Biotechnology & the Patent Quid Pro Quo: When Is "This" Enough For "That"?

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ABSTRACT

Patents play a key role in incentivizing investment in life-saving therapeutic innovations. But, over the past fifteen years, courts have increasingly found patents to life science inventions invalid for insufficiently disclosing the invention. Patent law's disclosure requirements are the inventor's end of a quid pro quo bargain: in exchange for their disclosure, inventors receive a limited monopoly over their invention. The limited monopoly incentivizes the inventor to invest in their innovation, while the disclosure requirement encourages investment in innovation by enabling competitors to assess the proprietary landscape to determine where they can freely operate and where they should seek collaborations through licensing. Disclosure requirements balance these innovation incentives by requiring inventors to disclose enough based on the state of the art in the field. The recent string of life sciences patents invalidated for insufficient disclosure creates unpredictability and demands reliable methods to disclose enough. Drawing from recent Federal Circuit decisions, this Note identifies and evaluates methods to disclose enough under one prong of the patent disclosure requirement (the written description requirement) for a common type of claim to life science inventions subject to written description challenges (combination genus claims). Based on mismatches between current written description jurisprudence and the science it governs, this Note advocates for adoption of the policy- and science-aligned approaches to satisfy the written description requirement.

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I. INTRODUCTION

Over forty percent of Americans will receive a "c"-word diagnosis in their life: cancer.[1] Recent advances in life science research, such as the development of immunotherapies like chimeric antigen receptor-T cells (CAR-T cells), are giving some doctors the chance to share a more hopeful "c"-word with their patients: cure.[2] But, recent patent law jurisprudence undermines incentive to invest in such life-saving technologies.

Since 2010, courts have overturned multiple, billion-dollar jury verdicts and held patents claiming life science inventions invalid for failing to satisfy disclosure requirements.[3] For example, in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, the Federal Circuit invalidated patent claims to an innovative and life-saving CAR-T cell cancer therapy for insufficiently disclosing parts of the invention already *known in the field*.[4] The result overturned a $1.2B jury award.[5]

These recent holdings create substantial uncertainty for life sciences inventors. Uncertainty about how to comply with patent requirements limits incentive to invest in innovation, especially life science innovation, which requires substantial pre-monetization investment (e.g., exploratory research and clinical trials). The uncertainty often arises from patent law's misunderstanding of the science it polices.

The stakes are high. Reduced investment in life science innovation may mean fewer life-saving drugs. Patent uncertainty may also encourage inventors to seek alternative forms of intellectual property protection, such as trade

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[1] *Cancer Statistics*, NATIONAL CANCER INSTITUTE (May 9, 2024), https://perma.cc/XYV7-PF5A.

[2] Angus Chen, *Researchers Label Early CAR-T Therapy Patient 'Cured' After Living a Decade Without Cancer*, STAT. (Feb. 2, 2022), https://perma.cc/7XAK-7WT7; Emily Whitehead, *First Pediatric Patient to Receive CAR T-Cell Therapy, Celebrates Cure 10 Years Later*, CHILDREN'S HOSP. OF PHILA. (May 11, 2022), https://perma.cc/V3NR-A6DW.

[3] *See, e.g.*, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1332 (Fed. Cir. 2021) (overturning $1.2B jury award), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023); Idenix Pharms. LLC v. Gilead Scis., Inc., No. 14-CV-846 LPS, 2018 WL 1313973, at *1–2 (D. Del. Mar. 14, 2018) (overturning $2.54B jury award), *aff'd in part*, *rev'd in part*, 941 F.3d 1149, 1164 (Fed. Cir. 2019) (additionally holding claims invalid for insufficient written description); Centocor Ortho Biotech., Inc. v. Abbott Lab'ys, 636 F.3d 1341, 1343–44 (Fed. Cir. 2011) (overturning $1.67B jury award).

[4] 10 F.4th at 1341–42 ("While it is true that scFvs in general were known, and even known to bind, the record demonstrates that, for even the narrowest claims at issue, the realm of possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most). The '190 patent, however, provides no details about which scFvs bind to CD19 in a way that distinguishes them from scFvs that do not bind to CD19. Without this guidance, under our controlling *Ariad* decision, no reasonable jury could find the '190 patent satisfies the written description requirement.").

[5] *Id.* at 1332.

secret protection, which do not afford the public the same disclosure requirements in exchange for protection.

This Note focuses on cases involving combination genus claims to life sciences inventions invalidated for failure to satisfy one prong of the disclosure requirement: the written description requirement.[6] Combination genus claims recite multiple elements, including at least one genus element (i.e., an element encompassing multiple species). Life sciences inventors often use combination genus claims to protect a range of related chemical or biological structures with similar functions. Recent decisions invalidating these claims expressly identify and implicitly encourage strategies for patentees to disclose enough to satisfy the written description requirement. This Note identifies seven strategies and evaluates each strategy for its alignment with written description policy aims in the context of combination genus claims to life science inventions. Six strategies further written description policy aims; one strategy stands in opposition to policy aims. Where relevant, the Note highlights inherent features of life sciences inventions that bear on proper application of the written description requirement to ensure the law gets the science right.

