*Harvard Journal of Law & Technology*
Volume 35, Number 1 Fall 2021

# THE DEATH OF THE GENUS CLAIM*

*Dmitry Karshtedt**, Mark A. Lemley*** & Sean B. Seymore*****

## ABSTRACT

The central feature of patent law in the chemical, biotechnology, and pharmaceutical industries is the genus claim — a patent claim that covers not just one specific chemical but a group of related chemicals. Genus claims are everywhere, and any patent lawyer will tell you they are critical to effective patent protection.

But as we show in this Article, the law has changed dramatically in the last thirty years, to the point where it is nearly impossible to maintain a valid genus claim. Courts almost always hold them invalid, either at trial or on appeal. Remarkably, courts do this without acknowledging that they've fundamentally changed an important area of law. More remarkably, it's not clear that patent lawyers and patent owners have noticed this shift. Invention, investment, patenting, and patent litigation continue much as they have before, but the genus patents that are thought to be the basis of this activity generally end up invalid.

We document this surprising shift in the law. We explain why we think it represents both bad law and bad policy. We also discuss why it hasn't seemed to matter to the relevant stakeholders, and what that fact says about the relevance of patent doctrine more generally.

---



** Associate Professor of Law, The George Washington University Law School.

*** William H. Neukom Professor, Stanford Law School; partner, Durie Tangri LLP.

**** John P. Murphy Foundation Professor of Law, Notre Dame Law School.

Thanks to Jonas Anderson, Shovon Ashraf, Stephanie Bair, Kevin Collins, Jonathan Darrow, Janet Freilich, Rose Hagan, Tim Holbrook, Chris Holman, Jonathan Masur, Craig Nard, Lisa Larrimore Ouellette, Nicholson Price, Arti Rai, Sarah Rajec, Jason Rantanen, Ana Santos Rutschman, Jake Sherkow, Norman Siebrasse, Jay Thomas, Kip Werking, Meng Xi, Joy Xiang, and the participants in the summer 2020 Junior IP Scholars Association Workshop, the Sixth Patent Scholars Roundtable, and the students in the Advanced Patents course at the Washington University School of Law, for valuable comments on earlier drafts. We also thank Michael Baldwin, Jordan Cowger, Benjamin DuBois, Hannah Fan, Matthew Pelcowitz, Gregory Persaud, and Tyler Robbins for research assistance and the participants in the 2020 IP Scholars Conference and in a seminar organized by the Innovation, Business & Law Center at the University of Iowa College of Law for feedback on presentations of this Article.

TABLE OF CONTENTS

## I. INTRODUCTION

The most fundamental rule of patent law is that what the patentee owns is defined not by what she actually built or described, but by the patent claim — the legal definition of the invention drafted by her patent lawyer. Lawyers draft those claims as broadly as the law appears to allow. In particular, lawyers are careful not to limit the claim to a particular thing or "species," even though that's normally what the patentee actually built or conceived. Instead, patent lawyers lead with a "genus claim" — a broad claim that covers a group of structurally related products that incorporate the basic advance of the patented invention.[1] They do this to make sure that no one can copy their basic idea by making a small change to it to avoid infringing the patent.

Nowhere is this more true than in the chemical arts.[2] Pharmaceutical, biotechnology, and chemical companies rely more heavily on the patent system than do other industries.[3] Some scholars have concluded that the system works well in those industries but not others.[4] And those industries make heavy use of genus claims. A chemical patent, for instance, might include one or more claims to a particular compound — a species — but almost invariably it starts with a claim to a group of chemicals — the genus. It bears emphasizing that these genus claims are thought important to prevent competitors from capturing the benefit of an invention while avoiding infringement by making a minor change to one aspect of it. The U.S. Patent and Trademark Office ("USPTO") grants broad genus claims as a matter of course in the chemical industries.[5] And those industries regularly attempt to enforce such claims in court.[6]

---

1. *See In re* Kalm, 378 F.2d 959, 963 (C.C.P.A. 1967) ("When one speaks of a 'genus' in the chemical arts, one ordinarily speaks of a group of compounds closely related both in structure and properties."). The U.S. Court of Customs and Patent Appeals ("CCPA") was a five-judge Article III appellate court on the same level as the U.S. Courts of Appeals. The Federal Courts Improvement Act of 1982 abolished the CCPA. *See* Pub. L. No. 97-164, § 122, 96 Stat. 25, 36 (1982) (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the U.S. Court of Appeals for the Federal Circuit adopted CCPA decisional law as binding precedent. *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

2. In this Article, we sometimes use the terms "chemical," "pharmaceutical," and "biotechnological" somewhat interchangeably to refer to industries focused on the development and use of new molecules and compounds. We view the term "chemical" as encompassing both biotechnology as well as more traditional organic and inorganic chemistry. Our Article is focused on those fields, and our argument does not extend to non-chemical industries. At various points, we do distinguish rules that apply differently to certain subfields, such as specialized rules for certain biotechnological inventions. We make clear when we are doing so.

3. *See infra* Part IV.

4. *See infra* Part IV.

5. *See* Sean B. Seymore, *Patenting the Unexplained*, 96 WASH. U. L. REV. 707, 729 (2019) (noting that genus claims are "ubiquitous" in these industries).

6. *See infra* Part III.

When they do, however, something surprising happens. As we show in this Article, courts almost invariably hold genus claims invalid under 35 U.S.C. § 112(a) for failure to enable or describe the full scope of the claimed invention. In the last thirty years, the U.S. Court of Appeals for the Federal Circuit (the court with exclusive jurisdiction over patent appeals) has struck down claim after claim on the theory that whatever the patentee has done to justify a broad claim to a group of chemicals, it isn't enough. It regularly reverses district courts that have found adequate support for the genus claim.[7] Not once but three times has the Federal Circuit thrown out a jury verdict of over a billion dollars because it concluded the genus claims at issue were invalid.[8] In fact, we find only a small minority of Federal Circuit decisions that have upheld a genus claim in the chemical industry in the past thirty years, and each of those has some idiosyncrasy that explains why it bucks the trend.[9] That trend, as reflected in dozens of cases, is unmistakable: biotechnology, chemical, and pharmaceutical genus claims lose in court.

It's unclear whether patent lawyers and scholars have discovered this shift in the jurisprudence. Patent lawyers continue to draft genus claims, the USPTO grants them, and patent owners attempt to enforce them in court. Lawyers and scholars sometimes lament individual decisions they disagree with. But the whole system seems to proceed merrily along on the assumption that the role of genus claims in supporting these industries is secure. It isn't.

We argue that the death of genus claims is the result of some subtle but important doctrinal shifts, and that those changes reflect a misunderstanding of the purposes that patent law is supposed to serve. The Federal Circuit has abandoned a practical focus on whether others could make and use the claimed invention, instead favoring a fruitless search for the exact boundaries of that invention. This "full-scope possession" theory invalidates a genus claim unless the patentee can show exactly which species within the genus will work as intended — an impossible task for a genus of any nontrivial size.[10] Given the importance of patents to the biotechnology, chemical, and pharmaceutical industries, and the importance of genus claims to those patents, we find the death of genus claims in modern courts troubling. If the doctrine continues down this path, it may threaten innovation in an important sector of the economy.

---

7. *See infra* Part III.

8. *See* Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1332 (Fed. Cir. 2021); Idenix Pharms. LLC v. Gilead Scis. Inc., 271 F. Supp. 3d 694, 696 (D. Del. 2017) (considering motion to enhance the jury's $2.54 billion damages award), *patent invalidated by* 941 F.3d 1149, 1165 (Fed. Cir. 2019); Centocor Ortho Biotech, Inc. v. Abbott Lab'ys, 636 F.3d 1341, 1341–42 (Fed. Cir. 2011).

9. *See infra* Section III.C.

10. *See infra* Section III.C.

We think the law should go back to the way it was: Genus claims should survive as long as they enable other researchers to make effective use of the teachings of the patent to make and use chemicals within the genus without too much experimentation.[11] As a doctrinal matter, the validity of a claim should not depend on whether others can identify and test all of the species, and as a matter of policy, genus claims are important to innovation in these industries.

But the importance of our discovery isn't limited to getting patent policy right. The death of genus claims is also an important lesson in how the law on the ground differs from the law on the books. The fact that the industry proceeds apace — investing in innovation, obtaining and enforcing patents, despite this surprising turn in the case law — suggests that we may know less than we think we do about whether and how the patent system supports chemical innovation.

In Part II, we introduce the role of genus claims in chemical, pharmaceutical, and biotechnology patents and outline the traditional applications of § 112(a)'s requirements of enablement and written description to these claims. In Part III, we discuss the validity of genus claims, documenting the striking trend to invalidate those claims in the past thirty years and the subtle doctrinal shifts that led to it. Finally, in Part IV, we further examine this trend and discuss its implications for innovation in those industries — and what it says about the importance of patent doctrine more generally.

## II. GENUS CLAIMING: THE TRADITIONAL VIEW

### *A. Understanding Patent Claims*

Claims are central to every aspect of patent law.[12] Claims are the numbered sentences at the end of the patent document that define the "technological territory" that the patentee claims is his or hers to

11. The approach we propose appears to have been adopted in a recent decision by the Court of Appeal, the highest court within the Senior Courts of England and Wales: "[I]t is not necessary as a matter of law, for sufficiency . . . , simply because the claim contains functional features (or a mix of functional and structural features) to establish that the skilled person can identify all or substantially all the compounds which satisfy the test . . . . For claims of this type, it must be possible for the skilled person, without undue burden, to identify some compounds beyond those named in the patent, which are within the claimed class and therefore are likely to have therapeutic efficacy." FibroGen Inc. v. Akebia Therapeutics Inc., [2021] EWCA (Civ) 1279 [95], [97] (Eng.).

12. Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101, 101 (2005); *see also* Giles S. Rich, *The Extent of the Protection and Interpretation of Claims — American Perspectives*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990) (stating that in patent law, "the name of the game is the claim"). At the application stage, the inventor "dicker[s] with the [USPTO] to obtain an expansive exclusory right; and in litigation the parties try to convince the court to construe the claims in their favor." Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 128–29 (2008) [hereinafter Seymore, *Heightened Enablement*].

control,[13] and thus set the scope of the exclusory right conferred by the patent.[14] The kinds of patent claims one encounters track the language of 35 U.S.C. § 101, which sets forth "any new and useful process, machine, manufacture, or composition of matter" as patentable subject matter.[15] At a high level, claims can refer to a structure, such as a chair or a chemical compound, or an activity, such as a process for manufacturing the table or a method of treating an illness with the compound. In the chemical and biochemical sciences, genus claims capture a group of related molecular structures.[16] While chemical genus claims are often composition (i.e., structure) claims, many claims we will encounter in this Article are actually method claims directed to an effective treatment of some condition or to other uses of the molecules belonging to a chemical genus.[17]

1. Claim Scope and the Disclosure Function of Patents

The permissible scope of patent claims, and the exclusive rights they confer, are closely tied to the amount of information that the patentee discloses in the patent. Put simply, the patentee must give more (information about the invention through disclosure) to get more (claim scope).[18] This give and take lies at the heart of the U.S. patent system, which is essentially a bargain or quid pro quo between the patentee and society.[19] The patentee gets the limited period of exclusivity conferred by the patent, as set forth in the claims, so that they might recoup their

13. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 844 (1990).

14. *See* Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989).

15. *See* 35 U.S.C. § 101 (2018) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . .").

16. *See In re* Kalm, 378 F.2d 959, 963 (C.C.P.A. 1967) ("When one speaks of a 'genus' in the chemical arts, one ordinarily speaks of a group of compounds closely related both in structure and properties.").

17. *See generally* Sean B. Seymore, *Patenting New Uses for Old Inventions*, 73 VAND. L. REV. 479 (2020) (discussing method of use patents).

18. The noted patent lawyer and judge Giles Sutherland Rich captured the tradeoffs involving claim scope: "*The stronger a patent the weaker it is and the weaker a patent the stronger it is.* To explain, a patent that is strong in that it contains broad claims which adequately protect the invention so they are hard to design around is weak in that it may be easier to invalidate and is therefore less likely to stand up in court because the claims are more likely to read on prior art or be broader than the disclosed invention . . . . On the other hand, the patent with narrow claims of the kind the Patent Office readily allows quickly without a contest is weak as protection and as incentive to invest but strong in that a court will not likely invalidate it." Giles S. Rich, *The Proposed Patent Legislation: Some Comments*, 35 GEO. WASH. L. REV. 641, 644 (1967).

19. *See* 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.").

investment in invention. In exchange, society gets two things: (1) use of the invention once the patent term expires,[20] and (2) the disclosure, which furnishes technical information about the invention (i.e., how to make and use it) as soon as the patent document publishes.[21] The disclosure "add[s] to the sum of useful knowledge"[22] and becomes a part of the technical literature.[23] Patent theory posits that the disclosure will stimulate other researchers to improve upon the invention, design around it, and make wholly new inventions — all during the patent term — and also to use the invention as claimed after the patent's expiration.[24] Indeed, an oft-touted justification for the patent system is that society will get some benefit from the invention's disclosure.[25]

2. Enablement and the Sufficiency of Disclosure

The bargain inherent to patent law only works if the patent's specification, the descriptive part of the patent document,[26] provides

20. Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 418 (1822) ("The object is to put the public in complete possession of the invention . . . so that interference with it may be avoided while the patent continues, and its benefits may be fully enjoyed by the public, after the patent expires.").

21. *See* Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 333 (2008) ("[I]t seems quite clear that dissemination, not just invention, of new information is one of the goals of the patent system."); Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 531, 552–71 (2012) (exploring the technical value of patent disclosures). Patent documents include issued patents and published patent applications. Since 1999, most patent applications publish eighteen months after the earliest effective filing date. *See* 35 U.S.C. § 122(b)(1)(A) (2018). Once a patent application publishes, the information it discloses is considered publicly known. *See id.* § 102.

22. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974); *cf. In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring) (noting that the full disclosure of how to make and use the invention "adds a measure of worthwhile knowledge to the public storehouse").

23. Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 400 (1960). Like technical journals, for example, patent disclosures can show the state of technology, set forth what others have already achieved, and provide technical information that others can avoid repeating. Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 623–24 (2010) [hereinafter Seymore, *Teaching Function*].

24. *Kewanee Oil*, 416 U.S. at 481; *see also* Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 264 (1994). Of course, others could use the patented invention during the term of the patent, too, under a license from the patentee.

25. *See Kewanee Oil*, 416 U.S. at 481 (explaining that we are "willing to pay the high price" of exclusivity conferred by a patent for its disclosure, which, "it is assumed, will stimulate ideas and the eventual development of further significant advances in the art"). How effective those disclosures are in practice is a matter of dispute. *Compare* Ouellette, *supra* note 21, at 552–53, *with* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 711, 747–48 (2012). But there is general agreement that the disclosure function works best in the chemical arts, where scientists have a shared language and the scope of patents is relatively clear. *See* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 14, 18 (2008).

26. Courts, scholars, practitioners, and the USPTO use the term "specification" to refer to the *written description* — the part of the patent document that provides descriptive details

sufficient technical information about the invention to enrich the public storehouse of knowledge. Section 112(a) of the Patent Act strives to achieve this aim by mandating that the patent "shall contain a written description of the invention . . . as to enable any person skilled in the art ["PHOSITA"][27] . . . to make and use the same . . . ."[28] As interpreted by courts, the enablement requirement created by this language compels a patentee to furnish a disclosure sufficient to teach the PHOSITA to make and use the claimed invention without undue experimentation.[29]

Enablement issues can arise in patent prosecution[30] or litigation.[31] In both contexts, "an enablement determination is made *retrospectively*, *i.e.*, by looking back to the filing date of the patent application and determining whether undue experimentation *would have been* required to make and use the claimed invention at that time . . . ."[32] The Federal Circuit set forth the relevant factors in *In re Wands*.[33] They are: (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

about the invention (e.g., "Background of the Invention," "Summary of the Invention," "Detailed Description of the Invention," and "Drawings"). CRAIG ALLEN NARD, THE LAW OF PATENTS 47 (5th ed. 2020). This is done, in part, to avoid confusion with the "written description" requirement of 35 U.S.C. § 112(a). *See infra* Section II.C.1.

27. The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in negligence law. Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology, the educational level of the inventor, the educational level of active workers in the field, the types of problems encountered in the art, prior art solutions to those problems, and the rapidity with which innovations are made. Env't Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983).

We use PHOSITA, not POSA, as one opinion recently declared it to be. Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1157 (Fed. Cir. 2019); *cf.* Joseph P. Meara, Note, *Just Who Is the Person Having Ordinary Skill in the Art? Patent Law's Mysterious Personage*, 77 WASH. L. REV. 267 (2002) (using the established term, PHOSITA).

28. 35 U.S.C. § 112(a) (2018). Note that prior to 2012, the relevant provision was codified as § 112, first paragraph, rather than in § 112(a).

29. *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993); Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987).

30. The process of obtaining a patent — where the inventor or his or her agent or attorney files an application with the USPTO — is called "patent prosecution." JANICE M. MUELLER, PATENT LAW 59 (5th ed. 2016). In prosecution, the examiner must prove by a preponderance of the evidence that the challenged claim is not enabled. *See In re* Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (discussing the examiner's burden of production and persuasion).

31. An issued patent is presumed valid in litigation; therefore, a challenger has the burden of proving that a claim is invalid for a lack of enablement by clear and convincing evidence. *See* Alcon Rsch. Ltd. v. Barr Lab'ys, Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014).

32. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371–72 (Fed. Cir. 1999) (citing Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986)).

33. 858 F.2d 731, 737 (Fed. Cir. 1988).

technology already available to the public),[34] (7) the breadth of the claims, and (8) the amount of experimentation necessary to practice the claimed invention.[35]

The *Wands* factors show that the nature of the underlying technology affects how much a patent's specification must teach to enable a patent claim. Historically, there has been a natural dichotomy in enablement jurisprudence: courts appeared to apply separate enablement standards for inventions in the predictable and unpredictable arts.[36] In the predictable arts, which include mechanical and electrical engineering, a detailed disclosure has not been required because the inventions are rooted in well-defined, predictable factors.[37] If a claim requires a "fastener," for instance, skilled artisans may well understand that a variety of different fasteners will work (nails, staples, glue, etc.) even if the patent itself doesn't specify any particular embodiment of a fastener. By contrast, in the unpredictable arts, which include experimental fields like chemistry, pharmaceuticals, and biotechnology, a detailed disclosure is required because PHOSITAs often cannot anticipate whether a process that works for one embodiment (or species) of an invention[38] will work for others.[39] For example, in chemistry, the PHOSITA often cannot take a result from one reaction and predict how similar compounds will behave with a reasonable expectation of

34. *See* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (citing Graham v. John Deere Co., 383 U.S. 1, 6 (1966)). Documents (i.e., issued patents and printed publications), devices, and activities are sources of prior art. *See* 35 U.S.C. § 102(a) (2018).

35. *See Wands*, 858 F.2d at 737.

36. For a deeper discussion of the predictable-unpredictable dichotomy, see Seymore, *Heightened Enablement*, *supra* note 12, at 136–39; Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 282–84 (2008).

37. *See In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) (noting that the requisite level of disclosure for an invention involving predictable mechanical or electrical elements is less than that required for the unpredictable arts).

38. An "embodiment" is a concrete, physical form of an invention described in a patent application or patent. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 33 (7th ed. 2017).

39. Cedarapids, Inc. v. Nordberg, Inc., 121 F.3d 727, 1997 WL 452801, at *2 (Fed. Cir. 1997) (unpublished table disposition); *see also In re* Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977) (noting "the high level of predictability in mechanical or electrical environments and the lower level of predictability expected in chemical reactions and physiological activity"). Courts have long recognized the differences between something like a simple mechanical device and a chemical compound. *See, e.g.*, Tyler v. Boston, 74 U.S. (7 Wall.) 327, 330 (1868) ("Now a machine which consists of a combination of devices is the subject of invention, and its effects may be calculated *a priori*, while a discovery of a new substance by means of chemical combinations of known materials is empirical and discovered by experiment."); Naylor v. Alsop Process Co., 168 F. 911, 919 (8th Cir. 1909) ("It should also be borne in mind in considering this subject that reasoning by analogy in a complex field like chemistry is very much more restricted than in a simple field like mechanics.").

success.[40] The standard for enablement is thus effectively industry-specific.[41] Nevertheless, even in a less predictable field like chemistry, inventors routinely obtained and successfully enforced patent claims covering a group of structurally related chemicals (i.e., genus claims) prior to the 1990s.[42]

3. Enablement's Commensurability Requirement

A perennial enablement question is what breadth and depth of disclosure is sufficient to entitle a patentee to a broad genus claim that covers various ways of implementing the invention. The short but unhelpful answer is that the information disclosed must be "commensurate" with the scope of the invention.[43] The basic premise and practical advantage of genus claims is that a detailed teaching involving one species can provide sufficient enablement for extrapolation across the entire scope of the claimed genus.[44] When it does, the patentee can satisfy enablement's commensurability requirement without demonstrating that each and every embodiment of a genus claim works for the intended purpose.[45] Claiming a genus thus allows the patentee to obtain rights to numerous structurally related species in the genus, including some that the patentee herself never thought of.

How can a patent claim cover something the patentee never thought of? Because a claimed invention may likely encompass many embodiments, courts have permitted the PHOSITA to engage in "a 'reasonable' amount of routine experimentation"[46] to distinguish the embodiments that work from those that don't.[47] The U.S. Court of

40. Seymore, *Heightened Enablement*, *supra* note 12, at 144–46 (emphasizing that, in chemistry, the "array of chemical compounds which are structurally similar may differ radically in their properties"); *cf. In re* Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1993) (testing enablement by determining if a skilled scientist working with RNA viruses would have reasonably believed that the inventor's success with the described embodiment(s) "could be extrapolated with a reasonable expectation of success" to other embodiments encompassed by the claims).

41. *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2002) [hereinafter Burk & Lemley, *Technology-Specific*].

42. *See infra* notes 138–141 and accompanying text.

43. *See* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999).

44. *Wright*, 999 F.2d at 1564.

45. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60 (1998) (explaining that "the word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea"); Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." (quoting *In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956))).

46. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371 (Fed. Cir. 1999).

47. *Id.* (citing *In re* Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988)) ("We have held that a patent specification complies with the statute even if a 'reasonable' amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be 'undue.'").

