CD34 antibodies, the single target, satisfied the enablement requirement).

125. *Doctrinal Structure*, *supra* note 53, at 1705–06.

126. Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1282–83 (Fed. Cir. 2007).

127. *Doctrinal Structure*, *supra* note 53, at 1712.

128. *Id.*

129. *See*, *e.g.*, *Technology-Specific*, *supra* note 46, at 1156; *Enablement Pendulum*, *supra* note 103, at 282.

130. *See* Amgen Inc. v. Sanofi (*Amgen I*), 872 F.3d 1367, 1378–79 (Fed. Cir. 2017).

131. *See*, *e.g.*, *Cedarapids, Inc. v. Nordberg, Inc.,* No. 95-1529, 1997 WL 452801 (Fed. Cir. Aug. 11, 1997) (finding enablement for a method claim for increasing the productivity of a rock crusher while the specification only disclosed the method pertaining to a seven-foot rock crusher).

132. *Id.* at *2.

for a generic claim."[133] Nonetheless, the court recognized: "It is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species."[134] Therefore, single-embodiment enablement is not different from the full-scope enablement: as long as the disclosure, with one or more disclosed embodiments, allows the PHOSITA to make and use the invention without undue experimentation, the enablement requirement is satisfied.

Understandably, enablement depends on the nature of the technical field, just like reasonableness on the circumstances in tort cases. This theory explains why the full-scope enablement is most often found in cases from unpredictable arts, but it has been undermined by the Federal Circuit's imposition of the full-scope enablement requirement on genus claims in predictable arts.[135] So maybe we should not think of the line between predictable arts and unpredictable arts as a hard, inflexible indicator of when single-embodiment enablement versus full-scope enablement requirement should be applied. Other factors, such as the size of the genus, also play

a role in the enablement analysis.[136] If a patent enables a single embodiment but not other covered embodiments, regardless of the field being predictable or unpredictable, the patent is invalid for nonenablement.

4. Doctrinal Drift in Enablement?

Professors Karshtedt, Lemley, and Seymore claim that over the past 30 years, courts have raised the bar of enablement.[137] Now the new full-scope enablement requirement presents a "nearly insurmountable" hurdle for genus claims because the enablement inquiry has drifted from "did I teach you enough such that you can make use of the full scope of the invention?" to "did I give you enough information to assess the full list of what works and what doesn't without undue experimentation?"[138] The alleged doctrinal drift has most impact in chemistry, pharmaceutical, and biotechnology industries, where the Federal Circuit regularly struck down genus claims for nonenablement.[139]

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133. *In re* Shokal, 242 F.2d 771, 773 (C.C.P.A. 1957).

134. *In re* Grimme, 274 F.2d 949, 952 (C.C.P.A. 1960).

135. Bernard Chao, *Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule*, 2009 STAN. TECH. L. REV. 3, ¶ 7 (2009) [hereinafter *Rethinking Enablement*] (commenting that "*Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* take the existing split in Federal Circuit law and pry it even further open").

136. *Shokal*, 242 F.2d at 773 (recognizing the number of species needed to establish a genus would vary in each case, e.g, a larger number for a larger genus).

137. *Genus Claim*, *supra* note 9, at 1, 62.

138. *Id.* at 35, 62.

139. *Id.* at 3–4.

But is that really so? Patentees were "*not* required to disclose *every species* encompassed by their claims even in an unpredictable art,"[140] and they are still not required to do so today.[141] To be sure, it was never the law that enablement was satisfied when the PHOSITA was only enabled to make and use *a part* of the invention.[142] Enablement always requires enablement across the full scope of the invention.[143]

I think there are other reasons for the apparent doctrinal drift. As with any legal doctrine, courts' applications of enablement law are not always uniform. Further exacerbating the application inconsistencies, the Federal Circuit has 12 judges, who mostly hear cases in three-judge panels.[144] By comparison, the predecessor of the Federal Circuit was a five-judge CCPA, which decided every case en banc.[145]

For an enablement challenge, patent challengers "routinely" must identify some embodiment(s) within the claim that is not enabled, including specific products or processes and experimentation required to make and use such products or processes.[146] With this, the breadth of the claim can be "shown concretely and not just as an abstract possibility."[147] For example, a district court rejected the alleged infringer's motion for summary judgment of nonenablement absent "a concrete example or description of the content allegedly covered but not enabled" notwithstanding the functional claim term, rationalizing that enablement challenges were "typically presented with reference to a dispute over the relevant support for a concrete embodiment or genus."[148] But the lack of such a showing did not matter in *Amgen*. There, the Federal Circuit affirmed the district court's finding of

140. *In re* Angstadt, 537 F.2d 498, 503 (C.C.P.A. 1976) (emphasis in original).

141. *Amgen III*, 987 F.3d 1080, 1085 (Fed. Cir. 2021) (internal quotation marks omitted) ("[A] specification does not need to describe how to make and use every possible variant of the claimed invention."). The Supreme Court confirmed. *See Amgen IV*, 598 U.S. 594, 615–16 (2023) (disagreeing with Amgen's interpretation of the Federal Circuit's opinions).

142. *See*, *e.g.*, *Amgen IV*, 598 U.S. at 610 ("The more one claims, the more one must enable."); Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47, 57 (1938) ("[T]he patent monopoly does not extend beyond the invention described and explained as the statute requires . . . ."); 35 U.S.C. § 112(a) ("to make and use the same").

143. *See*, *e.g.*, *Amgen IV*, 598 U.S. at 610 ("[T]he specification must enable the full scope of the invention as defined by its claims."); AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("[A]s 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."); *In re* Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983) (holding that "the enabling disclosure of the specification [must] be commensurate in scope with the claim under consideration"); *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (stating that "the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification").

