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The Death of the Genus Claim

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Abstract

The central feature of patent law in the chemical, biotechnology, and pharmaceutical industries is the genus claim—a patent 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 have a valid genus claim. Courts almost always hold them invalid, either at trial or on appeal. Remarkably, courts do this without having acknowledged that they have fundamentally changed an important area of law. More remarkably, patent lawyers and patent owners don't seem to have noticed. Invention, investment, patenting, and patent litigation continue much as they had before. It's just that 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 explain why it hasn't seemed to matter, and what that fact says about the relevance of patent doctrine more generally.

Introduction

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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 to be as broad as possible consistent with legal doctrine. 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 of. Instead, patent lawyers lead with a "genus claim"—a broad patent claim that covers a group of structurally related products that incorporate the basic advance of the patented invention.[5] They do that to make sure that no one can copy their basic idea but make a small change to it that avoids infringing the patent.

Nowhere is this more true than in the chemical arts. Pharmaceutical, biotechnology, and chemical companies rely more heavily on the patent system than do other industries. Some scholars have concluded that the system works well in those industries but not others.[6] And those industries make heavy use of genus claims. A chemical patent might include one or more claims to a particular chemical—a species—but almost invariably it starts with a claim to a group of chemicals. 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 a complex chemical. The

5 *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.").

6 *See infra* Part III.

U.S. Patent and Trademark Office (PTO) grants broad genus claims as a matter of course in the pharmaceutical and biotech industries. And those industries regularly enforce genus claims in court.[7]

When they do, however, something surprising happens. As we show in this paper, genus claims are almost invariably held 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 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. Not once but twice it has thrown out a multi-billion dollar jury verdict because it concluded the genus claim was 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: biotech, chemical, and pharmaceutical genus claims lose in court.

Patent lawyers and scholars don't seem to have discovered this. Patent lawyers write genus claims, the PTO grants them, and patent owners enforce them in court. Lawyers and scholars sometimes lament individual decisions they

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

8 *See* Idenix Pharm. LLC v. Gilead Sci. Inc., 941 F.3d 1149 (Fed. Cir. 2019); Centocor Ortho Biotech, Inc. v. Abbott Labs., 636 F.3d 1341 (Fed. Cir. 2011).

9 *See* Part II.C.

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 the law is supposed to serve. The Federal Circuit has abandoned a practical focus on whether others could make use of the claimed invention in favor of 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. Given the importance of patents to these industries, and given the importance of genus claims to those patents, we find the death of genus claims in modern courts troubling. If the doctrine continues going down this path, it may threaten innovation in an important sector of the economy.

We think the law should go back to the way it was. Genus claims should survive as long as other researchers can make effective use of the teaching of the patent to make and use chemicals within the genus without too much experimentation. The validity of a claim should not depend on whether others can identify and test *all* of them.

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 I, 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 II, 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 III, we further examine this trend and discuss its implications for innovation in those industries and for what it says about the importance of patent doctrine more generally.

I. Genus Claiming: The Traditional View

A. Understanding Patent Claims

Claims are central to every aspect of patent law.[10] These 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 control[11] and set the scope of the exclusory

[10] 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 [PTO] 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).

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

right conferred by the patent.[12] 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.[13] At a high level, claims can refer to a structure, such a table 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.[14] While chemical genus claims as such are 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 other uses of the molecules belonging to a chemical genus.[15]

1. Claim Scope and the Disclosure Function of Patents

The permissible scope of the claims is 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).[16] This give and take lies at the heart of the U.S. patent system, which

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[12] Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989).

[13] *See* 35 U.S.C. § 101 (2012) ("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 . . . .").

[14] *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.").

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

[16] The noted patent lawyer and judge Giles Sutherland Rich captured the tradeoffs involving claim scope. *See* Giles S. Rich, *The Proposed Patent Legislation: Some Comments*, 35 GEO. WASH. L. REV. 641, 643 (1967) ("*The stronger a patent the weaker it is and the*

is essentially a bargain or quid pro quo between the patentee and society.[17] The patentee gets the limited period of exclusivity conferred by the patent as set forth in the claims. Society gets two things: (1) use of the invention once the patent term expires[18] 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.[19] The disclosure "add[s] to the sum of useful knowledge"[20] and becomes a part of the

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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.") (emphasis in original).

[17] *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.").

[18] 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.").

[19] *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. 35 U.S.C. § 122(b)(1)(A) (2012). Once a patent application publishes, the information it discloses is considered publicly known. *See id.* § 102.

[20] 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"). 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, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the Federal

technical literature.[21] 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 is after the patent's expiration.[22] Indeed, an oft-touted justification for the patent system is that society will get some benefit from the invention's disclosure.[23]

2. Enablement and the Sufficiency of Disclosure

This bargain only works if the patent's specification (the descriptive part of the patent document)[24] provides sufficient technical information about the invention to enrich the public storehouse of knowledge. Section 112(a) of the Patent Act strives to achieve this goal by mandating that the patent "shall contain a written

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Circuit adopted CCPA decisional law as binding precedent. *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

[21] 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).

[22] *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).

[23] *See Kewanee Oil*, 416 U.S. at 481 (explaining that the federal government "is 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*, *with* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709 (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 (2008).

[24] Courts, scholars, practitioners, and the PTO use the term "specification" to refer to the *written description*—the part of the patent document that provides descriptive (textual) details about the invention (e.g., "Background of the Invention," "Summary of the Invention," "Detailed Description of the Invention"). CRAIG ALLEN NARD, PATENT LAW 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* Part I.B.1.

description of the invention . . . as to enable a person having ordinary skill in the art [PHOSITA][25] . . . to make and use the same . . . ."[26] This language provides the statutory basis for the enablement requirement, whose principal task is to safeguard the teaching function.[27] As interpreted by the courts, the enablement requirement compels a patentee to furnish a disclosure sufficient to allow a PHOSITA to make and use the claimed invention without undue experimentation.[28]

Enablement issues can arise in patent prosecution[29] or litigation.[30] In both contexts, "an enablement determination is made *retrospectively*, i.e., by looking back

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[25] The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts. 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. Envtl. 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 Pharm. LLC v. Gilead Sci. 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).

[26] 35 U.S.C. § 112(a) (2012). Note that prior to 2012, the relevant provision was codified as § 112, first paragraph, rather than § 112(a).

[27] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 4, at 3-4 (explaining that enablement plays a central role in "safeguard[ing] the patent system's disclosure function by ensuring relatively swift dissemination of technical information from which others . . . can learn").

[28] *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).

[29] The process of obtaining a patent—where the inventor or his or her agent or attorney files an application with the PTO—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 in nonenabled. *Wright*, 999 F.2d at 1561-62.

[30] An issued patent is presumed valid; therefore, a challenger has the burden of proving that a claim is invalid for a lack of enablement by clear and convincing evidence. Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014).

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 . . . ."[31] The Federal Circuit set forth the relevant factors in *In re Wands*.[32] 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 technology already available to the public),[33] (7) the breadth of the claims, and (8) the quantity of experimentation necessary to practice the claimed invention.[34]

The *Wands* factors show that how much a patent must teach to enable a patent claim depends on the nature of the technology. Historically, there has been a natural dichotomy in enablement jurisprudence: the courts appeared to apply separate enablement standards for inventions in the predictable and unpredictable arts.[35] In the predictable arts, which include mechanical and electrical engineering, a detailed disclosure has not been required because the inventions are rooted in

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[31] Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72 (Fed. Cir. 1999).

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

[33] *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 (like issued patents and printed publications), devices, and activities are sources of prior art. See 35 U.S.C. § 102(a) (2012).

[34] *See Wands,* 858 F.2d at 737.

[35] For a deeper discussion of the predictable-unpredictable dichotomy, see Seymore, *Heightened Enablement*, *supra* note 5, at 136-39; Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 282-84 (2008).

well-defined, predictable factors.[36] If a claim recites 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 include much detail. 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 reaction protocol that works for one embodiment of an invention[37] will work for others.[38] For example, in chemistry a PHOSITA often cannot take a result from one reaction and predict how similar compounds will react with a reasonable expectation of success.[39]

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[36] *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).

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

[38] Cedarapids, Inc. v. Nordberg, Inc., No. 95-1529, 1997 WL 452801, at *2 (Fed. Cir. Aug. 11, 1997); *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.").

[39] Seymore, *Heightened Enablement*, *supra* note 5, 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).

Nevertheless, assuming an adequate teaching in the specification, inventors in this field could routinely obtain patent claims covering a group of structurally related chemicals.[40]

3. The 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 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. 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.[41] Claiming a genus 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? The courts permit a PHOSITA to engage in "a reasonable amount of routine experimentation"[42] to figure out the embodiments that work from those that do

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[40] *See infra* notes 75-76 and accompanying text.

[41] 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))).

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

not.[43] The U.S. Court of Customs and Patent Appeals (CCPA)[44] recognized that the alternative of requiring the patentee to identify and test every possible chemical in a genus would be unworkable: "the research to do this would evidently be endless."[45] This is known as the inoperative embodiments doctrine—a broad claim that covers unknown species is not necessarily invalid as long as some (perhaps most) of the subject matter works as described.[46] Validity depends on the circumstances of each case—including the nature of the subject matter (predictable or unpredictable),[47] the PHOSITA's level of skill,[48] and the number of inoperative embodiments.[49]

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[43] *Id.* ("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.'" (citing *In re* Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988)).

[44] The CCPA was a predecessor to the U.S. Court of Appeals for the Federal Circuit. *See supra* note 12.

[45] *In re* Sarett, 327 F.2d 1005, 1019 (C.C.P.A. 1964); *see also* RIDSDALE ELLIS, PATENT CLAIMS § 214 (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").

[46] *See In re* Cook, 439 F.2d 730, 735 (C.C.P.A. 1971); *Sarett*, 327 F.2d at 1019 (noting that the mere inclusion of inoperative embodiments in a claim will not defeat patentability).

[47] *See supra* notes 24-27 and accompanying text.

[48] *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 a 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 note 23.

[49] *See, e.g.*, Consol. Electric Light Co. v. McKeesport Light Co. (*Incandescent Lamp Patent*), 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 [a 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 if the accused

But how are we to know when the patentee has taught enough to justify a claim to a group of chemicals? The Supreme Court faced this issue long ago in the famous *Incandescent Lamp Patent* case.[50] The patent-in-suit claimed a light bulb with a filament made of "carbonized fibrous or textile material."[51] 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.[52] 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.[53] The Supreme Court held that the patentee was entitled to a narrow claim for the carbonized paper embodiment, but not to the genus claim.[54]

Incandescent Lamp demonstrates an outer limit on claim scope—the claims are limited by what the patent teaches.[55] In *Incandescent Lamp*, the limited disclosure could not teach a PHOSITA how to find the embodiments that worked

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infringer shows that a "significant percentage" of embodiments encompassed by the claims are inoperable, that might be sufficient to prove invalidity).

[50] *Incandescent Lamp*, 159 U.S. 465.

[51] *Id.* at 468.

[52] *Id.* at 472.

[53] *Id.*

[54] As Justice 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.

[55] Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (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").

without undue experimentation.[56] Indeed, in that case it was not obvious that there was any meaningful genus of "carbonized fibrous and textile materials" that could function as a light bulb filament.[57]

Following *Incandescent Lamp*, in the 1928 case *Corona Cord Tire Co. v. Dovan Chemical Corp.*, the Supreme Court invalidated a broad genus claim to a class of chemicals because the patentee had not shown that there was "any general quality common to disubstituted guanidines which made them all effective" for use in the process of the invention.[58] Here too there was evidence that a substantial number of the claimed embodiments did not work.[59] These cases show that providing a limited number of species in the specification cannot serve as a "springboard" for claiming a genus if those species are not representative of the *entire* genus.[60] Again, the patentee must give more (disclosure) to get more (scope).

B. The Traditional Role of Genus Claims

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[56] 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 19 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 supra* note 23 and accompanying text (citing *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)).