Customs and Patent Appeals ("CCPA")[48] recognized that the alternative of requiring the patentee to identify and test every possible species in a genus would be unworkable: "[T]he research to do this would quite evidently be endless."[49] This is known as the inoperative embodiments doctrine — a broad claim that covers unknown species is not necessarily invalid as long as enough of the subject matter works as described.[50] Validity depends on the circumstances of each case — including the nature of the subject matter (whether predictable or unpredictable),[51] the PHOSITA's level of skill,[52] and the number of inoperative embodiments.[53]

But how are we to know when the patentee has taught enough to justify a claim to an entire genus? The Supreme Court faced this issue long ago in the famous *Incandescent Lamp* case.[54] The patent in suit claimed a light bulb with a filament made of "carbonized fibrous or textile material."[55] While this broad claim covered *every* "carbonized fibrous or textile material" used as a filament, the specification only disclosed light bulbs using carbonized paper and wood carbon.[56] Thomas Edison, the accused infringer, found through laborious trial and error that bamboo worked well as a filament for incandescent light bulbs, but over six thousand other substances covered by the genus claim did not.[57] The Supreme Court held that the patentee was entitled

48. This court was one of the predecessors to the U.S. Court of Appeals for the Federal Circuit, which adopted its decisions as binding precedent. *See supra* note 1.

49. *In re* Sarett, 327 F.2d 1005, 1019 (C.C.P.A. 1964); *see also* RIDSDALE ELLIS, PATENT CLAIMS § 214, at 275 (1949) (recognizing that in theory the only way that a chemist can determine if all species within a claimed genus will work as described is by testing "at least a majority of the members of that genus").

50. *See In re* Cook, 439 F.2d 730, 734 (C.C.P.A. 1971); *Sarett*, 327 F.2d at 1019 (noting that the mere inclusion of inoperative embodiments within the scope of a claim will not defeat patentability).

51. *See supra* notes 36–42 and accompanying text.

52. *See, e.g.*, *Cook*, 439 F.2d at 735 (noting that a broad claim that reads on a large number of inoperative embodiments is not necessarily invalid because the PHOSITA could figure out with minimal effort which of the unmade embodiments could work as intended). Recall that the PHOSITA's level of skill is a *Wands* factor. *See supra* text accompanying notes 33–35.

53. *See, e.g.*, Consol. Elec. Light Co. v. McKeesport Light Co. (*Incandescent Lamp*), 159 U.S. 465, 474 (1895) (determining that the claim was invalid because most of the claimed embodiments were inoperable); Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576–77 (Fed. Cir. 1984) ("[I]f the number of inoperative [embodiments] becomes significant, and in effect forces [the PHOSITA] to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid."); Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1306–07 (Fed. Cir. 2001) (determining that a showing that a "significant percentage" of embodiments encompassed by the claims is inoperable might be sufficient to prove invalidity).

54. *Incandescent Lamp*, 159 U.S. at 472.

55. *Id.* at 468.

56. *Id.* at 468–69, 472.

57. *Id.* at 472–76.

to a narrow claim for the carbonized paper embodiment, but not to the genus claim Edison was accused of infringing.[58]

*Incandescent Lamp* demonstrates an outer limit on claim scope — the claims are limited by what the patent teaches.[59] In *Incandescent Lamp*, the sparse disclosure didn't teach the PHOSITA how to find the embodiments that worked without undue experimentation.[60] Indeed, it wasn't clear that there was any meaningful genus of "carbonized fibrous and textile materials" that could function as a light bulb filament.[61]

Following *Incandescent Lamp*, in the 1928 case *Corona Cord Tire Co. v. Dovan Chemical Corp.*,[62] the Supreme Court invalidated a broad genus claim to a class of chemicals (guanidine derivatives) because the patentee hadn't shown that there was "any general quality common to disubstituted guanidines which made them all effective" for use in the process of the invention.[63] Here, too, there was evidence that a substantial number of the claimed embodiments didn't work.[64]

These cases show that providing a limited number of species in the specification can't serve as a "springboard" for claiming a genus if those species aren't representative of the entire genus.[65] Again, the patentee must give more (disclosure) to get more (scope).[66] This is the commensurability requirement. It's based on how much work the PHOSITA would have to do to make and use the subject matter of the patent claims. Given a claim of a particular scope, the number of examples the patent discloses can be a relevant factor in deciding

---

58. As Justice Henry Brown wrote, "the fact that paper belongs to the fibrous kingdom did not invest [the patentees] with sovereignty over this entire kingdom." *Id.* at 476.

59. Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed. Cir. 1999) (noting that enablement's purpose is to "ensure[] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims"); *see also* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1853) (holding that Samuel Morse's genus claim for *all* electronic communication made at a distance was "too broad, and not warranted by law").

60. To be sure, under modern enablement doctrine a court would invalidate the genus claim after concluding that undue experimentation would be required to practice the full scope of the genus claim. *See supra* note 29 and accompanying text. The relevant *Wands* factors would be the amount of guidance presented in the disclosure (which was limited), the existence of working examples (only one provided), the breadth of the claims (very large), and the quantity of experimentation required (substantial, as shown by Edison). *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

61. *See infra* Part IV.

62. 276 U.S. 358 (1928).

63. *Id.* at 385; *cf.* Consol. Elec. Light Co. v. McKeesport Light Co. (*Incandescent Lamp*), 159 U.S. 465, 472 (1895) ("If the patentees had discovered in fibrous and textile substances a quality common to them all, or to them generally . . . and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad.").

64. *See Corona Cord*, 276 U.S. at 385 ("[T]he experts show that there are between fifty and one hundred substances which answer this description, of which there is quite a number that are not accelerators at all.").

65. *See* Minn. Mining & Mfg. Co. v. Carborundum Co., 155 F.2d 746, 750 (3d Cir. 1946).

66. *See supra* note 18 and accompanying text.

commensurability and thus enablement, but it hasn't generally been determinative.[67]

### *B. The Traditional Role of Genus Claims in Chemistry*

Genus claims provide the broadest scope of patent protection.[68] These (typically) broad claims use functional language[69] or generic formulas to cover individual embodiments of the invention, or species, that share a common attribute or property.[70] For example, consider a claim to a plastic-coated steel screw. Given that there are many different plastics (e.g., nylon, polystyrene, polypropylene, polyvinyl chloride), the genus claim encompasses many species.[71]

Patentees opt for genus claims for two reasons. First, since patent law doesn't require an inventor to actually make each species covered by a claim,[72] genus claims can afford broad scope with relatively limited experimentation.[73] Second, genus claims prevent competitors from capturing the benefit of an invention (perhaps by making a minor variation to a molecule or changing the plastic used to make the screw)[74] because an unauthorized use of any species within the scope of the claimed genus is an act of patent infringement.[75]

Although genus claims appear in all areas of technology, they are ubiquitous in chemistry, pharmaceuticals, and biotechnology — the aforementioned unpredictable arts.[76] A common claiming technique is to draw a core generic chemical structure with an array of substituents (i.e., variables) appended to it — which can each represent numerous chemical groups.[77] For example, the representative claim at issue in

---

67. *See supra* text accompanying notes 33–35 (discussing the *Wands* factors).

68. *See* Seymore, *Heightened Enablement*, *supra* note 12, at 145–46.

69. Functional language describes an invention by what it does rather than by what it is. *In re* Swinehart, 439 F.2d 210, 212 (C.C.P.A. 1971) (allowing the use of functional claiming and recognizing that it can be a "practical necessity").

70. Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1168 (2008). Lefstin argues that most claims are genus claims. For example, a claim reciting "a chair with four legs" would cover "chairs of all sorts of materials, chairs of all sizes, chairs including contoured backrests, and chairs with roller wheels, etc." so long as they possess four legs. *Id.* at 1169–70.

71. Seymore, *Patenting the Unexplained*, *supra* note 5, at 729.

72. *See supra* note 45 and accompanying text.

73. *See* Seymore, *Heightened Enablement*, *supra* note 12, at 145–47; Seymore, *Teaching Function*, *supra* note 23, at 628–32.

74. When patentees draft narrow claims, an imitator would find a minor variation over the claimed embodiments, thereby rendering the patent useless. Merges & Nelson, *supra* note 13, at 845.

75. 35 U.S.C. § 271(a) (2018).

76. *See supra* notes 36–42 and accompanying text.

77. *See In re* Driscoll, 562 F.2d 1245, 1249 (C.C.P.A. 1977) (explaining that the practice of describing a class of chemical compounds in terms of structural formulas, where the substituents are recited in the claim language, has been allowed by courts).

*Idenix Pharmaceuticals LLC v. Gilead Sciences, Inc.*,[78] the case to which we will return in Part III, involved a claim to a five-membered ring structure with variable moieties on the periphery of the ring represented by the numbered "R" groups (see Figure 1 below).[79] This traditional manner of chemical genus claiming can allow for a variety of permutations, and therefore a large number of species, within the scope of the claim. As a result, genus claims are pervasive in the unpredictable arts and have received considerable treatment in treatises,[80] books,[81] and voluminous case law.[82]

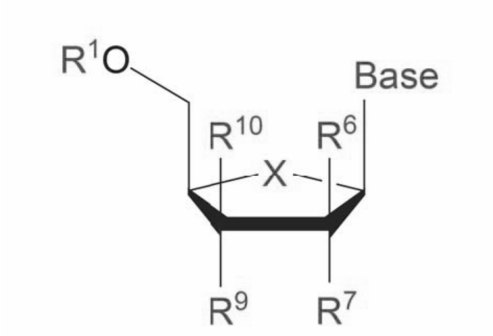


Figure 1: The Generic Chemical Structure Claimed in *Idenix*

How much must a patentee teach to enable a genus claim in unpredictable fields like chemistry? The early chemical cases were somewhat stringent. For instance, in the 1957 case *In re Shokal*,[83] the CCPA adopted the view that disclosure of "a single species can rarely, if ever, afford sufficient support for a generic claim."[84] By 1960, however, the

78. 941 F.3d 1149 (Fed. Cir. 2019).

79. *Id.* at 1154.

80. *See, e.g.*, EMERSON STRINGHAM, PATENT CLAIM DRAFTING § 5090, at 61 (2d ed. 1952).

81. *See, e.g.*, JOSEPH ROSSMAN, THE LAW OF PATENTS FOR CHEMISTS 109–12 (1932); EDWARD THOMAS, CHEMICAL INVENTIONS AND CHEMICAL PATENTS 323–25, 426–27 (1950); JOHN T. MAYNARD, UNDERSTANDING CHEMICAL PATENTS: A GUIDE FOR THE INVENTOR 18–19 (1978).

82. *See, e.g.*, cases cited *infra* notes 137–148. In addition, chemical claims can be drafted in a so-called "Markush group" form. *See Ex parte* Markush, 340 Off. Gaz. Pat. Office 839, 839 (July 9, 1924); *Driscoll*, 562 F.2d at 1249 (allowing the practice); *see also In re* Harnisch, 631 F.2d 716, 719–20 (C.C.P.A. 1980) (explaining the history and current law of Markush claiming practice).

83. 242 F.2d 771 (C.C.P.A. 1957).

84. *Id.* at 773. It is worth noting that this early case law somewhat conflated the concepts that are today understood to be embodied in separate requirements under § 112(a) — enablement and written description. *See, e.g.*, *In re* Soll, 97 F.2d 623, 625 (C.C.P.A. 1938) (cited in *Shokal*, 242 F.2d at 773) (holding that a single working example with fluoride could not support the four-member genus of halogens). In *Soll*, the CCPA did not make clear whether the

CCPA had moved away from *Shokal* and took the view that it is "manifestly impracticable" to require a detailed teaching "of every species falling within [a genus], or even to name every such species."[85] The amount of teaching required to enable a genus claim "will vary, depending on the circumstances of particular cases."[86] This liberalization opened the door for patentees in unpredictable fields to obtain broader genus claims with only a handful of working examples,[87] or even no working examples, if the disclosure provided sufficient teaching.[88]

A pivotal case illustrating this shift is *In re Angstadt*.[89] The genus claim at issue, which encompassed thousands of species, was directed to a method for catalytically transforming a class of organic compounds with metal catalysts. Although the applicant disclosed forty examples in the specification, the USPTO's position was that the disclosure left "too much to conjecture, speculation and experimentation" and was nonenabling because (1) the forty examples didn't teach across (and were not representative of) the entire genus, and (2) the disclosure didn't set forth those catalyst features that would allow the PHOSITA to produce materials with the intended function.[90] The CCPA reversed the enablement rejection, explaining that requiring a more detailed disclosure "would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments,"[91] which would "tend to discourage inventors from filing patent applications in an

---

genus failed because the patent did not teach the PHOSITA how to make and use the full scope of the genus, or because the failure to name more than one species in the specification indicated a lack of "possession" of the genus. *See id.* For more on written description and possession, see *infra* Section II.C.1.

85. *In re* Grimme, 274 F.2d 949, 952 (C.C.P.A. 1960). With respect to naming every species within a genus, recall the prior example where the patentee claimed "a plastic-coated steel screw." *See supra* text accompanying notes 69–71. Even if the disclosure only names or exemplifies a handful of species (e.g., polystyrene, polyethylene, etc.), it could enable other plastics that aren't specifically recited (including plastics that did not exist at the time of filing).

86. *In re* Cavallito, 282 F.2d 357, 361 (C.C.P.A. 1960) (quoting *Shokal*, 242 F.2d at 773); *see also In re* Borkowski, 422 F.2d 904, 910 (C.C.P.A. 1970) (explaining that there is "no magical relation" between the number of working examples disclosed and claim breadth); *Ex parte* Sloane, 22 U.S.P.Q. 222, 1934 WL 25325, at *2 (P.O.B.A. Jan. 18, 1934) ("[W]e do not think that a proper determination of the breadth of disclosure can be made solely from a consideration of the specific examples given. If the disclosure, taken as a whole, is generic, an applicant is entitled to generic claims if they are otherwise allowable.").

87. Working examples are embodiments of the invention that have been made or performed, which show that the invention can really achieve the intended result. Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1528 (2011).

88. *See In re* Strahilevitz, 668 F.2d 1229, 1232–34 (C.C.P.A. 1982) (upholding a genus claim covering methods for removing chemicals from blood because the disclosure was sufficiently detailed and the PHOSITA's level of skill was high, even though no working examples had been provided); *see also Borkowski*, 422 F.2d at 908 (explaining that there's no statutory basis for a working example requirement). The Supreme Court long ago allowed this practice in a famous decision. *See* The Telephone Cases, 126 U.S. 1, 535–36 (1888).

89. 537 F.2d 498 (C.C.P.A. 1976).

90. *Id.* at 501–02.

91. *Id.* at 502–03.

unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed."[92] Thus, the broad genus claim was enabled — even if the PHOSITA had to engage in some experiments to figure out which catalyst candidates worked and which didn't[93] — so long as the inventor demonstrated that some species do actually function as intended and provided direction for how to test the rest.[94] *Angstadt* aligns with the inoperative embodiments doctrine discussed above,[95] and the claims at issue satisfy the commensurability requirement.[96] In *Angstadt*, unlike *Incandescent Lamp*,[97] there really was a genus with embodiments that provided generally consistent effects and multiple disclosed species that worked for the intended purpose, supporting the generalization made by the claim.[98]

Early Federal Circuit opinions continued to resist enablement challenges to broad chemical genus claims. Consider *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*,[99] where the patent at issue involved emulsions[100] that were useful as blasting agents for mining and construction.[101] The genus claim covered various salts, fuels, and emulsifiers that could form thousands of emulsions.[102] The accused infringer argued that the genus claim was not enabled because the specification did not teach which combinations would work and thus was nothing more than "a list of candidate ingredients."[103] In addition, the record included evidence that a considerable number of the claimed combinations were inoperative.[104] The accused infringer argued that this supposed lack of commensurability between the disclosure and the genus claim would require the PHOSITA to experiment unduly to find an operable emulsion. The Federal Circuit disagreed, noting that "[i]t is not a function of the claims to specifically exclude . . . possible inoperative substances . . . ."[105] A detailed teaching was unnecessary because the

92. *Id.* at 503.

93. Seymore, *Heightened Enablement*, *supra* note 12, at 149.

94. *See Angstadt*, 537 F.2d at 503–04.

95. *See supra* notes 50–53 and accompanying text.

96. *See supra* notes 43–45 and accompanying text.

97. *See supra* notes 54–61 and accompanying text.

98. *See Angstadt*, 537 F.2d at 503.

99. 750 F.2d 1569 (Fed. Cir. 1984).

100. An emulsion "is a mixture of two [immiscible] liquids . . . with one of the liquids appearing as dispersed globules in the second." GIORA AGAM, INDUSTRIAL CHEMICALS: THEIR CHARACTERISTICS AND DEVELOPMENT 67 (1994).

101. *Atlas Powder*, 750 F.2d at 1571.

102. *Id.* at 1576.

103. *Id.*

104. *See id.* at 1577.

105. *Id.* at 1576 (quoting *In re* Dinh-Nguyen, 492 F.2d 856, 858–59 (C.C.P.A. 1974)); *see also In re* Cook, 439 F.2d 730, 735 (C.C.P.A. 1971) (explaining that there is "nothing wrong" with genus claims that encompass "vast numbers of inoperative embodiments" as long as the PHOSITA can figure out what works and what doesn't). But there seems to be an upper limit

PHOSITA could readily select the proper ingredients using a "basic principle of emulsion chemistry."[106] *Angstadt* and *Atlas Powder* show that courts would permit patentees to rely extensively on the PHOSITA's knowledge to provide enabling support for broad genus claims.

With that understanding, genus claims make complete sense. A patentee can claim a structural group of chemicals with an invariant backbone and varied groups attached to that core.[107] As numerous prosecution handbooks confirm, this is the typical kind of chemical genus claim that patent attorneys are taught to draft.[108] Some of those variants will work; others won't. But the inventor of a genus can claim that genus as long as there's enough information that the PHOSITA can identify some species within it that will work and determine how to make those species without too much effort.[109] The prevalence of advice for such claiming reflects a widespread understanding that those claims are valid.

### *C. Portents of Change*

#### 1. The Written Description Requirement

Section 112(a) of the Patent Act states that the patent's specification "shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable a [PHOSITA] . . . to make and use the same . . . ."[110] As noted above, this language provides the statutory basis for the enablement requirement.[111] However, in the 1967 case *In re Ruschig*,[112] the CCPA held that § 112(a) embodies an *additional* disclosure requirement: the "written description" requirement.[113] The issue is whether the specification, as of the filing date sought, conveys with reasonable clarity that the patentee "actually invented" the

---

on the amount of inoperability that will be tolerated. *See Atlas Powder*, 750 F.2d at 1576–77 ("[I]f 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.").

106. *Atlas Powder*, 750 F.2d at 1576.

107. *See supra* note 77 and accompanying text.

108. *See, e.g.*, CHRIS P. MILLER & MARK J. EVANS, THE CHEMIST'S COMPANION GUIDE TO PATENT LAW 7–8, 7 n.4 (2010); *supra* notes 77–82 and accompanying text.

109. *See supra* note 94 and accompanying text.

110. 35 U.S.C. § 112(a) (2018), discussed *supra* Section II.A.2.

111. *See supra* note 28 and accompanying text.

112. 379 F.2d 990 (C.C.P.A. 1967).

113. *Id.* at 995–96. For a comprehensive discussion of the history of the doctrine, see Katie Albanese, *When Is Enough Enough? What Constitutes Adequate Written Description of a Genus*, 29 FED. CIR. BAR J. 343 (2020).

claimed subject matter.[114] The requirement is met if the claimed subject matter is supported by an adequate description in the specification.[115]

How does the written description requirement differ from enablement? In the 1971 chemical case, *In re DiLeone*,[116] the CCPA explained that one can "*enable* the practice of an invention as broadly as it is claimed, and still not *describe* that invention."[117] *DiLeone* provides an illustration: "[C]onsider the case where the specification discusses *only* compound A and contains *no* broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described."[118] The converse is also true.[119]

While they are separate requirements, both enablement and written description share a policy objective: to prevent overreaching (and thus limit what can be patented) by requiring a correspondence between what is disclosed and what is claimed.[120] Enablement compels the patentee to teach the PHOSITA how to make and use an invention as broadly as it is claimed without undue experimentation;[121] written description requires the patentee to describe the invention in sufficient detail to allow the PHOSITA to recognize that the inventor actually invented what is claimed.[122] But to meet the written description requirement — for genus claims as for any others — it was traditionally sufficient for the patentee to simply mention the genus in the specification or among the originally filed claims.[123] In addition, as *DiLeone* suggests, listing some species belonging to the genus in the specification, along with broadening language, might also have been enough to adequately describe a genus claim.[124]

Early on, the written description requirement came into play only in two scenarios, both involving the problem of timing: (1) when claims not presented in the original patent application were amended or added

---

114. *Ruschig*, 379 F.2d at 995.

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

116. 436 F.2d 1404 (C.C.P.A. 1971).

117. *Id.* at 1405 (emphases added).

118. *Id.* at 1405 n.1.

119. *In re* Armbruster, 512 F.2d 676, 677 (C.C.P.A. 1975) (citation omitted) ("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' [the PHOSITA] to make or use the claimed invention.").

120. *See Vas-Cath*, 935 F.2d at 1561 (noting that the written description requirement guards against overreaching).

121. *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991).

122. *Cf. In re* Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989) ("[T]he description must clearly allow [the PHOSITA] to recognize that [the inventor] invented what is claimed."). Descriptive means include "words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

123. *Cf.* Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1311 (Fed. Cir. 2004) (Rader, J., dissenting from the order denying rehearing en banc) (discussing this case law).

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

to that application during prosecution,[125] or (2) when the inventor sought the benefit of the filing date of the original patent application for claims of a later-filed, co-pending application (known as a "continuation" application).[126] The key question common to these two scenarios is whether the specification provides "adequate support" for any claim that did not appear in the patent application at the time of filing.[127] As stated by the CCPA, "[t]he function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter *later* claimed by him."[128] Early Federal Circuit opinions agreed, noting that the "purpose and applicability" of the written description requirement was "where the claim at issue was filed *subsequent* to the filing of the application."[129]

To illustrate, consider the following hypothetical. The inventor files a patent application claiming "a stainless steel rake having a hardwood handle." The specification discloses numerous species of hardwood, including beech, hickory, maple, oak, and walnut. It also explains how to make and use the rake. While the application is pending at the USPTO, the inventor seeks to amend the application by adding a genus claim that recites "a stainless steel rake having a wooden handle."[130] Note that this claim comprises a larger genus because "wood" is broader than "hardwood." Enablement isn't an issue because rake-making is a predictable technology.[131] But unfortunately for the inventor, the specification only describes and exemplifies hardwoods. Accordingly, as the Federal Circuit held in *Gentry Gallery, Inc. v. Berkline Corp.*, the USPTO will deny the amendment (or a court will invalidate

125. *Vas-Cath*, 935 F.2d at 1560.