As background, Part II introduces: (1) the patent system, (2) its disclosure requirements and policy aims, and (3) the written description challenge for combination genus claims for life sciences inventions. Part III illustrates the challenge in claiming life sciences inventions through four recent cases. Part IV evaluates the extent to which several claiming and disclosure strategies expressly approved or implicitly encouraged by Federal Circuit written description jurisprudence align with policy aims.

II. PATENT LAW POSES ACUTE CHALLENGES FOR LIFE SCIENCE INVENTIONS

A. Patents Serve Inventors and the General Public

Notwithstanding their concerns about the "Nation's deep-seated antipathy to monopolies,"[7] the Nation's founders nonetheless viewed patent protection

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[6] *See, e.g.*, *Juno Therapeutics, Inc.*, 10 F.4th at 1332; *Centocor Ortho Biotech, Inc.*, 636 F.3d at 1343–44; Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353 (Fed. Cir. 2011). *But see* Immunex Corp. v. Sandoz Inc., 964 F.3d 1049 (Fed. Cir. 2020) (upholding combination genus claims to a life science invention against written description challenges).

[7] *See* Diamond v. Chakrabarty, 447 U.S. 303, 319 (1980) (Brennan, J., dissenting) ("The patent laws attempt to reconcile th[e] Nation's deep-seated antipathy to monopolies with the need to encourage progress.").

as vital to "promot[ing] the Progress of . . . useful Arts."[8] Patent protection was among the first pieces of legislation passed by the inaugural U.S. Congress.[9]

The patent system sets forth a series of requirements to ensure patent owners' rights are commensurate with the scope of their invention. Several requirements ensure the patentee invented something new; others ensure the patentee sufficiently disclosed their invention for the benefit of the public, including future inventors.[10]

The patent system serves two constituencies: patentees and the public (including other inventors). For patentees, the patent system aims to reduce risk associated with innovation by providing a limited period of exclusivity (i.e., a limited monopoly). During the exclusivity period, inventors try to recoup the investments required for their innovation without competition from copycats. For the public, the patent system creates a database of public knowledge. People can learn from this knowledge and, once the inventors' exclusivity ends, use the invention. For other inventors, the patent system acts as a notice system. Inventors can review patents to understand others' rights and innovate around those rights or seek a license from the patentee.

Statutory patent requirements attempt to balance patentees' interests with those of the public and competitors. For example, the novelty and obviousness requirements preclude patentees from claiming inventions already available to the public.[11] Disclosure requirements offer further protection.[12] The disclosure requirement contains two sub-requirements: enablement and written description.[13] The enablement requirement ensures patentees turn over to the public enough information for a person of ordinary skill in the art (POSA), such as a competitor, to make and use an invention once the exclusivity period expires.[14] The written description requirement limits patentees' monopoly scope commensurate with patent disclosure. This scope limit protects competitors' freedom to innovate outside of patentees' inventions during the exclusivity period.

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[8] U.S. CONST. art. I, § 8, cl. 8.
[9] An Act to Promote the Progress of Useful Arts, ch. 7, 1 Stat. 109 (1790).
[10] 35 U.S.C. §§ 102, 103, 112(a).
[11] *See* 35 U.S.C. §§ 102, 103.
[12] *See* 35 U.S.C. § 112(a).
[13] Ariad Pharms., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010).
[14] *Id.* at 1351.

B. 35 U.S.C. § 112 Holds Patentees to Their End of the Bargain

Courts have long recognized that "nothing can be more just and fair[,] both to the patentee and to the public[,] than that the former should understand, and correctly describe[,] just what he has invented[,] and for what he claims a patent."[15] The disclosure requirement represents the patentee's end of the quid pro quo bargain with the public: patentees receive a limited monopoly in exchange for disclosing their invention.[16] As clarified in an *en banc* 2010 Federal Circuit decision, adequate disclosure requires satisfaction of both elements in a two-pronged test: the enablement and written description requirements.[17]

The test for sufficient written description is a fact-dependent, objective inquiry into the patentee's "possession" of the claimed invention.[18] To demonstrate possession, an inventor must "describe an invention understandable to [a] skilled artisan" within the "four corners of the specification" sufficient to "show that the inventor actually invented the invention claimed."[19] The "possession" inquiry requires more or less disclosure "depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology."[20] For "genus" claims—claims encompassing several "species"—courts look to "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue."[21] The Federal Circuit rejected a bright-line rule like requiring disclosure of a minimum number of species; instead the disclosure "necessarily changes with each invention, and it changes with progress in a field."[22] In short, the written description test invites courts to evaluate inventions in the context of the relevant field at the time of invention to decide if a POSA would conclude the inventors "possessed" the invention they claim.