[57] *See infra* Part III.

[58] Corona Cord Tire Co. v. Dovan Chemical Corp., 276 U.S. 358, 385 (1928); *cf. Incandescent Lamp*, 159 U.S. at 472 ("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 . . . .").

[59] *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.").

[60] Minnesota Min. & Mfg. Co. v. Carborundum Co., 155 F.2d 746, 750 (3d Cir. 1946).

Genus claims provide the broadest scope of patent protection. These broad claims use functional language[61] or generic formulas to cover embodiments of the invention (species) that share a common attribute or property.[62] 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.

Patentees opt for genus claims for two reasons. First, since patent law does not require an inventor to actually make each species claimed,[63] genus claims can afford broad scope with relatively little experimentation.[64] 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)[65] because an unauthorized use of any species within the scope of the claimed genus is an act of patent infringement.[66]

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[61] 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) (sanctioning the use of functional claiming and recognizing that it can be a "practical necessity").

[62] 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.

[63] *See supra* note 36 and accompanying text.

[64] *See* Seymore, *Heightened Enablement*, *supra* note 5, at 145-54; Seymore, *Teaching Function*, *supra* note 13, at 628-32.

[65] When patentees draft narrow claims, an imitator would find a minor variation over the claimed embodiments; thereby rendering the patent useless. *See* Merges & Nelson, *supra* note 6, at 845.

[66] 35 U.S.C. § 271(a) (2012).

Although genus claims appear in all areas of technology, they are ubiquitous in chemistry, pharmaceuticals, and biotechnology—the aforementioned unpredictable arts.[67] A common claiming technique is to draw a core generic chemical structure with an array of variables appended to it—which can each represent numerous chemical moieties. For example, the representative claim at issue in *Idenix Pharmaceuticals v. Gilead Sciences*, the case to which we will return in Part II,[68] involved a claim to a five-membered ring structure with "wild cards" on the periphery of the ring represented by the numbered "R" groups (see below). 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. Genus claims are pervasive in the unpredictable arts and have received considerable treatment in treatises,[69] books,[70] and voluminous case law.[71]

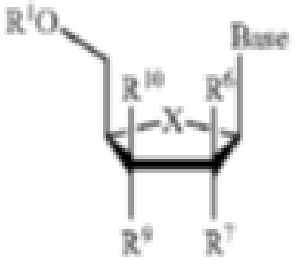
[67] *See supra* notes 24-27 and accompanying text.

[68] Idenix Pharm. LLC v. Gilead Sci. Inc., 941 F.3d 1149 (Fed. Cir. 2019).

[69] *See, e.g.*, EMERSON STRINGHAM, PATENT CLAIM DRAFTING § 5090 (2d ed. 1952); ROBERT D. FIER, CHEMICAL PATENT PRACTICE (1975).

[70] *See, e.g.*, JOSEPH ROSSMAN, THE LAW OF PATENTS FOR CHEMISTS (1932); EDWARD THOMAS, CHEMICAL INVENTIONS AND CHEMICAL PATENTS (1950); JOHN T. MAYNARD, UNDERSTANDING CHEMICAL PATENTS: A GUIDE FOR THE INVENTOR (1978).

[71] *See, e.g.*, cases cited *supra* note 59; *infra* notes 67-72. In addition, chemical claims can be drafted in a so-called "Markush group" form. *See Ex parte* Markush, 1925 Dec. Comm'r Pat. 126, 128, 340 OFF. GAZ. PAT. OFF. 839 (1924); *In re* Driscoll, 562 F.2d 1245, 1249 (C.C.P.A. 1977) (sanctioning the practice); *In re* Harnisch, 631 F.2d 716, 719-20 (C.C.P.A. 1980) (explaining the history and current law of Markush practice).



How much must a patentee teach to enable a genus claim in unpredictable fields? The early chemical cases were somewhat stringent. For instance, in the 1957 case *In re Shokal*,[72] the CCPA adopted the view that disclosure of "a single species can rarely, if ever, afford sufficient support for a generic claim."[73] By 1960, 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."[74] The amount of teaching required to enable a genus claim "will vary depending on the circumstances of particular

[72] *In re* Shokal, 242 F.2d 771 (C.C.P.A. 1957).

[73] *Id.* at 773. To be sure, 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.3d 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 genus failed because the patent did not teach a 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* Part I.C.1.

[74] *In re* Grimme, 274 F.2d 949, 952 (C.C.P.A. 1960). With respect to naming every species within a genus, recall the illustration presented above where the patentee claimed "a plastic-coated steel screw." Even if the disclosure only names or exemplifies a handful of species (e.g., polystyrene, polyethylene, etc.), it could enable other plastics that are not specifically recited (including plastics that did not exist at the time of filing).

cases."[75] This liberalization opened the door for patentees in unpredictable fields to obtain broader genus claims with only a handful of working examples,[76] or even *no* working examples, if the disclosure provided sufficient teaching.[77]

A pivotal case illustrating this shift is *In re Angstadt*.[78] The genus claim at issue, which encompassed thousands of species, was directed to a method for catalytically transforming a class of organic compounds. Although the applicant disclosed forty examples in the specification, the PTO's position was that the disclosure left "too much to conjecture, speculation, and experimentation" and was nonenabling because: (1) the forty examples did not teach across (and were not representative of) the entire genus and (2) the disclosure did not set forth those catalyst features that would allow a PHOSITA to produce materials with the

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[75] *In re* Cavallito, 282 F.2d 357, 360 (C.C.P.A. 1960); *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. 1934) ("While the number of specific substances mentioned is doubtless important, especially in a case where the generic nature of a case must be inferred from the mention of specific substances, we 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.").

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

[77] *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 is no statutory basis for a working example requirement). The Supreme Court long ago allowed this practice in a famous case. *See The Telephone Cases*, 126 U.S. 1, 535-36 (1888).

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

intended function.[79] 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,"[80] which would "tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed."[81] 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 did not[82]—so long as the inventor demonstrated that some species do actually function as intended and provided direction for how to test the rest.[83] *Angstadt* aligns with the inoperative embodiments doctrine discussed above.[84]

Early Federal Circuit opinions continued to resist enablement challenges to broad genus claims. Consider *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, where the patent-at-issue involved emulsions useful as blasting agents for mining and construction.[85] The genus claim covered various salts, fuels, and emulsifiers that could form thousands of emulsions.[86] The accused infringer argued that the

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[79] *Id.* at 501-02.

[80] *Id.* at 502-03.

[81] *Id.* at 503.

[82] Seymore, *Heightened Enablement*, *supra* note 5, at 149.

[83] *Angstadt*, 537 F.2d at 503.

[84] *See supra* notes 38-43 and accompanying text.

[85] Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1571 (Fed. Cir. 1984).

[86] *Id.* at 1576.

genus claim was nonenabled because the specification did not teach which combinations would work and thus was nothing more than "a list of candidate ingredients."[87] There was also record evidence that a considerable number of the claimed combinations were inoperative.[88] 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 . . . ."[89] A detailed teaching was unnecessary because a PHOSITA could readily select the proper ingredients using a "basic principle of emulsion chemistry."[90] *Angstadt* and *Atlas Powder* show that the 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 variance of the groups attached to that core. As numerous prosecution handbooks confirm, this is the typical kind of chemical genus claim that patent attorneys are taught to

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87 *Id.*

88 *See id.* at 1577.

89 *Id.* at 1576 (citing *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 does not work). But there seems to be an upper limit 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.").

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

draft.[91] Some of those variants will work; others won't. But the inventor of a genus can claim that genus as long as there is enough information that the PHOSITA can figure out some species within the genus that will work and how to make those species without too much effort. The prevalence of advice for such claiming reflects a widespread understanding that they 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 sufficiently full, clear, concise, and exact terms as to enable a [PHOSITA] . . . to make and use the same . . . ."[92] As noted above, this language provides the statutory basis for the enablement requirement.[93] However, in the 1967 case *In re Ruschig*, the CCPA held that this language embodies an *additional* disclosure requirement: the "written description" requirement.[94] The issue is whether the specification, as of the filing date sought, conveys with reasonable clarity that the patentee "actually invented" the claimed subject matter.[95] The requirement is met if the claimed subject matter is supported by an adequate description in the specification.[96]

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91 *See, e.g.*, CHRIS P. MILLER & MARK J. EVANS, THE CHEMIST'S COMPANION GUIDE TO PATENT LAW 7-8 & n.4 (2010); *see supra* notes 70-71 and accompanying text.

92 35 U.S.C. § 112(a) (2012), discussed *supra* Part I.A.2.

93 *See supra* note 21 and accompanying text.

94 *In re* Ruschig, 379 F.2d 990, 995-96 (C.C.P.A. 1967).

95 *Id.* at 995.

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

How does the written description requirement differ from enablement? In the 1971 chemical case *In re DiLeone*, the CCPA explained that one can "*enable* the practice of an invention as broadly as it is claimed, and still not *describe* that invention."[97] *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."[98] The converse is also true.[99]

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 that is disclosed and what is claimed.[100] Enablement compels the patentee to teach a PHOSITA how to make and use an invention as broadly as it is claimed without undue experimentation;[101] written description requires the patentee to describe the invention in sufficient detail to allow a PHOSITA to recognize that the inventor actually invented what is

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97 436 F.2d 1404, 1405 (C.C.P.A. 1971) (emphases added).

98 *Id.* at 1405 n.1 (emphases in original).

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

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

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

claimed.[102] 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.[103] In addition, as *DiLeone* suggests, listing some species belonging to the genus in the specification, along with some broadening language, might also have been enough to adequately describe a genus claim.[104]

Indeed, 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 to that application during prosecution;[105] 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).[106] The key question common to these two scenarios

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[102] *Cf. In re* Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989) ("[T]he description must clearly allow [a 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. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

[103] *See* 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).

[104] *DiLeone*, 436 F.2d at 1405 n.1.

[105] *Id.* at 1560.

[106] *Vas-Cath*, 935 F.2d at 1560. A continuation application is a second application for the same invention disclosed in a parent (original) application that is filed before the parent application either issues as a patent or becomes abandoned. 35 U.S.C. § 120. It has the identical specification as the parent and enjoys the benefit of the parent's earlier filing date. *Id.* Applicants file continuation applications for many reasons. For example, an applicant may decide to prosecute a parent application with narrow claims (which will issue relatively quickly) and then prosecute broader claims in the continuation application. *See* ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 161-62 (4th ed. 2006).

is whether the specification provides "adequate support" for any claim that did not appear in the patent application at the time of filing.[107] 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."[108] Early Federal Circuit cases 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."[109]

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 hardwoods; including beech, hickory, maple, oak, and walnut. It also explains how to make and use the rake. While the application is pending at the PTO, the inventor seeks to amend the application by adding a genus claim that recites "a stainless steel rake having a wooden handle."[110] 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

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[107] *Vas-Cath*, 935 F.2d at 1560.

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

[109] *Vas-Cath*, 935 F.2d at 1562 (emphasis added) (quoting *In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1978)); *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").

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

technology.[111] But unfortunately for the inventor, the specification only describes and exemplifies hardwoods. Accordingly, as the Federal Circuit held in *Gentry Gallery v. Berkline Corp.*, the PTO will deny the amendment (or a court will invalidate the claims) for a lack of written description because "[the] original disclosure serves to limit the permissible breadth of the later-drafted claims."[112] 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 the process by the patent applicant."[113]As of the 1980s, then, written description was a separate requirement from enablement, but it was one that 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.[114] This form of written description, however, did not pose a threat to genus claims unless such claims were added after filing and the specification included no indication that the inventors believed that their invention was generic.[115]

2. The Rise and Nature of Biotech Inventions

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[111] *See supra* note 29 and accompanying text.

[112] *Gentry Gallery*, 134 F.3d at 1479.

[113] 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)).

[114] 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").