144. *See Rethinking Enablement*, *supra* note 135, at ¶¶ 53–55 (observing some judges are responsible for decisions on both sides of the single-embodiment/full-scope enablement split).

145. *Doctrinal Structure*, *supra* note 53, at 1694, 1697.

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

147. *Id.*

148. Honeywell Int'l Inc. v. ICM Controls Corp., 45 F. Supp. 3d 969, 980–81 (D. Minn. 2014).

nonenablement, acknowledging the challenger's failure to identify any antibody that could not be made by following the specification's teachings.[149]

5. Case Analysis: Wands and Amgen

An in-depth analysis of two cases—*Amgen* and *Wands*—illustrates how the *Amgen* court and the *Wands* court analyzed enablement differently. Although both cases concerned monoclonal antibodies and broad claims with functional limitations, they reached opposite outcomes.

In *Amgen*, the Federal Circuit affirmed the district court's finding of nonenablement based on several *Wands* factors: the scope of the claim, the predictability of the field, and the guidance provided by the specification.[150] In particular, the claim scope was broad because of the claims' functional limitations.[151] The court further emphasized that where a claim has both structural and functional limitations, undue experimentation can include undue experimentation in identifying, from the structurally identified compounds, those that satisfy the functional limitation.[152]

In *Wands*, the disputed patent involved "immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM isotype."[153] The Federal Circuit reversed the finding by the USPTO that undue experimentation would be required because the "production of high-affinity IgM anti-HBsAg antibodies [was] unpredictable and unreliable."[154] The *Wands* court found no undue experimentation because (1) the patent application provides "considerable direction and guidance on how to practice" the invention as well as working examples, (2) "[t]here was a high level of skill in the art at the time when the application was filed," and (3) "all of the methods needed to practice the invention were well known."[155]

The tension between *Amgen* and *Wands* may be derived both from inconsistent applications of the enablement doctrine and the facts of each case, including the invention, the art, and the evidence presented to the court.[156] First, although the *Wands* court did not directly address the breadth of the claims, the claims were somewhat different in *Wands* and *Amgen*.[157] The

149. *See Amgen III*, 987 F.3d 1080, 1082, 1085 (Fed. Cir. 2021).

150. *Id.* at 1087–88.

151. *Id.* at 1087.

152. *Id.* at 1086–87 (citing McRO, Inc. v. Bandai Namco Games Am. Inc., 959 F.3d 1091, 1100 n.2 (Fed. Cir. 2020)).

153. *In re* Wands, 858 F.2d 731, 733 (Fed. Cir. 1988).

154. *Id.* at 735.

155. *Id.* at 740.

156. *See Amgen III*, 987 F.3d at 1088.

157. The district court questionably tried to distinguish *Wands* from *Amgen* on the ground of claim type (method claims in *Wands* v. genus claims in *Amgen*). Amgen Inc. v. Sanofi (*Amgen II*), No. 14-1317-RGA, 2019 U.S. Dist. LEXIS 146305, at *24 n.8 (D. Del. Aug. 28, 2019). In any event, the district

claims in *Amgen* were purely functional, whereas those in *Wands* arguably contained a structural limitation—the claimed antibodies were IgM, a particular isotype of antibodies—in addition to defining the antibodies by their function—binding to hepatitis B surface antigen with high affinity. Thus, the claims in *Wands* were narrower in scope than the claims in *Amgen*. However, this difference is probably not important because no antibody sequences were claimed, and even with IgM antibodies, the claim scope was still broad.

Second, the courts viewed the antibody field differently. The *Wands* court acknowledged that methods for obtaining and screening monoclonal antibodies were well known in 1980.[158] The court was not shy of testing—routine screening to identify the covered antibodies from candidates—needed.[159] But the *Amgen* court deviated from the *Wands* court. While the district court recognized the methods disclosed in the patent were routine and well-known and the PHOSITA would be familiar with those methods, the court concluded that the art was unpredictable because testing was needed to determine if a particular antibody had the claimed function.[160] And the Federal Circuit agreed.[161]

Third, the two cases presented different arguments. The patent applicant in *Wands* conceded the first four fusions to produce hybridoma were failures but contended that they failed because they were not skilled in the art.[162] "Once they became skilled in the art, they invariably obtained numerous hybridomas that made high-binding antibodies against HBsAg and, in each fusion where they determined isotype and binding affinity they obtained hybridomas that fell within the claims."[163] Furthermore, the *Wands* court noted that "[n]o evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen."[164]

By contrast, the *Amgen* court recognized "the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods" despite evidence that "a small subset of examples of antibodies can predictably be generated."[165] This, coupled with the millions of antibody candidates within the scope of the claims and narrow guidance and examples in the specification, led the court to

court in *Amgen II* correctly observed that a finding of enablement in *Wands* did not mean all patents in the context of antibody technology were enabled. *Id.*

158. *Wands*, 858 F.2d at 736.

159. *Id.* at 740 ("The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody.").

160. *Amgen II*, 2019 U.S. Dist. LEXIS 146305, at *23–28.

161. *Amgen III*, 987 F.3d at 1087.

162. *Wands*, 858 F.2d at 739.

163. *Id.*

164. *Id.* at 740.