The written description requirement serves several important purposes distinct from the enablement requirement. The enablement requirement ensures the public receives enough description to "make and use" the claimed

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[15] Merrill v. Yeomans, 94 U.S. 568, 573–74 (1876).
[16] *See* Universal Oil Prod. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944).
[17] *Ariad Pharms., Inc.*, 598 F.3d at 1340.
[18] *Id.* at 1351.
[19] *Id.*
[20] *Id.*
[21] *Id.* (quoting Capon v. Eshhar, 418 F.3d 1349, 1357–58 (Fed. Cir. 2005)).
[22] *Id.*

invention.[23] By contrast, the written description requirement prevents the inventor from excluding others from subject matter the inventor did not invent.[24] It allows the public to "understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights."[25] Enablement alone, in its current state, cannot satisfy this function.[26]

Overbroad or overly narrow application of the written description requirement can undermine innovation. The written description requirement polices the breadth of a private ownership right. While scholars dispute the extent to which such a private ownership scheme spurs innovation[27] or hinders it,[28] research certainly requires funding to produce useful innovations[29] and private ownership is one method to encourage investment in innovative

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[23] *Id.* at 1345.

[24] *Id.* at 1352–54.

[25] *Id.* at 1345.

[26] *See* Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1159 (2008); *see also* J. Peter Paredes, *Written Description Requirement in Nanotechnology*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 489, 499–504 (2006) (explaining the importance of the written description requirement for nanotechnology inventions); Benjamin Hattenbach, *On Illuminating Black Holes in Patent Disclosures: Toward a Structured Approach to Identifying Omitted Elements Under the Written Description Requirement of Patent Law*, 38 HOUS. L. REV. 1195, 1199 (2001) (explaining the written description requirement "ensures that patentees are not awarded unjustifiably overbroad monopolies covering inventions they did not possess when they originally sought patent protection"); William C. Mull, *Using the Written Description Requirement to Limit Broad Patent Scope, Allow Competition, and Encourage Innovation in Biotechnology*, 14 HEALTH MATRIX 393, 405 (2004) (explaning the written description requirement shows "that the inventor was in possession of the claimed invention at the time of the filing of application"); Joseph Jakas, *Encouraging Further Innovation: Ariad v. Eli Lilly and the Written Description Requirement*, 42 SETON HALL L. REV. 1287, 1292 (2012) (describing the written description requirement as a "tool for courts in determining what invention an inventor actually possessed at the time he filed his claim"); Alison E. Cantor, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J. L. & TECH. 267, 282 (2000) (identifying two purposes for the written description requirement: to "validate[] the fact that the inventor was truly in possession of the invention on the date that the application was filed" and to "give[] the public notice of the limits of the patent in order to allow third parties to improve on and invent around the patent without infringing.").

[27] *See generally* Jonathan M. Barnett, *The Anti-Commons Revisited*, 29 HARV. J. L. TECH. 127 (2015); *see also* Talya Ponchek, *Does the Patent System Promote Scientific Innovation? Empirical Analysis of Patent Forward Citations*, 25 ALB. L.J. SCI & TECH. 289, 307–10 (2015).

[28] *See generally* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

[29] *See, e.g.*, Gary Anderson, John Jankowski & Mark Boroush, *U.S. R&D Increased by $51 Billion in 2020 to $717 Billion; Estimate for 2021 Indicates Further Increase to $792 Billion*, NATIONAL SCIENCE FOUNDATION 23-320, 1 tbl.1 (Jan. 4, 2023), https://perma.cc/66XA-CHGA (Table 1 estimating $717 billion in research and development expenditures in the United States in 2020).

research.[30] At one extreme, a low written description bar disincentivizes non-inventors from innovating because patentees can obtain property rights far beyond their invention. Innovation stalls in the space adjacent to the invention (Figure 1).[31] At the opposite extreme, a high written description bar disincentivizes patentees from innovating because they cannot fully exclude competitors. Intellectual property is intangible; it is a right to ideas. Unlike tangible items or land, a party can use an intangible idea at the same time as one or more other parties. Use is non-rivalrous—one person's use does not deplete or prevent another's concurrent use.[32] Thus, a high written description bar forces patentees to compete with copyists who benefitted from patentees' disclosures and made marginal tweaks to the invention (Figure 1).[33]

[30] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1600–04 (2003) (explaining private ownership as one theoretical solution to motivate investment in innovation); *see also* Heidi L. Williams, *How Do Patents Affect Research Investments?*, 9 ANN. REV. ECON. 441, 448–50 (2017) (summarizing survey data showing patent protection motivated private investment in research); Karen G. Potter, *Getting Written Description Right in the Biotechnology Arts: A Realist Approach to Patent Scope*, 28 BIOTECHNOLOGY L. REP. 1, 2 (2009) (explaining "[w]ithout a guarantee of patent protection, investors are reluctant to risk financially backing a biotechnology company").

[31] *See, e.g.*, Robert P. Merges & Richard R. Nelson, *On Limiting or Encouraging Rivalry in Technological Progress: The Effect of Patent Scope Decisions*, 25 J. ECON. BEHAV. & ORG. 1, 16 (1994) (concluding "granting and enforcing of broad pioneer patents . . . has made entry of creative and energetic newcomers difficult").

[32] *See* Abraham Bell & Gideon Parchomovsky, *A Theory of Property*, 90 CORNELL L. REV. 531, 55–62, 78 (2005) (explaining historical development of property theories); *see also* Burk & Lemley, *supra* note 30, at 1605 (explaining why intangible resources are nonrivalrous).

[33] *See, e.g.*, Potter, *supra* note 30, at 13–14.