126. *Id.* A continuation application is a second application for the same invention disclosed in a parent (i.e., original) application that is filed before the parent application either issues as a patent or becomes abandoned. 35 U.S.C. § 120 (2018). It has the identical specification as the parent and enjoys the benefit of the parent's earlier filing date. *Id.*; MPEP § 201.07 (9th ed. Rev. 4, June 2020). Applicants file continuation applications for many reasons. For example, an applicant may decide to prosecute a parent application with narrow claims (which may issue relatively quickly) and then prosecute broader claims in a continuation application. *See* ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 161–62 (4th ed. 2006).

127. *Vas-Cath*, 935 F.2d at 1560.

128. *In re* Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976) (emphasis added).

129. *Vas-Cath*, 935 F.2d at 1562 (emphasis added) (quoting *In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1973)); *see also* Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985) (explaining that, in the context of claiming entitlement to the priority date of an earlier application, the written description requirement is met if "the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter'" (quoting *In re* Kaslow, 707 F.2d 1366, 1375 (Fed. Cir. 1983))).

130. Applicants broaden claims during prosecution for a variety of reasons, including a desire to ensnare a competitor's product. *See, e.g.*, Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998).

131. *See supra* notes 36–37 and accompanying text.

the claims) for a lack of written description because "[the] original disclosure serves to limit the permissible breadth of [the] later-drafted claims."[132]

In sum, the traditional role of written description was to act as "a timing mechanism to ensure fair play in the presentation of claims after the original filing date and to guard against manipulation of that process by the patent applicant."[133] As of the 1980s, then, written description was a separate requirement from enablement, but it was limited to the timing of claims and thus designed to prevent what we might call "late claiming" — obtaining a claim based on later knowledge or realization, but trying to get the benefit of an earlier filing date.[134] This form of written description, however, didn't pose a threat to genus claims unless such claims were added after filing and the specification included no indication that the researchers believed that their invention was generic.[135]

2. The Rise and Nature of Biotechnological Inventions

The requirements of enablement and written description come up frequently in biotechnology patent cases, and many of the cases we discuss that limit genus claims come from biotechnology. During the 1980s, the Federal Circuit routinely upheld genus claims in the biotechnology field against § 112(a) challenges. Two seminal cases during this era involved "monoclonal antibodies."[136] In *Hybritech Inc. v. Monoclonal Antibodies, Inc.*,[137] the genus claim covered an "immunoassay" method employing highly sensitive monoclonal antibodies to determine the presence or concentration of an antigen.[138] In this infringement litigation, the defendant asserted that the patent was invalid for nonenablement because the specification failed to disclose either how to make monoclonal antibodies or how to screen them to achieve the claimed

132. *Gentry Gallery*, 134 F.3d at 1479.

133. Janice M. Mueller, *Patent Misuse Through the Capture of Industry Standards*, 17 BERKELEY TECH. L.J. 623, 638 (2002) (quoted in PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1306 (Fed. Cir. 2008)).

134. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003) (explaining that the written description requirement focuses on preventing a patentee from "later asserting that he invented that which he did not").

135. *See, e.g.*, *In re* DiLeone, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971).

136. Monoclonal antibodies are man-made proteins designed to find and attach to specific antigens (e.g., viruses or bacteria) circulating throughout the body. Once attached, they can force the immune system to destroy cells containing the antigen. The term "monoclonal" means that the man-made antibody is synthesized by clones from a single parent immune cell. Monoclonal antibodies are used extensively in R&D and as treatments for various diseases, infections, and cancers. *See* RICHARD COICO & GEOFFREY SUNSHINE, IMMUNOLOGY: A SHORT COURSE 80–81 (2015).

137. 802 F.2d 1367 (Fed. Cir. 1986).

138. *Id.* at 1369–71. "Sensitivity" is the ability of an antibody to detect and bind to a particular antigen. *Id.* at 1369.

sensitivity.[139] The Federal Circuit rejected both arguments, noting that the synthetic and screening techniques were well-known in the art and that there wasn't "a shred of evidence that undue experimentation was required by [the PHOSITA] to practice the invention."[140] The court famously stated that "a patent need not teach, and preferably omits, what is well known in the art."[141]

In the other seminal case, *In re Wands*, the genus claim covered an immunoassay method employing highly sensitive monoclonal antibodies capable of detecting a hepatitis B antigen.[142] The issue was whether the disclosure enabled practicing the genus claim without undue experimentation.[143] In order to make the antibodies to practice the patented method, the PHOSITA would have had to engage in an extensive amount of experimentation that included isolating and cloning specialized cells, culturing them, testing the antibodies they produced to determine which would bind to the hepatitis B antigen, and further screening to select those with the claimed sensitivity.[144] Applying the aforementioned *Wands* factors,[145] however, the court determined that the claim was enabled because the specification gave considerable direction, guidance, and working examples; the PHOSITA's level of skill was high; and all of the required methods were well known in the art.[146] Enablement was not precluded, even if extensive routine experimentation was needed to practice the invention, because "[t]he key word is 'undue,' not 'experimentation.'"[147]

For the Federal Circuit in the 1980s, then, biotechnology was a new technology, but it didn't call for new legal doctrine. The enablement question continued to apply as it had within other scientific fields — can the PHOSITA figure out how to make and use species within a claimed genus without too much work or too many false starts? The written description requirement remained limited to the problem of lack of specification support for claims added after filing.[148]

But all that was about to change.

---

139. *Id.* at 1384.

140. *Id.*

141. *Id.* (citing Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1463 (Fed. Cir. 1984)). *But cf.* Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (holding that the patentee cannot rely heavily on PHOSITA knowledge outside of the specification to enable the "novel aspects" of the claim).

142. *In re* Wands, 858 F.2d 731, 734 (Fed. Cir. 1988).

143. *Id.* at 736–37.

144. *Id.* at 737–38.

145. *See supra* notes 33–35 and accompanying text.

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

147. *Id.* at 737 (quoting *In re* Angstadt, 537 F.2d 498, 504 (C.C.P.A. 1976)).

148. *See, e.g.*, *In re* Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

## III. THE MODERN ERA: GENUS CLAIMS FAIL IN COURT

Courts' initially favorable response to biotechnology patents helped to spur research and development in this industry and to bring forth groundbreaking, commercially significant inventions.[149] But the trend soon began to reverse. Beginning in the 1990s, defendants in biotechnology and even traditional chemistry cases began to turn to § 112(a) as a critical shield,[150] putting pressure on this provision's functions of policing claim overbreadth and early patenting.[151] The strategy bore fruit, as the Federal Circuit increasingly came to rely on the enablement requirement, as well as a powerful new variant of the written description requirement, to strike down generic patent claims in the life science fields. Indeed, ten years ago, Dmitry Karshtedt observed that the court's enablement and written description opinions in the 1990s and 2000s showed "discomfort with broad claims of biotechnology."[152]

In this Article, we show that in the past decade the Federal Circuit extended this trend to traditional chemistry genus claims — and has frequently done so in ways that disserve the purposes of the § 112(a) doctrine. Successful recent lines of attack by patent challengers include arguments pointing out inadequate guidance for how the patent specification's teachings would translate across the genus's full scope;[153] an excessive amount of experimentation needed to identify potentially inoperative claim embodiments;[154] and the lack of precise structural information in the specification about the bounds of the genus.[155] While some prior precedent exists for these approaches to invalidating patents

149. For another significant example of a pro-biotechnology decision involving a different section of the Patent Act, 35 U.S.C. § 101, see Diamond v. Chakrabarty, 447 U.S. 303 (1980).

150. *See, e.g.*, *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *In re* Vaeck, 947 F.2d 488, 495–96 (Fed. Cir. 1991); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1214 (Fed. Cir. 1991). *See generally* Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233 (2000).

151. *See* Seymore, *Heightened Enablement*, *supra* note 12, at 128–30; Karen S. Canady, Note, *The* Wright *Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455, 461–62 (1994).

152. Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology's Compliance with the Enablement Requirement*, 3 HASTINGS SCI. & TECH. L.J. 109, 154 (2011) [hereinafter Karshtedt, *Hard-to-Reproduce Inventions*]. While Karshtedt argues that the claims to so-called "biologics" that are the focus of that paper are nonenabled, the mostly chemical claims we discuss in this Article present significantly different issues.

153. Wyeth v. Abbott Lab'ys, 720 F.3d 1380, 1384–85 (Fed. Cir. 2013).

154. Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340, 1349 (Fed. Cir. 2019).

155. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566–67 (Fed. Cir. 1997).

for inadequate disclosure,[156] their deployment has become significantly more vigorous over time.

The resulting shift is dramatic, as we show in this Part. Among the earlier cases, one is hard-pressed to find appellate decisions invalidating claims under § 112(a) based on notions of claim overbreadth or of "gun jumping" by filing an application too early in the research process.[157] By contrast, in the past thirty years, there are virtually no significant examples of genus claims in the life science fields upheld on appeal as compliant with § 112(a) outside the unique context of interference proceedings.[158] The Federal Circuit's shift in its approach to genus claims and the regularity with which those claims are now struck down reflect a fundamental — and not widely appreciated — change in patent doctrine.

### *A. Rejecting Claims on Enablement Grounds*

#### 1. The Antecedents of Doctrinal Drift

The tightening of § 112(a) began in the early 1990s. A significant case in this line is *Amgen Inc. v. Chugai Pharmaceutical Co.*, in which patents relating to gene-mediated synthesis of a protein called erythropoietin ("EPO") were invalidated for lack of enablement.[159] EPO is a hormone that "stimulates the production of red blood cells" and is therefore valuable in the treatment of "anemias or blood disorders characterized by low or defective bone marrow production of red blood cells."[160] Given the prevalence of these disorders, isolated EPO has been a highly sought-after therapeutic, and the litigation was a hard-fought battle between U.S. and Japanese biotechnology giants competing in this space.[161] The claims asserted against Amgen were invalidated based on the evidence that the method in the specification did not

156. *See, e.g.*, *In re* Fisher, 427 F.2d 833, 833, 837 (C.C.P.A. 1970); *In re* Rainer, 390 F.2d 771, 775–76 (C.C.P.A. 1968). *Cf. generally* Kevin T. Richards, Note, *Experimentation and Patent Validity: Restoring the Supreme Court's* Incandescent Lamp Patent *Precedent*, 101 VA. L. REV. 1545, 1575–76 (2015) (arguing that Supreme Court precedent supports an enablement standard that is less patent-friendly than *Wands*).

157. For typical examples of § 112(a) failures from the 1980s, see Quaker City Gear Works, Inc. v. Skil Corp., 747 F.2d 1446, 1455 (Fed. Cir. 1984) (affirming the judgment of nonenablement where matter critical for practicing the claimed invention was incorporated by reference from an unavailable publication); *In re* Wilder, 736 F.2d 1516, 1521 (Fed. Cir. 1984) (affirming a written description rejection of claims to subject matter not disclosed in the original patent application); White Consol. Indus., Inc. v. Vega Servo-Control, Inc., 713 F.2d 788, 790–92 (Fed. Cir. 1983) (holding claims nonenabled where technology necessary to practice the invention was kept as trade secret).

158. For a discussion of interference proceedings, see *infra* Section III.C.1.

159. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1215–17 (Fed. Cir. 1991).

160. *Id.* at 1203.

161. *See* Michael S. Greenfield, Note, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1051–55, 1064 (1992).

actually produce the EPO with the claimed activity, which is a fairly uncontroversial application of the enablement requirement.[162] By contrast, in its own patent that it asserted against Chugai, Amgen did actually teach how to make some EPO analogs.[163]

Nonetheless, Amgen ran into an overbreadth-based enablement challenge. Amgen's representative claim was directed to a genus of deoxyribonucleic acids ("DNAs") — molecules of life known more commonly as genes[164] — as defined by their function of producing EPO and its analogs: "A purified and isolated DNA sequence . . . encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of [EPO] to allow possession of the biological property of causing bone marrow cells to increase production of . . . red blood cells, and to increase hemoglobin synthesis or iron uptake."[165]

The Federal Circuit noted that this claim encompasses a "potentially enormous" number of isolated DNA sequences.[166] Any sequence that will encode for and thus cause the production of EPO or EPO-like products — proteins with a structure similar enough to EPO to generate red blood cells — would be covered by this claim.[167] The court acknowledged that "a patent applicant is entitled to claim his invention generically" when the claims "are of a scope appropriate to the invention disclosed."[168] But it explained that the specification of Amgen's patent had "little enabling disclosure" of the potential DNA variants encoding EPO, or of "how to make them."[169] After further flagging "the manifold possibilities for change in [the claimed] structure, with attendant uncertainty as to what utility will be possessed by these analogs," the Federal Circuit concluded that "[i]t is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity."[170]

Amgen's claims thus presented a commensurability problem.[171] Indeed, because the specification disclosed only a few examples of a large and complex genus of DNAs whose varied structures could

---

162. *Amgen*, 927 F.2d at 1215–17.

163. *See id.* at 1213.

164. If this case were decided today, the claims would have likely been invalid for the separate reason that isolated genomic DNA is not patentable subject matter under 35 U.S.C. § 101. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

165. *Amgen*, 927 F.2d at 1204.

166. *Id.* at 1213.

167. *See id.* at 1212. Note this functional aspect of the claim. As we discuss below, this is a hallmark of many claims that the Federal Circuit has properly invalidated under § 112(a), but the court's doctrinal path has also endangered claims that we believe to be deserving. *See infra* notes 283–287 and accompanying text.

168. *Amgen*, 927 F.2d at 1213–14.

169. *Id.* at 1213.

170. *Id.* at 1214.

171. *See supra* Section II.A.3.

unpredictably affect their EPO-producing function, the Federal Circuit did not even formally consider the *Wands* factors before readily reaching the conclusion of nonenablement.[172] But the attitude of the opinion differs markedly from the CCPA's *In re Angstadt* decision.[173] That court, one will recall,[174] upheld a rather broad claim against a nonenablement challenge in part *because of*, rather than in spite of, the fact that identifying working embodiments within the claims' scope required "the types and amount of experimentation which the uncertainty of [the] art makes inevitable."[175] In so doing, the CCPA rewarded a significant discovery in the unpredictable field of chemistry with the meaningful protection of a broad genus claim.[176]

To be sure, one could have distinguished *Amgen* from *Angstadt* on the respective cases' facts and invalidated the *Amgen* claims by comfortably applying the *Angstadt* precedent. The *Angstadt* claims were in the well-established field of chemical catalysis that, to channel the immortal words of Donald Rumsfeld, brought with it "known unknowns"[177] — an evocative version of the CCPA's nod to the inevitable but acceptable uncertainty involved in practicing Angstadt's invention.[178] In contrast, *Amgen* dealt with the field of recombinant DNA technology that was just emerging when the applications that matured into the patents in suit were filed, bringing with it many "unknown unknowns."[179] In addition, and in further contrast to *Angstadt*, *Amgen*'s claims were largely defined by the function of EPO-like activity and did not include much in the way of actual structure, unlike the catalysts described in *Angstadt*.[180] The *Amgen* court, however, did not attempt to distinguish *Angstadt*.[181] As we show in this Section, the Federal Circuit's failure to square *Angstadt* with its later § 112(a) case

172. *Amgen*, 927 F.2d at 1213.

173. 537 F.2d 498 (C.C.P.A. 1976).

174. *See supra* notes 89–94 and accompanying text.

175. *Angstadt*, 537 F.2d at 504; *cf. In re* Wands, 858 F.2d 731, 740 (Fed. Cir. 1988) (explaining that some areas of science require laborious experimentation to practice inventions in spite of "a high level of skill in the art").

176. *Cf.* Canady, *supra* note 151, at 457–58 (noting that in certain fields of technology, extensive experimentation is inevitable).

177. David A. Graham, *Rumsfeld's Knowns and Unknowns: The Intellectual History of a Quip*, ATLANTIC (Mar. 27, 2014), https://www.theatlantic.com/politics/archive/2014/03/rumsfelds-knowns-and-unknowns-the-intellectual-history-of-a-quip/359719 [https://perma.cc/TR6X-PLFV].

178. *Angstadt*, 537 F.2d at 504.

179. For another example in which the nascent nature of the field led to the conclusion of nonenablement, see Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1367–68 (Fed. Cir. 1997). *See also* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1255 (Fed. Cir. 2004) (exemplifying a similar approach in the context of the written description requirement); Seymore, *Heightened Enablement*, *supra* note 12, at 149.

180. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1204, 1214 (Fed. Cir. 1991).

181. *Id.* at 1213 (citing *Angstadt*, 537 F.2d at 502–03, but only to support the innocuous proposition that "it is not necessary that a patent applicant test all the embodiments of his invention").

law has led to instability and, ultimately, a marked doctrinal drift. Any broad genus claim, not just one in an emerging field, would soon become vulnerable.

In addition to the Federal Circuit's increased scrutiny of claim overbreadth, groundwork for change was created by the court's subtle but significant recasting of the sorts of experimentation that can be considered undue under the *Wands* standard. That shift arguably began in a 1999 biotechnology enablement opinion, *Enzo Biochem, Inc. v. Calgene, Inc*.[182] This case involved "antisense" technology that, as the court held, was also claimed in a plainly overbroad manner.[183] Briefly, antisense is a method for regulating the gene-mediated production of proteins with the aid of synthetic DNA molecules.[184] This technology embodies a powerful method of controlling the body's immune response, and has therefore paved the way for therapies that can treat inflammations and various autoimmune disorders. The claims encompassed antisense-promoting synthetic DNAs "present in a prokaryotic and eukaryotic cell containing a gene" and prokaryotic or eukaryotic cells containing those DNAs.[185] The inventors got the antisense technology to work in some genes of the *E. coli* bacteria, disclosed those methods in the specification, and asserted that antisense was generalizable to other genes and organisms, including eukaryotes.[186]

The Federal Circuit found that all the *Wands* factors pointed towards nonenablement: the claims were broad; the technology, nascent and unpredictable; and the experimentation needed to practice it, especially in eukaryotes, challenging and rife with failure.[187] As to the direction in the specification and working examples, the Federal Circuit agreed with the lower court's conclusion that the patents "provided little guidance . . . as to the practice of antisense in cells other than *E. coli*, and that such minimal disclosure constituted no more than a plan or invitation to practice antisense in those cells."[188]

But the *Enzo* court didn't stop there. While the experimentation needed to practice the claimed invention there was anything but routine, the court implied in passing that even routine experimentation can sometimes be "undue" within the *Wands* framework if it is too

182. 188 F.3d 1362 (Fed. Cir. 1999).

183. *Id.* at 1368, 1377.

184. An example of "gene expression" is production of EPO mediated by the EPO genes, discussed above in the context of the *Amgen* case. *See supra* notes 164–165 and accompanying text.

185. *Enzo*, 188 F.3d at 1368. Prokaryotes are lower organisms such as the well-known *E. coli* bacteria, while eukaryotes are higher organisms like animals and plants. *Id.* at 1366 n.2.

186. *Id.* at 1367–68. The defendant's product was a tomato, which is eukaryotic. *Id.* at 1377.

187. *Id.* at 1370–74.

188. *Id.* at 1375.

extensive.[189] This seemingly insignificant, almost throwaway, language has nonetheless been used to great effect in recent enablement cases.[190] The Federal Circuit affirmatively restated *Enzo*'s "routine" notion in *ALZA Corp. v. Andrx Pharmaceuticals, LLC*,[191] decided in 2010, when it observed that "[e]nablement is not precluded where a 'reasonable' amount of routine experimentation is required to practice a claimed invention, however, [sic] such experimentation must not be 'undue.'"[192] Although *ALZA* itself did not deal with a generically claimed invention, a series of subsequent Federal Circuit decisions striking down chemical genus claims made much use of the "routine but undue" argument.[193] This theory further paved the way for invalidating claims directed to technologies that, unlike recombinant DNA or antisense, were not nascent or emerging, but arguably unpredictable only in the "known unknowns" sense that the CCPA had previously found acceptable in cases like *Angstadt* and *Atlas Powder*.[194]

2. The New Law of Genus Claim Nonenablement

Of late, § 112(a) has been applied with increasing rigor against patents in areas with "known unknowns." The first opinion in this line of cases, *Wyeth v. Abbott Laboratories*,[195] involved a traditional chemical genus rather than a biotechnological invention.[196] The underlying discovery addressed a condition called restenosis, which is the re-narrowing of an artery after a catheter has been used to open it.[197] The claims recited a method of treating this condition with a therapeutically effective amount of a chemical belonging to the class of compounds called "rapamycin."[198] The rapamycin compounds all have a particular "macrocyclic" (i.e., large-ring) structure, but one of the chemical groups

189. *Id.* at 1371.

190. *Cf.* Matthew D. Kellam, Comment, *Making Sense Out of Antisense: The Enablement Requirement in Biotechnology After* Enzo Biochem v. Calgene, 76 IND. L.J. 221, 227 (2001) ("Avoiding trial and error experiments and unpredictable results in this field is impossible." (citation omitted)); Canady, *supra* note 151, at 457–58.

191. 603 F.3d 935, 940 (Fed. Cir. 2010).

192. *Id.* (citations omitted).

193. *See infra* Section III.A.2.

194. *See supra* notes 99–106 and accompanying text; *cf. In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) ("[T]here may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling . . . . This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles."). This older view thus held that claims failed enablement if the underlying subject matter could not be made at all because it did not work, and a genus was therefore not really invented. That is very different than saying it is routine but time-consuming to figure out all the operable species in the genus.

195. 720 F.3d 1380 (Fed. Cir. 2013).

196. *Id.* at 1384.

197. *Id.* at 1382.