165. *Amgen III*, 987 F.3d at 1087–88.

conclude that it "would take a substantial amount of time and effort," thus would be undue experimentation, to discover undisclosed, claimed antibodies.[166]

Besides the different facts of the two cases, the most important reason for the different outcomes lies in the evaluation of required experimentation. The *Wands* court warned that "in the monoclonal antibody art it appears that an 'experiment' is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen," which "entails immunizing animals, fusing . . . cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics."[167] The *Wands* court went on to emphasize that the patent applicant successfully carried out the entire procedure three times and obtained at least one covered antibody each time.[168]

But the *Amgen* court did not heed the *Wands* court's warning. Instead, the *Amgen* court focused only on screening, noting the lack of a structure-function relationship.[169] Indeed, a key to the district court's decision seemed to be that the PHOSITA searching for a claimed but undisclosed antibody through random generation[170] "would have to do essentially the same amount of work as the inventors."[171] Furthermore, "even conservative substitutions may have unexpected results,"[172] and there was no testimony "that every antibody within the scope of the claims could be made through *intelligent* substitution."[173] This difference in the experimentation examined explains not only why the *Amgen* court viewed the field as unpredictable, but also its decision that undue experimentation was required for the discovery of undisclosed antibodies.[174]

Maybe the *Amgen* court did what it did just to reach the conclusion because of its concerns with functional claims.[175] The concerns are justified, but the fluctuations in court's evaluation of enablement cast doubt not only on the law itself, but also on the survivability of genus claims.

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166. *Id.* (quoting *Amgen II*, No. 14-1317-RGA, 2019 U.S. Dist. LEXIS 146305, at *34 (D. Del. Aug. 28, 2019))

167. *Wands*, 858 F.2d at 740.

168. *Id.*

169. *Amgen III*, 987 F.3d at 1087–88.

170. In random generation, antibodies are generated "de novo according to a randomization-and-screening roadmap" provided in the patent specification. *Id.* at 1088 (internal quotation marks omitted).

171. *Amgen II*, 2019 U.S. Dist. LEXIS 146305, at *34 (quoting MorphoSys AG v. Janssen Biotech, Inc., 358 F. Supp. 3d 354, 372 (D. Del. 2019)).

172. *Id.* at *36. In conservative substitution, an amino acid in an antibody (most likely one involved in antigen binding) is replaced with one of its conservative counterparts (amino acids with similar properties).

173. *Id.* at *20 (emphasis added).

174. The Supreme Court sided with the lower courts by calling these two approaches—random generation and conservative substitution—"research assignments" or "hunting license[s]," *Amgen IV,* 598 U.S. 594, 614 (2023) (quoting Brenner v. Manson, 383 U.S. 519, 536 (1966)). .

175. *See id.* at 1257 ("[W]e review judgments of the lower courts, not statements in their opinions.").

III. SOLVING THE GENUS CLAIM PROBLEM

Considering the importance of the genus claims, especially in chemistry, pharmaceutical, and biotechnology fields, the decried "death of the genus claim" is

certainly not a good thing.176 Therefore, there is a need for a better approach to evaluate patent disclosure sufficiency with respect to genus claims. As discussed above, genus claims may contain structural or functional limitations, and sometimes both; a genus claim that contains only functional limitations is qualitatively different from a genus claim that contains at least one structural limitation, with or without functional limitations.177 To address the enablement of genus claims, I propose a bifurcated approach.

A. Functional Genus Claims

A functional claim recites an invention only by what it does rather than by what it is. This shows how broad a functional can be: it covers all means that achieve an end. The harm is obvious: all improvements on existing means and all design-arounds are preempted.[178]

1. Functional Claiming

Patent law disfavors functional claims. "A claim covers and secures a process, a machine, a manufacture, a composition of matter, or a design, but *never* the function or result of either . . . ."[179] But functional claiming is not new. Famously, the Supreme Court in the 1940s held functional claims inconsistent with the policies underlying the patent law.[180] Before and after that, courts repeatedly ruled functional claims invalid.[181]

Much has been written about functional claiming.[182] Functional claiming is particularly prevalent in software patents,[183] and it is not uncommon in the pharmaceutical and biotechnology fields.[184] Take *Amgen* as an

176. *Genus Claim*, *supra* note 9, at 4.

177. *See supra* Section II.A.

178. *See*, *e.g.*, O'Reilly v. Morse, 56 U.S. 62, 113 (1853). The patent in *Morse* related to Morse's invention of the single-wire telegraph. There, the Court rejected a broad claim, reasoning that allowing such a functional claim would permit the patent to cover future inventions of a "mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of [Morse's] process." *Id.*

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

180. *See* Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1, 11–13 (1946).

181. *See*, *e.g.*, *Morse*, 56 U.S. at 113; *In re* Hyatt, 708 F.2d 712, 715 (Fed. Cir. 1983).

182. *See*, *e.g.*, *Paradox*, *supra* note 3; *Software Patents*, *supra* note 38.

183. *Software Patents*, *supra* note 38, at 905.

184. *See*, *e.g.*, Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340, 1358 (Fed. Cir. 2010); AbbVie Deutschland GmbH v. Janssen Biotech, Inc., 759 F.3d 1285, 1291–92 (Fed. Cir. 2014) (claim directed to fully human antibodies that bind to and neutralize the activity of human interleukin 12, which can cause psoriasis and arthritis); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 918 (Fed. Cir. 2004) (claim directed to a method of selectively inhibiting the COX–2 enzyme by administering

example. The three claims at issue,[185] claims 19 and 29 of U.S. Patent 8,829,165 and claim 7 of U.S. Patent 8,859,741 patent, were all purely functional claims.[186] Compare them with the following antibody claim:

> 15. An isolated neutralizing human monoclonal antibody that binds to a PCSK9 protein comprising:
>
> a heavy chain polypeptide comprising the following complementarity determining regions (CDRs): a heavy chain CDR1 that is a CDR1 in SEQ ID NO: 67; a heavy chain CDR2 that is a CDR2 in SEQ ID NO: 67; a heavy chain CDR3 that is a CDR3 in SEQ ID NO: 67; and
>
> a light chain polypeptide comprising the following CDRs: a light chain CDR1 that is a CDR1 in SEQ ID NO: 12; a light chain CDR2 that a CDR2 in SEQ ID NO: 12; and a light chain CDR3 that is a CDR3 in SEQ ID NO: 12,wherein each CDR is defined in accordance with the CDR definition of Kabat.[187]

This claim is undoubtedly narrower in scope, containing both functional ("binds to a PCSK9 protein") and structural limitations (e.g., heavy chain and light chain sequences).