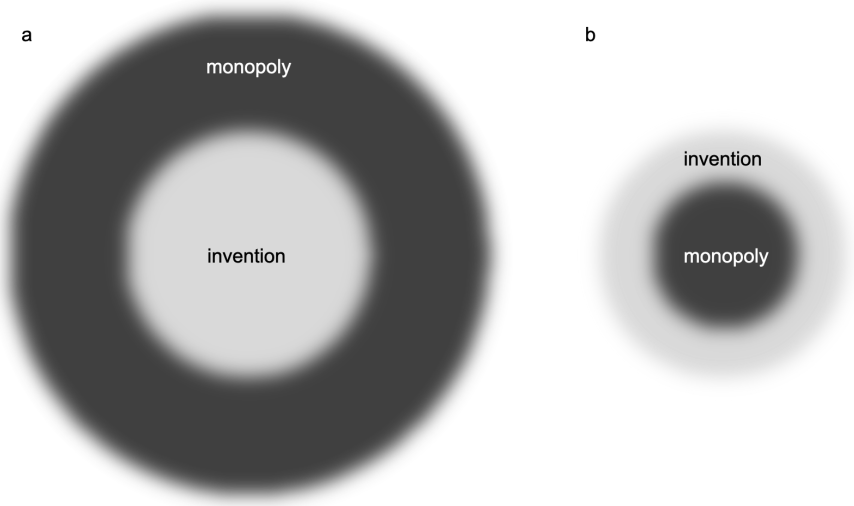

Figure 1. Illustration of monopoly rights relative to invention scope under (a) a low written description bar and (b) a high written description bar.

C. Life Sciences Combination Genus Claims

Although facially trans-substantive, the "possession" test poses an acute challenge to life sciences inventions. The challenge arises both from application of the written description requirement and features inherent to the life sciences.

First, courts frequently subject life sciences inventions to heightened disclosure requirements because they find such inventions "unpredictable," in contrast to mechanical or electrical inventions.[34] In *Juno*, the Federal Circuit found a claimed element (an antibody fragment designed to bind to an antigen) "unpredictable" despite acknowledging significant progress in the relevant field

[34] *See, e.g.*, Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987) (holding "results are predictable" for inventions in "mechanical as opposed to chemical arts" for enablement analysis); Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1370 (Fed. Cir. 2011) (Gajarsa, J., concurring) (agreeing with the district court finding that "the chemical arts have long been acknowledged to be unpredictable" for enablement analysis); Ariad Pharms., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1358 (Fed. Cir. 2010) (quoting Capon v. Eshhar, 418 F.3d 1349, 1358 (Fed. Cir. 2005)).

and multiple functional embodiments known in the art (i.e., multiple antibody fragments known to bind antigens specifically, including a claimed antigen).[35]

Second, although the possession test rejects a bright line rule for the number of disclosed species to support such a genus, courts appear suspicious of claims to hundreds, thousands, or millions of species when the specification only explicitly discloses a few.[36] Yet, inherent redundancy and similar functionality in chemical and biological systems means a vast number of species can predictably perform the same function.

Consider a patentee seeking to protect a new antibody-based drug. Let's call that antibody "Antibody α." The patentee could claim a genetic sequence (DNA or RNA) which encodes for Antibody α as well as Antibody α directly (i.e., a protein comprising a known amino acid sequence) (Figure 2). Two inherent biological features require the patentee to draft claims to a broad genus comprising many different genetic sequences to effectively exclude competitors from Antibody α. First, redundancy in the genetic code means many different genetic sequences can encode for Antibody α. While the number of genetic sequences capable of producing Antibody α could be as large as 6^{1540}, none of these are unpredictable.[37] The sequences are predictable, despite their vast number, because researchers know which codons can encode for the same amino acid (Figure 2).[38] Claiming a genus comprising "millions of billions" of species may be supported by disclosing only a single species, if all

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[35] 10 F.4th 1330, 1338 n.2, 1341–42 (Fed. Cir. 2021) ("While it is true that scFvs were known, and even known to bind, the record demonstrates that, even for the narrowest claims at issue, the realm of possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most)."), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).

[36] *See, e.g.*, *id.* at 1341.

[37] Anywhere from one to 6^{1540} mRNA sequences may encode for Antibody α (Figure 2). An antibody includes about 1,320 to 1,540 amino acids (antibodies have two "heavy chains" comprised of 440-550 amino acids each and two "light chains" comprised of 220 amino acids each). TRANSPLANTATION BIOLOGY: CELLULAR AND MOLECULAR ASPECTS 457 (Leendert C. Paul, Nicholas L. Tilney, & Terry B. Strom eds., 1996). One to six different mRNA codons encode for the same amino acid. Subhash Kak, *Your Genetic Code has Lots of 'Words' for the Same Thing – Information Theory May Help Explain the Redundancies*, THE CONVERSATION (July 17, 2023), https://perma.cc/A6K6-KK3W. Assuming the least sequence redundancy (i.e., a sequence where only one codon encodes for each amino acid), there exists only a single mRNA sequence encodes for the antibody. Assuming the longest length antibody (about 1,540 amino acids) with the greatest sequence redundancy (i.e., six codons encode for each amino acid), 6^{1540} mRNA sequences encode for the same antibody.