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

The requirements of enablement and written description come up frequently in biotechnology patent cases, and many of the cases we discuss limiting 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 so-called "monoclonal antibodies."[116] In *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, the genus claim covered a so-called "immunoassay" method employing highly-sensitive monoclonal antibodies to determine the presence or concentration of an antigen.[117] 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 sensitivity.[118] The Federal Circuit rejected both arguments, noting that the synthetic and screening techniques were well known in the art and the absence of "a shred of evidence that undue experimentation was required by [a PHOSITA] to practice the invention."[119] The

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116 Monoclonal antibodies are man-made proteins designed to find and attach to specific antigens (e.g., viruses, 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 cancer. *See* RICHARD COICO & GEOFFREY SUNSHINE, IMMUNOLOGY: A SHORT COURSE 80-81 (2015).

117 Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1369-71 (Fed. Cir. 1986). "Sensitivity" is the ability of an antibody to detect and bind to a particular antigen. *Id.* at 1369.

118 *Id.* at 1384.

119 *Id.*

court famously stated that "a patent need not teach, and preferably omits, what is well known in the art."[120]

In *In re Wands*, the genus claim covered an immunoassay method employing highly-sensitive monoclonal antibodies capable of detecting a hepatitis-B antigen using a highly-sensitive monoclonal antibody.[121] The issue was whether the disclosure enabled practicing the genus claim without undue experimentation.[122] In order to make the subject matter of the invention, a PHOSITA would have 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.[123] Applying the aforementioned *Wands* factors,[124] the court determined that the claim was enabled because the specification gave considerable direction and guidance; working examples were provided; the PHOSITA's level of skill was high; and all of the required methods were well known in the art.[125] Enablement was not precluded if extensive, routine

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[120] *Id.* (citing Lindemann Maschinenfabrik GMBH v. Am. Hoist and Derrick Co., 730 F.2d 1452, 1463 (Fed. Cir. 1984)). *But cf.* Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1368 (Fed. Cir. 1997) (holding that the patentee cannot rely heavily on PHOSITA knowledge outside the specification to enable the claim).

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

[122] *Id.* at 735.

[123] *Id.* at 737-78.

[124] *See supra* text accompanying note 26 (citing *Wands*, 858 F.2d at 737).

[125] *Wands*, 858 F.2d at 740.

experimentation is needed to practice the invention because "the key word is 'undue,' not 'experimentation.'"[126]

For the Federal Circuit in the 1980s, then, biotechnology was a new technology, but it didn't call for new legal doctrines. The enablement question was the same as it had been with any other field of science—can the PHOSITA figure out how to make and use species within a claimed genus without too much work or too many false starts?—and the written description requirement continued to be limited to the problem of lack of specification support for claims added after filing.[127]

But all that was about to change.

II. The Modern Era: Genus Claims Fail in Court

The courts' initially favorable response to biotech patents helped to spur research and development in this industry and to bring forth groundbreaking, commercially significant inventions.[128] But the trend soon began to reverse. Beginning in the 1990s,[129] defendants in biotech and even traditional chemistry cases began to turn to § 112(a) as a critical shield, putting pressure on this

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

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

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

[129] *See, e.g.*, *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (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).

provision's functions of policing claim overbreadth and early patenting.[130] The strategy bore fruit, as the Federal Circuit increasingly came to rely on the enablement requirement, and then also on a powerful new variant of the written description requirement, to strike down generic patent claims in the life science fields.

Karshtedt observed ten years ago that the court's enablement and written description opinions in the 1990s and 2000s "have shown discomfort with broad claims of biotechnology."[131] In this Article, we show that the Federal Circuit extended this trend to traditional chemistry genus claims in the 2010s—and has frequently done so in ways that disserves the purposes of § 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[132] and an excessive amount of experimentation needed to identify potentially inoperative claim embodiments.[133] and the lack of precise structural information about the bounds of the genus.[134] While some prior precedent exists for these routes of invalidating patents for

130 *See* Seymore, *Heightened Enablement*, *supra* note 5; Karen S. Canady, Note & Comment, *The* Wright *Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455 (1994).

131 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).

132 Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380 (Fed. Cir. 2013).

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

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

inadequate disclosure,[135] their deployment has become significantly more vigorous over time.

The resulting shift is dramatic, as we show in this Part. Especially in the 1980s, one is hard pressed to find appellate cases invalidating claims under § 112(a) based on notions of claim overbreadth.[136] 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 so-called "interference" proceedings. The Federal Circuit's shift in its approaches to genus claims and the regularity with which those claims are now struck down reflect a fundamental—and previously unnoticed—change in patent doctrine.

A. Rejecting Claims on Enablement Grounds

1. The antecedents of doctrinal drift

The tightening of § 112(a) began in early 1990s. A significant early case in this line is *Amgen Inc. v. Chugai Pharmaceutical Co.*,[137] in which both parties'

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[135] *See, e.g.*, *In re* Fisher, 427 F.2d 833 (C.C.P.A. 1970); *In re* Rainer, 390 F.2d 771 (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*).

[136] For typical examples of § 112(a) failures from the 1980s, *see* Quaker City Gear Works, Inc. v. Skil Corp., 747 F.2d 1446 (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 (Fed. Cir. 1984) (affirming a written description rejection of claims to subject matter not disclosed in the original patent); White Consol. Indus., Inc. v. Vega Servo-Control, Inc., 713 F.2d 788 (Fed. Cir. 1983) (holding claims nonenabled where technology to practice invention was kept as trade secret).

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

patents had claims relating to gene-mediated synthesis of a protein called erythropoietin (EPO) invalidated for lack of enablement. 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."[138] 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 biotech giants competing in this space. While Chugai's claims were invalidated based on the evidence that the method in the specification did not actually produce the EPO with the claimed activity, a fairly uncontroversial application of the enablement requirement,[139] Amgen did actually teach how to make EPO.

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[140]—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

[138] *Id.* at 1203.

[139] *Id.* at 1215-17.

[140] If this case were decided today, the claims would have 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).

cells to increase production of . . . red blood cells, and to increase hemoglobin synthesis or iron uptake."[141]

The Federal Circuit noted that this claim encompasses a "potentially enormous" number of isolated DNA sequences.[142] Any gene that "encodes," or causes 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.[143] 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."[144] 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."[145] 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,"[146] 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."[147]

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

142 *Id.* at 1213.

143 Note this functional aspect of the claim. As we discuss below, this is a hallmark of claims that the Federal Circuit properly invalidated under § 112(a), but the court's doctrinal path has also endangered claims that we believe to be deserving. *See infra.*

144 *Id.* at 1213-14.

145 *Id.* at 1213.

146 *Id.* at 1214.

147 *Id.*

Amgen's claims thus presented a commensurability problem.[148] Indeed, because the specification disclosed only a few examples of a large and complex genus of DNAs whose varied structures could unpredictably affect their EPO-producing function, the Federal Circuit did not even formally consider the *Wands* factors and readily reached the conclusion of nonenablement.[149] Still, the attitude of the opinion differs markedly from the CCPA's *In re Angstadt* decision.[150] That court, one will recall,[151] upheld a rather broad claim against a nonenablement challenge in part *because*, rather than in spite of, identifying working embodiments within the claims' scope required "the types and amount of experimentation which the uncertainty of [the] art makes inevitable."[152] In so doing, the CCPA rewarded a significant discovery in the unpredictable field of chemistry with a meaningful protection of a broad genus claim.[153]

To be sure, distinctions between *Angstadt* and *Amgen* are possible. 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"—an evocative version of the CCPA's nod to the inevitable but acceptable

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148 *See supra* Part I.A.3.

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

150 537 F.2d 498 (C.C.P.A. 1976).

151 *See supra* notes 78-81 and accompanying text.

152 *Angstadt*, 537 F.2d at 504; *cf. In re* Wands, 585 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").

153 *Cf.* Canady, *supra* note 131 (noting that in certain fields of technology, extensive experimentation is inevitable).

uncertainty involved in practicing Angstadt's invention. 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."[154] 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.[155] The *Amgen* court, however, did not attempt to distinguish *Angstadt*.[156] As we show in this section, the Federal Circuit's failure to square *Angstadt* with its later § 112(a) case 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 what sorts of experimentation can be considered undue under the *Wands* standard. This shift arguably began in a 1999 Federal Circuit biotech enablement opinion, *Enzo Biochem v. Calgene, Inc*.[157] This case involved so-called "antisense" technology that, as the court held, was also claimed in a plainly overbroad manner.[158] Briefly,

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[154] For an 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, 1368 (Fed. Cir. 1997); *see also* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004) (similar in the context of the written description requirement); Seymore, *Heightened Enablement*, *supra* note 5.

[155] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1204, 1214 (Fed. Cir. 1991).

[156] *Id.* at 1213 (citing *Angstadt*, 537 F.2d at 502, but only for the for the innocuous proposition that "it is not necessary that a patent applicant test all the embodiments of his invention").

[157] Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed. Cir. 1999).

[158] *Id.* at 1368, 1377.

antisense is a method for regulating the gene-mediated production of proteins with the aid of synthetic DNA molecules.[159] 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 were drawn to antisense-promoting synthetic DNAs "present in a prokaryotic and eukaryotic cell containing a gene" and prokaryotic or eukaryotic cells containing those DNAs.[160] The inventors got the antisense technology to work in some genes in *E. Coli*., disclosed those methods in the specification, and asserted that antisense was generalizable to other genes and organisms, including eukaryotes.[161]

The Federal Circuit found that all the 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.[162] 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

[159] An example of this so-called "gene expression" is production of EPO mediated by the EPO genes, discussed above in the context of the *Amgen* case.

[160] *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.

[161] *Id.* at 1368. The defendant's product was a tomato, which is eukaryotic. *Id.* at 1377.

[162] *Id.* at 1370-75.

than *E. coli*, and that such minimal disclosure as there was constituted no more than a plan or invitation to practice antisense in those cells."[163]

But the court didn't stop there. A point implied in passing in *Enzo*—arguably dictum because experimentation needed to practice the claimed invention was shown to be anything but routine—was that even routine experimentation can sometimes be "undue" within the *Wands* framework if it is too extensive.[164] This seemingly insignificant, almost throwaway, language has nonetheless been used to great effect in recent enablement cases.[165] The Federal Circuit affirmatively restated *Enzo*'s "routine" notion in *ALZA Corp. v. Andrix Pharmaceuticals*,[166] 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.'"[167] 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.[168] This theory further paved the way for invalidating claims directed to technologies that, unlike recombinant DNA or

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163 *Id*. at 1375.

164 *Id.* at 1370.

165 *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)); *see also* Canady, *supra* note 131.

166 ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935 (Fed. Cir. 2010).

167 *Id*. at 940 (citations omitted).

168 *See infra* Part II.A.2.

antisense, were not nascent or emerging, but arguably unpredictable only in the "known unknowns" context that the CCPA previously found acceptable in cases like *Angstadt* and *Atlas Powder*.[169]

2. The new law of genus claim nonenablement

Of late, § 112(a) began to be applied with increasing rigor against patents in areas with "known unknowns." The first opinion in this latest line of cases, *Wyeth & Cordis v. Abbott*,[170] involved a traditional chemical genus rather than a biotech invention. The underlying discovery addressed a condition called restenosis, which is the narrowing of arteries that can take place when a catheter is inserted to clear out plaque,[171] and the claims recited a method of treating it with a therapeutically effective amount of a chemical belonging to the class of compounds called "rapamycin."[172] The rapamycin compounds all have a particular "macrocyclic" (i.e., large-ring) structure, but one of the chemical groups attached to the ring is allowed to vary. The inventors thus claimed the class of potential therapeutic agents much as one would a traditional chemical genus. While many such claims are directed to

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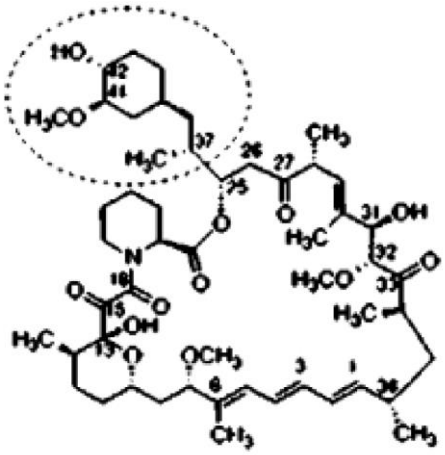
[169] *See supra*; *cf. In re* Mazrocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) ("In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles."). This older view thus holds that claims fail enablement if the underlying subject matter cannot be made at all because it does 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.