Functional claims are often invalidated for failing to meet enablement, such as the claims in *Amgen*.[188] As the Federal Circuit summarized, "the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short."[189] The court also acknowledged that

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a non-steroidal compound that selectively inhibits the COX–2 enzyme); Regents of the Univ. of Calif. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997) (claim directed to recombinant plasmids and microorganisms that produce insulin).

185. *Amgen III*, 987 F.3d 1080, 1082 (Fed. Cir. 2021).

186. The relevant '165 patent claims are:

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR;
>
> 19. The isolated monoclonal antibody of claim 1 wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3;
>
> 29. A pharmaceutical composition comprising an isolated monoclonal antibody, wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO: 3 and blocks the binding of PCSK9 to LDLR by at least 80%;

The relevant '741 patent claims are:

> 1. An isolated monoclonal antibody that binds to PCSK9, wherein the isolated monoclonal antibody binds an epitope on PCSK9 comprising at least one of residues 237 or 238 of SEQ ID NO: 3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR;
>
> 2. The isolated monoclonal antibody of claim 1, wherein the isolated monoclonal antibody is a neutralizing antibody;
>
> 7. The isolated monoclonal antibody of claim 2, wherein the epitope is a functional epitope;

187. U.S. Pat. No. 8,168,762, claim 15.

188. *Amgen III*, 987 F.3d 1080, 1082 (Fed. Cir. 2021).

189. *Id.* at 1086.

"functional claim limitations . . . pose high hurdles in fulfilling the enablement requirement for claims with broad functional language."[190]

A functional claim can also fail the written description requirement, which requires "a description of an invention, not an indication of a result that one might achieve if one made that invention."[191] This is because a functional claim "does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus."[192] Accordingly, the Federal Circuit affirmed the invalidity of a claim reciting cDNA encoding insulin, which "does not distinguish the claimed genus from others, except by function."[193]

2. Means-Plus-Function (MPF) Claiming

Congress has spoken with respect to functional limitations. In the Patent Act of 1952, MPF claiming was first introduced and remains in the current Patent Act.[194] 35 U.S.C. Section 112(f) provides:

> An element in a claim for a combination may be expressed as a *means* or step for performing a specified *function* without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.[195]

Thus, when an element in a combination claim (a claim with at least two elements) is written in functional terms, it is limited to the particular means of implementation (i.e., structure, material, or acts) disclosed by the patentee in the specification and the equivalents of the disclosed means. This allows a patentee to claim an invention based on functionality without allowing them to own the function itself.

Although MFP claiming is disfavored because it narrows the claim scope, the doctrine of equivalents helps protect a patentee because an MPF limitation covers equivalents of the "structure, material, or acts described in the specification."[196] Importantly, an MPF claim implicates the doctrine of equivalents on two layers. On the first layer, the disclosed embodiments and

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190. *Id.* at 1087.

191. *See* Regents of the Univ. of Calif. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997).

192. *Id.*

193. *Id.*

194. There seems to be a disagreement of the effect of Section 112(f) on the Supreme Court precedent *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946). *Compare Paradox*, *supra* note 3, at 1056 (arguing Congress reversed *Halliburton* by allowing MPF claiming), *with* Brief for HTIA, *supra* note 5, at 28 (arguing Congress codified *Halliburton* with the same statute).

195. 35 U.S.C. § 112(f) (emphasis added). The language is identical to Section 112, ¶ 6 of the Patent Act of 1952.

196. *Id.*

their equivalents infringe an MPF claim. On top of that, one can apply the doctrine of equivalents, e.g., when the function is similar but not identical, to determine if there is infringement by equivalents.[197]

There are two tests under the doctrine of equivalents. One is the "function-way-result" test, asking whether the feature of an accused product performs substantially the same function in substantially the same way to achieve substantially the same result as the claim element.[198] The other is the "insubstantial differences" test, asking whether the differences between the claim element and the feature of the accused product are insubstantial or not.[199] Between the two, the insubstantial differences test is less used because there is no clear standard for when a difference is substantial or insubstantial.[200]

The recitation of the word "means" (or "step") is not dispositive in deciding whether MPF claiming applies.[201] The inquiry is whether the words of the claim are understood by the PHOSITA to "have a sufficiently definite meaning as the name for structure."[202] Nonetheless, the presence or absence of the word "means" invokes one of the two presumptions. The use of the word "means" creates a presumption that Section 112(f) applies;[203] this is overcome by reciting sufficient structure in theclaim.[204] Conversely, where the claim does not recite the word, the presumption is that the limitation does not invoke Section 112(f).[205] This presumption is surmountable if the claim "fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function."[206] Moreover, the Federal Circuit abandoned the characterization of this latter presumption as "strong" and the requirement of "a showing that the limitation essentially is devoid of anything that can be construed as structure" to rebut the presumption.[207]

3. Proposal for Functional Claims

I propose the evaluation of claims with only functional limitations as MPF claims under Section 112(f), regardless of whether the claims recite the

197. *Paradox*, *supra* note 3, at 1058 n.410.