[38] *See, e.g.*, Potter, *supra* note 30, at 4, 13–14.

species are closely related.[39] In other words, disclosing one genetic sequence encoding for Antibody α actually discloses millions of sequences encoding for Antibody α; an inventor may need to claim all of these sequences to exclude copycats. Second, many antibodies, though differing to some extent from Antibody α's amino acid sequence, can perform similarly to Antibody α. Generally, swapping out a few amino acids in the highly specific Antibody α binding region would likely change Antibody α's function, while swapping them out in the non-binding constant region could leave Antibody α relatively functionally unchanged. To the extent researchers can predict the specific amino acid replacements that would minimally erode functionality—an often challenging and resource-intensive process—they can swap one amino acid for a chemically similar amino acid[40] through genetic engineering techniques.[41] To exclude copyists from their invention, the patentee must seek genus claims encompassing a vast number of equivalent or similar sequences and proteins (Antibody α and/or the genetic sequences encoding Antibody α as well as Antibody α's functional equivalents). In other words, a life sciences genus including a vast number of species when the specification discloses only a few species, should not, alone, support a finding of insufficient written description. The key is whether the claimed genus covers only species similar to the disclosed species.

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[39] *Compare Juno Therapeutics, Inc.*, 10 F.4th at 1341–42 (invalidating claims to a genus comprising "millions of billions" of potentially "highly diverse" species because "the realm of possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most)"), *with* AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1300 (Fed. Cir. 2014) ("Although the number of the described species appears high quantitatively, the described species are all of the similar type and do not qualitatively represent other types of antibodies encompassed by the genus.").

[40] *See* Karen Steward, *Essential Amino Acids: Charts, Abbreviations, and Structure*, TECH. NETWORKS (Dec. 18, 2023), https://perma.cc/4XR5-CEG6 (showing amino acids grouped by properties).

[41] *See, e.g.*, Sasha B. Ebrahimi & Devleena Samanta, *Engineering Protein-Based Therapeutics Through Structural and Chemical Design*, 14 NATURE COMMC'NS 2411, 3–4 (2023).

The Central Dogma of Biology

- Cells contain genetic material in their deoxyribonucleic acid (DNA) sequence.
- DNA is comprised of four nucleotides: adenosine (A), guanosine (G), cytidine (C), and thymidine (T).
- Proteins in cells read DNA to produce ribonucleic acid (RNA).
- RNA is comprised of four nucleotides: A, G, C, and uracil (U) instead of T.
- Other proteins read a type of RNA, called mRNA ("messenger RNA"), to produce proteins.
- These proteins read three mRNA nucleotides (a "codon") at a time.
- One codon corresponds to one amino acid.
- However, multiple, different codons may encode the same amino acid.

Figure 2. The genetic code is redundant: multiple DNA and RNA sequences encode the same protein because multiple codons encode the same amino acid.[42]

Combination genus claims are particularly valuable for life sciences inventions. This claim structure explicitly recognizes that the inventive nature arises from a combination of multiple known elements or an inventive element with one or more known elements. For example, the Antibody α inventors could start from a prior art antibody and discover a particularly useful new binding region. A combination genus claim might include a known element (e.g., the prior art antibody constant region) and an inventive element (e.g., the new binding region).

The written description requirement serves important policy functions when its application aligns with the nature of the underlying science. Part II, *infra*, describes four cases to illustrate the high—sometimes too high—written description bar courts apply to life sciences combination genus claims. This high written description bar for life science genus claims has created unpredictability. Unpredictability harms other inventors who lack notice about the scope of patentees' rights.[43] Unpredictability also disincentives potential patentees from innovating because they face uncertain intellectual property protection.[44] This unpredictability-causing high written description bar often arises from the law getting the underlying science wrong.

[42] *See, e.g.*, Subhash Kak, *supra* note 37.
[43] *See* Shahrokh Falati, *A Singular Disclosure Requirement is Necessary for Patent Law*, 24 COLUM. SCI. & TECH. L. REV. 249, 265 (2023).
[44] *See id.*

III. INVENTORS LACK PREDICTABILITY IN SATISFYING THE WRITTEN DESCRIPTION REQUIREMENT FOR LIFE SCIENCE COMBINATION GENUS CLAIMS

This Note relies on four cases to illustrate the unpredictability in applying the written description possession test to life sciences combination genus claims: *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, 636 F.3d 1341 (Fed. Cir. 2011), *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011), *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020), and *Juno Therapeutics, Inc. v. Kite Pharma, Inc*., 10 F.4th 1330 (Fed. Cir. 2021).[45] *Centocor Ortho Biotech, Inc.* demonstrates insufficient disclosure for an inventive element in combination with a known element. *Boston Scientific Corp.* demonstrates insufficient disclosure for a known element in combination with other known elements. *Immunex* demonstrates sufficient disclosure for a combination of known elements. *Juno* demonstrates insufficient disclosure for a known element in a combination with an inventive element. These four holdings illustrate a trend in challenging life sciences combination genus claims based on claim breadth relative to the number of disclosed species (Table 1).