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

[171] *Id.* at 1382.

[172] *Id.*

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,[173] the patentee simply used the word "rapamycin" to convey both the core and the substituent concepts (see below—the group in the dashed oval is allowed to vary).[174]



The specification demonstrated that at least one of the species within the rapamycin genus, "sirolimus," was effective in treating restenosis.[175] It also disclosed assays for testing if other rapamycins have the requisite therapeutic property,[176] and an expert explained that the substituent group must be below a certain molecular weight in order to have an antirestenotic function.[177] But all this was not enough. After noting that even routine experimentation "is not 'without

[173] *See supra* Part I.B.

[174] *Wyeth*, 720 F.3d at 1383.

[175] *Wyeth*, 720 F.3d at 1384.

[176] *Id.*

[177] *Id.*

bounds'" for the purpose of the undue experimentation standard,[178] the Federal Circuit cited *ALZA* for the proposition that the need for "an iterative, trial-and-error process to practice the claimed invention even with the help of the . . . specification" can lead to an enablement problem and invalidated the claims.[179] The court explained that the synthesis of the "tens of thousands of candidate[]" sirolimus compounds was laborious, the assays were time-consuming,[180] and the guidance on structural parameters that could help a PHOSITA identify working species within the claimed genus and thus accomplish this work more quickly was inadequate.[181]

The genus in *Wyeth* is reasonably large. Nevertheless, the problem in *Wyeth* is one of "known unknowns." 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. This is a far cry from, for example, demonstrating a proof of concept of just-discovered antisense technology in *E. coli*, as in *Enzo*, and then claiming antisense DNA for every living organism under the sun.[182] 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 if any particular compound satisfying the claim's structural limitations works for the

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178 *Id.* at 1386 (quoting Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1339 (Fed. Cir. 2013)).

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

180 *Id.* at 1385.

181 *Id.* at 1386.

182 *See supra* notes 157-161 and accompanying text.

intended catalytic purpose by testing it out.[183] Practicing the claims in *Wyeth*, as in *Angstadt*, did not seem to require "ingenuity beyond that to be expected of one of ordinary skill in the art," but the patentee lost in *Wyeth* and won in *Angstadt*.[184]

Key to the different results seems to be a significant, though unacknowledged, shift in how the Federal Circuit thinks about enablement of genus claims. *Angstadt* and *Atlas Powder* are focused on the practical challenge facing a PHOSITA—how to make and use *a species within the genus*. If it's too hard to find one that works, whether because the genus itself isn't really a genus, as in *Incandescent Lamp*, or because of the related problem that the number of inoperative species is too high,[185] the PHOSITA would have to engage in undue experimentation.

Wyeth, by contrast, worries that the synthesis of the "tens of thousands of candidate[]" sirolimus compounds would require undue experimentation.[186] That does indeed sound like a lot of work. But why would a PHOSITA have to synthesize tens of thousands of candidates? Even if half of the species in the genus don't work (and there was no evidence that this was actually the case in *Wyeth*), on average

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[183] *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.

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

[185] *See supra* notes 46-49 and accompanying text.

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

(i.e., working at random) a PHOSITA might have to try two before finding one that does. Nevertheless, *Wyeth* reflects a move away from this kind of thinking. To gauge whether the "full scope" of the genus claim is enabled, the court seems to assume that the PHOSITA must test *every* species within the genus for enablement purposes. That's a significant new requirement, 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, "requiring 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."[187]

As two 2019 Federal Circuit opinions confirm, 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 v. Roche Molecular Systems*, the court emphasized that "[a]s in *Wyeth*, the asserted claims here require not just a particular structure, but a particular functionality."[188] 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."[189] Therapeutic efficacy is a claim-narrowing limitation, so one would

187 *In re* Bundy, 642 F.2d 430, 434 (C.C.P.A. 1980).

188 Enzo Life Sci., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340, 1346 (Fed. Cir. 2019).

189 *Id*.

think that it is easier to enable a claim 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 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.[190]

The Federal Circuit's analysis of the functionality limitation in *Enzo* suffers from the same problem as the "antirestenotis 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, but 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?[191] *Wyeth* and *Enzo* represent a categorical shift in thinking away

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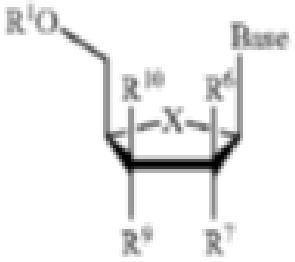
190 *Id*.

191 *Cf*. Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1306 (Fed. Cir. 2002) (explaining that full scope enablement does not require enablement of a specific embodiment of the claim); *see also 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 a PHOSITA could build an embodiment of the invention.

from teaching the PHOSITA and towards 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.[192]

That shift was cemented in *Idenix Pharmaceuticals v. Gilead Sciences*.[193] In *Idenix*, a divided panel held that the claims at issue failed both the enablement and the written description[194] requirements as a matter of law.[195] The representative claim[196] 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 below] . . .



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. As in *Wyeth*, the chemical backbone (here, a so-called "furanosyl nucleoside") has an invariant core

192 *Cf. supra* Part I.B.

193 Idenix Pharm. LLC v. Gilead Sci. Inc., 941 F.3d 1149 (Fed. Cir. 2019).

194 The written description part of *Idenix* is discussed *infra* in Part II.B.

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

196 *Id.* at 1155.

and some structural wild cards on the periphery. The 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.[197]

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."[198] Estimating the factorial, one finds that the total number of possible structures within the scope of the claim reaches into several thousand species.

That sounds like a lot, but such large numbers are typical in chemical genus claiming—and having a massive genus of compounds to be tested for catalytic activity did not ultimately result in an enablement problem in *Angstadt* or *Atlas Powder*, which were not cited. Moreover, as the district court in *Idenix* recognized, the knowledge of the PHOSITA could help reduce the number of potentially working species somewhat based on the judgment that certain substitution patterns would prevent a species from functioning as efficacious therapy against HCV

197 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).

198 *Idenix*, 941 F.3d at 1158.

infections.[199] 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.[200] Finally, the specification provided several working embodiments, and the Federal Circuit agreed that the record supported all these findings.[201]

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."[202] 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.[203] 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,"[204] and the answer was "no." 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. While any particular molecule that falls within the scope of

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[199] Idenix Pharm. LLC v. Gilead Sci. Inc., No., 14-846-LPS, 2018 WL 922125, at *14 (D. Del. Feb. 16, 2018); *see Idenix*, 941 F.3d at 1158.

[200] *Idenix*, 941 F.3d at 1159-60.

[201] *Id*. at 1161.

[202] *Id*. at 1162.

[203] *Id*. at 1162-63 (citing Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1384-86 (Fed. Cir. 2013)).

[204] *Id*. at 1156 (emphasis added).

the genus and is effective against HCV might be readily found, the overall sorting process was held to require undue experimentation.[205]

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.[206] As the CCPA astutely noted, if this were so "then all experimentation is undue, since the term experimentation implies that the success of the particular activity is uncertain."[207] 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 catalysis is 'reasonable,' even if the end result is uncertain."[208] Such unpredictability was characteristic of this mature field—and traversing the claimed genus was a matter of "known unknowns."

But that is no longer the law. After *Wyeth* and *Idenix*, uncertainty with respect to whether some subset of species of a chemical genus would achieve the

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[205] *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*, and *Enzo*)).

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

[207] *Id.*

[208] *Id.* at 504.

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 so even when the patentee attends to the field's inevitable unpredictability by disclosing a screening mechanism that gives a 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 cases like *Atlas Powder*, a defendant could in theory invalidate a claim for lack of enablement if it could demonstrate that so many embodiments within the scope of the claim did not actually work for the invention's intended purpose that the PHOSITA, like Edison in *Incandescent Lamp*, would have to try hundreds or thousands to find one that worked well.[209] But it is crucial to point out that those were *not* the showings made in *Wyeth* and *Idenix*. Indeed, in both cases, the respective defendants actually did find a species within the genus that ended up working perfectly well[210]—and did not demonstrate that the research that led to this 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

[209] Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1576-77 (Fed. Cir. 1984); *see* Consol. Electric Light Co. v. McKeesport Light Co. (*Incandescent Lamp Patent*), 159 U.S. 465 (1895).

[210] *See* Idenix Pharm. LLC v. Gilead Sci. Inc., 941 F.3d 1149, 1171-73 (Newman, J., dissenting); *see also id.* at 1152 (majority opinion) (noting Food and Drug Administration approval for the defendant's product); Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1383 (Fed. Cir. 2013).

argued that *all* the operative embodiments would be time-consuming to identify, and the court accepted this evidence by itself as decisive of invalidity.

This is a massive doctrinal shift in the Federal Circuit's enablement doctrine. Indeed, while the court once seemed to suggest that "operability limitations" in patent claims can forestall enablement problems altogether,[211] we have now reached the point that adding such limitations can present nearly insurmountable § 112(a) difficulties for inventors seeking genus claims that also recite a therapeutic 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 whether making and using the invention requires undue experimentation to whether such experimentation is required to figure out which of all the possible species within the genus work for the invention's claimed therapeutic purpose and therefore to define the "full scope" of the invention. Counterintuitively, it may now be better to draft broader claims (e.g., pure composition claims) if possible so as to forestall arguments about how numerous "variables would or would not impact the functionality" of the claimed invention.[212] But even that won't necessarily help if

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

[212] Enzo Life Sci., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340, 1346 (Fed. Cir. 2019).

the claims don't make clear exactly what 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 the defendants to argue that genus claims are overbroad on their face. Genus claims now fail enablement even when the inventor is not 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.[213] Any genus claim covering a significant number of species in the life sciences and chemical fields, which typically come with built-in unpredictability even if the claimed technology is mature, is now in question. 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 from drafting or amending claims after the filing date[214] to a powerful limit on the scope of patent claims.[215]

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[213] Merges & Nelson, *supra* note _, at 904-08 (discussing problems with allowing broad patents on "science-based" inventions); *see also* Canady, *supra* note 131.

[214] *See supra* Part I.B.1.

[215] 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).

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.[216]

1. Lilly *and Written Description as Enablement Plus*

As we noted in Part I, the focus of the original version of the written description requirement was on claims introduced after the filing date. To review earlier discussion,[217] 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.[218] Thus, even if a PHOSITA would have no trouble extrapolating from the teachings for making A to synthesize numerous other species (B, C, D) that 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. A court or the PTO would say that a PHOSITA reading the original filing would conclude that the

216 Idenix Pharm. LLC v. Gilead Sci. Inc., 941 F.3d 1149 (Fed. Cir. 2019); Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368 (Fed. Cir. 2019).

217 *See supra* Part I.C.1.

218 *See supra* notes 106-109 and accompanying text.

inventors were not subjectively "in possession" of the genus—they did not appreciate that the synthesis of A readily generalized to other species (B, C, D) and ultimately to X.[219] 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 genus claim should indicate to a PHOSITA that the inventors thought they possessed the genus. Before the 1990s, patent attorneys were thus probably safe in assuming that any genus claimed at the time of filing was also possessed, thus satisfying the written description requirement.[220] That changed, however, with *UC Regents v. Eli Lilly & Co.*, the case that created a significant new route for policing the scope of genus claims (among other impacts).[221]

In *Lilly*, the patentee described the structure of a so-called "complementary" DNA (cDNA) that encodes insulin in the rat, and attempted to extrapolate from this discovery to the cDNAs for insulin in any mammal.[222] The practical implications are worth appreciating here: no one really cared about rat cDNA for its own sake because the commercially valuable use of the invention was to produce insulin in

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[219] *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).