198. Abbott Lab'ys v. Sandoz, Inc., 566 F.3d 1282, 1296 (Fed. Cir. 2009).

199. *Id.* at 1297.

200. MASUR & OUELLETTE, *supra* note 21, at 357.

201. Cole v. Kimberly–Clark Corp., 102 F.3d 524, 531 (Fed. Cir. 1996) (stating that presence or absence of the word "means" does not "automatically" make or prevent application of MPF claiming).

202. Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (citing Greenberg v. Ethicon Endo–Surgery, Inc., 91 F.3d 1580, 1583 (Fed. Cir. 1996)).

203. *Personalized Media Commc'ns, LLC v. ITC,* 161 F.3d 696, 703 (Fed. Cir. 1998).

204. TriMed, Inc. v. Stryker Corp., 514 F.3d 1256, 1259 (Fed. Cir. 2008).

205. *Personalized Media,* 161 F.3d at 703–04.

206. *Williamson*, 792 F.3d at 1348 (internal quotation marks omitted) (citing Watts v. XL Sys., Inc., 232 F.d 877, 880 (Fed. Cir. 2000)).

207. *Id.* at 1349 (overruling precedent).

term "means." A similar proposal has been written for software patents[208] and antibody patents[209]

However, there is a caveat: Section 112(f), on its face, can only be applied to combination claims, but not single-means claims.[210] A single-means claim is a claim with one and only one limitation that is an MPF limitation, whereas a combination claim contains more than one limitation. Among the three disputed claims in *Amgen*, one is a combination claim, whereas the other two are single-means claims. So, Section 112(f) would only save the combination claim but not the two single-means claims in *Amgen*. "The long-recognized problem with a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those means known to the inventor."[211] Then a court would reject single-means claims under Section 112(a) just for being single-means claims.[212]

Under the proposed approach, MPF claiming applies to combination as well as single-means claims. There does not seem to be any conceptual obstacle in applying MPF construction to single-means claims.[213] Indeed, as one court acknowledged, single-means claims "are not explicitly prohibited by statute or common law"; they are prohibited only because Section 112(f) provides that "[a]n element in a claim *for a combination* may be expressed as a means or step for performing a specific function."[214]

With the proposed approach, one limits the three functional claims in *Amgen* to the disclosed antibodies in the respective patents and their equivalents. For instance, an antibody obtained through conservative substitution of a disclosed antibody that meets the functional limitations is likely an

208. *Software Patents*, *supra* note 38, at 943–48.

209. *Paradox*, *supra* note 3, at 1055–61. While this cited article recommends patentees write claims in the traditional MPF format (i.e., with the word "means") to invoke Section 112(f), in my proposal, the format does not matter. What matters is whether the claim is a purely functional claim.

210. *In re* Hyatt, 708 F.2d 712, 715 (Fed. Cir. 1983) (affirming the rejection of a single-means claim for nonenablement and clarifying that the MPF provision of Section 112 saves combination claims from undue breadth, but not single-means claims).

211. *Id.* at 714 (declaring single-means claims had been "regarded as improper" since O'Reilly v. Morse, 56 U.S. 62, 112 (1853)).

212. Single-means claims can also be invalid for failing to satisfy the written description requirement. Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (claiming all DNA encoding a specific protein).

213. *See* Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1318 (Fed. Cir. 1999) ("[W]hen it is apparent that the [claim] element invokes purely functional terms, without the additional recital of specific structure or material for performing that function, the claim element may be a means-plus-function element despite the lack of express means-plus-function language.")

214. Enfish, LLC v. Microsoft Corp., 9 F. Supp. 3d 1126, 1127–28 (C.D. Cal. 2014) (emphasis in original) (quoting 35 U.S.C. § 112(f)).

equivalent covered under MPF claiming. The substituted antibody (containing only one or a few substitutions) is structurally similar to the disclosed antibody; it may bind to the same residues on the antigen with similar affinity—thus performing substantially the same function in substantially the same way to achieve the same result as the disclosed antibody. On the other hand, antibodies binding more or different residues, such as the competitors' antibodies in *Amgen*,[215] are probably not equivalents (at least for failing the same way requirement) even though they meet the functional limitations, and competitors could sell those antibodies without infringing the patents.

This approach gives something to each side of the patent bargain. A patentee at least has a claim not invalidated in court for nonenablement and enjoys protection against literal infringement and infringement by equivalents. With this, the patent law preserves some incentive for patentees, and the public can rest assured that the future is not preempted. This approach also does not offend full-scope enablement. By narrowing the scope of a functional claim to the specific means disclosed in the specification, the full-scope enablement requirement becomes easy to meet.

As a last note, surprisingly or maybe even incredibly, the functional claims at dispute in *Amgen* had survived patent prosecution, and the district court did not construct the claims or apply Section 112(f).[216] Instead, the district court and the Federal Circuit examined these claims as regular genus claims.[217]

B. Structural Genus Claims

If a claim contains any structural limitation, even if it also contains one or more functional limitations, the proposed approach incorporates the inoperative embodiments doctrine.[218] The inoperative embodiments doctrine is a less prominent enablement doctrine compared to the single-embodiment and full-scope enablement doctrines. Under the inoperative embodiments doctrine, a broad claim that covers inoperative species is not necessarily invalid as long as enough of the subject matter works as described.[219]

215. Brief for Respondents at 15, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757) (examples of such antibodies).

216. Brief for HTIA, *supra* note 5, at 20–22, 28–32.

217. *See Amgen III*, 987 F.3d 1080, 1085–86 (Fed. Cir. 2021) (citing only cases involving claims with both functional and structural limitations).