198. *Id.*

attached to the ring is allowed to vary.[199] The inventors thus claimed the class of potential therapeutic agents much as one would claim a traditional chemical genus. While many such claims are directed to a structure with an invariant chemical core and a "wild-card" substituent denominated as "R," "X," or some other indicator of a variable chemical group,[200] the patentee simply used the word "rapamycin" to refer to the entire generic chemical structure, in which the substituent indicated by the dashed oval in Figure 2 below can vary.[201]

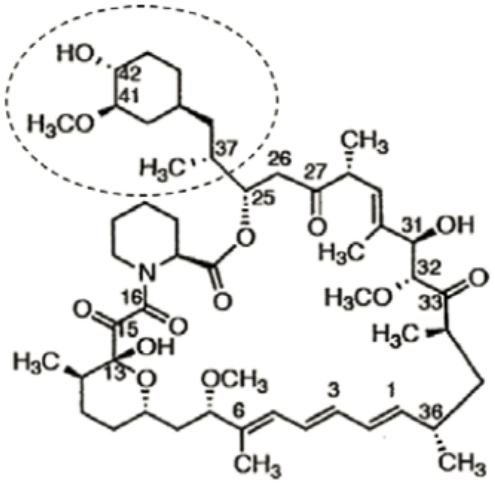


Figure 2: The Generic Chemical Structure Claimed in *Wyeth*

The specification demonstrated that at least one of the species within the rapamycin genus, "sirolimus," was effective in treating restenosis.[202] It also disclosed assays for testing whether other rapamycins have the requisite therapeutic property.[203] Further supporting enablement, an expert explained in an affidavit that the PHOSITA would know that a substituent group must be below a certain molecular weight in order to have an antirestenotic function.[204] But all of this wasn't enough. After noting that even routine experimentation "is not 'without bounds'" under the undue experimentation standard,[205] the Federal Circuit cited *ALZA* for the proposition that the need for "an iterative, trial-

199. *Id.*
200. *See supra* Section II.B.
201. *Wyeth*, 720 F.3d at 1383.
202. *Id.* at 1384.
203. *Id.*
204. *Id.*
205. *Id.* at 1386 (quoting Cephalon, Inc. v. Watson Pharms., Inc., 707 F.3d 1330, 1339 (Fed. Cir. 2013)).

and-error process to practice the claimed invention even with the help of the . . . specification" can lead to an enablement problem.[206] It therefore invalidated the claims on summary judgment, explaining that the synthesis of the "tens of thousands of candidate[]" sirolimus compounds was laborious, the assays were time-consuming,[207] and the guidance on structural parameters that could help the PHOSITA more expediently identify the working species within the claimed genus was inadequate.[208]

The genus in *Wyeth* is reasonably large. Nevertheless, the problem in *Wyeth* is one of "known unknowns." Specifically, identifying antirestenotic members of the rapamycin genus may have been time-consuming, but it was solvable with the aid of established techniques of organic synthesis and the assays disclosed in the specification.[209] This is a far cry from cases like *Enzo*, in which the inventors demonstrated a proof of concept of just-discovered antisense technology in *E. coli* and then claimed antisense DNA for every living organism under the sun.[210] Instead, the facts of *Wyeth* are much closer to those of *Angstadt*, in which the CCPA allowed the broad genus claims after concluding that a follow-on inventor could ascertain whether any particular compound satisfying the claim's structural limitations works for the intended catalytic purpose by testing it out.[211] Practicing the claims in *Wyeth*, as in *Angstadt*, didn't seem to require "ingenuity beyond that to be expected of one of ordinary skill in the art," and yet the patentee lost in *Wyeth* and won in *Angstadt*.[212]

Key to the different results seems to be a significant but unacknowledged shift in how the Federal Circuit thinks about enablement of genus claims. *Angstadt* and *Atlas Powder* are focused on the practical challenge facing the PHOSITA — how to make and use a species within the genus. If it's too hard to find one that works, either because the claimed genus itself isn't really a well-defined genus, as in *Incandescent Lamp*,[213] or because of the related problem that the

206. *Id.* (quoting ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 943 (Fed. Cir. 2010)).

207. *Id.* at 1385.

208. *Id.* at 1386.

209. *Id.* at 1384–85.

210. *See supra* notes 182–188 and accompanying text.

211. *In re* Angstadt, 537 F.2d 498, 503 (C.C.P.A. 1976). One difference from *Wyeth* is that the compounds that must be synthesized and experimented on to practice the claims in *Angstadt* are inorganic rather than organic. But as two of us can attest (Karshtedt and Seymore; Lemley is not a chemist), inorganic synthesis is no easier than organic synthesis, and some would say much tougher. *See generally* Ruren Xu, *Introduction*, *in* MODERN INORGANIC SYNTHETIC CHEMISTRY 1–7 (Ruren Xu & Yan Xu eds., 2d ed. 2017) (exploring the challenges, rigor, and "major scientific issues" in modern synthetic inorganic chemistry).

212. *Angstadt*, 537 F.2d at 503 (quoting Fields v. Conover, 443 F.2d 1386, 1390–91 (C.C.P.A. 1971)).

213. *See supra* notes 54–61 and accompanying text.

number of inoperative species is too high,[214] the PHOSITA would have to engage in undue experimentation.

The *Wyeth* court, by contrast, was worried that the synthesis of the "tens of thousands of candidate[]" sirolimus compounds would require undue experimentation.[215] That does indeed sound like a lot of work. But why would the PHOSITA have to synthesize tens of thousands of candidates?[216] Even if half or more of the species in the genus don't work (and there was no evidence that this was actually the case in *Wyeth*), on average (i.e., working at random) the PHOSITA might have to try two or three candidates before finding one that does. Nevertheless, *Wyeth* reflects a move away from this kind of pragmatic thinking. To gauge whether the "full scope" of the genus claim is enabled, the Federal Circuit seems to implicitly assume that the PHOSITA must test *every* species within the genus for enablement purposes. That's a significant new requirement and one that will prove impossible to meet for any sufficiently large genus. And the implications are problematic: as the CCPA observed in a related context, "[r]equiring specific testing of the thousands of [chemical] analogs encompassed by the present claim in order to satisfy the how-to-use requirement of § 112 would delay disclosure and frustrate, rather than further, the interests of the public."[217]

As two 2019 Federal Circuit opinions confirm, however, the *Wyeth* view has now won out. In addition, these latest cases have reinforced a troubling dynamic involving therapeutic efficacy limitations in claims that also include a chemical genus. In *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*,[218] the court emphasized that "[a]s in *Wyeth*, the asserted claims here require not just a particular structure, but a particular functionality."[219] The court then concluded that the claims were not enabled because "the specification fails to teach one of skill in the art whether the many embodiments of the broad claims would exhibit that required functionality."[220] Therapeutic efficacy is a claim-narrowing limitation, so one would think that it is easier to enable a claim that is so limited as opposed to a broader, purely structural claim. But the Federal Circuit seemed to say that such limitations in fact made the patentee's job more difficult. The court explained that "even if we assume that the specification teaches one of skill in the art how to create the

214. *See supra* notes 48–53 and accompanying text.

215. Wyeth v. Abbott Lab'ys, 720 F.3d 1380, 1385 (Fed. Cir. 2013).

216. *See id.* ("[T]here is no genuine dispute that it would be necessary to first synthesize and then screen *each* candidate compound using the assays disclosed in the specification to determine whether it has immunosuppressive and antirestenotic effects.").

217. *In re* Bundy, 642 F.2d 430, 434 (C.C.P.A. 1981).

218. 928 F.3d 1340 (Fed. Cir. 2019). This is a different *Enzo* case than the one discussed above and we refer to it as "*Roche*."

219. *Id.* at 1346.

220. *Id.*

broad range of [structures] covered by the claims . . . the specification still fails to teach one of skill in the art which combinations" will produce a product with the claimed functional properties.[221]

The Federal Circuit's analysis of the functionality limitation in *Roche* suffers from the same problem as the "antirestenosis effective" limitation in *Wyeth*. Yes, the PHOSITA needs to find a species that works. But the PHOSITA doesn't need to find *every* species that works to make and use the invention. It is enough to get hold of just one, or perhaps a few, structural analogs within the genus that accomplish the claimed or intended purpose. The Federal Circuit seems concerned that we don't know the exact boundaries of the genus if operability is an element of the patent claim. But so what? The concern of enablement law has always been with practical workability: Does the patent teach others what they need to know?[222] *Wyeth* and *Roche* represent a categorical shift in thinking away from teaching the PHOSITA and toward a precise delineation of the boundaries of the claim — even when, as in those cases, the genus was well defined as a matter of structure.[223]

The second notable case from 2019, *Idenix Pharmaceuticals LLC v. Gilead Sciences, Inc*.,[224] cemented that shift. In *Idenix*, a divided panel held that the claims at issue failed both the written description[225] and enablement requirements as a matter of law.[226] The representative claim was directed to "[a] method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine ß-D-2'-methyl-ribofuranosyl nucleoside [depicted in Figure 3 below]."[227]

---

221. *Id.*

222. *Cf.* Durel Corp. v. Osram Sylvania, Inc., 256 F.3d 1298, 1306 (Fed. Cir. 2001) (explaining that full-scope enablement does not require enablement of a specific embodiment of the claim); *In re* Cook, 439 F.2d 730, 735 (C.C.P.A. 1971) (noting that "given the complexities of zoom lens design, the determination, while routine, could be very time-consuming" but explaining that this in itself is not enough to find the claims nonenabled). In *Cook*, the CCPA ultimately did strike down the claims because the inventors "never produced . . . calculations to substantiate the truthfulness of the teaching in their specification which the examiner challenged." *Cook*, 439 F.2d at 736. This is a more traditional view of the enablement requirement, which demands a showing that the inventor demonstrate how the PHOSITA could build an embodiment of the invention.

223. *Cf. supra* Section II.B.

224. 941 F.3d 1149 (Fed. Cir. 2019).

225. For a discussion of the written description part of *Idenix*, see *infra* Section III.B.

226. *Idenix*, 941 F.3d at 1153.

227. *Id.* at 1155.

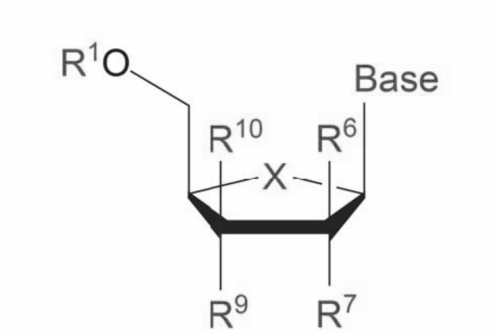


Figure 3: The Generic Chemical Structure Claimed in *Idenix*

While the claimed invention ultimately recites a method of treating the hepatitis C virus ("HCV"), the structural limitation depicted above follows the standard approach to claiming chemical compositions generically.[228] As in *Wyeth*, the chemical backbone (here, called a "furanosyl nucleoside") has an invariant core and some variable chemical groups on the periphery. The *Idenix* panel majority had no trouble invalidating this patent, and even Judge Pauline Newman in dissent argued only that it should have been upheld under the significantly narrower claim construction that she favored.[229]

As in *Wyeth*, the majority began by observing that the genus was large. It noted that while the claimed structure is limited to a methyl in the 2'-up (i.e., R6) position, "the formula provides more than a dozen options at the R1 position, more than a dozen independent options at the 2'-down position [(R7)], more than a dozen independent options at the 3'-down position [(R9)], and multiple independent options for the base."[230] Estimating the factorial, one finds that the total number of possible structures within the scope of the claim reaches into several thousand species.

But such large numbers are typical in chemical genus claiming[231] — and having a massive genus of compounds to be tested for catalytic activity didn't ultimately result in an enablement problem in *Angstadt* or *Atlas Powder*, neither of which *Idenix* cited. Moreover, as

228. *See supra* note 77 and accompanying text.

229. *Idenix*, 941 F.3d at 1167 (Newman, J., dissenting). Claim construction is an exercise of determining claim scope that must often be performed before patent validity is determined. Often, claims fail on § 112(a) grounds in cases in which the patentee seeks a broad claim construction. *See, e.g.*, Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1378–79 (Fed. Cir. 2007).

230. *Idenix*, 941 F.3d at 1158 (majority opinion).

231. Seymore, *Heightened Enablement*, *supra* note 12, at 146 ("Indeed, a single generic claim can easily encompass millions, billions, or [more] compounds." (citations omitted)).

the district court in *Idenix* recognized, the knowledge of the PHOSITA could help reduce the number of potential working species based on the judgment that certain substitution patterns would prevent a species from functioning as efficacious therapy against HCV infections.[232] With the genus thus limited, *Idenix* further explained that some candidate species could be bought off the shelf as part of a compound library, while others could be synthesized using routine methodologies.[233] Finally, the specification provided several working embodiments, and the Federal Circuit agreed that the record supported all these findings.[234]

Nevertheless, the court concluded that the patent leaves one "searching for a needle in a haystack to determine which of the 'large number' of 2'-methyl-up nucleosides falls into the 'small' group of candidates that effectively treats HCV."[235] Applying *Wyeth*, it held that the PHOSITA would just have too many compounds to obtain and screen because it was not possible to tell in advance for many candidates whether their structures would have the desired HCV-treating property.[236] As the Federal Circuit framed it, "[t]he key enablement question is whether a [PHOSITA] would know, without undue experimentation, which 2'-methyl-up nucleosides would be effective for treating HCV," and the answer was "no."[237] Even accepting that the disclosed screening process allowed for straightforward identification of working embodiments, the court determined the work involved to be excessive for enablement purposes.[238] While any individual molecule that falls within the scope of the genus and is effective against HCV might be readily found, the overall sorting process was held to require undue experimentation.[239]

This approach is problematic. It focuses on "knowing" instead of "making and using," which is what the text of § 112(a) actually requires, and discounts *Angstadt*'s warning that ex ante "reasonable certainty" that a particular chemical structure would work for its intended purpose cannot be required to enable the claims.[240] As the CCPA

232. Idenix Pharms. LLC v. Gilead Scis., Inc., No. 14-846-LPS, 2018 WL 922125, at *14 (D. Del. Feb. 16, 2018); *see Idenix*, 941 F.3d at 1158.

233. *Idenix*, 941 F.3d at 1159–60.

234. *Id.* at 1161.

235. *Id.* at 1162.

236. *Id.* at 1162–63 (citing Wyeth v. Abbott Lab'ys, 720 F.3d 1380, 1384–86 (Fed. Cir. 2013)).

237. *Id.* at 1156.

238. *Id.* at 1162–63.

239. *Cf.* McRO, Inc. v. Bandai Namco Games Am. Inc., 959 F.3d 1091, 1100 n.2 (Fed. Cir. 2020) ("In cases involving claims that state certain structural requirements and also require performance of some function (*e.g.*, efficacy for a certain purpose), we have explained that undue experimentation can include undue experimentation in identifying, from among the many concretely identified compounds that meet the structural requirements, the compounds that satisfy the functional requirement." (citing *Idenix*, *Roche*, *Wyeth*, *Enzo*, and *ALZA*)).

240. *In re* Angstadt, 537 F.2d 498, 503 (C.C.P.A. 1976).

astutely noted, if such a requirement were imposed, "then *all* 'experimentation' is 'undue,' since the term 'experimentation' implies that the success of the particular activity is *uncertain*."[241] Even though "thousands" of candidates exist and the catalysis field as a whole is "an unpredictable art," the *Angstadt* genus was enabled because "[i]n this art the performance of trial runs using different catalysts is 'reasonable,' even if the end result is uncertain."[242] Such unpredictability was characteristic of this mature field — and traversing the claimed genus was a matter of "known unknowns."

But that's no longer the law. After *Wyeth* and *Idenix*, uncertainty with respect to whether some subset of species of a chemical genus would achieve the recited therapeutic efficacy — in other words, whether any given species is within the boundaries of the claim — can be a fatal flaw for enablement purposes. This is true even when the patentee attends to the field's inevitable unpredictability by disclosing a screening mechanism that gives the PHOSITA parameters for "making and using" any given embodiment within the structural genus of the claimed invention.

To be sure, even under older Federal Circuit precedents like *Atlas Powder*, defendants could in theory try to invalidate a claim for lack of enablement if they could demonstrate that so many embodiments within the scope of the claim didn't actually work for the invention's intended purpose so that the PHOSITA, like Edison in *Incandescent Lamp*, would have to try hundreds or thousands to find one that worked well.[243] But it's crucial to point out that those were not the showings made in *Wyeth* and *Idenix*. Indeed, in both cases, the respective defendants did find a species within the genus that worked perfectly well[244] — and they didn't demonstrate that the research leading to this actual result was difficult to accomplish in view of the patent's disclosure (or that a significant number, or even any, of the species within the genus were ineffective). Instead, the respective defendants argued that *all* the operative embodiments would be time-consuming to identify, and the court accepted this evidence by itself as decisive of invalidity.[245]

This doctrinal shift is a massive change in the Federal Circuit's enablement doctrine. The court once seemed to suggest that "operability

241. *Id.*

242. *Id.* at 502–04.

243. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576–77 (Fed. Cir. 1984); *see* Consol. Elec. Light Co. v. McKeesport Light Co. (*Incandescent Lamp*), 159 U.S. 465, 472–73 (1895).

244. *See* Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1171–73 (Newman, J., dissenting); *see also id.* at 1153 (majority opinion) (noting the Food and Drug Administration approval of the defendant's product); Wyeth v. Abbott Lab'ys, 720 F.3d 1380, 1383 (Fed. Cir. 2013) (noting that the defendant came up with a commercial product covered by the now-invalidated claim).

245. *See Idenix*, 941 F.3d at 1162–63; *Wyeth*, 720 F.3d at 1385–86.

limitations" in patent claims can forestall enablement problems altogether by limiting the scope of the genus to only the species that work for their intended purpose.[246] But we've now reached the point that adding such limitations can present nearly insurmountable § 112(a) difficulties for inventors seeking genus claims that also recite a functional property of the compounds.

In sum, the Federal Circuit's latest enablement case law suggests that the process of sorting operative from inoperative embodiments, whether routine or not, may be emerging as a critical challenge for patentees defending against claims of nonenablement. The enablement inquiry has shifted from the question of whether making and using the invention requires undue experimentation to whether such experimentation is required to define the "full scope" of the invention by figuring out which of all the possible species within the genus work for the invention's claimed purpose. Counterintuitively, it may now be better to draft broader composition claims with no functional limitations so as to forestall arguments about how numerous "variables would or would not impact the functionality" of the claimed invention.[247] But even that won't necessarily help if the claims don't make clear exactly what the working chemicals are or if it takes a long time to make every single chemical within the genus.

Worse yet, the "routine but undue" theory makes it much easier for defendants to argue that genus claims are overbroad on their face. Genus claims now fail enablement even when the inventor isn't using the scope of the claim to effectively lock up a scientific discovery like antisense or technology in a nascent field like the use of recombinant DNA for EPO synthesis.[248] This development calls into question any genus claim covering a significant number of species in the life sciences and chemical fields because they typically come with built-in unpredictability even when the claimed technology is mature. Accordingly, examples of claims surviving enablement challenges on appeal are becoming increasingly rare.

### *B. Written Description and the Possession of Genus Claims*

The shift in enablement law we described in the previous Section is bad enough for chemical patentees. But there's more. The written description requirement, also drawn from § 112(a), has in the last thirty years morphed from a fairly limited tool for preventing the inventor

246. *See, e.g.*, Union Carbide Chem. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1186 n.10 (Fed. Cir. 2002).

247. Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340, 1347 (Fed. Cir. 2019).

248. Merges & Nelson, *supra* note 13, at 904–08 (discussing problems with allowing broad patents on "science-based" inventions); *see also generally* Canady, *supra* note 151.

from adding or amending claims after the filing date[249] to a powerful check on claim scope.[250]

As we show in this Section, the heightened enablement requirement and the new, broader written description doctrine have reinforced one another so as to turn § 112(a) into an extremely powerful weapon against generic claiming in the life sciences. Although the new written description requirement appears to be concerned mainly with premature patenting (or "gun jumping"), it has expanded to invalidate originally filed generic claims as well as those added or amended during prosecution. Finally, as with enablement, therapeutic efficacy limitations can create special written description problems for the patentee.[251]

1. *Lilly* and Written Description as Enablement Plus

As we noted in Part II, the focus of the original version of the written description requirement was on claims introduced after the filing date. To review earlier discussion,[252] if the patent describes (and even claims) only an individual chemical species A and does not include any broadening language, an attempt to add a new generic claim X during prosecution will run into a written description problem.[253] Thus, even if the PHOSITA would have no trouble extrapolating from the teachings for making A to synthesize numerous other species (B, C, D) that fall within genus X without undue experimentation, the patent's failure to indicate that the method for making A is generalizable can be fatal to claiming X.[254] A court or the USPTO would say that the PHOSITA reading the original filing would conclude that the inventors were not "in possession" of the genus — they didn't appreciate that the synthesis of A readily generalized to other species (B, C, D) and ultimately to X.[255] This example illustrates that a generic claim can be enabled, but not described.

One way an inventor could solve the problem, it would seem, is by including a claim to X as part of the original patent filing, because a

249. *See supra* Section II.C.1.

250. For early commentary on the shift, see Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 62–88 (2000); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 633–49 (1998); Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 222–26 (1998).

251. *See* Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1161 (Fed. Cir. 2019); Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc., 923 F.3d 1368, 1377 (Fed. Cir. 2019).

252. *See supra* Section II.C.1.

253. *See supra* notes 116–124 and accompanying text.

254. *Id.*

255. *See generally* Jules E. Goldberg, *Genus, Species, and the Patent Law*, 53 J. PAT. OFF. SOC'Y 73 (1971) (discussing the failures of genus claims that were not supported by enough species in the patent's specification).

genus claim should indicate to the PHOSITA that the inventors possessed the genus. Before the 1990s, patent attorneys would deploy that very strategy and were probably safe in assuming that any genus claimed at the time of filing was also possessed, satisfying the written description requirement.[256] That changed, however, with *Regents of the University of California v. Eli Lilly & Co.*,[257] a case that created a significant new route for policing the scope of genus claims (among other impacts).

In *Lilly*, the patentee described the structure of a "complementary" DNA ("cDNA") that encodes insulin in the rat, and attempted to extrapolate from this discovery to the cDNAs for insulin in any mammal.[258] The practical implications are worth appreciating here: no one really cared about rat cDNA for its own sake, but rather because the commercially valuable use of the invention was to produce insulin in other mammals — particularly, humans — the inventors included a generic mammalian claim in their original patent filing.[259]

The reader may recall the foregoing discussion of *Amgen* and conclude that this claim at least had an enablement problem — only one species of DNA is disclosed, and a large number (the whole mammalian kingdom!) is claimed.[260] However, as much as we humans might not like it, there can be significant homology (i.e., similarity) between the corresponding genes of rats and humans.[261] And if the methodology for isolating rat insulin cDNA readily translates to cDNAs coding for insulin in humans and other mammals, we have the very scenario discussed in the previous paragraph: the making of A (rat insulin cDNA) can be extrapolated to B (human), C (non-human primate), and D (dolphin), and the genus X (mammalian insulin cDNA) is enabled.[262]

But in *Lilly*, the Federal Circuit didn't reach the enablement question at all. Instead, it invalidated the mammalian insulin cDNA claim for inadequate written description, rejecting the argument that its inclusion in the original filing showed the inventors' rat work was generalizable to other mammals like humans.[263]

---

256. *See* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 161–63 (2006).

257. 119 F.3d 1559 (Fed. Cir. 1997).

258. *Id.* at 1563. Another claim covered the genus of vertebrates. *Id.* at 1567–68.

259. *Id.* at 1562–63.

260. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213–14 (Fed. Cir. 1991).