[220] *See* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 161-63 (2006).

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

[222] *Id*. at 1563. Another claim covered the genus of vertebrates.

other mammals—particularly, humans—so the inventors included a generic mammalian claim in their original patent filing.[223]

The reader may recall the foregoing discussion of *Amgen v. Chugai* 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.[224] However, as much as we humans might not like it, there is significant homology (i.e., similarity) between the DNA of rats and humans – something on the order of 97%.[225] And if the methodology for isolating rat insulin cDNA readily translates from rats to cDNAs coding for insulins 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 (primate), and D (dolphin), and the genus X (mammalian insulin cDNA) is enabled.[226]

But 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' appreciation that their rat work generalizes to other mammals like humans.

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223 *Id*. at 1564.

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

225 Graeme I. Bell et al., *Sequence of the human insulin gene*, 284 NATURE 26 (1980); Colin W. Hay & Kevin Docherty, *Comparative Analysis of Insulin Gene Promoters: Implications for Diabetes Research*, 55 DIABETES 3201 (2006).

226 Perhaps, the homology may have been sufficient to save this claim from an enablement challenge. *See* Sampson, *supra* note _.

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, is not an adequate written description of the genus because it does not 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."[227] In so doing, the Federal Circuit rejected the view that the written description requirement is used to police only priority (e.g., introduction of claims after filing, narrow or broad, that are not supported by the specification),[228] as opposed to early patenting or claim scope.[229]

The University of California inventors were thus left with an essentially worthless exclusive right to the rat insulin cDNA.[230] 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"[231] in order to describe a genus claim, even if the

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227 *Lilly*, 113 F.3d at 1568.

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

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

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

231 *Lilly*, 113 F.3d. at 1568.

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 figuring out 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."[232] Indeed, *Lilly* was arguably more about timing than overbreadth, as the narrow claim to human insulin DNA was also invalidated for lack of written description.[233] For both the human species and the mammalian genus claims, the Federal Circuit's problem was the lack of information about the structure of insulin cDNAs other than for those of the rat. As a result, the applicants effectively used "cDNA" as a functional term—equivalent to "any sequence that codes for insulin"—in the human and mammalian claims. Nonetheless, as we will soon see, *Lilly* has had a lasting impact on more traditional (i.e., non-functional) genus claims too.

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 and written description different prongs of § 112(a), presage the doctrinal drift that is now making genus claims practically impossible to defend in court. *Lilly* has created a second way of challenging genus

232 *Id*. at 1566.

233 *Id*. at 1567.

claims that is similar to enablement,[234] but without explaining precisely how the process of proper extrapolation from species to genus differs for written description.[235] We do know, however, that post-*Lilly* written description does not require addressing undue experimentation or priority issues. A generic claim may well be enabled based on a 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.

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 biotech inventions.[236] That extra hurdle can't be satisfied by showing 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

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[234] 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); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1653-54 (2003).

[235] *See* Guang Ming Whitley, Note, *A Patent Doctrine Without Bounds: The "Extended" Written Description Requirement*, 71 U. CHI. L. REV. 617, 624 (2004).

[236] Burk & Lemley, *Policy Levers*, *supra* note 230; Holman, *supra* note 230.

Amgen)[237] or even all of them (as in written description decisions, particularly those involving functional claims). One way or another, the court concluded, the claims in *Amgen* and *Lilly* had to be invalid, and the new tests 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 Circuit's approach has come with the costs of eroding doctrinal stability: the focus of enablement shifted from targeting "unknown unknowns" to "known unknowns,"[238] and written description drifted to endanger genus claims that have not presented significant gun jumping or late claiming concerns.

These doctrinal shortcuts are worth lingering on because their effects on the § 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

[237] *See* Kellam, *supra* note 164; *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).

[238] *See supra* note 154.

Written description is not going away. Controversy over this requirement[239] prompted the Federal Circuit to convene en banc in *Ariad Pharmaceuticals v. Eli Lilly & Co*.[240] In *Ariad*, the court reaffirmed both that the written description requirement was separate from enablement and that it could apply to originally filed claims.[241] 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 biotech and chemical genus claims.

Similar to *UC Regents v. 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 the patent as a whole must "demonstrate[ ] that the applicant has invented species sufficient to support a claim to a genus."[242] Expanding on this point, it then noted that "[t]he problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus."[243] This language is something of a hedge, suggesting that functional claiming may signal a

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239 Lizardtech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1376 (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, 1326-27 (Fed. Cir. 2004) (Linn, J., dissenting from the order denying rehearing en banc); *Rochester*, 375 F.3d at 1315-21 (Rader, J., dissenting from the order denying rehearing en banc); Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 981–83 (Fed. Cir. 2002) (Rader, J., dissenting from the order denying rehearing en banc).

240 *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1358 (Fed. Cir. 2010) (en banc).

241 *Id.*

242 *Id*. at 1349.

243 *Id*.

written description problem,[244] but is not required to invalidate claims on this ground. But this was not all, as the court also described the claim as directed to a "research hypothes[i]s" and "an unfinished invention." This language conveys yet another problem—with early patenting—which may yet be still further reason that the claims should be invalid.

As a factual matter, there were plenty of reasons to reject Ariad's claim, and we believe that the functional nature of it was the strongest one—because of potentially infinite scope of functional claims. The overarching issue was that the inventors did not 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. And ultimately, in invalidating the claims, the Federal Circuit reiterated that the claims and their description had problems with breadth, functionality, and timing. But it was not apparent whether all the reasons for holding the claims invalid meant that the result in *Ariad* was overdetermined,[245] and the opinion never made it clear which rationale was particularly critical to its decision.[246]

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[244] 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 (Fed. Cir. 2014); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, (Fed. Cir. 2004).

[245] *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).

[246] *Id.* at 1354-58.

Some parsing may 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, even when the invention is "finished," the patent attorney still chooses to claim it by function), and so on. Consistent with the history of the written description requirement, the thrust of the policy behind the opinion appeared to be timing—in that a purely functional claim suggests that the inventor has jumped the gun and filed the application to soon. The *Ariad* court forcefully stated near the conclusion of its exposition of the law that "requiring a written description of the invention limits patent protection to those who actually perform the difficult work of 'invention.'"[247] Nevertheless, the doctrinal analysis was not explicitly so cabined. It may be that any one of the three potential problems would have doomed the claims, only some, or perhaps it was their combination or cumulation that was the real issue. 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.

b. Further impact on genus claims

Boston Scientific Corp. v. Johnson & Johnson illustrates the dynamics of written description as a weapon against genus claims.[248] The technology will be

[247] *Id.* at 1353.

[248] Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353 (Fed. Cir. 2011).

familiar from the *Wyeth* decision 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.[249] Instead of method claims as in *Wyeth*, the patents at issue in *Boston Scientific* were directed to stent devices covered with therapeutic agents.[250] Similar to *Wyeth*, however, the patent specifications in *Boston Scientific* were focused on one therapeutic species, sirolimus, but broadly claimed various macrocyclic analogs of the rapamycin genus.[251] Instead of invalidating the claims for lack of enablement as in *Wyeth*, however, the court relied on written description.

But the Federal Circuit's problem with the claims in *Boston Scientific* was very different from that in the key written description precedents that we 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*, a PHOSITA could readily "visualize or recognize" the structures of the various rapamycin macrocycles. In addition, while 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,the inventors in *Boston Scientific* actually reduced the invention to practice with the sirolimus species, getting antirestenosis

[249] The two cases, however, dealt with patents of somewhat different scope and the court used slightly different terminology in naming the genus.

[250] *Id*. at 1357-58.

[251] *Id*. at 1358-59.

to work on a stent with this molecule. Nevertheless, as the Federal Circuit saw it, the claims still had an overbreadth problem.[252] Even though the claims were drafted in structural rather than functional terms, they still failed for lack of adequate written description.

The *Boston Scientific* court did discuss function, but in a very different sense from *Lilly* and *Ariad*—in which the claims were wholly devoid of chemical structure. Instead, 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."[253] 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 rapamycins would affect their antirestenotic properties.

But the effect of structural changes in chemical compounds on therapeutic efficacy can rarely be predicted ex ante, so it is really not clear how much more the patentee could have done if it wanted to claim its antirestenosis invention as a chemical genus. Indeed, as Jake Sherkow observed, "drug composition claims may allow so much variability . . . as to make the written-description requirement virtually impossible."[254] In *Wyeth*, the court at least relied on an undisputed factual

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[252] 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.

[253] *Id.* at 1366.

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

assertion that synthesizing and testing the members of the structural genus for antirestenotic activity would take a long time as it concluded that the claims were not enabled. But in *Boston Scientific*, the court did not even do that. It invalidated the claims for lack of "possession" of the genus because a link between structure and properties was missing.[255] 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 did not reach, the patentee still failed under written description because it didn't give us a complete map of which structures performed the desired function. The genus claim simply had no chance.

Idenix Pharmaceuticals v. Gilead Sciences, first 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.[256] In this 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.[257] Indeed, the 2'-fluoro-down material played a critical role in the Federal Circuit's decision that the genus was not 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

[255] *Bos. Sci.*, 647 F.3d at 1364.

[256] Idenix Pharm. LLC v. Gilead Sci. Inc., 941 F.3d 1149 (Fed. Cir. 2019).

[257] *Id*. at 1155.

product."[258] The Federal Circuit, in sum, invalidated the claims under written description because a particular set of working species was not specifically called out in the patent, even though the specification taught PHOSITAs 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,[259] but the accused fluorine-substituted product was not 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,"[260] even though fluorine may not warrant explicit mention because it is a common substituent that can be readily visualized by a PHOSITA. In doing so, the court came close to punishing the patentee for providing *too many* representative examples, noting that the various formulas listed in specification included numerous substitution patterns except for the 2'-fluoro-down.[261]

The absence of this set of species doomed the entire genus under the written description ground both for reasons of structure and function. The Federal Circuit concluded that the patent "fails to provide sufficient blaze marks to direct a

[258] *Id.* at 1163-64.

[259] *Id.* at 1161.

[260] *Id*. at 1165.

[261] *Id*.

[PHOSITA] to the specific subset of 2'-methyl-up nucleosides that are effective in treating HCV."[262] It further explained that, in spite of 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."[263] But in unpredictable life sciences arts there often is no "method" other than trial and error. As suggested above, a tiny structural change can lead to massive therapeutic differences, so the patentee can often provide no "blaze marks"[264] other than by conducting experiments on as many species as possible. Here, 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.[265]

Idenix is particularly notable because it doesn't map to any of the justifications for the written description doctrine. The claim was not drafted in purely functional terms; the patentees did not 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—not just one, as in *Boston Scientific*. But the claim failed written description because the defendant's compound was not specifically listed among the identified working examples. As a result, even if a PHOSITA could synthesize and test the claim's various species so

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[262] *Id*. at 1164.

[263] *Id*.

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

[265] *Cf.* Pitlick, *supra* note _, at 221 (predicting this problem in his analysis of *UC Regents v. Lilly*).

rapidly that experimentation to select the operative embodiments was facile enough to pass enablement, the claim would have 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.[266]

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The combination of enablement and written description has proven particularly difficult for patentees to overcome. 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, look on the face of the patent, and hold that there is no "possession" and thus a written description

[266] 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.

failure.[267] 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, still failed enablement.[268] 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 striking down genus claims for lack of enablement, written description, or both during the post-1990 era, often overturning the district court or a jury verdict in the process.[269] 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

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[267] *See, e.g.,* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1334 (Fed. Cir. 2003) (claim can satisfy enablement but still fail written description); *compare* Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353 (Fed. Cir. 2011), *with* Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1384-86 (Fed. Cir. 2013) (using written description and enablement, respectively, to invalidate similar patents).