218. Of course, Section 112(f) may still apply to a structural genus claim, depending on claim elements. But on top of that, the proposed approach applies to the claim as a whole.

219. *Genus Claim*, *supra* note 9, at 11.

1. The Inoperative Embodiments Doctrine

Under the inoperative embodiments doctrine, a claim is not invalid merely because some of the claimed embodiments are inoperative.[220] Without this doctrine, an inventor may be required "to carry out a prohibitive number of actual experiments," which could discourage them "from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed."[221]

Several factors are relevant to the inoperative embodiments doctrine: nature of the subject matter (predictable v. unpredictable), the PHOSITA's level of skill, and the number of inoperative embodiments.[222] With respect to the last factor, case law is not clear about how many inoperative embodiments are too many for the claim validity analysis. On the one hand, the CCPA explained that there is "nothing wrong" with genus claims that encompass "vast numbers of inoperative embodiments," "so long as it would be obvious to one of ordinary skill in the relevant art how to . . . make the embodiment operative rather than inoperative."[223] This is because it "is not a function of the claims to specifically exclude . . . possible inoperative substances."[224] On the other hand, a claim may be too broad "to the point of invalidity" for including a significant number of inoperative embodiments."[225] If "the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid."[226]

The inoperative embodiments doctrine is patentee-friendly.[227] It incentivizes disclosure, provides more desirable protection for patentees, and makes the prosecution process more manageable.[228] In particular, during litigation where claims cannot be amended, the doctrine reflects "the court's reluctance to permit an infringer to raise an invalidity defense" after a diligent search for one or more inoperative embodiments.[229]

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220. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984).

221. *In re* Angstadt, 537 F.2d 498, 502–03 (C.C.P.A. 1976).

222. *Genus Claim*, *supra* note 9, at 11.

223. *In re* Cook, 439 F.2d 730, 735 (C.C.P.A. 1971) (explaining that the claims were not too broad because the PHOSITA could figure out what would be inoperative with "no more effort than is normally required of a lens designer checking out a proposed set of parameters").

224. *Atlas Powder*, 750 F.2d at 1576 (quoting *In re* Dinh-Nguyen, 492 F.2d 856, 858–59 (C.C.P.A. 1974)).

225. Graver Tank & Mfg. Co. v. Linde Air Products Co., 336 U.S. 271, 276–77 (1949) (agreeing with the district court that the claims were too broad because only nine metallic silicates were proven operative while the claims read on all silicates or all metallic silicates).

226. *Atlas Powder*, 750 F.2d at 1576–77.

227. *Around Failure*, *supra* note 37, at 1167.

228. *Id.* at 1170.

229. *Id.* at 1168; *see also Rethinking Enablement*, *supra* note 135, at ¶¶ 64–71 (arguing the full-scope enablement is subject to litigation abuse).

Admittedly, the doctrine of inoperative embodiments is in tension with the full-scope enablement doctrine.[230] The very existence of inoperative embodiments means enablement short of the full scope—how is an embodiment that does not work enabled? But I think the doctrine of inoperative embodiments is a practical doctrine consistent with the patent bargain. The inoperative embodiments represent a "no harm, no foul" situation; if some inoperative embodiments are incidental to an otherwise valid claim, exclusive rights of these inoperative embodiments cause no harm because no one wants to do something that is inoperative. Undue experimentation is still the key here—as long as the PHOSITA can tell apart operative embodiments from inoperative embodiments without undue experimentation, the patent bargain is not undermined. Moreover, full-scope enablement does not have to mean that every covered embodiment must be operative; as long as there are operative embodiments across the entire scope of the invention, full-scope enablement requirement is satisfied.

2. Proposal for Structural Claims

For a structural genus claim, the enablement inquiry should be: is it reasonably likely that the PHOSITA, by following the patent disclosure, can reach operative embodiments of the invention without undue experimentation? Remember a patentee only has to defeat a nonenablement challenge when raised, but not demonstrate full-scope enablement.[231] Therefore, if a patent challenger establishes that it is not reasonably likely that the PHOSITA can reach operative embodiments somewhere within the full scope of the invention without undue experimentation, the invention is not enabled. Implicitly, reaching an operative embodiment means the PHOSITA can make and use the embodiment. Also, if it takes undue experimentation to know which embodiments would work and which would not, the invention is not enabled.

This inquiry attempts to fill in the gap left by the case law: how many inoperative embodiments are too many?[232] The "reasonably likely" standard is flexible and avoids assigning a fixed numerical value. An easy case would be when operative embodiments and inoperative embodiments comprise discrete groups, e.g., only part of a range is operative,[233] or that the operative embodiments are unique within the scope of the claimed invention, such as bamboo as a light bulb filament compared to claimed carbonized fibrous or

230. *See Around Failure*, *supra* note 37, at 1168, 1171–72 (arguing the inoperative embodiments doctrine vitiates full-scope enablement and has been undermined by the Federal Circuit's move away from single-embodiment enablement towards full-scope enablement).

231. *Doctrinal Structure*, *supra* note 53, at 1703.

232. *See supra* Section III.B.1.

233. *See* AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("[W]hen a range is claimed, there must be reasonable enablement of the scope of the range.").

textile material[234] Such claims would fail for nonenablement. A trickier case would be when operative embodiments are interspersed with inoperative embodiments across the entire scope of the invention (e.g., at and between both ends of a range). In this scenario, forbidding a claim to cover any inoperative embodiment will no doubt make claim drafting extremely difficult, if not impossible. But even in this scenario, the proposed test will not be hard to apply because it falls within courts' expertise in determining reasonableness.