261. Andy Coghlan, *Rat Genome Reveals Supercharged Evolution*, NEWSCIENTIST (Mar. 31, 2004), https://www.newscientist.com/article/dn4840-rat-genome-reveals-supercharged-evolution/ [https://perma.cc/8C4J-5T6R] ("Even today, [humans, rats, and mice] share 280 large chunks of chromosomes that are virtually identical, suggesting that they are indispensable."); Claude Szpirer, *Rat Models of Human Diseases and Related Phenotypes: A Systematic Inventory of the Causative Genes*, 27 J. BIOMED. SCI. 84, at 2 (2020) (noting that "a considerable number of conserved genes have similar effects on biological traits in rats and humans").

262. *See* Sampson, *supra* note 150, at 1260–61 (suggesting this possibility).

263. *Eli Lilly*, 119 F.3d at 1568–69.

How could there be a written description problem when the originally filed claim itself contained the genus claim? Proceeding from the starting point that a DNA is at bottom a chemical compound, the court explained that there can be no possession of the DNA without knowledge of its "sequence," or chemical structure. The court noted that "a generic statement such as . . . 'mammalian insulin cDNA,' without more, isn't an adequate written description of the genus because it doesn't distinguish the claimed genus from others, except by function," or "define any structural features commonly possessed by members of the genus that distinguish them from others."[264] In so doing, the Federal Circuit rejected the view that the written description requirement is used to police only priority of invention (i.e., introduction of claims after filing, narrow or broad, that are not supported by the specification),[265] as opposed to early patenting or claim scope.[266]

The University of California inventors were thus left with an essentially worthless claim to the rat insulin cDNA.[267] And inventors more generally were left with a problem: they had to provide "'a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials"[268] in order to describe a genus claim, even if the PHOSITA could figure out what was in the genus and how to use it without undue experimentation.

*Lilly* quite clearly rested on the Federal Circuit's policy judgment that the inventors filed their patent application too soon in the research process by trying to lay claim to human insulin cDNA before determining its structure. The court said as much when it noted that the specification and claims were directed only to "a mere wish or plan for obtaining the claimed chemical invention."[269] The court also invalidated the narrow claim to human insulin DNA, which is evidence that *Lilly* was more about filing too early than claiming too broadly.[270] For both the human species and the mammalian genus claims, the Federal Circuit took issue with the lack of information about the structure of insulin cDNAs of organisms other than the rat. Nonetheless, as we discuss below, *Lilly* has had a lasting impact on more traditional (i.e., nonfunctional) genus claims too.

---

264. *Id.*

265. *See, e.g.*, Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991).

266. *See* Dan L. Burk, *Biotechnology at the Federal Circuit: A Clockwork Lemon*, 46 ARIZ. L. REV. 441, 451–53 (2004).

267. *See* Karen G. Potter, *Getting Written Description Right in the Biotechnology Arts: A Realist Approach to Patent Scope*, 28 BIOTECH. L. REP. 1, 6, 14 (2009).

268. *Eli Lilly*, 119 F.3d at 1568 (first quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993), and then citing *In re* Smythe, 480 F.2d 1376, 1383 (C.C.P.A. 1973)).

269. *Id.* at 1566 (citing *Fiers*, 984 F.2d at 1171).

270. *See id.* at 1567.

The *Lilly* court's efforts to square its policy focus on early patenting with the distinct problem of generic claiming, as well as its struggle to distinguish how genus claims are analyzed under the enablement versus written description prongs of § 112(a), presage the doctrinal drift that is now making genus claims practically impossible to defend in court. The Federal Circuit created a second way of opposing genus claims that is similar to an enablement challenge,[271] but it did not explain precisely how the process of proper extrapolation from species to genus differs for written description.[272] We do know that unlike traditional enablement doctrine, post-*Lilly* written description doesn't require addressing undue experimentation. A generic claim may well be enabled based on the PHOSITA's ability to readily make multiple species, but not described — even if the inventor attempts to show the genus's possession by claiming it in the original filing or using broadening language.[273]

The *Lilly* opinion also reveals an important dynamic in the Federal Circuit's use of § 112(a) as a policy tool. Indeed, some commentators have explicitly called *Lilly* written description "super-enablement" or "enablement plus," suggesting that it creates an extra hurdle for biotechnological inventions.[274] That extra hurdle can't be satisfied by showing, for instance, that the PHOSITA can make and use human insulin cDNA without undue experimentation.

The Federal Circuit's overarching desire to prevent patentees from jumping the gun and locking up nascent technology may explain its willingness to dispense with considering certain *Wands* factors, as in some enablement cases like *Amgen*,[275] or even all of them, as in written description decisions and particularly those involving functional claims like those in *Lilly*. One way or another, the court concluded, the claims in *Amgen* and *Lilly* had to be invalid, and the new tests it introduced ensured the court's ability to reach the results it believed to be correct on policy grounds. But the court never explicitly tied these opinions to concerns with early patenting, which meant that *Amgen* and *Lilly* could henceforth be used against genus claims directed to relatively mature generically claimed inventions, not just nascent ones. Thus, the Federal

---

271. Christopher M. Holman, *Is* Lilly *Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of* Eli Lilly *and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1, 4, 17, 78–80 (2007); *see* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1653–54 (2003) [hereinafter Burk & Lemley, *Policy Levers*].

272. *See* Guang Ming Whitley, Note, *A Patent Doctrine Without Bounds: The "Extended" Written Description Requirement*, 71 U. CHI. L. REV. 617, 623–24 (2004).

273. *See supra* notes 117–124 and accompanying text.

274. *See* Burk & Lemley, *Policy Levers*, *supra* note 271, at 1653; Holman, *supra* note 271, at 4.

275. *See* Kellam, *supra* note 190, at 227–29; *see also* Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1368 (Fed. Cir. 1997) (failing to credit the level of skill in the art in the *Wands* analysis).

Circuit's approach has eroded doctrinal stability: the focus of enablement shifted from targeting "unknown unknowns" to "known unknowns,"[276] and written description expanded so as to endanger genus claims that have not presented significant gun-jumping or late-claiming concerns.

These doctrinal shortcuts are worth exploring because their effects on § 112(a)'s many functions are crucial to understanding the origins of the Federal Circuit's current attitude toward — really, against — genus claiming. To be clear, the written description requirement continues to play multiple discrete, and rather different, roles. It polices priority, and after *Lilly*, it also prevents gun jumping and functional claiming. But today, it also significantly limits claim scope.

2. Entrenchment and Growth as a Weapon Against Genus Claims

*a. The* Ariad *Case*

Written description is not going away. Controversy over this requirement[277] prompted the Federal Circuit to convene en banc in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*[278] In *Ariad*, the court reaffirmed both that the written description requirement was separate from enablement and that it could apply to originally filed claims.[279] But while the court reached a result that we believe to be correct given the facts of the case, it further contributed to the undeserved demise of biotechnology and chemical genus claims.

Similar to *Lilly*, the claim at issue in *Ariad* was drafted in functional terms. But the Federal Circuit's analysis of Ariad's patents reveals a subtle interplay of distinct policy concerns with overbreadth, functional language, and timing. The court observed that the claim at issue was broad and reaffirmed *Lilly* when it stated that the patent as a whole must "demonstrate[ ] that the applicant has invented species sufficient to support a claim to a genus."[280] The court found written description problems "especially acute with genus claims that use functional language to define the boundaries of a claimed genus."[281] This language suggests

276. *See supra* Section III.A.2.

277. *See generally, e.g.*, Lizardtech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1376–81 (Fed. Cir. 2006) (Rader, J., dissenting from the order denying rehearing en banc); Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1325–27 (Fed. Cir. 2004) (Linn, J., dissenting from the order denying rehearing en banc); *Rochester*, 375 F.3d at 1307–25 (Rader, J., dissenting from the order denying rehearing en banc) (providing an appendix summarizing academic commentary and debate over written description); Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 976–83 (Fed. Cir. 2002) (Rader, J., dissenting from the order denying rehearing en banc).

278. 598 F.3d 1336, 1340, 1358 (Fed. Cir. 2010) (en banc).

279. *Id.* at 1358.

280. *Id.* at 1349.

281. *Id.*

that the court approaches functional claiming as somewhat of a heuristic that may signal a written description problem.[282]

As a factual matter, there were plenty of reasons to reject Ariad's claim, which the court described as directed to a "research hypothes[i]s" and "an unfinished invention."[283] The overarching issue was that the inventors didn't sufficiently disclose any chemicals that could accomplish the claimed function, for the simple reason that they hadn't actually discovered or tested any such chemicals.[284] Ultimately, in invalidating the claims, the Federal Circuit reiterated that the claims had problems with breadth, functionality, and timing.[285] But it wasn't apparent whether all the reasons for holding the claims invalid meant that the result in *Ariad* was overdetermined,[286] and the opinion never made it clear which rationale was particularly critical to its decision.[287]

Some parsing would have been useful, however. Claims can be broad, but neither early nor functional (many chemical genus claims); narrow, early, and functional (the human insulin cDNA claim in *Lilly*); broad, functional, but not early (as when the invention is "finished" but the patent attorney still chooses to claim it by function); and so on. Consistent with the history of the written description requirement, the policy concern animating the opinion appeared to be timing — in that a purely functional claim suggests that the inventor has jumped the gun and filed the application too soon. Specifically, the *Ariad* court stated near the conclusion of its exposition of the law that "[r]equiring a written description of the invention limits patent protection to those who actually perform the difficult work of 'invention . . . .'"[288] Nevertheless, the doctrinal analysis wasn't explicitly so cabined. Perhaps any one of the three potential problems — of function, timing, or breadth — would have doomed the claims, or perhaps the problem was their combination. As a doctrinal matter, the court's lack of clarity on this score was significant: it created openings for multiple distinct lines of written description attacks, which have been pursued with great success against genus claims in subsequent cases.

---

282. For straightforward examples of purely functional claims invalidated for lack of adequate written description, see AbbVie Deutschland GmbH v. Janssen Biotech, Inc., 759 F.3d 1285, 1290 (Fed. Cir. 2014); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 917 (Fed. Cir. 2004).

283. *Ariad*, 598 F.3d at 1353.

284. *Id.* at 1356–68.

285. *Id.* at 1358.

286. *Cf.* Michael Risch, *A Brief Defense of the Written Description Requirement*, 119 YALE L.J. ONLINE 127, 139–42 (2010) (arguing that the written description requirement doesn't necessarily prohibit broad claims).

287. *See Ariad*, 598 F.3d at 1354–58.

288. *Id.* at 1353.

*b. Further Impact on Genus Claims*

*Boston Scientific Corp. v. Johnson & Johnson*, which relied heavily on *Ariad*, illustrates the dynamics of written description as a weapon against genus claims.[289] The technology is familiar from *Wyeth*, discussed above in the enablement Section: it involved the clearing of arterial plaque with stents while mitigating the dangerous hardening of the arteries, or "restenosis."[290] Unlike the method claims in *Wyeth*, the patents at issue in *Boston Scientific* were directed to stent devices covered with therapeutic agents.[291] Similar to *Wyeth*, however, the specifications in *Boston Scientific* were focused on one therapeutic species, sirolimus, but the patents broadly claimed various macrocyclic analogs of the rapamycin genus.[292] But instead of invalidating the claims for lack of enablement as in *Wyeth*, the court relied on written description to do so.[293]

But the Federal Circuit's problem with the claims in *Boston Scientific* was very different from that in the key written description precedents just discussed. Unlike *Lilly* or *Ariad*, the inventors in *Boston Scientific* hardly jumped the gun to patent a mere "research hypothesis." In contrast to the dearth of chemical information for human insulin DNA in *Lilly*, the PHOSITA could readily "visualize or recognize"[294] the structures of the various rapamycin macrocycles, for they are "tangible things" that lend themselves to description.[295] In addition, the *Ariad* inventors claimed every chemical under the sun that could accomplish a particular biological function without providing any examples of such chemicals, or really any structural information at all. In contrast, the inventors in *Boston Scientific* actually reduced the invention to practice (i.e., created a working embodiment), getting antirestenosis to work on a stent with a molecule falling within the claimed genus.[296] Nevertheless, as the Federal Circuit saw it, the claims still had an overbreadth problem.[297] Even though the claims were drafted in structural rather than functional terms, they still failed for lack of adequate written description.

---

289. Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1363–66 (Fed. Cir. 2011).

290. *Id.* at 1356; Wyeth v. Abbott Lab'ys, 720 F.3d 1380, 1382–83 (Fed. Cir. 2013). The two cases, however, dealt with patents of somewhat different scope and the court used slightly different terminology in naming the genuses.

291. *Bos. Sci.*, 647 F.3d at 1357–58.

292. *Id.* at 1358–60.

293. *Id.* at 1367–69.

294. *Id.* at 1363.

295. Jacob S. Sherkow, *Describing Drugs: A Response to Professors Allison and Ouellette*, 65 DUKE L.J. ONLINE 127, 131 (2016).

296. *Bos. Sci.*, 647 F.3d at 1364.

297. Thus, invalidating one group of claims under review, the court explained that "[w]hile a small number of [sirolimus] analogs were known in the prior art, the claims cover tens of thousands of possible macrocyclic lactone analogs." *Id.* at 1365.

The *Boston Scientific* court did discuss function, but in a very different sense from *Lilly* and *Ariad*, which involved claims that were wholly devoid of chemical structure. It explained that "there is insufficient correlation between the function and structure of [sirolimus] and its analogs to provide adequate written description support for the entire genus of macrocyclic lactone analogs of rapamycin."[298] As in *Wyeth*, an enablement case, the Federal Circuit in *Boston Scientific* thus found it significant that the inventors lacked the knowledge of how structural modifications of the rapamycin core would affect antirestenotic properties.

But the effect of structural changes in chemical compounds on therapeutic efficacy can rarely be predicted ex ante,[299] so it's really unclear how much more the patentee could have done if it wanted to claim its antirestenosis invention as a chemical genus. Indeed, as Jake Sherkow observes, "drug composition claims may allow so much variability . . . as to make the written-description requirement virtually impossible."[300] In *Wyeth*, the court at least relied on an undisputed factual assertion that synthesizing and testing the members of the structural genus for antirestenotic activity would take a long time when it concluded that the claims were nonenabled.[301] But in *Boston Scientific*, the court didn't even do that. It invalidated the claims for lack of "possession" of the genus because a link between structure and properties was missing.[302] The patentee knew what the genus was and how some embodiments worked. But even if the genus were enabled, which is an issue the Federal Circuit didn't reach, the patentee still failed to adequately describe the invention because it didn't give a complete map of which structures performed the desired function. The genus claim simply had no chance.

*Idenix Pharmaceuticals LLC v. Gilead Sciences, Inc.*,[303] discussed above in the enablement Section, also relied on written description as an alternative ground to invalidate the claims directed to a method of treating the hepatitis C virus with a class of compounds having a furanosyl nucleoside core.[304] In that part of the opinion, the court focused on the defendant's infringing product, which had a fluorine substituent on the core nucleoside ring in the so-called "2'-down" position.[305] Indeed, species with the 2'-fluoro-down substituent played a critical role in the Federal Circuit's decision that the genus was not

298. *Id.* at 1366.

299. *See, e.g.*, Hendra Wahyudi & Shelli R. McAlpine, *Predicting the Unpredictable: Recent Structure-Activity Studies on Peptide-Based Macrocycles*, 60 BIOORGANIC CHEM. 74 (2015).

300. Sherkow, *supra* note 295, at 131.

301. Wyeth v. Abbott Lab'ys, 720 F.3d 1380, 1384–86 (Fed. Cir. 2013).

302. *Bos. Sci.*, 647 F.3d at 1364.

303. 941 F.3d 1149 (Fed. Cir. 2019).

304. *Id.* at 1153, 1155.

305. *Id.* at 1155.

adequately described because the court framed the validity inquiry in terms of "whether the specification demonstrates possession of the [fluorine-substituted] nucleosides that are the basis for [defendant's] accused product."[306] The Federal Circuit, in sum, invalidated the claims under written description because a particular set of working species made by the defendant was not specifically called out in the patent, even though the specification taught the PHOSITA how to make structurally analogous molecules and even to test whether varying the structures produced molecules that worked.

The court's methodology is notable. The patent listed numerous examples of compounds falling within the scope of the generic structure and having the claimed therapeutic property of treating HCV,[307] but the accused fluorine-substituted product wasn't mentioned. Seizing on this point, the court noted several times that the specification's failure to recite this material or other fluorine-based derivatives at the 2'-down position was "conspicuous[],"[308] even though fluorine may not warrant explicit mention because it's a common substituent that can be readily visualized by the PHOSITA. In doing so, the court effectively punished the patentee for providing *too many* representative examples, noting that the various formulas listed in the specification included numerous substitution patterns except for the 2'-fluoro-down.[309]

The absence of this set of species doomed the entire genus under the written description requirement both for reasons of structure and function. The Federal Circuit concluded that the patent "fails to provide sufficient blaze marks to direct a [PHOSITA] to the specific subset of 2'-methyl-up nucleosides that are effective in treating HCV."[310] It further explained that, despite the disclosed working examples, "[t]he specification . . . provides no method of distinguishing effective from ineffective compounds for the compounds reaching beyond the formulas disclosed in the '597 patent."[311] But in unpredictable life sciences arts there often is no "method" other than trial and error.[312] As suggested above, a tiny structural change can lead to massive therapeutic differences, so the patentee can often provide no "blaze marks"[313] other than by conducting experiments on as many species as possible. Here,

306. *Id.* at 1163–64.
307. *Id.* at 1161.
308. *Id.* at 1165.
309. *Id.*
310. *Id.* at 1164.
311. *Id.*
312. *See* sources cited *supra* note 190; Patent & Trademark Office Society, *Statement of the P.T.O.S. to the U.S.P.T.O. on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, First Paragraph "Written Description" Requirement*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 140, 142 (1999) (recognizing "*highly* unpredictable areas in biotechnology . . . where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error").
313. *In re* Ruschig, 379 F.2d 990, 995 (C.C.P.A. 1967).

the patentee did just that. But because it didn't specifically list the 2'-fluro-down subgenus, the claim was invalidated for lack of written description.[314]

*Idenix* is particularly notable because it doesn't map to any of the justifications for the written description doctrine. The claim wasn't drafted in purely functional terms; the patentees didn't jump the gun because the invention was reduced to practice and numerous working examples were provided; and the genus, though broad, was supported by several species,[315] and not just one, as in *Boston Scientific*. But the claim failed written description because the defendant's compound wasn't specifically listed among the identified working examples.[316] As a result, even if the PHOSITA could synthesize and test the claim's various species so rapidly that experimentation to select the operative embodiments was facile enough to pass enablement, the claim would've still been invalid. The inventors' only option for keeping the broad claim, it seems, was to make and test nearly every possible species. Even then, their claim would seemingly be invalid under *Idenix* as long as the defendant came up with an unlisted species that worked. That turns the law of genus claims on its head.[317]

* * * * *

The combination of enablement and written description has proven particularly difficult for patentees to overcome.[318] It is, of course, not unusual for a judgment to be reachable on two or more alternative grounds. But the now close similarity between written description and enablement as tools for challenging genus claims essentially allows defendants to characterize various pieces of evidence (disclosures in the specification, the state of the art, expert testimony) in such a way as to take two shots at the claims in the hope that one of them sticks. Often, they do: for example, even if the plaintiff introduces enough testimony on the *Wands* factors to raise a genuine issue of material fact regarding undue experimentation, the court can sidestep that testimony by looking on the face of the patent and holding that the written description

314. *Cf.* Pitlick, *supra* note 250, at 221–22 (predicting this outcome in his analysis of *Lilly*).

315. *See supra* notes 232–234 and accompanying text.

316. *See Idenix*, 941 F.3d at 1164–65.

317. Of course, another approach was to claim only a narrow subgenus of the species that worked and avoid generalizing altogether. But that defeats the whole purpose of genus claiming as a way of creating meaningful patent protection beyond the working embodiments in the specification.

318. *Cf.* Mark A. Lemley, *The Fractioning of Patent Law*, *in* INTELLECTUAL PROPERTY & THE COMMON LAW 504, 506–08 (Shyamkrishna Balganesh ed. 2013) (explaining how the multiplying number of ways that defendants can attack a patent can help them avoid liability).

fails because it does not show "possession."[319] We have seen the converse as well: a claim that survived a written description challenge on remand, in spite of the Federal Circuit's strong suggestion that it was invalid under this requirement,[320] still failed enablement.[321] As weapons against genus claims, enablement and written description make for a powerful combination both procedurally and substantively.

### *C. Claims Surviving § 112(a) Challenges*

The cases we have highlighted so far in this Part are just a sampling of the Federal Circuit's rejection of genus claims. There are many more appellate decisions after 1990 striking down genus claims for lack of enablement, written description, or both, often overturning the district court or a jury verdict in the process.[322] These cases illustrate a consistent pattern of genus claim failure. There are only a few post-1990 exceptions, and we think they actually prove the rule that such claims usually have no chance at the Federal Circuit. Each comes with a special (and limited) circumstance.[323]

One notable category of appeals in which genus claims were sometimes upheld against § 112(a) challenges involved interferences, which

---

319. *See, e.g.*, Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1255, 1261 (Fed. Cir. 2004); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334–35 (Fed. Cir. 2003) (claim can satisfy enablement but still fail written description); *compare* Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1361–69 (Fed. Cir. 2011) (determining that since the patent at issue was invalid for lack of written description, there was no need to separately address enablement), *with* Wyeth v. Abbott Lab'ys, 720 F.3d 1380, 1384–86 (Fed. Cir. 2013) (using lack of enablement to invalidate patents similar to those in *Boston Scientific*).

320. *See* Amgen Inc. v. Sanofi, 872 F.3d 1367, 1375–79 (Fed. Cir. 2017) (determining that the test embodied in the district court's jury instruction on the written description requirement was improper because it "allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen").

321. On remand, the properly instructed jury still found adequate written description (and enablement). *See* Amgen Inc. v. Sanofi, 987 F.3d 1080, 1084 (Fed. Cir. 2021). However, on appeal from the decision on remand, the Federal Circuit affirmed a judgment as a matter of law that the patents were nonenabled (without reaching written description). *See id.* at 1084–88.