[268] Amgen Inc. v. Sanofi, No. 14-1317-RGA, 2019 WL 4058927, at *3-13 (D. Del. Aug. 28, 2019), *on remand from* Amgen Inc. v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017), *appeal after remand docketed*, No. 20-1074 (Fed. Cir. Oct. 24, 2019).

[269] *See, e.g.,* Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368 (Fed. Cir. 2019); Amgen Inc. v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017); 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 (Fed. Cir. 2013); Centocor Ortho Biotech, Inc. v. Abbott Labs., 636 F.3d 1341 (Fed. Cir. 2011); *In re* '318 Patent Infringement Litig., 583 F.3d 1317 (Fed. Cir. 2009); *In re* Alonso, 545 F.3d 1015 (Fed. Cir. 2008); Carnegie Mellon Univ. v. Hoffmann-La Roche, Inc., 541 F.3d 1115 (Fed. Cir. 2008); *In re* Wallach, 378 F.3d 1330 (Fed. Cir. 2004); Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, (Fed. Cir. 2004); Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004); Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir. 1997).

such claims usually have no chance at the Federal Circuit. Each comes with a special (and limited) circumstance.[270]

One notable category of appeals in which genus claims were sometimes upheld against § 112(a) challenges involved so-called interferences, which are now-obsolete adversarial PTO proceedings for resolving who among two or more competing inventors, or groups of inventors, came up with the claimed subject matter first.[271] 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 well-known already and are not the invention's focus; and other outlier examples, which feature unusual genus claims, failures of proof, as well as combinations of some of these characteristics. We believe that these cases, which we consider below in turn, are also of limited practical significance for the validity of traditional genus claims.

1. Interferences

An interference proceeding is a so-called "priority contest" between two or more parties.[272] Although the standards for enablement and written description in

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[270] There are also cases in which genus claims prevailed in a patent case where the defendant 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 III.

[271] *See* 35 U.S.C. § 135 (2012).

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

interferences are congruent with those in appeals from PTO 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. As a result, an interference proceeding typically ends with *someone*'s claims getting upheld as the earlier of the two inventors. 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*, in which the Federal Circuit affirmed the PTO's grant of priority to an inventor of a so-called "DNA construct" claim, deferring to the agency's conclusion that it was adequately described and enabled.[273] 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."[274]

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.*

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[273] 317 F.3d 1334, 1343-46 (Fed. Cir. 2003).

[274] Bilstad v. Wakapoulos, 386 F.3d 1116, 1121 (Fed. Cir. 2004). In contrast, some of the cases striking down genus claims (e.g., *Enzo v. Calgene* and *Ariad v. Lilly*) have been cited numerous times for substantive propositions in subsequent Federal Circuit opinions.

Esshar.[275] This case, similar to *UC Regents v. Eli Lilly & Co.*,[276] involved claims directed to DNAs for which structural information was lacking. Oddly enough, the parties ended up on the same side of the appeal after the PTO concluded *sua sponte* that neither set of claims was adequately described.[277] The Federal Circuit vacated and remanded, holding that the PTO "erred that § 112 requires a *per se* rule requiring recitation in the specification of the nucleotide sequence of the claimed DNA, when that sequence is already known in the field."[278] At the Federal Circuit, *Capon* was followed in another interference appeal[279] and cited for basic propositions in other cases.[280] *Capon*, however, has been consistently distinguished in non-interference written description cases involving the validity of genus claims, including *Ariad* and *Boston Scientific*.[281] More telling, the Federal Circuit even distinguished *Capon* in another written description case involving DNA, *Carnegie Mellon University v. Hoffman-La Roche*,[282] in which the court followed *UC Regents*

275 418 F.3d 1349 (Fed. Cir. 2005).

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

277 *Capon*, 418 F.3d at 1350.

278 *Id*. at 1360-61; *cf. Lilly,* 119 F.3d 1559 (arguably creating just such a *per se* rule outside the interference context).

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

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

281 Ariad Pharm., 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).

282 541 F.3d 1115, 1126 (Fed. Cir. 2008).

v. Eli Lilly & Co. instead and invalidated the claims at issue.[283] In sum, *Capon* has not had a lasting influence at the Federal Circuit.

2. Small Genuses and Genuses Known Prior to the Invention

Another example of a patent surviving § 112(a) challenges at the Federal Circuit, from the case of *Martek Biosciences v. Nutrinova, Inc.*,[284] involves a relatively narrow genus claim, as well as an apparent failure to offer proof of nonenablement. The claims at issue in *Martek* were directed to a process of extracting fatty acids from certain kinds of fish.[285] The defendants introduced evidence of nonenablement of the broad independent claim in the patent in suit, but "failed to present any evidence . . . that one of ordinary skill in the art must perform undue experimentation"[286] to practice the narrower dependent claims. Moreover, at trial, an expert opined that these claims encompass 22 biological species, a statement that the Federal Circuit determined to "support an inference that there are a relatively few potential species that may meet the limitations of" these

[283] *Id.* at 1124-27.

[284] Martek Biocis. Corp. v. Nutrinova, Inc., 579 F.3d 1363 (Fed. Cir. 2009).

[285] *Id.* at 1367.

[286] *Id.* at 1379.

claims.[287] The court thus upheld the claims, but as with *Singh*, future Federal Circuit panels relied on *Martek* only for neutral propositions.[288]

The written description challenge addressed in the recent *Ajinomoto Co. v. International Trade Commission* decision failed for a different reason—it was lodged at a genus that was well-known prior to the invention at issue.[289] The asserted claims were directed to cultivating *E. coli* 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,"[290] and the invalidity arguments were focused on the "more potent promoter" limitation.[291] The focus of the invention was not the promoters at all, but the discovery of the gene whose modification with a promoter boosted the amino acid production. As for the promoters themselves, "the genus of more potent promoters was already well

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[287] *Id*. To similar effect is *Alcon Research Ltd. v. Barr Labs, 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.

[288] *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 of the latter).

[289] 932 F.3d 1342 (Fed. Cir. 2019); *see also* Monsanto Corp. v. Scruggs, 459 F.3d 1328 (Fed. Cir. 2006) (holding that use of well-known promoters was enabled).

[290] *Id*. at 1347.

[291] *Id*. at 1358-59.

explored in the relevant art"[292] and the specification mentioned several of them. 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."[293] 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.[294] As a result, "a skilled artisan could make relatively predictable changes to the native promoter to arrive at a more potent promoter"[295] and the claims survived § 112(a).

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 are not easy to classify precisely, but that we believe are unusual. In *Invitrogen Corp. v. Clontech Laboratories*, the claims in suit were directed to a so-called "reverse transciptase" (RT), which is an enzyme involved in DNA replication.[296] In its enablement challenge, the defendant complained that the specification failed to describe all the possible methods of making the enzyme.[297] This argument was

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[292] *Id*. at 1359.

[293] *Id*.

[294] *Id*. at 1360-61.

[295] *Id*. at 1361.

[296] Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1058 (Fed. Cir. 2005).

[297] *Id*. at 1070.

unsuccessful: while the universe of methods for making a particular composition might be described as a kind of a genus,[298] in practice the Federal Circuit has consistently treated claims characterized as directed to "a genus of methods" differently (and apparently much more leniently) than claims to a traditional structural genus.[299] 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.[300]

The written description challenge to a specific group of RT claims, which were drafted in functional terms to recite "[a]n isolated polypeptide . . . *having substantially reduced RNase H activity*,"[301] also failed. 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."[302] 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"

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[298] Karshtedt, *Limits on Hard-to-Reproduce Inventions*, *supra* note _, at 130-33.

[299] *Cf.* Bernard Chao, *Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule,* 2009 STAN. TECH. L. REV. 3; Tun-Jen Chiang, *The Levels of Abstraction Problem in Patent Law*, 105 NW. U.L. REV. 1097 (2011); Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083 (2009); Timothy Chen Saulsbury, *Pioneers Versus Improvers: Enabling Optimal Claim Scope*, Note, 16 MICH. TELECOMM. & TECH. L. REV. 439 443, 463 (2010).

[300] *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, 1681-83 (2016).

[301] *Invitrogen*, 429 F.3d at 1072 (emphasis in original).

[302] *Id.* at 1073.

and "disclose[d] test data that the enzyme produced by the listed sequence has the claimed features—DNA polymerase activity without RNase H activity."[303] While it is not entirely clear what the genus size was, the defendant never made an overbreadth argument,[304] which rendered this question irrelevant. 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.[305]

We finally come to the complex opinion in *Amgen Inc. v. Hoechst Marion Roussel*,[306] in which a split Federal Court panel affirmed the judgment after a bench trial that the claims at issue were adequately described and enabled. A representative claim recited "[a] pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin . . . , wherein said erythropoietin is *purified from mammalian cells grown in culture.*"[307] After "commend[ing] the district court for its thorough, careful, and precise work on what is indubitably a legally difficult and technologically complex case,"[308] the majority deferred heavily to the lower court's fact findings. The court also noted that the trial judge had in turn relied to a significant extent on the clear and convincing standard

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303 *Id*.

304 The defendant's failure to make an overbreadth argument 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* Part III.

305 *See, e.g., In re* '318 Patent Infringement Litig., 583 F.3d 1317, 1323 (Fed. Cir. 2009) (citing *Invitrogen* for a generic proposition).

306 Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003).

307 *Id*. at 1323.

308 *Id*. at 1320.

required to prove invalidity and had concluded that the defendant did not meet this burden.[309]

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"[310] and concluded that the defendant failed to overcome the presumption of validity. Indeed, the lower "court weighed the testimony and found that the evidence showed that the descriptions adequately described to those of ordinary skill in the art [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."[311] The Federal Circuit found no error, explaining that cases like *UC Regents v. Lilly* were distinguishable because the claim 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."[312] The word "mammalian," the court noted, readily "'convey[ed] distinguishing information concerning [the genus's] identity' such that 'one of

[309] *Id*. at 1331, 1339.

[310] *Id*. at 1330-31.

[311] *Id*. at 1331.

[312] *Id*. at 1332.

ordinary skill in the art could 'visualize or recognize the identity of the members of the genus.'"[313]

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, expressly incorporating many of its factual determinations made with respect to written description."[314] One of the findings was that the method of production of EPO generalizes readily from two mammals for which it was actually done to others: "the [trial] court accepted testimony indicating that [a 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 hormones like EPO by means of the same fundamental processes."[315] After noting that "[t]hese are all findings of fact and they have not shown to be clearly erroneous," the majority upheld the claims.[316]

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.[317] The dissent's main concern was that the panel majority misapplied § 112(a) law to "source and process"

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[313] *Id*. (quoting *Eli Lilly*, 119 F.3d at 1567).

[314] *Id*. at 1334-35.

[315] *Id*. at 1335.

[316] *Id*.

[317] *Id*. at 1361 (Clevenger, J., dissenting).

limitations of the claims, such as "mammalian," a framing suggesting a limit to the scope of the holding because such limitations do not often come up in genus claiming.[318] As such, this case, too, had limited impact.[319]

Amgen v. Hoechst is the case that looks most like the § 112(a) jurisprudence of old. But it is more than 17 years old, drew a dissent, and has not been used to justify broad claims in the decades since its decision.

* * *

The path of the law is messy. That is even more so when courts are moving the law in new directions, as they are with enablement and written description. But while the cases aren't unanimous, the opinions discussed in this section do not detract from the conclusion that the Federal Circuit's approach to traditional genus claims in chemical and biological sciences has been hostile. All these cases present 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 another claiming or procedural feature, such as process limitations and exhaustive fact findings in the *Hoechst* bench trial, that made the genus unusually susceptible to being upheld.

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[318] *Id*. at 1359. For discussion of such claims, *see* Karshtedt, *Limits on Hard-to-Reproduce Inventions*, *supra* note _.