This approach considers the underlying policy considerations of patent law and tries to balance patentees' interests with the public's interests. For one, it polices claim scope. Reasonable likelihood supplies some predictability requested by the *Amgen* court.[235] It also aligns with the idea that the specification should provide guidance on the direction of experimentation.[236] But by asking for reasonable likelihood, the inquiry does not require absolute certainty.[237] It allows room for the unpredictability of the arts[238] and leaves sufficient incentive for inventors. The proposed solution also addresses Professor Chao's concern that an alleged infringer can always find inoperative embodiments.[239] So, a patent will not be invalidated just because a challenger comes forward with one or more unenabled embodiments; it is invalidated when the disclosure does not allow the PHOSITA to reach enabled embodiments with reasonable likelihood.

True, this inquiry is not much different from the traditional enablement inquiry. But there is no good reason to abandon the existing law. Even if the doctrinal drift in enablement has indeed happened,[240] the inquiry helps courts focus on the making and using of the invention—"operative embodiments" means the invention can be made and used—and resist "assess[ing] the full list of what works and what doesn't"[241] because the burden is on a patent challenger to show the lack of reasonable likelihood that the PHOSITA can reach an operative embodiment somewhere within the full scope of the invention. With this, the breadth of the claim can be shown concretely and not just as an abstract possibility.[242]

There are several things to keep in mind when making the inquiry. First, the fact that screening is needed cannot be dispositive of the inquiry. Requiring a clear structure-function relationship in an unpredictable art may be akin

234. *The Incandescent Lamp Case*, 159 U.S. 465 (1895).

235. *Amgen III*, 987 F.3d 1080, 1087–88 (Fed. Cir. 2021) (noting "the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods").

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

237. *See* Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 270 (1916) (requiring no "greater than is reasonable" for enablement).

238. *See In re* Angstadt, 537 F.2d 498, 503 (C.C.P.A. 1976) (recognizing that the term "experimentation" involves uncertainty).

239. *Rethinking Enablement*, *supra* note 135, at ¶ 78.

240. *See supra* Section II.C.4.

241. *Genus Claim*, *supra* note 9, at 62.

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

to requiring a disclosure to "transcend the level of knowledge" in the art.[243] Indeed, screening is necessary and is routinely performed by the PHOSITA in an unpredictable art.[244] The fact that a patentee has to screen for desired embodiments does not mean the PHOSITA cannot do so or has to spend less time doing so, unless the invention itself is directed to the process of screening or an apparatus used in screening.

Relatedly, when examining the experimentation required, it is the entire attempt to make and use the invention that is examined.[245] The undue experimentation inquiry cannot focus only on the screening part.[246] It is for this reason that although the claims in *Amgen* are problematic, they are not problematic because screening is needed or because of the amount of screening needed.[247] A reasonable likelihood that the PHOSITA can reach operative embodiments means the PHOSITA can make and use the invention after one entire attempt or only a few—not undue experimentation—by following the roadmap provided by the patentee.[248] This test ensures the patentee still has an obligation to render an enabling disclosure, even in the absence of a clear structure-function relationship.

Third, to the extent courts look to precedent for guidance, when evaluating the predictability of a field, scientific and technological developments should be taken into account. Even the unpredictable arts obtain predictability with time, so courts should examine and update their views of unpredictable arts periodically. Also, different unpredictable arts should not be treated the same. For example, the field of chemical catalysis have many "known unknowns," while the field of recombinant DNA technology when it was just emerging brought with it many "unknown unknowns".[249] With respect to the latter field, no one will question we have better understanding now compared with 1980s.[250] Moreover, more tools are at the PHOSITA's disposal now. High throughput screening can make screening faster, easier, and

243. *In re Angstadt*, 537 F.2d at 503.

244. *Id.* at 504 ("[The PHOSITA] would know how to perform processes within the scope of the claims, within the ambit of the types and amount of experimentation which the uncertainty of this art makes inevitable.").

245. *In re* Wands, 858 F.2d 731, 740 (Fed. Cir. 1988) (clarifying that the entire "process entails immunizing animals, fusing . . . cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics").

246. *See supra* Section II.C.2 for other cases where the court focused on screening.

247. *See supra* Section II.C.5.

248. *See Wands*, 858 F.2d at 739–40.

249. *Genus Claim*, *supra* note 9, at 25.

250. Another example is presented to explain the Federal Circuit's recent, apparent hostility towards functional antibody claims. Antibody claims are traditionally written as functional claims because it was not practical to define antibodies except by their antigens. With scientific developments, it has become easier to identify the sequences and other attributes of antibodies. *Paradox*, *supra* note 3, at 1044.

cheaper,[251] and computer programs are commonly used in intelligent design of molecules, although experimental confirmation is still needed.

C. Differentiating Functional and Structural Claims

The proposed approach bifurcates on the treatment of a genus claim depending on whether it is functional or structural. And this determination is a question of law to be resolved at the claim construction stage.[252] The good news is there does not seem to be great difficulties in differentiating functional claims and structural claims. In the event of doubt, one can resort to the test developed to determine whether Section 112(f) MPF construction applies to a claim limitation and analyze all claim elements under the test—whether the claim limitation recites, from the perspective of a PHOSITA, definite structure that performs the claimed function.[253] If "a claim recites a function, but then goes on to elaborate sufficient structure, material, or acts within the claim itself to perform entirely the recited function,"[254] the claim is not a functional one. "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure."[255] A court must examine the claim as a whole, as opposed to focusing on single words.[256]

Importantly, the recitation of structure in the claim, sufficient to avoid the classification as a functional claim, does not need to be explicit or specific.[257] In fact, a description of structure as commonly understood by the PHOSITA suffices.[258] It is also worth noting that not all structure recitation satisfies the "sufficient structure" requirement. For example, reciting structural location of the means for the function is not the same as reciting the

251. *Amgen II*, No. 14-1317-RGA, 2019 U.S. Dist. LEXIS 146305, at *33 (D. Del. Aug. 28, 2019) (testimony as to high-throughput screening).