322. *See, e.g.*, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1342 (Fed. Cir. 2021); Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc., 923 F.3d 1368, 1384 (Fed. Cir. 2019); AbbVie Deutschland GmbH v. Janssen Biotech, Inc., 759 F.3d 1285, 1290 (Fed. Cir. 2014); Novozymes A/S v. DuPont Nutrition Bioscis. APS, 723 F.3d 1336, 1351 (Fed. Cir. 2013); Centocor Ortho Biotech, Inc. v. Abbott Lab'ys, 636 F.3d 1341, 1344 (Fed. Cir. 2011); *In re* '318 Pat. Infringement Litig., 583 F.3d 1317, 1323–27 (Fed. Cir. 2009); *In re* Alonso, 545 F.3d 1015, 1019–22 (Fed. Cir. 2008); Carnegie Mellon Univ. v. Hoffmann-La Roche, Inc., 541 F.3d 1115, 1117 (Fed. Cir. 2008); *In re* Wallach, 378 F.3d 1330, 1335–36 (Fed. Cir. 2004); Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1255, 1261 (Fed. Cir. 2004); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 930 (Fed. Cir. 2004); Noelle v. Lederman, 355 F.3d 1343, 1348–53 (Fed. Cir. 2004); Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1368 (Fed. Cir. 1997).

323. There are also cases in which genus claims prevailed where the defendants didn't raise full-scope enablement or written description arguments. We don't include them in our analysis here, though we discuss their significance *infra* Part IV.

are now-obsolete adversarial USPTO proceedings for resolving who among two or more competing inventors, or groups of inventors, came up with the claimed subject matter first.[324] Interferences are a special case, and the Federal Circuit's interference decisions have had a limited impact on the court's § 112(a) jurisprudence more generally.

The remaining few cases we identified in which generic claims survived enablement or written description attacks on appeal can be classified into claims directed to a relatively small genus; challenges to the breadth of limitations directed to claim features that are already well-known and are not the invention's focus; and other outlier examples that feature unusual genus claims, defendant failures to offer factual support for their invalidity assertions, or combinations of some of these characteristics. We believe that these cases, which we consider below in turn, are thus of limited practical significance for the validity of traditional genus claims.

1. Interferences

An interference proceeding is a "priority contest" between two or more parties.[325] Although the standards for enablement and written description in interferences are congruent with those in appeals from USPTO rejections or district court judgments, the ultimate question is which of the parties in a race to be the first to patent the invention is entitled to priority.[326] As a result, an interference proceeding typically ends with *someone*'s claims getting upheld as the earlier of the two inventors.[327] Neither party to an interference has an incentive to argue that no one can have a claim that broad. Instead, their arguments tend to focus on more traditional timing issues around written description — did the alleged first inventor jump the gun by filing too early?

Perhaps because an interference must usually result in a winner, § 112(a)'s requirements may be applied in a manner more friendly to genus claims than in other types of appeals. One example is *Singh v. Brake*,[328] in which the Federal Circuit affirmed the USPTO's grant of priority to an inventor of a "DNA construct" claim, deferring to the

---

324. *See* 35 U.S.C. § 135 (2012). A few interferences involving patents not subject to the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284, 288 (2011), are currently in progress, but the number of such patents is dwindling and interferences will thus completely disappear with the passage of time. *See* Gene Quinn, *Reform Doing Away with Interference Proceedings & First to Invent*, IPWATCHDOG (Mar. 26, 2010), https://www.ipwatchdog.com/2010/03/26/reform-doing-away-with-interference-proceedings-first-to-invent [https://perma.cc/UE6P-BHFL]; *infra* note 423 and accompanying text.

325. Brown v. Barbacid, 276 F.3d 1327, 1339 (Fed. Cir. 2002).

326. *Id.*

327. *See, e.g.*, *id.*

328. 317 F.3d 1334 (Fed. Cir. 2003).

agency's conclusion that it was adequately described and enabled.[329] The § 112(a) discussion in *Singh* has only been cited in one other precedential Federal Circuit opinion, and only for the basic proposition that "the written description requirement . . . is a question of fact, reviewed for substantial evidence."[330] By contrast, some of the cases striking down genus claims (e.g., *Calgene* and *Lilly*) have been cited numerous times for substantive propositions in subsequent Federal Circuit opinions.[331]

Another pro-patentee result in an interference appeal — which, however, does not follow the usual pattern of someone being declared a winner — is *Capon v. Eshhar*.[332] This case, similar to *Regents of the University of California v. Eli Lilly & Co.*,[333] involved claims directed to DNAs for which structural information was lacking.[334] Oddly enough, the parties ended up on the same side of the appeal after the USPTO concluded sua sponte that neither set of claims was adequately described.[335] The Federal Circuit vacated and remanded, holding that the USPTO "erred in ruling that § 112 imposes a per se rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field."[336] *Capon* was followed in another Federal Circuit interference appeal[337] and cited for basic propositions in other cases.[338] *Capon*, however, has been consistently distinguished in non-interference written description cases involving the validity of genus claims, including *Ariad* and *Boston Scientific*.[339] More telling, the Federal Circuit even distinguished *Capon* in another written description case involving DNA, *Carnegie Mellon University v. Hoffman-La Roche*,[340] in which the court followed

329. *Id.* at 1343–46.

330. Bilstad v. Wakapoulos, 386 F.3d 1116, 1121 (Fed. Cir. 2004).

331. *Enzo v. Calgene* is cited in, e.g., Cephalon, Inc. v. Watson Pharms., Inc., 707 F.3d 1330, 1336 (Fed. Cir. 2013); ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010); Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Rsch., 346 F.3d 1051, 1054–57 (Fed. Cir. 2003). *Ariad v. Eli Lilly* is cited in, e.g., Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1335–42 (Fed. Cir. 2021); Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1163–65 (Fed. Cir. 2019); Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1361–66 (Fed. Cir. 2011).

332. 418 F.3d 1349 (Fed. Cir. 2005).

333. 119 F.3d 1559 (Fed. Cir. 1997).

334. *Capon*, 418 F.3d at 1349.

335. *Id.* at 1350.

336. *Id.* at 1360–61; *cf. Eli Lilly*, 119 F.3d at 1567 (arguably creating just such a per se rule outside the interference context).

337. Falkner v. Inglis, 448 F.3d 1357, 1366–67 (Fed. Cir. 2006).

338. *In re* Packard, 751 F.3d 1307, 1311 (Fed. Cir. 2014) (per curiam); Goeddel v. Sugano, 617 F.3d 1350, 1353 (Fed. Cir. 2010).

339. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1358 (Fed. Cir. 2010) (en banc); Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1365 (Fed. Cir. 2011); *see also* Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1338–39 (Fed. Cir. 2021) (distinguishing *Capon* and invalidating the claims for lack of adequate written description).

340. 541 F.3d 1115, 1126 (Fed. Cir. 2008).

*Regents of the University of California v. Eli Lilly & Co.* instead and invalidated the claims at issue.[341] In sum, *Capon* has not had a lasting influence at the Federal Circuit.

2. Small Genuses and Genuses Known Prior to the Invention

A second set of patents that survive § 112(a) challenges at the Federal Circuit involve small genuses and genuses that are already fully understood in the prior art. In *Martek Biosciences Corp. v. Nutrinova, Inc.*,[342] for example, the claims were directed to a process of extracting fatty acids from certain kinds of fish.[343] The defendants introduced evidence of nonenablement of the patent's broad independent claim, but "failed to present any evidence . . . that one of ordinary skill in the art must perform undue experimentation" to practice the narrower dependent claims.[344] Moreover, at trial, an expert opined that these dependent claims encompassed only 22 biological species, a far cry from the 10,000-plus species encompassed in the main claim.[345] The Federal Circuit took this statement to "support[] an inference that there are relatively few potential species that may meet the limitations of" these claims.[346] The court thus upheld the claims, but as with *Singh*, future Federal Circuit panels have relied on *Martek* only for neutral propositions.[347]

The written description challenge in the recent *Ajinomoto Co. v. International Trade Commission*[348] decision failed for a different reason — it was lodged at a genus that was well-known prior to the invention at issue.[349] The asserted claims were directed to cultivating *E. coli*

341. *Id.* at 1124–27.

342. 579 F.3d 1363 (Fed. Cir. 2009).

343. *Id.* at 1367.

344. *Id.* at 1379.

345. *Id.*

346. *Id.* To similar effect is *Alcon Research Ltd. v. Barr Laboratories, Inc.*, 745 F.3d 1180 (Fed. Cir. 2014). In *Alcon*, the Federal Circuit overturned invalidations on both enablement and written description grounds. While the case was presented as a full-scope enablement case, the court concluded that while there were many different possible variants of the claim, the PHOSITA would understand that they all worked as intended and claimed and varied only in efficacy. *Id.* at 1189. It found the claims valid "because Barr did not show that any claimed embodiments would be inoperable and that a person of ordinary skill in the art would have been unable to practice the asserted claims without resorting to any experimentation, let alone undue experimentation . . . ." *Id.* at 1190. The claims likewise survived a written description attack. *Id.* at 1191–92.

347. *See, e.g.*, Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1355 (Fed. Cir. 2012) (citing *Martek* for the proposition that enablement is a question of law based on underlying facts, resulting in plenary review of the former and substantial evidence review of the latter).

348. 932 F.3d 1342 (Fed. Cir. 2019).

349. *Id.* at 1359; *see also* Bayer Healthcare LLC v. Baxalta Inc., 989 F.3d 964, 980–82 (Fed. Cir. 2021) (upholding patent against an enablement challenge where the genus at issue

bacteria to produce an essential amino acid "by replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter . . . ."[350] The invalidity arguments were focused on the "more potent promoter" limitation.[351] Yet, the focus of the invention was not the promoters at all, but rather the discovery of the gene whose modification with a promoter boosted the amino acid production.[352] As for the promoters themselves, "the genus of more potent promoters was already well explored in the relevant art" and the specification mentioned several of them.[353] The Federal Circuit determined that the patentee sufficiently supported the genus by including in the "specification, read in light of the background knowledge in the art, a representative number of species for the genus of more potent promoters."[354] The court also distinguished *Lilly* and *Boston Scientific* and concluded that the art's familiarity with more potent promoters meant that the common structural features of the genus were also adequately described.[355] Thus, "a skilled artisan could make relatively predictable changes to the native promoter to arrive at a more potent promoter" and the claims survived § 112(a).[356]

3. Other Cases

We have found only two more Federal Circuit opinions upholding genus claims in the past thirty years. Both decisions were made for reasons that aren't easy to classify precisely, but that we believe are unusual. In *Invitrogen Corp. v. Clontech Laboratories, Inc.*,[357] the claims in suit were directed to a so-called "reverse transcriptase" ("RT"), an enzyme involved in DNA replication.[358] In its enablement challenge, the defendant complained that the specification failed to describe all the possible methods of making the enzyme.[359] This argument was unsuccessful: while the universe of methods for making a particular composition might be described as a kind of genus,[360] in practice the Federal Circuit has consistently treated claims directed to "a genus of methods"

---

was not the inventive part of the patent); Monsanto Co. v. Scruggs, 459 F.3d 1328, 1338 (Fed. Cir. 2006) (holding that use of well-known promoters was enabled). *But cf.* Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1342 (Fed. Cir. 2021) (invalidating a claim for lack of adequate written description even given a well-known genus).

350. *Ajinomoto*, 932 F.3d at 1347.
351. *Id.* at 1358–59.
352. *Id.* at 1359.
353. *Id.*
354. *Id.*
355. *Id.* at 1360–61.
356. *Id.* at 1361.
357. 429 F.3d 1052 (Fed. Cir. 2005).
358. *Id.* at 1058.
359. *Id.* at 1070.
360. Karshtedt, *Hard-to-Reproduce Inventions*, *supra* note 152, at 130–33.

differently — and apparently much more leniently — than claims to a traditional structural genus.[361] In this context, "the enablement requirement is met if the description enables *any* mode of making and using the invention" and the one method for making the enzyme disclosed in the specification was sufficient under this rule.[362]

The defendant also challenged the written description of a specific group of RT claims, which were drafted in functional terms to recite "[a]n isolated polypeptide . . . *having substantially reduced RNase H activity*," but that argument also failed.[363] The defendant argued that the "DNA or protein sequences" of the enzyme were not recited, but the Federal Circuit retorted that this argument "proceeds from a factual premise contrary to the record."[364] Instead, as the court noted, the specification "recite[d] both the DNA and amino acid sequences of a representative embodiment of the claimed RT enzyme" and "disclose[d] test data that the enzyme produced by the listed sequence has the claimed features — DNA polymerase activity without RNase H activity."[365] While it is not entirely clear what the genus size was, the defendant never made an overbreadth argument.[366] In any event, *Invitrogen* — like the other cases discussed in this Section — has had limited impact on the development of the Federal Circuit's law of enablement, and has been cited only for uncontroversial general propositions of law.[367]

We finally come to the complex opinion in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,[368] in which a split Federal Circuit panel affirmed the bench trial judgment that the claims at issue were adequately described and enabled.[369] A representative claim recited "[a] pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin . . . , wherein said erythropoietin is *purified from*

---

361. *Cf.* Bernard Chao, *Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule*, 2009 STAN. TECH. L. REV. 3; Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083, 1093–94 (2009); Timothy Chen Saulsbury, Note, *Pioneers Versus Improvers: Enabling Optimal Claim Scope*, 16 MICH. TELECOMM. & TECH. L. REV. 439, 443, 448–52, 463 (2010).

362. *Invitrogen*, 429 F.3d at 1071 (emphasis added) (quoting Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1361 (Fed. Cir. 1998)); *see also* Jason Rantanen, *The Doctrinal Structure of Patent Law's Enablement Requirement*, 69 VAND. L. REV. 1679, 1681–84 (2016) (discussing various strategies for attacking patent claims on overbreadth grounds).

363. *Invitrogen*, 429 F.3d at 1074.

364. *Id.* at 1073.

365. *Id.*

366. The defendant's failure to make an overbreadth argument, as made possible by Federal Circuit opinions like *Idenix*, might explain some examples of cases in which genus claims have survived district court proceedings. *See infra* Section IV.A (discussing the contours of "full-scope" enablement).

367. *See, e.g.*, *In re* '318 Pat. Infringement Litig., 583 F.3d 1317, 1323 (Fed. Cir. 2009) (citing *Invitrogen* only for the well-established proposition that enablement is a question of law).

368. 314 F.3d 1313 (Fed. Cir. 2003). This is a different *Amgen* case than the one discussed above and we refer to it as "*Hoechst*."

369. *Id.* at 1313.

*mammalian cells grown in culture.*"[370] After "commend[ing] the district court for its thorough, careful, and precise work on what is indubitably a legally difficult and technologically complex case," the majority deferred heavily to the lower court's fact findings.[371] The court also noted that the trial judge had in turn heavily emphasized the clear and convincing standard required to prove invalidity and had concluded that the defendant did not meet this burden.[372]

One of the issues in *Hoechst* was whether the "mammalian" limitation made the claim overbroad. Emphasizing that compliance with the written description requirement is a question of fact reviewed for clear error after a bench trial, the Federal Circuit noted that "the district court carefully examined whether [the] specification adequately described the full breadth of the claims"[373] and concluded that the defendant failed to overcome the presumption of validity.[374] Indeed, the lower "court weighed the testimony and found that the evidence showed that the descriptions adequately described to [the PHOSITA at the time of filing] the use of the broad class of available mammalian and vertebrate cells to produce the claimed high levels of human EPO in culture."[375] The Federal Circuit found no error, explaining that cases like *Lilly* were distinguishable because the claim in *Hoechst* was not directed to DNA but rather to the mammalian genus itself as the source of EPO, and there was no doubt what animals fit in the genus "mammal."[376] The word "mammalian," the court noted, "readily 'convey[ed] distinguishing information concerning [the genus's] identity' such that one of ordinary skill in the art could 'visualize or recognize the identity of the members of the genus.'"[377]

The defendant fared no better on enablement, with the Federal Circuit noting that "the district court made thorough and complete factual findings supporting its holding that the claims were not proven not enabled."[378] One of the findings was that the method of production of EPO generalizes readily from the two mammals for which it was actually done to all other mammals: "[T]he [trial] court accepted testimony indicating that [the PHOSITA] would infer from the [representative] cell examples that similar outcomes could be expected from other mammalian cells since all mammalian cells produce and secrete

370. *Id.* at 1323.
371. *Id.* at 1320.
372. *Id.* at 1331, 1339.
373. *Id.* at 1330–31.
374. *Id.* at 1339.
375. *Id.* at 1331.
376. *Id.* at 1332.
377. *Id.* (quoting Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567–68 (Fed. Cir. 1997)).
378. *Id.* at 1334–35.

hormones like EPO by means of the same fundamental processes."[379] After noting that "[t]hese are all findings of fact and they have not been shown to be clearly erroneous," the majority upheld the claims.[380]

In dissent, Judge Raymond Clevenger wryly noted that "[w]hile I share my colleagues' admiration for the considerable efforts of the district court in this complicated case, I cannot share their faith that the district court properly and conscientiously applied" Federal Circuit precedent.[381] The dissent's main concern was that the panel majority misapplied § 112(a) law to "source and process" limitations of the claims, such as "mammalian." However, such limitations don't often come up in genus claiming, so the scope of this holding is inherently narrow.[382] As such, this case also had limited impact.[383]

*Hoechst* is the opinion that looks most like the § 112(a) jurisprudence of old, which was much more accepting of genus claims. But it is nearly 20 years old, drew a dissent, and has not been used to justify broad claims in the decades since the case was decided.

* * * * *

The path of the law is messy. And particularly so when courts are moving the law in new directions, as they are with enablement and written description. But while the case law isn't unanimous, the outlier opinions discussed in this Section do not detract from the conclusion that the Federal Circuit's primary approach to traditional genus claims in chemical and biological sciences has become increasingly hostile. Indeed, the anomalous cases in this Section presented features such as an unusual procedural posture (indeed, for interference appeals, one that no longer exists); a challenge against a genus that was small or well-known; or odd claiming or procedural aspects, such as the combination of process limitations and exhaustive fact findings in the *Hoechst* bench trial, that made the genus unusually susceptible to being upheld.

Notwithstanding these exceptions, we conclude that chemical genus claims do not do well against § 112(a) challenges at the Federal Circuit, and haven't for almost thirty years.[384] That is a fundamental

379. *Id.* at 1335.

380. *Id.*

381. *Id.* at 1361 (Clevenger, J., dissenting).

382. *Id.* at 1359. For a discussion of such claims, see generally Karshtedt, *Hard-to-Reproduce Inventions*, *supra* note 152.

383. The most significant Federal Circuit opinion relying on *Hoechst* to uphold claims against a written description challenge is *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005), discussed above. In other cases, such as *In re Wallach*, 378 F.3d 1330, 1333–34 (Fed. Cir. 2004), *Hoechst* was distinguished.

384. *See supra* note 322 and accompanying text.

reversal of the way the law used to be — and the way many lawyers, companies, and scholars may assume it still is.

## IV. SHOULD WE SAVE GENUS CLAIMS?

### *A. A Troubling Shift in Precedent*

The move to invalidate large genus claims on enablement and written description grounds reflects a puzzling and troubling doctrinal shift. In this Section, we argue that the Federal Circuit has significantly altered what it means to enable (or describe) the full scope of the claim in ways that make many genus claims unsustainable. In doing so, it has conflated different legal theories and justifications for restricting the scope of genus claims. And it has broken the symmetry that has traditionally existed between obviousness analysis under § 103 and the disclosure rules of § 112.

#### 1. What Does the PHOSITA Know?

Both § 103 (which sets forth the nonobviousness requirement) and § 112 rely on standards based on the knowledge and experience of the person having ordinary skill in the art, or PHOSITA. When we test whether a patent embodies something nonobvious under § 103, we ask whether the PHOSITA would've been motivated to create the new invention and would've had a reasonable expectation of success.[385] And when we decide how much information the patentee must disclose, we turn again to the PHOSITA, making sure the patent discloses enough that the PHOSITA can make and use the invention.[386] The § 103 and § 112 PHOSITAs aren't always exactly the same; they were traditionally imagined as working at different points within the patenting process, and they're doing somewhat different things (inventing versus making and using).[387] But in general there is symmetry between obviousness and disclosure that turns on the level of skill in the art.[388] If the PHOSITA in a field knows a lot, an invention is more likely to be

385. Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1366–69 (Fed. Cir. 2016).

386. *See* Burk & Lemley, *Technology-Specific*, *supra* note 41, at 1189–90.

387. For obviousness under § 103, the relevant standard is technically what the PHOSITA would have known at the time the invention was made. For § 112, the standard has traditionally been what they would have known at the time the application is filed, somewhat after the date of invention. *See id.* at 1190. But that changed with the America Invents Act. For patent applications filed on or after March 16, 2013, both doctrines ask what the PHOSITA would know as of the filing date. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284, 288 (2011).

388. *See* Burk & Lemley, *Technology-Specific*, *supra* note 41, at 1190 (discussing this difference); *see also* Alan L. Durham, *Patent Symmetry*, 87 B.U. L. REV. 969, 978 (2007) (describing the § 112 PHOSITA as "a bit of a plodder").

obvious, but that also means that the patent doesn't need as much detail to educate and thus enable her.[389] If she knows very little, by contrast, it's easier to show nonobviousness (because she was less likely to come up with it), but she also must be taught more for purposes of enablement.

That symmetry held for decades in the chemical arts. Courts regularly tell us that chemistry is an unpredictable art, so PHOSITAs can't know what effects modifications would have.[390] But chemical compounds have a regular and well-understood structure, so courts confronting obviousness challenges have long held, and the Federal Circuit confirmed in the seminal case of *In re Dillon*, that variants of a known chemical may likely be obvious (i.e., prima facie obvious) unless they embody unexpected results.[391] That principle typically applies whether the prior art is a single lead chemical, as in *Dillon*, or a genus.[392] Just recently, the Federal Circuit reaffirmed that rationale in an obviousness case that involved the motivation to make a claimed invention based on a known "lead compound."[393]

But a parallel assumption is strikingly absent from the Federal Circuit's enablement and written description cases over the past three decades. To the contrary, the cases discussed in Part III generally start from the premise that the chemical arts are unpredictable, but then apply the opposite of the *Dillon*-type analysis. They assume that no one could figure out what works in a genus unless there are "blaze marks" showing which variants on a lead chemical compound will have the same effects and which ones won't, or that even if one could figure it out, it would take too much experimentation. The result for chemical

---

389. *See* Seymore, *Patenting the Unexplained*, *supra* note 5, at 718 n.85 ("[I]f the PHOSITA is really smart . . . an applicant need not disclose what the PHOSITA already knows or can easily figure out . . . ." (citing Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987))).

390. *See* Eisai Co. Ltd. v. Dr. Reddy's Lab'ys, Ltd, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (noting how chemistry is "often" an unpredictable art); Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340, 1347 (Fed. Cir. 2019) (finding a chemical process for labeling nucleotides "highly unpredictable" at the time of invention); *see also* Brenner v. Manson, 383 U.S. 519, 532 (1966) (recognizing the unpredictability of chemical compounds in the steroid field). *See generally* Seymore, *Heightened Enablement*, *supra* note 12.