No Species	Insufficient Species	Sufficient Species
Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1354-58 (Fed. Cir. 2010).	*Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1365-69 (Fed. Cir. 2011).	*Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285-87 (Fed. Cir. 2012).
Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc., 642 F.3d 1031, 1037 (Fed. Cir. 2011).	*AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299-1302 (Fed. Cir. 2014).	*Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1190-92 (Fed. Cir. 2014).
Centocor Ortho Biotech, Inc. v. Abbott Lab'ys, 636 F.3d 1341, 1350-51 (Fed. Cir. 2011).	*Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1165 (Fed. Cir. 2019).	*GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 729-32 (Fed. Cir. 2014).
	Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1339-40 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022), *reh'g denied*, 143 S. Ct. 631 (2023).	*Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1062-65 (Fed. Cir. 2020).
	BASF Plant Sci., LP v. Commonwealth Sci. & Indus. Rsch. Organisation, 28 F.4th 1247, 1268-69 (Fed. Cir. 2022).	*BASF Plant Sci., LP v. Commonwealth Sci. & Indus. Rsch. Organisation*, 28 F.4th 1247, 1265-68 (Fed. Cir. 2022).

Table 1. The table indicates several representative post-Ariad written description holdings for life sciences claims ranging from no species disclosure to sufficient species disclosure.

The possession test polices different conduct depending on whether the insufficiently disclosed element is known or inventive. The cases involving claims invalidated on the inventive element appear to police gun-jumping (i.e.,

[45] 647 F.3d 1353, 1356–57 (Fed. Cir. 2011); 636 F.3d 1341, 1351 (Fed. Cir. 2011); 10 F.4th 1330, 1341-42 (Fed. Cir. 2021). *But see* 964 F.3d 1049, 1054 (Fed. Cir. 2020).

preventing the inventor from claiming a problem without disclosing solutions).[46] By contrast, the cases involving claims invalidated on known elements provide inventive solutions but attempt to claim application of those solutions to future iterations of the known elements.[47] While policing the former incentivizes (or at least does not disincentive) others to innovate to address a broad problem separate from patentees' inventions, policing the latter, in some cases, disincentivizes inventors by limiting their ability to fully exclude copyists.

A. Centocor

The *Centocor* holding illustrates how the written description requirement polices gun jumping. The *Centocor* combination genus claims covered antibodies comprising two elements: a constant region (the known element), and a variable region with therapeutically desirable properties (the inventive element).[48] Illustrative claims read:[49]

> 1. An isolated recombinant anti-TNF-α anti-body or antigen-binding fragment thereof, said antibody or antigen-binding fragment comprising a human constant region, wherein said antibody or antigen binding fragment (i) competitively inhibits binding of A2 (ATCC Accession No. PTA–7045) to human TNF-α, and (ii) binds to a neutralizing epitope of human TNF-α in vivo with an affinity of at least 1×10 8 liter/mole, measured as an association constant (Ka), as determined by Scatchard analysis.

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[46] *See Centocor Ortho Biotech, Inc.*, 636 F.3d at 1353; Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc., 642 F.3d 1031, 1037 (Fed. Cir. 2011) (finding insufficient written description for the inventive element when the specification "does not identify even a single species that satisfies the claims").

[47] *Compare Juno Therapeutics Inc.*, 10 F.4th at 1338–39 (invalidating claims to "all scFvs, known and unknown" when the specification disclosed only two scFvs and the prior art disclosed several others), *and Bos. Sci. Corp.*, 647 F.3d at 1364, 1367 (invalidating claims to "macrocyclic lactone analogs of rapamycin" and "rapamycin or a macrocyclic triene analog thereof" when the specification disclosed only rapamycin and the prior art disclosed some analogs), *with Immunex Corp.*, 964 F.3d at 1064 (finding sufficient written description when prior art disclosed the full sequence of a challenged known element).

[48] *Centocor Ortho Biotech, Inc.*, 636 F.3d at 1345, 1352; *see also Billups-Rothenberg, Inc.*, 642 F.3d at 1037 (finding insufficient written description for a claimed inventive element (*i.e.*, detecting genetic mutations related to a particular disease) because the specification disclosed no species (*i.e.*, mutations related to the disease) and neither did the prior art).

[49] *Centocor Ortho Biotech, Inc.*, 636 F.3d at 1346-47.

> 2. The antibody or antigen-binding fragment of claim 1, wherein the antibody or antigen-binding fragment comprises a human constant region and a human variable region.

As background, antibodies, also called immunoglobins (Ig), are proteins the body naturally creates to selectively bind to a target (i.e., antigens). Scientists discovered antibodies in the 1890s in serum derived from subjects recovering from infection.[50] By the 1970s, scientists developed benchtop methods to produce mixtures of antibodies (i.e., polyclonal antibodies).[51] Hybridoma technology, developed soon after, enabled scientists to make monoclonal antibodies (i.e., antibodies designed to selectively bind to a single antigen).[52]

Therapeutic antibodies can block disease-causing molecules' activity by specifically binding to key areas on the molecule (i.e., the antigen).[53] Antibodies' structure enables their binding specificity. Antibodies have four peptide chains: two heavy chains and two light chains.[54] Chemical bonds hold four chains together in a Y-shaped configuration.[55] The Y base is a "constant" region while the Y arms include "variable" regions.[56] Within an antibody sub-class (e.g., IgG1), antibodies largely share the same constant region sequence, but differ in the variable region sequences.[57] The variable regions form the antigen-specific binding site.[58]