[319] 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, 418 F.3d 1349, 1357 (Fed. Cir. 2005), discussed above. In other cases, such as *In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004), *Hoechst* was distinguished.

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

III. 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 (and likely unintentionally) shifted 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 sections 103 and 112 set standards based on the knowledge and experience of the person having skill in the art, or PHOSITA. The PHOSITA is rather like the "reasonable expert" in patent law. When we test whether a patent has done something nonobvious under § 103, we ask whether the PHOSITA would have been motivated to make the new invention and had a reasonable expectation

of success.[320] 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. The PHOSITAs aren't always exactly the same; they are working as of different times, and they are doing somewhat different things (inventing versus making and using),[321] but in general there is symmetry between obviousness and disclosure that turns on the level of skill in the art. If the PHOSITA in a field knows a lot, an invention is more likely to be obvious but also doesn't need as much detail to educate her. If she knows very little, by contrast, it's easier to show nonobviousness (because she was less likely to figure it out) but you must teach more to make sure she understands it.

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.[322] 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

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

321 *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1189-90 (2002) (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").

322 Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (noting how chemistry is "often" an unpredictable art); *see* Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (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). *See generally* Seymore, *Heightened Enablement, supra* note 5.

on a known chemical may likely be obvious (i.e., *prima facie* obvious) unless they embody unexpected results.[323] That principle typically applies whether the prior art is a single lead chemical, as in *Dillon*, or a genus.[324] The Federal Circuit reaffirmed that structural rationale for a motivation to make the claimed invention based on a known "lead compound" just this past year—*in an obviousness case*.[325]

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 we discussed in Part II generally start from the premise that the chemical arts are unpredictable and then apply the opposite of the *Dillon*-type analysis. They assume that no one would be able to figure out what works in a genus unless there are "blaze marks" telling us 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 long to do so. The result for chemical patentees is the worst of both worlds—we will presume the new species you claim isn't patentable because the PHOSITA could figure out how to make it if it's just a structural

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323 919 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 in obviousness doctrine, see Dmitry Karshtedt, *Nonobviousness: Before and After*, 106 IOWA L. REV. (forthcoming 2021) (to be posted on SSRN).

324 Merck & Co. v. Biocraft Labs., Inc., 874 F.2d 804 (Fed. Cir. 1989). If the genus in the prior art disclosure is extremely large, however, the motivation to make a particular species might not be present for obviousness purposes. *See, e.g.*, *In re* Baird, 16 F.3d 380, 382 (Fed. Cir. 1994); *In re* Jones 958 F.2d 347, 350 (Fed. Cir. 1992).

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

variant on an existing one, but we won't presume the PHOSITA understands the same thing when she is reading your genus claim.

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. 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."[326] 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 is frequently impossible to test all or even a "representative number" of species of a genus that may contain millions of different species.[327] 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. 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

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[326] These are scare quotes.

[327] Indeed, Jeff Lefstin notes that most genus claims are open-ended and so contain a potentially infinite number of species. Lefstin, *supra* note 60, at 1168-74.

would likely only have to try two or maybe three compounds to find one that would work.[328] That required some experimentation, but the law has traditionally allowed claims that require experimentation as long as it is not "undue." There may be some genus claims that give so little information that trying to find a species that works takes too much effort, but that is likely to be rare in traditional pharmaceuticals claims if the genus is properly specified.[329]

More to the point, it's not what is going on in the cases we discussed in Part II. 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 which ones 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 a PHOSITA to make and use the invention without undue experimentation. And it has proven in practice to be an impossible burden.

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328 *Atlas Powder*, 750 F.2d at 1577.

329 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 the pharmaceutical industry 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 (Fed. Cir. 2017). We don't want to get into the 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. 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*.

3. Understanding 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 people will know whether or not the chemicals they make fall within that genus, a PHOSITA will be able to make and use the full scope of that genus so long as she can figure out how to make chemicals within the genus and determine 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? And true, the PHOSITA might have to experiment to figure out whether the species she made works for the intended purpose, but that has not been a problem so long as she doesn't have to do too much experimentation.

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.[330] But that isn't limited to broad genus claims. The claims may well be narrow, even directed to one species, but they are invalid if the specification fails to give the appropriate instructions, like concentrations and ratios of reagents or components,

[330] *See, e.g.*, Tyler v. Boston, 74 U.S. (7 Wall.) 327, 330 (1868); Wood v. Underhill, 46 U.S. (5 How.) 1 (1846); Quaker City Gear Works, Inc. v. Skil Corp., 747 F.2d 1446 (Fed. Cir. 1984); White Consol. Indus., Inc. v. Vega Servo-Control, Inc., 713 F.2d 788 (Fed. Cir. 1983).

and the PHOSITA wouldn't be able to figure out how to make the invention work at all. This is the traditional purpose of enablement doctrine.[331]

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. Cases like *Wyeth*,[332] *Idenix*,[333] and *Boston Scientific*,[334] 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 is no reason anyone needs to make that 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 figure that out: 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.[335]

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

332 Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380 (Fed. Cir. 2013).

333 Idenix Pharm. LLC v. Gilead Sci. Inc., 941 F.3d 1149 (Fed. Cir. 2019).

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

335 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 16 tiles in a 4x4 grid. Kristina Caggiano Kelly & Paul A. Calvo, *The Scope of a Sextillion—How Courts Misapply Law of Enablement to Life Sciences*, BNA IP LAW NEWS, May 1, 2020, *available at* https://news.bloomberglaw.com/ip-law/insight-the-scope-of-a-sextillion-how-courts-misapply-law-of-enablement-to-life-sciences.

In these cases, ironically, having an operability or therapeutic efficacy limitation may hurt the patentee because it caused the court to focus on operability as an element of the inventions: "You told us the compounds are antirestenotic, but it's awfully challenging to figure out which of the many chemicals having the generic structure will work for their intended purpose."[336] *Idenix*, for instance, holds there are no "blaze marks" for structural modifications within the large genus that will achieve the claimed invention's purpose.[337] 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.[338] And if the PHOSITA would know now to make and use the chemicals within that genus, it is enabled and adequately described under traditional principles. Adding the purpose as a claim limitation narrows the claim rather than broadening it. 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.

The courts that have done so seem to be articulating a concern about "possession" of a genus in both enablement and written description contexts—not 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

336 *Wyeth*, 720 F.3d at 1386

337 *Id.* at 1164.

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

patent law.[339] But for § 112, it should matter only in two discrete sets of circumstances: where we think there is no proper genus at all, or where the patentee hasn't yet figured out that genus.

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 relevant 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 won't work.

The *Incandescent Lamp Patent* case,[340] first discussed above,[341] is a good example of this sort of possession problem, which we might call improper generalization.[342] Sawyer and Man, the inventors, had built a working light bulb filament from carbonized paper and wood carbon, and they properly claimed those species.[343] When it came time to define the genus, however, they guessed—and, it turns out, ultimately guessed wrong. While carbonized paper was in fact a species of the broader genus they claimed ("vegetable and fibrous material"), there was nothing about that genus that made it particularly well suited to work as a light bulb filament. Indeed, as the defendant, Thomas Edison, later found, the vegetable fibers in the genus of plants interfered with rather than promoted the use of the

339 *Cf*. Holbrook, *supra note* 216 (arguing that possession plays a central role in this and other patent law doctrines).

340 159 U.S. 465 (1895).

341 *See supra* Part I.A.3.

342 *Incandescent Lamp*, 259 U.S. at 472.

343 *See id.*

material as a filament.[344] Sawyer and Man hadn't taught how to make and use the genus claim, not simply because it took a lot of experimentation to figure out what plant species worked, but because the genus was essentially a random 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.[345]

Improper generalization is not about the overall size of the genus, or even the number of inoperative embodiments,[346] though if you haven't figured out what the relevant genus is 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.[347] 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

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344 *Id.*

345 Corona Cord Tire Co. v. Dovan Chemical Corp., 276 U.S. 358, 385 (1928); *see supra notes*

346 *In re* Soll, 97 F.2d 623 (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.

347 *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 (1996).

this principle.[348] 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 generalize only thanks to luck. Therefore, we believe that the judgments of invalidity in *Chugai* and *Calgene* were correct.

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 figure out which ones work and which ones don't, she has the information she needs to make and use the invention.

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

348 *See supra* Part II.A.

first means being first to file an application with the PTO.[349] Gun jumping is frequently associated with functional claiming—identifying a problem and claiming "anything that solves that problem." The law disfavors functional claims, and normally limit them to the specific examples the patentee has identified.[350] One example is *Ariad v. Eli Lilly*.[351] 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.[352]

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, 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.[353]

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

350 35 U.S.C. § 112(f) (2012); *see also* Lemley, *supra* note _, at 910-19 (discussing the history of functional claiming).

351 Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

352 *Id.*; *cf.* Nuvo Pharm. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368 (Fed. Cir. 2019) (striking down the claims under written description for lack of proof of therapeutic efficacy at time of filing); *In re* '318 Patent Infringement Litig., 583 F.3d 1317 (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.

353 *Cf. generally* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65 (2009); John F. Duffy et al., *Early Patent Publication: A Boon or Bane? A Discussion on the Legal and Economic Effects of Publishing Patent Applications after Eighteen Months of Filing*, 16 CARDOZO ARTS & ENT. L.J. 601 (1998); Mark A. Lemley, *Ready for Patenting*, 96 B.U.L. REV. 1171 (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 v. Berkline Corp.*, for instance, the patentee came up with an improvement in sofa technology that allowed two sofa sections side by side to recline. It built a fixed console to house the controls for the sofa recliner section.[354] When it saw that competitors found other places to put the controls, it retroactively changed its patent claims to cover any location for the controls.

A patentee who tries to retroactively fix its claims in this manner isn't entitled to assert that they owned the invention all along. They weren't in possession of 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 lay claim to at the time they filed their patent application.

The enablement cases dealing with improper generalization and written description cases dealing with gun jumping or unsupported claiming make sense, and they define a legitimate set of circumstances to cabin genus claims. But they aren't cabining those claims simply because they are too broad. They are cabining the claims 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

[354] 134 F.3d 1473 (Fed. Cir. 1998).

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."[355] We have converted the full-scope enablement inquiry from "did I teach you enough that you can make use of the full scope of the invention" (which allows some inoperative species, *à la Atlas Powder*, as long as people can figure out whether a particular species works without too much effort) to "did I give you enough information to figure out the full list of what works and what doesn't?" That is an impossible requirement to meet. 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 people can use what you taught them (an enablement question).

That category error is at the heart of the demise of genus claims in the chemical arts today. And it's not something patentees can simply draft around. A chemical genus with any decently large number of species will never be able to satisfy the *Idenix* court. The claims might be in danger of failing enablement because the testing will take time, but that is 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 we won't know whether they are properly included in the genus, so the claim would fail written description. That doesn't matter under the old view of the world; all that we cared about was

[355] For a discussion of enablement as possession, *see* Holbrook, *supra* note 216, at 146-61.

whether the PHOSITA could make a species and figure out whether it worked. But it is fatal to genus claims in the new world.[356]

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 line up behind strong protection, with the software and Internet industries on the opposite side.[357] As Dan Burk and Mark Lemley explain, those political differences reflect very real differences in how the industries use and experience the patent system.[358] Patents really are more important to those industries than to others. Further, the patent system seems to function more like it was designed to in the chemical industries. The scope of claims is clearer,

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356 This new full scope doctrine has been exported to United Kingdom law. *See* Regeneron Pharmaceuticals Inc. v. Kymab, Ltd., [2020] UKSC 27 (holding that showing "some embodiments" is not enough, and 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 . . .").

357 *See generally* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009); JOHN R. THOMAS, CONG. RES. SERV., R43264, TAILORING THE PATENT SYSTEM FOR SPECIFIC INDUSTRIES (2015); WENDY H. SCHACHT, CONG. RES. SERV., RL33367, PATENT REFORM: ISSUES IN BIOMEDICAL AND SOFTWARE INDUSTRIES (2006).