391. 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc); *see also* Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1364 (Fed. Cir. 2007) (Dyk, J., concurring) (noting the validity of subject matter involving unexpected results relative to a known compound was "not in question" on obviousness grounds). For an analysis of structural similarity and other issues in obviousness doctrine, see generally Dmitry Karshtedt, *Nonobviousness: Before and After*, 106 IOWA L. REV. 1609 (2021).

392. If the genus in the prior art disclosure is extremely large, however, the existence of that genus does not necessarily motivate one to make a particular species within that genus, ultimately rendering that species nonobvious. *See, e.g.*, *In re* Baird, 16 F.3d 380, 382–83 (Fed. Cir. 1994); *In re* Jones, 958 F.2d 347, 350 (Fed. Cir. 1992) (rejecting the proposition that a disclosure of a chemical genus, however broad, "renders obvious any species that happens to fall within it").

393. Valeant Pharms. Int'l, Inc. v. Mylan Pharms. Inc., 955 F.3d 25, 32 (Fed. Cir. 2020).

patentees is the worst of both worlds — we'll presume the new species you claim isn't patentable because the PHOSITA could figure out how to make it if it's just an obvious structural variant on an existing one, but we won't presume that the PHOSITA understands the same thing when she's reading your genus claim. The Federal Circuit's modern genus claim cases, in other words, have shifted the role of the PHOSITA in a way that breaks the symmetry between § 103 and § 112.[394]

2. "Making and Using . . . the Full Scope of the Invention"

There is a second, and more fundamental, shift in the Federal Circuit's § 112 case law. Using both enablement and written description, the court has changed the focus of the § 112(a) inquiry from "what information would be required to permit the PHOSITA to make and use species in the invention" to "what information is required to teach the PHOSITA which species in the genus work and which ones don't."[395] Put another way, thirty years ago § 112(a) was about use and practice of the invention, while today it's primarily about understanding the boundaries of the invention. That shift has profound implications for large genus claims. It's frequently impossible to test all or even a "representative number" of species of a genus that may contain millions of different species.[396] Even a patentee that tests quite a few species may be unable to predict which species will work and which won't. The question is whether that inability should matter, and why.

If the goal is to enable the PHOSITA to make and use the invention, the inability to predict in advance which species will work doesn't matter much except at the extremes. For instance, Atlas Powder didn't know which of its claimed dynamite compounds would work and which wouldn't, but with a 40% failure rate a user would likely only have to try two or maybe three compounds to find one that would work.[397] That required some experimentation, but the law has traditionally allowed claims requiring experimentation as long as it is not "undue."[398] There may be some patents claiming genuses that give so little information that trying to find a species that works takes too much

394. *Cf.* Albanese, *supra* note 113, at 359–60 (recognizing this but suggesting it is a good thing).

395. These are scare quotes.

396. Indeed, Jeff Lefstin notes that most genus claims are open-ended and so contain a potentially infinite number of species. Lefstin, *supra* note 70, at 1168–74.

397. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1577 (Fed. Cir. 1984).

398. *See supra* notes 99–106 and accompanying text.

effort, but that is likely to be rare in traditional pharmaceutical claims if the genus is properly specified.[399]

More to the point, what's going on in the cases discussed in Part III isn't an assessment of whether the PHOSITA could make the invention work without undue experimentation. Rather, those cases reflect a new and different goal for § 112(a) — explaining to the PHOSITA what subset of the genus claims will work and what subset won't. The goal of those cases seems to be knowledge of the precise boundaries of the genus. That may be desirable in some cases, as we note below. But it isn't normally required for the PHOSITA to make and use the invention without undue experimentation. And it has proven in practice to be an impossible burden.

### 3. Recognizing When We Need to Understand What Works . . . and When We Don't

We think this move from undue experimentation to a search for a clear definition of which species work and which don't misunderstands the basic purpose of the § 112(a) inquiry. If the patentee defines a clear genus, so that people will know whether or not the chemicals they make fall within that genus, the PHOSITA will be able to make and use the full scope of that genus so long as she can determine how to make chemicals within the genus and assess whether they work for the intended purpose without having to engage in undue experimentation. True, she won't be able to make every species. But why would she want to? That is not the point of § 112(a). And true, the PHOSITA might have to experiment to figure out whether the particular species she made works for the intended purpose, but that is not a problem unless she has to engage in too much experimentation.

---

399. There may be more systematic uncertainty in biotechnology, both because we know less about the field and because the nature of large molecules is different and less predictable than the small molecules that the pharmaceutical industry traditionally works with. For some biotechnology inventions, such as antibodies, the invention may be defined only in functional terms (as binding to a particular epitope of an antigen with a certain specificity), and it may well require undue experimentation to determine what antibodies fit within the scope of the claim at all. This was at issue in *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1375 (Fed. Cir. 2017), *appeal after remand*, 987 F.3d 1080 (Fed. Cir.), *reh'g denied*, 850 Fed. App'x 794 (Fed. Cir. 2021) (nonprecedential). In this Article, we don't want to get into the particular question of whether functional claiming of such antibodies is appropriate. *Cf.* Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905, 923 [hereinafter Lemley, *Functional Claiming*] (exploring the problems with functional claiming in the software context, and noting that in some instances the function a given claim performs "may be simple or complex, broad or narrow, but . . . [the claim can be drafted to] effectively cover *any device* that performs that function in any way"). But functional antibody claims that read on any antibody binding to a specific epitope on an antigen may fail the traditional enablement requirement if those of skill in the art can't identify and make antibodies within the scope of the claims without undue experimentation. But it is that question, not the question of "did you identify all of them?", that should resolve cases like *Sanofi*.

To be sure, there will be cases where the patent doesn't give enough information to allow her to do even that much without undue experimentation.[400] But that isn't limited to broad genus claims. The claims may well be narrow, even directed to one species, but they're invalid if the specification fails to give the appropriate instructions — like concentrations and ratios of reagents or components — such that the PHOSITA wouldn't be able to make the invention work at all. This is the traditional purpose of enablement doctrine.[401]

If that isn't true — if the PHOSITA can figure out how to make a working embodiment without too much effort — there is no reason to require more in most cases. Decisions like *Wyeth*,[402] *Idenix*,[403] and *Boston Scientific*,[404] which focus on the number of species covered by the genus claim as a reason to reject it, miss the point. The genus is very large and it would take an impossible effort to identify all the species within its scope that work. But there's no reason anyone needs to make that much effort (except that more and more Federal Circuit cases seem to require it). Anyone who wants to know if their chemical is within the scope of the claim can readily make that assessment: by hypothesis, the boundaries of the chemical genus are well-specified, and it doesn't take much effort to determine whether or not any particular chemical works for its intended purpose.[405]

In these cases, ironically, having a functional limitation like that requiring operability or therapeutic efficacy may have hurt the patentee because it caused the court to focus on operability as an element of the inventions.[406] *Idenix*, for instance, holds that there are no "blaze marks" for structural modifications within the large genus that will achieve the claimed invention's purpose.[407] But that shouldn't matter. A claim to a new chemical genus is patentable as long as it has a disclosed utility, whether or not that utility is claimed.[408] And if the PHOSITA would

400. *See, e.g.*, Tyler v. Boston, 74 U.S. (7 Wall.) 327, 330 (1868); Wood v. Underhill, 46 U.S. (5 How.) 1, 5 (1846); White Consol. Indus., Inc. v. Vega Servo-Control, Inc., 713 F.2d 788, 791 (Fed. Cir. 1983).

401. *See, e.g.*, *In re* Cook, 439 F.2d 730, 735–36 (C.C.P.A. 1971).

402. Wyeth v. Abbott Lab'ys, 720 F.3d 1380, 1385 (Fed. Cir. 2013).

403. Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1164 (Fed. Cir. 2019).

404. Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1369 (Fed. Cir. 2011).

405. Kristina Caggiano Kelly and Paul Calvo offer an excellent illustration of this. They point to an artist named Martin Silfen who uses a combination of just sixteen geometric tiles to create paintings. Because the tiles can be rotated and can each be used in a different order, there are 89 sextillion different possible tile combinations. But no one needs to try all or even very many of those combinations to make the invention work; they just need to know to lay out sixteen tiles in a 4x4 grid. Kristina Caggiano Kelly & Paul A. Calvo, *Insight: The Scope of a Sextillion — How Courts Misapply Law of Enablement to Life Sciences*, BLOOMBERG L. (May 1, 2020, 4:00 AM), https://news.bloomberglaw.com/ip-law/insight-the-scope-of-a-sextillion-how-courts-misapply-law-of-enablement-to-life-sciences [https://perma.cc/APE9-KSWX].

406. *See Wyeth*, 720 F.3d at 1386.

407. *Idenix*, 941 F.3d at 1164.

408. *See, e.g.*, *In re* Brana, 51 F.3d 1560, 1565 (Fed. Cir. 1995).

know how to make and use the chemicals within that genus, the claim is enabled and adequately described under traditional principles. Adding the purpose as a claim limitation narrows rather than broadens the claim. If the patentee has enabled the broad claim, it doesn't make sense to hold that the narrower claim is not enabled even though the PHOSITA can identify and use some operable species defined by the narrowing limitations within the broader genus.

The courts that have done so seem to be articulating a concern about "possession" of a genus in both enablement and written description contexts. Their fear isn't that the PHOSITA can't make and use the invention, but that the patentee can't actually tell us what exactly is in the genus. Possession can sometimes matter in patent law.[409] But for § 112, it should matter only in two discrete sets of circumstances: when there is no proper genus at all, or when the patentee hasn't yet invented that genus.

*a. Improper Generalization*

In the first set of cases, the problem is that the patentee has defined a genus of things that don't really have anything in common. The genus may well be small, but some species are not at all like the others given the purpose or nature of the invention, and just wouldn't work.

The *Incandescent Lamp* case,[410] discussed above,[411] is a good example of this sort of possession problem, which we might call improper generalization.[412] Sawyer and Man, the inventors, had built a working light bulb filament from carbonized paper and wood carbon, and they properly claimed those species.[413] When it came time to define the genus, however, they guessed — and ultimately, it turns out, guessed wrong. While carbonized paper was in fact a species of the broader genus they claimed — "fibrous and textile materials," which encompassed "fibrous vegetable materials"[414] — there was nothing about that genus that made it particularly well suited to work as a light bulb filament.[415] Indeed, as the defendant, Thomas Edison, later found, the vegetable fibers in the genus of plants generally interfered with, rather than promoted, the use of the material as a filament.[416] Sawyer and Man hadn't really taught how to make and use the genus claim, not simply

409. *Cf.* Holbrook, *supra* note 256, at 146–59 (arguing that possession plays a central role in this and other patent law doctrines).

410. Consol. Elec. Light Co. v. McKeesport Light Co. (*Incandescent Lamp*), 159 U.S. 465 (1895).

411. *See supra* Section II.A.3.

412. *Incandescent Lamp*, 159 U.S. at 472.

413. *See id.*

414. *Id.* at 465.

415. *See id.* at 472.

416. *Id.* at 473.

because it took a lot of experimentation to identify which plant species worked, but because the genus was essentially an arbitrary collection of things. Sawyer and Man might as well have claimed a genus of "filaments beginning with the letter P." The *Corona Cord Tire* case, in which the Supreme Court faulted the patentee for improperly generalizing from a disclosed species, appears to be to the same effect.[417]

Improper generalization is not about the overall size of the genus, or even the number of inoperative embodiments,[418] though if you haven't identified what the relevant genus is, then there will often be a lot of examples that don't work. Rather, the problem is ultimately one of possession — the patentee didn't invent a genus because she didn't actually identify a group of chemicals with a relevant property in common.[419] That should disqualify even a small genus, because the patentee in reality hasn't disclosed a genus at all.

Relatedly, the improper generalization rationale can invalidate claims on truly nascent technologies. Cases like *Amgen v. Chugai* and *Enzo v. Calgene* reflect this principle.[420] Even granting that the patents at issue in those two cases provided some examples of how to make the inventions as claimed, the patentee shouldn't be permitted to lock up an entire new field of research if these teachings don't generalize or generalize solely thanks to luck.[421] Therefore, we believe that the judgments of invalidity in *Chugai* and *Enzo* were correct.[422]

Conversely, though, a properly defined genus sharing a relevant structural characteristic shouldn't be invalidated for improper generalization simply because the group has many members, some of which may not work. As long as the technology is advanced enough that the PHOSITA can assess which species work and which ones don't, she has the information needed to make and use the invention.

---

417. Corona Cord Tire Co. v. Dovan Chem. Corp., 276 U.S. 358, 385 (1928); *see supra* notes 62–64 and accompanying text.

418. *In re Soll*, 97 F.2d 623, 624–25 (C.C.P.A. 1938), for instance, rejects a genus with only four species in it because the patentee gave no indication that it thought the invention was a property of that genus and included no broadening language in the specification.

419. *See* Brian P. O'Shaughnessy, *The False Inventive Genus: Developing a New Approach for Analyzing the Sufficiency of Disclosure Within the Unpredictable Arts*, 7 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 147, 153 (1996).

420. *See supra* Section III.A.

421. *See supra* notes 164–170 & 182–188 and accompanying text.

422. *See also* Pac. Bioscis. of Cal., Inc. v. Oxford Nanopore Techs., Inc., 996 F.3d 1342, 1352 (Fed. Cir. 2021) (upholding a finding of no enablement where evidence showed the PHOSITA wasn't "able to use nanopore sequencing to sequence biological DNA" until well after the filing date of the patent application). Indeed, this case can be characterized as one where the specification has not provided enough information to make the invention at all. *See supra* note 400 and accompanying text.

*b. Gun Jumping and Late Claiming*

The second set of circumstances in which possession matters for genus claims relates to the timing of those claims. This is, first and foremost, the proper province of the written description requirement. The claim may be narrow and even enabled as to making, but the inventor raced to the USPTO before she actually had the invention figured out (gun jumping), or alternatively wrote an amended claim after she figured it out but sought to get an earlier priority date for it (late claiming).

Gun jumping is common in the chemical and biotechnological arts because the importance of patents leads to a race to be first. And in the modern world, being first means being first to file an application with the USPTO.[423] Gun jumping is frequently associated with functional claiming — identifying a problem and claiming "anything that solves that problem." The law disfavors functional claims, and sometimes limits them to the specific examples the patentee has identified.[424] One example is *Ariad*.[425] In *Ariad*, the patentee claimed the idea of creating chemicals to have a particular effect, but couldn't give any examples of chemicals that would fit that genus.[426]

Notably, the problem with gun jumping isn't that the claim is too broad per se, though many functional claims are quite broad. Had Ariad identified some specific chemicals that inhibited the biological pathway it discovered, it may well have taught people enough to make and use a broader genus of those chemicals. Rather, the problem is that the patentee didn't get there yet,[427] and the law does not want them to discourage further work by those who do actually take the time to find the solution and not just predict it.[428]

---

423. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284, 285 (2011).

424. *See* 35 U.S.C. § 112(f) (2018); *see also* Lemley, *Functional Claiming*, *supra* note 399, at 916–17 (discussing how courts interpreted the statute to limit claim breadth to "the particular technologies described in the patent specification" because otherwise, a claim could "cover every means of performing the function").

425. *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

426. *Id.* at 1357–58; *cf.* Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc., 923 F.3d 1368, 1383–84 (Fed. Cir. 2019) (striking down the claims under written description for lack of proof of therapeutic efficacy at time of filing); *In re* '318 Pat. Infringement Litig., 583 F.3d 1317, 1327 (Fed. Cir. 2009) (striking down claims for lack of how-to-use enablement, i.e., lack of utility, for similar reasons). How-to-use enablement can be a problem under *Manson* even if the utility is not recited as a limitation. *See* Brenner v. Manson, 383 U.S. 519, 534–36 (1966) (holding that a claim to a process of making a chemical was invalid for lack of utility because the chemical itself lacked utility).

427. *See generally* Dmitry Karshtedt, *The Completeness Requirement in Patent Law*, 56 B.C. L. REV. 949 (2015) (framing this problem as a trans-doctrinal issue of "completeness" of the claimed invention).

428. *Cf.* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 112, 115–16 (2009); Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1186–90 (2016).

Timing can also be a problem in the opposite direction when the patentee didn't actually see an aspect of her own invention until after filing. In the well-known case of *Gentry Gallery, Inc. v. Berkline Corp.*,[429] the patentee came up with an improvement in sofa technology that allowed two sofa sections side by side to recline.[430] They built a fixed console to house the controls for the sofa between the recliner sections.[431] But after seeing that competitors found other places to put the controls, the patentee sought to retroactively change its patent claims to cover any location for the controls.[432]

A patentee who tries to fix claims in this manner after filing isn't entitled to assert that they owned the invention all along. They didn't possess the invention they now claim when they filed their patent. The problem isn't that the PHOSITA couldn't make or use the invention; a reasonable sofa designer could easily imagine a number of places to put the controls. Rather, the problem is that the patentee didn't actually think of the genus they now claim at the time they filed their patent application.

4. The New Full-Scope Requirement

The enablement cases dealing with improper generalization and written description cases dealing with gun jumping or unsupported claiming make sense, and both define a legitimate set of circumstances when it's proper to disallow genus claims. But these cases aren't cabining those claims simply because they are too broad. They are cabining them because the patentee couldn't or didn't actually identify the genus in a meaningful way at the time it filed its patent application. Unfortunately, courts have expanded those specific circumstances in which a possession inquiry makes sense into a general requirement that patentees must "possess" the full scope of the invention, by which they seem to mean "know which species work and which ones don't."[433] In effect, courts have converted the full-scope enablement inquiry from "did I teach you enough such that you can make use of the full scope of the invention?"[434] to "did I give you enough information to assess the full list of what works and what doesn't without undue experimentation?" That's an impossible requirement to meet. And it doesn't serve the purposes of § 112. It's asking the wrong question, because it's confusing possession of the genus (a written description question) with how

429. 134 F.3d 1473 (Fed. Cir. 1998).

430. *Id.* at 1473.

431. *Id.* at 1475.

432. *Id.* at 1475–77.

433. For a discussion of enablement as possession, see Holbrook, *supra* note 256, at 146–61.

434. This formulation allows for some inoperative species, *à la Atlas Powder*, as long as the PHOSITA can determine whether a particular species works without too much effort.

people can use what you taught them (an enablement question). An inventor can develop a new genus without pre-identifying every species in that genus.

This category error is at the heart of the demise of genus claims in the biotechnological, chemical, and pharmaceutical arts today. And it's not something patentees can simply draft around. A chemical genus with any decently large number of species will never satisfy the *Idenix* standard. The claims might be in danger of failing enablement because the testing will take time, but that's not even the worst of the inventor's problems. No matter how much testing the patentee does, there will always be untested species, and because those species aren't tested, the PHOSITA won't know whether they are properly included in the genus, so the claim would fail written description.[435] That didn't matter under courts' old doctrinal view of the world; all the law cared about was whether the PHOSITA could make a species and figure out whether it worked. But the new version of the full-scope enablement requirement is fatal to genus claims.[436]

### *B. Can Pharmaceutical Patent Owners Survive Without Genus Claims?*

Patent protection is understood to be important in the pharmaceutical and biotechnology industries, perhaps more than anywhere else. Certainly, the industries themselves seem to think so. Policy disputes in courts and Congress over the past two decades have time and again seen the chemical and biomedical industries advocating for strong protection, with the software and Internet industries on the opposite side.[437] As Dan Burk and Mark Lemley explain, those policy differences reflect very real disparities in how various industries use and experience the

---

435. This is a particular problem when the claims include a functionality limitation. But as we saw in Part III, the Federal Circuit is now requiring the identification of all the working species in a genus even when the claims do not include such a limitation. *See supra* Sections III.A.2 & III.B.2.b.

436. This new full-scope doctrine has been exported to United Kingdom law. *See* Regeneron Pharms. Inc. v. Kymab Ltd. [2020] UKSC 27 [56] (holding that "[e]nablement across the scope of a product claim is not established merely by showing that all products within the relevant range will . . . deliver the same general benefit" despite the fact that the patentee had disclosed some embodiments). *But cf.* Illumina Cambridge Ltd. v. Latvia MGI Tech SIA [2021] EWHC (Pat) 57 [276]–[279] (Eng.) (limiting the *Regeneron* sufficiency doctrine to some degree). More recently, an English decision moved even further away from the U.S. approach and moved closer to the framework proposed in this Article. *See supra* note 11 and accompanying text.

437. *See generally* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009) [hereinafter BURK & LEMLEY, PATENT CRISIS]; WENDY H. SCHACHT, CONG. RSCH. SERV., RL33367, PATENT REFORM: ISSUES IN BIOMEDICAL AND SOFTWARE INDUSTRIES (2006); *see also* JOHN R. THOMAS, CONG. RSCH. SERV., R43264, TAILORING THE PATENT SYSTEM FOR SPECIFIC INDUSTRIES (2015) (discussing the merits and feasibility of implementing sector-specific patenting parameters in the patent system).

patent system.[438] Patents really are more important to the chemical and biomedical industries than to others.[439] Further, the patent system seems to function more like it was designed to in the chemical industries. The scope of claims is clearer, independent invention is rarer, "stacking" of multiple patents is less common,[440] and the slower pace of change means that a company thinking of making a product could search for and find the relevant patents, something that is not true in many other industries.[441] Jim Bessen and Mike Meurer go so far as to suggest that the patent system may work well only in the pharmaceutical industry.[442]

Given the importance of strong patent protection in these industries, the unwillingness of courts to permit chemical genus claims seems quite troubling as a policy as well as a doctrinal matter. And yet these industries seem to be doing just fine. Pharmaceutical patent owners are making record revenues, up more than 800% from 1992 to 2017.[443] They are still obtaining patents in record numbers.[444] They continue to enforce patents in court; the number of pharmaceutical patent suits filed has remained steady and even increased as patent suits overall have dropped in the last few years.[445] They are suing on larger and larger patent portfolios.[446] And finally, when pharmaceutical patent

438. BURK & LEMLEY, PATENT CRISIS, *supra* note 437, Part II, Ch. 5; *see also* Burk & Lemley, *Policy Levers*, *supra* note 271, at 1615 ("The range of patent theories parallels the range of ways in which the patent system affects companies in different industries.").

439. *See* BURK & LEMLEY, PATENT CRISIS, *supra* note 437, at 50; BESSEN & MEURER, *supra* note 25, at 18.

440. *But cf.* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIS. 590, 602 (2018).

441. *See* BESSEN & MEURER, *supra* note 25, at 89–93 (discussing the qualities of the pharmaceutical industry that make it amenable to the patent system).