252. *See Personalized Media Commc'ns, LLC v. ITC,* 161 F.3d 696, 702 (Fed. Cir. 1998).

253. Cole v. Kimberly-Clark Corp., 102 F.3d 524, 531 (Fed. Cir. 1996) (requiring "the alleged means-plus-function claim element must *not* recite definite structure which performs the described function").

254. Sage Products, Inc. v. Devon Industries, Inc., 126 F.3d 1420, 1427–28 (Fed. Cir. 1997).

255. TriMed, Inc. v. Stryker Corp., 514 F.3d 1256, 1259–60 (Fed. Cir. 2008).

256. Apex Inc. v. Raritan Computer, Inc., 325 F.3d 1364, 1374 (Fed. Cir. 2003) (reversing the district court's finding of MPF because it erroneously relied on single words of the limitation and emphasizing the limitation contained "additional adjectival qualifications further identifying sufficient structure to perform the claimed functions" to the PHOSITA).

257. *See Personalized Media*, 161 F.3d at 704 (finding the term "detector" a sufficient recitation of structure).

258. Mass. Inst. of Tech. v. Abacus Software, 462 F.3d 1344, 1356 (Fed. Cir. 2006) (internal quotations omitted) ("[I]t is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their function.").

structure for performing the function.[259] Neither is the recitation of structure only to assist in further specifying the function to be performed.[260]

In addition, case law has provided some specific guidance on how much structural recitation is needed. "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass."[261] For a genetic sequence, at least some nucleotide sequence is needed.[262] This can be achieved by either a recitation of the nucleotide sequences of a "representative number of cDNAs" in the genus or a recitation of one or more fragments of sequence common to the cDNAs in the genus.[263] For an antibody claim, mere recitation of the antigen may not be enough because the antibody-antigen relationship more aptly resembles "a lock and a ring with a *million* keys on it" instead of "a key in a lock."[264]

D. Impact of the Proposed Approach on the Written Description Requirement

Since enablement and written description are related requirements that often stand or fall together,[265] it is necessary to examine the impact of the proposed bifurcated solution on the written description requirement. Yet it is important to note that the proposed approach is designed to address enablement, so it does not apply directly to written description, a separate patentability requirement.

As discussed in Part III.A.1, functional claims often fail the written description requirement. Indeed, "[f]unctionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support," unless "a reasonable structure-function correlation is established."[266] Moreover, "merely drawing a fence around a perceived genus is not a description of the genus"; rather, it is "only a research plan."[267]

For functional claims, resorting to MPF claiming simultaneously narrows the claim scope for both enablement and written description analyses.

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259. Loral Fairchild Corp. v. Sony Corp., 181 F.3d 1313, 1328 (Fed. Cir. 1999) (affirming construction of the claim limitation as an MFP limitation because the structure recited in the limitation only described the *location* of the means element, but not the actual structure of the means element).

260. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1536 (Fed. Cir. 1991) (holding that a claim element reciting some structure can still be a means-plus-function element because the recited structure merely served to tell the function of the means, but not what the means was structurally).

261. Regents of the Univ. of Calif. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997).

262. *Id.* at 1568–69 (clarifying that "a cDNA is not defined or described by the mere name 'cDNA,' even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA.").

263. *Id.* at 1569.

264. *Amgen II*, No. 14-1317-RGA, 2019 U.S. Dist. LEXIS 146305, at *27 (D. Del. Aug. 28, 2019) (internal quotation marks omitted) (emphasis in original) (quoting *Amgen I*, 872 F.3d 1367, 1377 (Fed. Cir. 2017)).

265. *See supra* Section I.E.

266. AbbVie Deutschland GmbH v. Janssen Biotech, Inc., 759 F.3d 1285, 1301 (Fed. Cir. 2014).

267. *Id.* at 1300.

By limiting a functional claim to those embodiments disclosed in the patent plus their equivalents, the claim would not cover "an enormous number" of embodiments,[268] and the patent disclosure would provide a "precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials,"[269] as required by an adequate written description. Thus, the proposed approach helps functional claims meet written description requirement "especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus."[270]

While the proposed approach narrows the scope of functional claims, it may not have similar effects on structural claims. But the separate treatment of functional and structural genus claims may provide an incentive for patentees to move away from functional claims. Nonetheless, for structural genus claims, the proposed inquiry, by touching on the reasonably likely outcome of following a patent's guidance, can add confidence that the inventor(s) actually invented the claimed invention.

CONCLUSION

Genus claims are important, but one cannot ignore the concerns brought by the breadth of the genus claims. Genus claims are often invalidated on the enablement ground, and scholars lament a doctrinal drift in enablement that has raised the standard for genus claims. To better apply the enablement doctrine, I propose using a bifurcated approach. For functional genus claims, MPF claiming will apply, even if the claim is a single-means claim. For structural genus claims, a challenger has the burden to establish that it is not reasonably likely that the PHOSITA can reach operative embodiments somewhere within the full scope of the invention without undue experimentation. The proposed approach balances the competing policy considerations underlying the patent bargain—to reward patentees for their inventions and to guarantee the public will have complete possession of the inventions in exchange.

268. Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336 (2021).
269. Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010).
270. *AbbVie*, 759 F.3d at 1301.