The *Centocor* claims covered a variable region that bound to a protein called tumor necrosis factor-α (TNF-α) to treat autoimmune and inflammatory diseases like rheumatoid arthritis (RA).[59] The Federal Circuit found the specification lacked sufficient written description for the inventive variable region.[60]

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[50] Stefan H. E. Kaufmann, *Immunology's Coming of Age*, 10 FRONTIERS IN IMMUNOLOGY 684, 3–5 (2019).
[51] MARY A. RITTER, DIAGNOSTIC AND THERAPEUTIC ANTIBODIES 23–24, 27 (Andrew J.T. George et al. eds., 2000).
[52] RITTER, *supra* note 51, at 27-28; *see also* Paula Dobosz & Tomasz Dzieciatkowski, *The Intriguing History of Cancer Immunotherapy*, 10 FRONTIERS IN IMMUNOLOGY 2965, 3-4 (2019).
[53] PETER C. TAYLOR, DIAGNOSTIC AND THERAPEUTIC ANTIBODIES 115–16, 121-26 (Andrew J.T. George et al. eds., 2000).
[54] ANDREW J.T. GEORGE, DIAGNOSTIC AND THERAPEUTIC ANTIBODIES 1–2 (Andrew J.T. George et al. eds., 2000).
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] U.S. Patent No. 7,070,775 (filed Jul. 12, 2002).
[60] Centocor Ortho Biotech, Inc. v. Abbott Lab'ys, 636 F.3d 1341, 1350-51 (Fed. Cir. 2011).

1. Centocor *Specification Disclosed No Claimed Species*

The *Centocor* case illustrates proper application of the written description requirement to prevent gun jumping. The asserted claims in *Centocor* covered an improved anti-human TNF-α therapeutic antibody.[61] Prior art anti-human TNF-α antibodies were largely derived from mice and provided limited therapeutic benefits due to low binding affinity and toxicity.[62] The prior art also disclosed chimeric antibodies—antibodies comprising antibody components derived from different sources fused together (e.g., part murine antibody, part human antibody)—as a solution to murine antibody toxicity.[63] The asserted patent claimed priority to an earlier filed application ("priority application"), which disclosed a chimeric anti-human TNF-α antibody containing a human constant region and murine variable regions, as a solution to the toxicity problem with fully murine antibodies.[64] The priority application's specification disclosed the sequence for the murine variable regions.[65] It did not provide sequences encoding a human variable region or a method to produce a human variable region with high affinity for human TNF-α.[66] Despite this omission, the later-filed, asserted patent claimed fully-human, high-affinity, TNF-α binding antibodies comprising human constant and variable regions (i.e., the inventive element). The *Centocor* patentees had to rely on the priority application filing date because by the time they filed the asserted patent, the accused infringer "had already discovered and patented a fully human antibody to TNF-α that had high affinity and neutralizing activity."[67] Thus, the *Centocor* patentees argued the priority application's specification provided written description for the fully human anti-human TNF-α antibody claimed in the asserted child patent.

The Federal Circuit held the claims invalid for insufficient written description for the inventive element of the combination genus claim. Because the priority application specification did not "describe a single antibody that satisfie[d] the claim limitations," "disclose any relevant identifying characteristics for such fully-human antibodies or even a single human variable region," or "disclose any relationship between the human TNF-α protein, the known mouse variable region that satisfie[d] the critical claim limitations, and

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[61] *Id.* at 1344; *see also* '775 Patent.
[62] '775 Patent.
[63] *Id.*
[64] *Centocor Ortho Biotech, Inc.*, 636 F.3d at 1347-49.
[65] *Id.* at 1349-50.
[66] *Id.*
[67] *Id.* at 1348.

potential human variable regions that w[ould] satisfy the claim limitations," the Federal Circuit found the specification failed to sufficiently demonstrate possession.[68] And, at the priority application filing date, "it was entirely possible that no fully-human antibody existed that satisfied the [asserted child patent's] claims."[69] The court further rejected disclosure of TNF- α (the antigen) structure as sufficient written description because "obtaining a high affinity, neutralizing, [antigen-]specific antibody with a human variable region [with only the antigen] was not possible in 1994 using 'conventional,' 'routine,' 'well developed and mature' technology."[70] In other words, the inventors jumped the gun in the metaphorical race to invent by claiming a problem yet to be solved.

This outcome aligns with written description policy aims, because patentees failed to uphold their end of the quid pro quo bargain by not disclosing a single claimed species. Enforcing these claims would stall innovation adjacent to the patentee's actual invention.

B. Boston Scientific

The *Boston Scientific* holding illustrates how the written description requirement polices inventors' attempts to claim future iterations of known elements when the inventive aspect is a combination of known elements. The *Boston Scientific* claims covered a drug-eluting stent comprising a known stent coated in a known genus of anti-proliferative drugs: "rapamycin, or a macrocyclic lactone analog thereof" or "rapamycin, or a macrocyclic triene analog thereof."[71]

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[68] *Id.* at 1350–51.

[69] *Id.* at 1351.