442. *Id.*

443. Michael A. Carrier, Mark A. Lemley & Shawn P. Miller, *Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy*, 71 HASTINGS L.J. 307, 316–17 (2019). True, other industries may have a greater profit margin, but the fact that pharmaceutical companies keep increasing revenues and investing more and more in developing drugs suggests they see it as a profitable business.

444. I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES (2018), https://www.ftc.gov/system/files/documents/public_comments/2018/08/ftc-2018-0055-d-0036-155042.pdf [https://perma.cc/SZ54-QW7T]; Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-on Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 316–17 (2010) (analyzing the increase in the number of patents per drug from 1985 to 2005).

445. *See Pharmaceutical Patent Litigation Filings Have Risen Significantly Since 2014, According to Lex Machina's 2015 Hatch-Waxman/ANDA Report* (Apr. 26, 2016), https://lexmachina.com/media/press/pharmaceutical-patent-litigation-filings-risen-since-2014/ [https://perma.cc/6BWT-WU2F].

446. *See* Ouellette, *supra* note 444; *see also* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1386 (2013) (discussing the rise of secondary patents).

owners do take chemical patents to court, they win more often and their patents are less likely to be invalidated than those in any other field.[447]

What is going on? Why does innovation and even patent litigation seem to be proceeding apace in the pharmaceutical industry when the very genus claims that are supposed to be so critical are being struck down left and right? We see two possible answers.

First, it may be that the pharmaceutical industry simply hasn't internalized the sea change we describe here. After all, they are patenting and litigating (and innovating) as if the law remained the way it was thirty years ago.

The reader should be skeptical of this claim. It is worth reiterating exactly what it entails: in a critical sector of the economy — the one in which patents matter the most — dozens of appellate decisions have fundamentally rewritten the law in ways that threaten to undermine its very purpose . . . and no one really noticed![448] That's surprising, if true. These industries care immensely about patents. Not only do they say they care a lot, but they also invest heavily in obtaining patents, in filing and fighting patent lawsuits, and in lobbying Congress to change the law in their favor.[449] And some of the cases we describe here have billions of dollars at stake. One would think lawyers and clients would have ample incentive to keep up with the intricacies of the law and, having done so, would notice the fundamental shift we describe.

For just that reason, we ourselves were skeptical that nobody has noticed the sea change in Federal Circuit case law. Indeed, in an earlier draft of this Article we dismissed that possibility out of hand. But we've received a surprising number of comments from both lawyers and scholars along the lines of "but that can't be true, what about case X, where the patent owner won with a genus claim?" In every such case we examined, however, the patent owner won because the defendant didn't raise enablement or written description arguments based on claim overbreadth.[450] This observation suggests two things. First,

---

447. John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. 1073, 1097–99 (2015). Note that those numbers conceal significant variation by industry. Pharmaceutical patents do very well but biotechnology industry patents do quite poorly, which (as we explain in this Section) may be because biotechnology plaintiffs have to rely more frequently on genus claims in brand-brand litigation.

448. This covert rewriting of patent law evokes the theories of "acoustic separation" and "selective transmission" that Meir Dan-Cohen proposes while analyzing the relationship between conduct rules and decision rules in criminal law. Meir Dan-Cohen, *Decision Rules and Conduct Rules: On Acoustic Separation in Criminal Law*, 97 HARV. L. REV. 625, 625 (1984).

449. The United States' largest companies spent an average of $3.3 billion on intellectual property litigation, about $1.5 million per matter, in 2019. MORRISON & FOERSTER, BENCHMARKING IP LITIGATION 2019 2 (2019), https://media2.mofo.com/documents/benchmarking-ip-litigation-2019.pdf [https://perma.cc/F2QA-TVUL]. Congress's attempts to update the patent system in 2005 became an arduous seven-year saga culminating in enactment of the America Invents Act in 2011. *See generally* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. BAR J. 435 (2011).

450. *See, e.g.*, Immunex Corp. v. Sandoz Inc., 964 F.3d 1049 (Fed. Cir. 2020).

patentees are in fact winning cases because defendants don't realize they have a powerful new tool to challenge those patents. Second, both lawyers and scholars are buying into the conventional understanding of Federal Circuit law. So we can't discount the possibility that knowledge of legal change diffuses slowly, and that many key players simply haven't yet realized how different modern Federal Circuit precedent is. That's surprising, if true. It's also troubling, because it suggests that innovation might suffer as genus claim owners gradually realize they are playing a losing game.

If ignorance of the law is not the explanation, the alternative is perhaps even more striking. Maybe the substance of patent doctrine doesn't matter that much to innovation, even in the very industry in which it's supposed to matter most. One of us has previously documented the "surprising resilience" of the patent economy.[451] Lemley argues that the patent system as a whole has kept operating pretty much in the way it always has, regardless of changes in the law that either strengthen or weaken patent protection.[452] He speculates that the real value companies find in patents may have little or nothing to do with the ability to successfully enforce those patents in court, so changes in legal doctrine that affect whether courts ultimately find patents valid and infringed simply may not matter very much in practice.[453] Perhaps pharmaceutical genus claims are just another example of the resilience of the patent system.

One reason to think that might be true with genus claims is that the cases we have discussed almost all involve infringement suits rather than an inventor's challenge to the USPTO's refusal to grant a patent. That's not an accident. The USPTO does notoriously little examination or rejection based on enablement and written description.[454] This means that the Federal Circuit's changes in the law don't stop companies from getting patents; they just leave many of those patents more vulnerable to invalidation if they ever get to court. And getting to court

---

451. *See generally* Mark A. Lemley, *The Surprising Resilience of the Patent System*, 95 TEX. L. REV. 1 (2016) [hereinafter Lemley, *Surprising Resilience*].

452. *Id.*

453. *Id.* at 40–42 (discussing other benefits of patents, from marketing value to facilitating transactions to the exclusionary power of even unsuccessful lawsuits).

454. *See, e.g.*, Dennis Crouch, *An Empirical Study of the Role of the Written Description Requirement in Patent Examination*, 104 NW. U. L. REV. 1665, 1667 (2010) (internal quotations omitted) (concluding it is indeed "exceedingly rare that the patent office hangs its case on written description"); *see also* Janet Freilich, *Ignoring Information Quality*, 89 FORDHAM L. REV. 2113, 2126–29 (2021) (noting the USPTO's difficulties with enforcing § 112(a)). *But cf.* Greg Reilly, *The Complicated Relationship of Patent Examination and Invalidation*, 69 AM. U. L. REV. 1095, 1102 (2020) (arguing that "stretching" of claim scope in infringement cases can contribute to the disconnect between prosecution and litigation). For further analysis of the disconnect between prosecution and litigation, see generally Greg Reilly, *Decoupling Patent Law*, 97 B.U. L. REV. 551 (2017).

can take more than a decade.[455] If you just care about having a patent for its own sake — for vanity, to trade with others, to lure venture investment, to structure licensing deals for your underlying technology, or as an asset when you sell the company — the fact that it may turn out not to be enforceable down the line simply doesn't matter very much.[456]

Even those who rely on enforcing patents may not care as much as we expect. As Lemley explains, much of the value of patent litigation can come from filing cases, not winning them.[457] That's especially true in the pharmaceutical industry, where the brand firm's mere act of filing a suit against a "generic" competitor, no matter how weak the patent, gets the patent owner an automatic 30-month delay in the generic entering the market.[458] And brand firms often don't even need to sue for infringement until after years of regulatory exclusivity administered by the Food and Drug Administration ("FDA") has expired.[459] Further, most patent cases settle,[460] and until recently, pharmaceutical cases in particular frequently settled with the patent owner paying the generic company to stay off the market for some period of time.[461] When we couple that with the fact that, as discussed further below, the species

---

455. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 236 (1998) (finding the average lag time between patent filing and dispute resolution is over twelve years).

456. Lemley, *Surprising Resilience*, *supra* note 451, at 40–42. There is a robust literature on non-litigation uses for patents. *See generally* Hanna Hottenrott, Bronwyn H. Hall & Dirk Czarnitzki, *Patents as Quality Signals? The Implications for Financing Constraints on R&D*, 25 ECON. INNOVATION & NEW TECH. 197 (2016); Joan Farre-Mensa, Deepak Hegde & Alexander Ljungqvist, *What Is a Patent Worth? Evidence from the US Patent "Lottery"*, 75 J. FIN. 639 (2020); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137 (2000); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625 (2002); Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521 (2005).

457. Lemley, *Surprising Resilience*, *supra* note 451, at 47.

458. 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii) (2018).

459. *See* Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 481–84 (2003).

460. *See* Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237, 273–74 (2006); John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1777 (2014).

461. *See generally* Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249 (2019); William Choi, Bruce Den Uyl & Mat Hughes, *Pay-for-Delay Practices in the Pharmaceutical Sector:* Lundbeck*,* Actavis*, and Others*, 5 J. EUR. COMPETITION L. & PRAC. 44 (2014). However, the prevalence of such transactions seems to have abated after the Supreme Court decision in *FTC v. Actavis, Inc.*, 570 U.S. 136, 158–60 (2013), which held that those agreements can violate antitrust laws. *See* Feldman & Misra, *supra*, at 250–52. But some scholars claim that pay-for-delay has simply "found better ways to camouflage itself." *Id.* at 253. Indeed, a surprising number of settlements still involve concealed payments. *See* King Drug Co. v. SmithKline Beecham Corp., 791 F.3d 388, 404 (3d Cir. 2015) ("It seems to us that no-AG agreements are likely to present the same types of problems as reverse payments of cash."); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating* Actavis, 28 ANTITRUST 16, 18 (2013).

claim may be enough to prevent generic entry, the loss of genus claims may not matter all that much in pharmaceutical and biotechnology cases against generic and biosimilar firms.

Indeed, in significant swaths of the pharmaceutical industry, the species claim may be more important than the genus claim because of regulatory exclusivities and the FDA's requirements for generics. The pharmaceutical patent owner may claim a genus, but it sells a specific chemical. That's what gets FDA approval, and that's what is entitled to regulatory exclusivity.[462] If a competitor wants to make a different chemical than the one the patentee does, it generally has to go through the same expensive, time-consuming New Drug Application ("NDA") process the patentee did.[463] To take advantage of the cheaper, faster Abbreviated New Drug Application ("ANDA") process, generic companies that file with the FDA basically need to copy the patentee's specific drug, and can't substitute a different species within the same genus. That is even more true if they hope to take advantage of state generic substitution laws that allow pharmacists to fill brand name drug prescriptions with cheaper generics.[464] The generic drug must generally be identical (or "AB-rated") to the one prescribed.[465]

In sum, for the most important class of pharmaceutical patent cases — litigation against generics — it's the patent on the specific chemical actually sold, and not the genus claim, that's critical.[466] That may explain an otherwise-curious feature of enablement and written description cases: even though most pharmaceutical company litigation is against generics, almost all of the § 112(a) cases involving genus claims are against competing brand companies. It is only in those less common competitor cases in which genus claims really matter. Still, that doesn't mean there is no problem with eliminating genus claims. Enforcing genus claims may drive certain classes of innovation, pushing pharmaceutical research away from "me-too" drugs towards new

---

462. Regulatory exclusivity gives the first company to submit a new drug for approval a period of time during which no one can use its data or tests to get a generic equivalent drug approved. Those exclusivity periods are independent of patent rights. *See* Eisenberg, *supra* note 459, at 483; John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39, 42–43, 42 n.40 (2015).

463. The § 505(b)(2) "paper NDA" route provides something of an exception. *See generally* Jonathan J. Darrow, Mengdong He & Kristina Stefanini, *The 505(b)(2) Drug Approval Pathway*, 74 FOOD & DRUG L.J. 403 (2019).

464. *See* Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1151 (2019).

465. *Id.*

466. At least, that is true for the drug's active ingredient, which must generally be identical to the marketed one. Generic companies have more ability to vary formulations of excipients, so genus claims may be more important in ANDA litigation over such secondary patents. *See* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents* 22–23 (W. Va. Univ. Coll. L., Research Paper No. 2021-015, 2021), https://ssrn.com/abstract=3903513 [https://perma.cc/KK42-2P55] (finding that the overwhelming majority of patent suits triggered by ANDA filings involved secondary patents).

classes of treatments.[467] Nonetheless, the fact that run-of-the-mill pharmaceutical cases involve species, not genus, claims may help explain why the sky hasn't fallen on the pharmaceutical industry even as those genus claims fail.

Large-molecule life science and biotechnology fields — which produce so-called "biologic" drugs — are in a similar, though not identical, position. Until quite recently there was no FDA approval process for "biosimilars" — the rough biotechnology equivalent of generic substitutes.[468] As a result, anyone who wanted to make a variant or even a copy of the patentee's species had to go through the same FDA approval process the patentee did. There is now, however, the rough equivalent of an ANDA for biosimilars, and it has a key characteristic that renders it comparable to the ANDA process: the biosimilar needs to make a fairly close copy of the actual species that was approved, not just some chemical in the broader genus. Indeed, getting biosimilars to market is significantly harder than doing so with generic pharmaceuticals. This is both because Congress extended data exclusivity from five years in the case of pharmaceuticals to twelve years for biologic drugs, meaning that the biosimilar (or bioequivalent) product can't get approved until much later,[469] and because copying biotechnological materials turns out to be much tougher and less certain than copying small-molecule chemicals.[470]

As a result, genus claims may not actually be needed to prevent copying by generics in either the pharmaceutical or biologics industries, but only to stop competing branded drug companies from producing their own new chemical or biologic products. And while restricting that competition can be important to pharmaceutical companies, these companies may already have enough incentive to invent based on the regulatory exclusivities and the barriers to entry competitors will face — even if the weakness of genus claims ultimately leads to competition from other branded firms filing their own NDAs. That competitors can't cheaply or quickly enter the market with a different species, but must go through their own FDA approval process, can discourage competitive entry and give the patent owners substantial time to recoup

467. On "me-too" drugs, see generally Ron A. Bouchard, *Qualifying Intellectual Property I: Harmonized Measurement of New and Follow-On Drug Approvals, Patents and Chemical Components*, 18 B.U. J. SCI. & TECH. L. 38, 61 (2012); Joshua J. Gagne & Niteesh K. Choudhry, *How Many "Me-Too" Drugs Is Too Many?*, 305 JAMA 711, 711–12 (2011).

468. *See* Karshtedt, *Hard-to-Reproduce Inventions*, *supra* note 152, at 136.

469. 42 U.S.C. § 262(k)(7)(A) (2018).

470. *See* Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 338 n.155 (2015); W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1032–33, 1049 (2016).

their expenses.[471] Patent owners may also buy potential competitors in order to blunt the effect of some of this competition.[472]

The pharmaceutical industry is the poster child for strong patent protection. But if it turns out the industry does just fine with narrow patent protection coupled with regulatory limits on copying, without the need for patents that prevent companies from marketing their own competing drugs that aren't basically identical to the patentee's, a major part of the case for expansive patent protection disappears. We're not persuaded that is true, and genus claims still seem important to us. But the fact that the sky hasn't fallen on the pharmaceutical industry even though genus claims have been systematically invalidated should give us pause, requiring further inquiry into how much patent protection really is necessary.

Nonetheless, even though a major change in pharmaceutical patent law doesn't seem to have affected industry behavior, that doesn't mean we should ignore legal doctrine. But it may be healthy to temper our disputes over legal doctrine with a recognition that law in action may diverge substantially from the law on the books.[473] The story of genus claims is a remarkable example of how a sophisticated industry and its lawyers keep operating as if the law still works the way it once did (and the way they would like it to).

### *C. Implications for Other Industries*

None of the highly rigorous regulatory structure discussed above exists for non-medical chemistry. A solvent, a new petroleum blend, or an agricultural biotechnology invention doesn't get regulatory exclusivities or face generic substitution laws.[474] Early competitive entry may thus be more likely in those industries in the absence of effective genus claims. So we shouldn't be completely sanguine about the continued success of the chemical industries outside the pharmaceutical arena despite the invalidity of genus claims. The change in the law may still have significant effects in those industries,[475] as well as in competitor cases in the life sciences.

---

471. *See* BURK & LEMLEY, PATENT CRISIS, *supra* note 437, at 132–34 (discussing the relative costs of innovating relative to copying as a policy consideration in intellectual property).

472. *See* Peter Lee, *Reconceptualizing the Role of Intellectual Property Rights in Shaping Industry Structure*, 72 VAND. L. REV. 1197, 1217–21 (2019) (documenting consolidation in the pharmaceutical industry and linking it to the need to acquire valuable patents).

473. *See generally* Dan-Cohen, *supra* note 448.

474. To be sure, pesticide registration under the Federal Insecticide, Fungicide, and Rodenticide Act includes provisions for generic entry that are somewhat similar to the ANDA process for pharmaceutical drugs. *See* 7 U.S.C. § 136a(c)(3)(B) (2018).

475. For an example of a failure of purely structural chemical claims from the pesticide industry, see Syngenta Crop Protection AG v. FMC Corp., No. PGR2020-00028, 2020 WL 5539136, at *12–14 (P.T.A.B. Sept. 15, 2020) (granting institution of a post-grant review of

Further, the rules the Federal Circuit is applying to genus claims may reverberate beyond chemistry altogether. While Dan Burk and Mark Lemley argue that the Federal Circuit applies different § 112 rules to the life sciences than it does elsewhere,[476] the court denies doing so, taking the position that its doctrines apply across the board.[477] Traditionally we've not seen strict application of the § 112 doctrines to either the mechanical arts or to the IT industry,[478] perhaps because of the court's intonation that those arts are "predictable."[479] Indeed, the absence of effective enablement and written description doctrines in software cases has led to functional claiming — patent claims that target the problem to be solved and cover any solution to that problem.[480]

But that's changing. The Federal Circuit's insistence on applying doctrines like written description across all technology areas has led it to invalidate software and hardware claims for lack of written description.[481] And the court has sometimes applied the idea of full-scope enablement to invalidate genus claims outside chemistry, even where

---

a pesticide genus patent on § 112(a) enablement grounds in view of *Idenix*), *further proceedings*, Paper 33, at 51 (P.T.A.B Aug. 31, 2021) (invalidating the claims at issue under *Idenix* in a final written decision).

476. *See* Burk & Lemley, *Technology-Specific*, *supra* note 41, at 1156; Burk & Lemley, *Policy Levers*, *supra* note 271, at 1652–54.

477. *See* Amgen Inc. v. Sanofi, 872 F.3d 1367, 1378–79 (Fed. Cir. 2017) (rejecting the notion of a separate, and more lenient, written description rule for antibodies and recognizing that the court has "generally eschewed judicial exceptions to the written description requirement based on the subject matter of the claims." (citing Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 925 (Fed. Cir. 2004))); Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc) (same).

478. BURK & LEMLEY, PATENT CRISIS, *supra* note 437, at 59–62.

479. *See supra* notes 36–39 and accompanying text (discussing predictable technologies); Collins, *supra* note 361, at 1088, 1114, 1121 (discussing the enablement requirement as applied to software inventions). In the early days of computer programming, courts considered the act of translating thoughts into code "a mere clerical function to a skilled programmer." *In re* Sherwood, 613 F.2d 809, 817 & n.6 (C.C.P.A. 1980) (finding disclosure of "menial" tools used in programming unnecessary). More recently, however, this view shifted in favor of more disclosure. *See*, *e.g.*, Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1351 (Fed. Cir. 2015) (en banc in relevant part) (holding that even if "one of skill in the art could program a computer to perform the recited functions[, that] cannot create structure where none otherwise is disclosed"); LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1346 (Fed. Cir. 2005) (finding "describing one embodiment of the thing" was not sufficient to provide adequate § 112(a) support for the claimed software invention).

480. Lemley, *Functional Claiming*, *supra* note 399, at 905; *see* Otis Elevator Co. v. Pac. Fin. Corp., 68 F.2d 664, 669 (9th Cir.), *supplemented on reh'g*, 71 F.2d 641, 641–42 (9th Cir. 1934).

481. *See, e.g.*, Taylor v. Iancu, 809 Fed. App'x 816, 820 (Fed. Cir. 2020) (nonprecedential) (holding claims for a GPS information system invalid for lack of written description); Realtime Data, LLC v. Morgan Stanley, 554 Fed. App'x 923, 937 (Fed. Cir. 2014) (nonprecedential) (holding claims relating to data transmission and encryption systems invalid for lack of written description). While these are not treated as genus claim cases in the way that pharmaceutical cases are, the use of the written description requirement to invalidate software claims is still notable.

those genuses are quite small.[482] A number of commentators have noted the conflict between single-embodiment and full-scope enablement in non-pharmaceutical cases.[483] We may see more such cases in the future.

Restricting broad claims in fields like IT may be less troubling than in the chemical arts, however. After all, abundant evidence suggests that broad patent protection is less important in IT than in other industries.[484] And laxness in enforcing § 112 in those industries has led to endemic problems with overbroad patents not tied to any particular technology.[485] At the same time, however, the full-scope enablement idea seems troubling in many areas of technology. As Jeff Lefstin reminds us, almost all patent claims are directed to an indefinitely large genus in some sense because they incorporate various concepts that could be implemented in multiple ways, and because a defendant who uses the claimed elements does not avoid infringement by adding new elements.[486] Too strict a focus on the full scope of the claim rather than what the PHOSITA could figure out could in theory doom most patent claims in a variety of fields.

## V. CONCLUSION

The story of genus claims is a story of the disconnect between the past and the present, between perception and reality, and between theory and practice. Patent law has always venerated the genus claim. Patent lawyers and patent owners still do. But courts have changed their thinking — and changed the law — to such a dramatic extent that patent owners who sue on genus claims almost always lose at the Federal Circuit. And yet life continues much as it did before. In part, that reflects the fact that perhaps people haven't recognized the size or importance of the change in the law. But it may also indicate that the law itself matters less than we think, even for companies that seem to depend on patent law for their livelihoods.

---

482. *See* Trs. of Bos. Univ. v. Everlight Elecs. Co., 896 F.3d 1357, 1364 (Fed. Cir. 2018) (finding patent relating to a semiconductor device did not teach the full scope of the claimed invention).

483. *See* Chao, *supra* note 361, at 6–7; Tun-Jen Chiang, *Fixing Patent Boundaries*, 108 MICH. L. REV. 523, 537–38 (2010). *But cf.* Rantanen, *supra* note 362, at 1683 (denying there is a split); *see also supra* notes 360–362 and accompanying text (discussing the "genus of methods" problem).

484. *See* BESSEN & MEURER, *supra* note 25, at 22; BURK & LEMLEY, PATENT CRISIS, *supra* note 437, at 81–83.

485. *See* Lemley, *Functional Claiming*, *supra* note 399, at 908–09, 948.

486. *See* Lefstin, *supra* note 70, at 1168–74.