358 BURK & LEMLEY, PATENT CRISIS, *supra* note 355, Part II, Ch. 5; *see also* Mark A. Lemley & Dan L. Burk, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1615 (2003) ("The range of patent theories parallels the range of ways in which the patent system affects companies in different industries.").

independent invention is rarer, "stacking" of multiple patents is less common,[359] 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.[360] Jim Bessen and Mike Meurer have gone so far as to suggest that the patent system works *only* in the biomedical industries.[361]

Given the perceived 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 those industries seem to be doing just fine. Pharmaceutical patent owners are making record revenues, up more than 800% from 1992 to 2017.[362] They are still obtaining patents in record numbers.[363] They continue to enforce patents in court; the number of pharmaceutical patent suits filed has remained steady even as patent suits overall have dropped in the last few years.[364] They are suing on larger and larger patent

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

360 JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION AT RISK 89-93 (2008) (discussing the qualities of the pharmaceutical industry that allow to that are amenable to the patent system).

361 *Id.*

362 Michael A. Carrier, Mark A. Lemley & Shawn Miller, *Playing Both Sides: Brand Sales, Generic Drugs, and Antitrust Policy,* 71 HASTINGS L.J. 307, 317 (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.

363 *Id.*

364 *See* 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).

portfolios.[365] When they do take patents to court, chemical patents win more often and are less likely to be invalidated than patents in any other technology.[366]

What is going on? Why does innovation and even patent litigation seem to be proceeding apace in the pharmaceutical industry at the same time the 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. 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!*[367] That is surprising, if true. It's not that no one cares about patents. To the contrary, the industries affected here not only say they care a lot, but they invest a lot in obtaining patents, in filing and fighting patent lawsuits, and in lobbying Congress

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[365] *See id.*; *see also* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court,* 339 SCI. 1386 (discussing the rise of secondary patents).

[366] John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. 1073, 1097 (2015). Note that those numbers conceal significant variation by industry. Pharmaceutical patents do very well but biotechnology industry patents do quite poorly.

[367] This covert rewriting of patent law evokes the theories of "acoustic separation" and "selective transmission" that Dan-Cohen proposed 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 (1984).

to change the law in their favor.[368] 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.

We ourselves are skeptical of this explanation, for just that reason. Indeed, in an earlier draft of this paper we dismissed it out of hand. But we have 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 full-scope enablement or written description arguments.[369] That suggests two things. First, 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 wisdom. 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 patentees gradually realize they are playing a losing game.

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368 The United States' largest companies spent an average of $3.3 billion on IP litigation, about $1.5 million per matter, in 2019. Morrison & Foerster, *Benchmarking IP Litigation 2019* (2019). Congress's attempts to update the patent in 2005 became an arduous seven-year saga culminating in enactment of America Invents Act in 2011. Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435 (2011).

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

If ignorance of the law is not the explanation, the alternative is perhaps even more striking. Maybe the merits of patent doctrine don't matter that much to innovation, even in the very industry where they are supposed to matter most. One of us has previously documented the "surprising resilience" of patent law.[370] Lemley argues that the patent system as a whole has kept operating pretty much the way it always has regardless of changes in the law that either strengthen or weaken patent protection. He speculates that the real value companies find in patents may have little or nothing to do with the ability to 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.[371] 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, not the inventor's challenges to the PTO's refusal to grant a patent. That's not an accident. The PTO does notoriously little examination or rejection based on enablement and written description.[372] That means that the Federal Circuit's changes in the law don't stop

370 Mark A. Lemley, *The Surprising Resilience of the Patent System*, 95 TEX. L. REV. 1 (2016).

371 *Id*. at 8-10.

372 *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, 1167 (2010) (concluding it is indeed "exceedingly rare that the patent office hangs its case on written description"); (internal quotations omitted); Janet Freilich, *Matching and Digging: Evidentiary Analysis at the Patent Office* (on file with the authors). *But cf*. Greg Reilly, *The Complicated Relationship of Patent Examination and Invalidation*, 69 AM. U. L. REV. 1095 (2020)

companies from getting patents; they just make many of those patents unenforceable if they ever get to court. And getting to court can take more than a decade.[373] 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.[374]

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.[375] That is 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.[376] And brand firms often don't even need to file a

(arguing that "stretching" of claim scope in infringement cases can contribute to the disconnect between prosecution and litigation.). On the disconnect between prosecution and litigation, see Greg Reilly, *Decoupling Patent Law*, 97 B.U. L. Rev. 1551 (2017).

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

374 Lemley, *Surprising Resilience*, *supra* note 382. There is a robust literature on non-litigation uses for patents. *See* generally, Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV 625 (2002); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137 (2000); 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); and Joan Farre-Mensa, Deepak Hegde & Alexander Ljungqvist, *What Is a Patent Worth? Evidence from the US Patent "Lottery"*, 75 J. OF FIN. 639 (2020).

375 Lemley, *Surprising Resilience*, *supra* note 382, at 47.

376 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

patent case until after years of regulatory exclusivity administered by the Food and Drug Administration (FDA) expires.[377] Further, most patent cases settle, 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.[378] When we couple that with the fact that, as further discussed below, the species 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.[379] If a competitor

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377 *See* Eisenberg, *supra* note 365.

378 *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 Huges, *Pay-for-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and others*, 5 J. EUR. COMPETITION L. & PRAC. 44 (2014). That is less true after the Supreme Court decision in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), which held that those agreements generally violate the antitrust laws. But a surprising number of settlements still involve concealed payments. *See* King Drug Co. of Florence, Inc. 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 et. al, *Activating* Actavis, 28 ANTITRUST 16 (2013).

379 Regulatory exclusivity gives the first company to submit a new drug for approval a period of time during which no one can use their data or tests to get a generic equivalent drug approved. Those exclusivity periods are independent of patent rights. *See generally* Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477 (2003); John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39 (2015).

wants to make a different chemical than the one the patentee does, it has to go through the same expensive, time-consuming New Drug Application (NDA) process the patentee did. To take advantage of the cheaper, faster Abbreviated New Drug Application (ANDA) process, generic companies that file with the FDA need to copy the patentee's specific drug, not substitute a different species in 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. The generic drug must be identical (or "AB-rated") to the one prescribed.[380]

That means that for the most important class of pharmaceutical patent cases—litigation against generics—it is the patent on the specific chemical actually sold, not the genus claim, that is important.[381] 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 competitor cases where genus claims really matter. That doesn't mean there is no problem with eliminating genus claims. Those competitor cases may drive certain classes of innovation, pushing pharmaceutical research away from "me-too"

380 *See* Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1029 (2019).

381 At least, that is true for the active ingredient, which must 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.

drugs towards new classes of treatments. But it may help explain why the sky has not 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 process for approval for so-called "biosimilars"—the biotechnology equivalent of generic substitutes. So anyone who wanted to make a variant on the patentee's species had to go through the same approval process the patentee did. There is now the rough equivalent of an ANDA for biosimilars, but it has the same characteristic for our purposes as the ANDA process does: the biosimilar needs to copy the actual species that was approved, not just some chemical in the broader genus.[382] Indeed, making biosimilars is significantly harder than making generic pharmaceuticals, both because Congress extended data exclusivity from five years in the case of pharmaceuticals to twelve years for biologic drugs (meaning that the ANDA can't get approved until much later)[383] and because copying biotechnological materials turns out to be much harder and less certain than copying small-molecule chemicals.[384]

As a result, genus claims may not actually be needed to prevent copying by generics in either the pharmaceutical and biologics industries, but only to stop

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382 These chemicals often appear naturally in the human body, making substitution in the case of biosimilars even harder to justify.

383 47 U.S.C. § 262(k)(7)(a).

384 Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299 (2015); W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023 (2016).

competing new chemical or biological entities made by competing branded drug companies. And while restricting that competition can be important to pharmaceutical companies, they may have enough incentive to invent based on the regulatory exclusivities and the costs competitors will face even if the weakness of genus claims ultimately leads to competition from other branded firms doing their own NDAs. The fact that competitors can't cheaply or quickly enter the market with a different species, but must go through their own FDA approval process, gives the patent owners substantial time in which to recoup its expenses.[385] The industry may also use mergers and acquisitions to blunt the effect of some of this competition.[386]

If that is the explanation, it suggests that we may need to rethink our patent policies. The pharmaceutical industry is the poster child for strong patent protection. 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 identical to the patentee's, a major part of the case for expansive patent protection disappears. We're not persuaded that is true. Genus claims seem important to us. But the fact that the sky hasn't fallen on the pharmaceutical industry as they have been

385 *See* BURK & LEMLEY, PATENT CRISIS, *supra* note 355, at 132-34 (discussing how the relative costs of innovating to copying as a policy consideration in intellectual property).

386 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).

systematically invalidated should give us pause, requiring further inquiry into how much patent protection really is necessary.

The fact that a major change in pharmaceutical patent law doesn't seem to have affected industry behavior 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.[387] 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 this regulatory structure 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. Early competitive entry may 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, as well as in competitor cases in the life sciences.

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 rules than

[387] Dan-Cohen, *supra* note 380.

it does elsewhere,[388] the court denies doing so, taking the position that its doctrines apply across the board.[389] Traditionally we have not seen strict application of the § 112 doctrines to either the mechanical arts or to the IT industry,[390] perhaps because of the court's intonation that those arts are "predictable."[391] Indeed, the absence of effective enablement and written description doctrines in software has led to functional claiming—patent claims that target the problem to be solved and cover any solution to that problem.[392]

But that is 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.[393] And it has sometimes

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388 Burk & Lemley, *Technology Specific*, *supra* note 323 at 41; Burk & Lemley, *Policy Levers*, *supra* note 356 at 1652-53.

389 Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc).

390 BURK & LEMLEY, PATENT CRISIS, *supra* note 355.

391 *See supra* notes 33-34 and accompanying text (discussing predictable technologies); Kevin E. Collins, *supra* note 299, at 1121 (discussing the enablement requirement with 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) (holding that "that one of skill in the art could program a computer to perform the recited functions 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 for an enabling disclosure of a claimed software invention).

392 Lemley, *Functional Claiming, supra* note __; *see* Otis Elevator Co. v. Pac. Fin. Corp., 68 F.2d 664 (9th Cir.), *supplemented on reh'g*, 71 F.2d 641 (9th Cir. 1934).

393 *See, e.g.*, Taylor v. Iancu, 809 F. App'x 816, 820 (Fed. Cir. 2020) (nonprecedential) (affirming claims for a GPS information system were invalid for lack of written description); Realtime Data, LLC v. Morgan Stanley, 554 F. App'x 923, 937 (Fed. Cir. 2014) (nonprecedential) (affirming claims relating to data transmission and encryption systems were invalid for lack of written description).

applied the idea of "full scope enablement" to invalidate "genus" claims outside chemistry, even where those genuses are quite small.[394] A number of commentators have noted the conflict between single-embodiment and full-scope enablement in non-pharmaceutical cases.[395] 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. After all, abundant evidence suggests that broad patent protection is less important in IT than in other industries.[396] And laxness in enforcing § 112 in those industries has led to endemic problems with overbroad patents not tied to any particular technology. 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 you can add more to them without avoiding infringement.[397] 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.

IV. Conclusion

394 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.)

395 Tun-Jen Chiang, *Fixing Patent Boundaries*, 108 MICH. L. REV. 523, 537-38 (2010); Chao, *supra* note _, at 7. *But cf.* Rantanen, *supra* note _, at 1683 (denying there is a split); *see also supra* (discussing the "genus of methods" problem).

396 BESSEN & MEURER, PATENT FAILURE, *supra* note 357; BURK & LEMLEY, PATENT CRISIS, *supra* note 355.

397 Lefstin, *supra* note 60, at 1168-74.

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 mind—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 people have not 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.