[70] *Id.* at 1352.

[71] *See* U.S. Patent No. 7,217,286 col. 8 ll. 15–20 (filed May 15, 2007); U.S. Patent No. 7,223,286 col. 7 ll. 50–54 (filed May 29, 2007); U.S. Patent No. 7,229,473 col. 8 ll. 13–24 (filed June 12, 2007); U.S. Patent No. 7,300,662 col. 17 ll. 23–31, col. 18 ll. 1–12 (filed Nov. 27, 2007); *see also* Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1356-57 (Fed. Cir. 2011) (explaining "[i]n the 1980s, physicians began using bare metal coronary stents to support the artery after the physician deflates the balloon" and "[p]rior to the filing of the 1997 patents, some analogs of rapamycin were disclosed in the prior art").

1. Boston Scientific *Specification Disclosed Insufficient Species by Reference to the Prior Art*

Because the *Boston Scientific* priority application[72] provided only an "ipsis verbis disclosure of the claimed genus" (i.e., "rapamycin, or a macrocyclic lactone analog thereof" or "rapamycin, or a macrocyclic triene analog thereof") in an "unpredictable" field, the Federal Circuit held the claims invalid for insufficient written description of rapamycin analogs.[73] The priority application disclosed "[r]apamycin (sirolimus) structural analogs (macrocyclic lactones) and inhibitors of cell-cycle progression" as drugs useful in stent coatings.[74] The priority application's examples only used rapamycin; none used rapamycin "structural analogs."[75] Further, the priority application's specification provided no "guidance on how to properly determine whether a compound is a macrocyclic lactone analog of rapamycin besides vaguely indicating they must be 'structural[ly] similar.'"[76] While the prior art disclosed some species in the claimed "analogs" genus, the court found the art was too "unpredictable" and knowledge too "scant" for these disclosures to make up for the specification's omission.[77] The Federal Circuit held the *Boston Scientific* claims invalid for insufficient written description for the known genus element.

This outcome illustrates the high bar life sciences inventions face to comply with the written description requirement because the court invalidated claims to structurally similar analogs of a known element. In other words, the court limited the patentee to the disclosed—prior art—species and no more. Such an application of the written description requirement limits patentees' ability to recover the investment required to create a therapeutically beneficial drug eluting stent by allowing copyists to capitalize on the invention (a stent coated in drug) with minor modifications to known drugs. Section IV(B)(1) offers inventors a policy-aligned disclosure method to better support known claim elements.

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[72] Like the *Centocor* asserted patent, the *Boston Scientific* asserted patents claim priority to an earlier filed application ("priority application") to establish an early filing date and, thus, rely on the priority application's specification to satisfy the written description requirement. *Bos. Sci. Corp.*, 647 F.3d at 1358–59.

[73] *Id.* at 1364.

[74] '286 Patent col. 6 ll. 4–5.

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

[76] *Id.*

[77] *See id.*

C. Immunex

By contrast to *Boston Scientific*, the *Immunex* holding illustrates how inventors may claim prior art elements with sufficient disclosure when the inventive aspect is a combination of known elements. The *Immunex* claims covered a fusion protein (called etanercept) containing parts of two known proteins (human tumor necrosis factor receptor (TNFR) protein and immunoglobulin G1 (IgG1)) and methods of making it.[78] An exemplary asserted claim recited:

> 11. The protein of claim 1, wherein the protein consists essentially of the extracellular region of the insoluble human TNF receptor and all the domains of the constant region of a human IgG_1 immunoglobulin heavy chain other than the first domain of the constant region.[79]

The inventors prevailed by claiming only known elements and disclosing structural variants with comparable functionality.

1. Immunex *Specification Sufficiently Disclosed the Full-Length Sequence for the Claimed Species*

The Federal Circuit upheld the *Immunex* claims because the prior art disclosed sequences for both known elements (the TNFR extracellular portion and IgG1)[80] and the specification[81] directed a POSA to those sequences and explained which structural variations would result in comparable functionality. First, the *Immunex* specification sufficiently disclosed known elements by their sequence. The specification provided a sequence identification number corresponding to a publicly accessible, full-length TNFR sequence listing in an open source database.[82] The specification also referenced a scientific publication which provided this reference number.[83] And, the specification referenced deposited DNA samples encoding the IgG1 protein.[84] Second, the

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[78] *See* Immunex Corp. v. Sandoz Inc., 964 F.3d 1049, 1054 (Fed. Cir. 2020).
[79] U.S. Patent No. 8,063,182 col. 39 ll. 60–64 (filed Nov. 22, 2011).
[80] *See Immunex Corp.*, 964 F.3d at 1064–65.
[81] Like the *Centocor* asserted patent and the *Boston Scientific* asserted patents, the *Immunex* asserted patent claims priority to an earlier filed application ("priority application") to establish an early filing date and, thus, relies on the priority application's specification to satisfy the written description requirement. *Immunex Corp.*, 964 F.3d at 1054.
[82] *Immunex Corp.*, 964 F.3d at 1063–64.
[83] *Id.* at 1064.
[84] *Id.* at 1065.

specification expressly "embrace[d] allelic variants and DNA sequences resulting from deletions, substitutions, and additions of one or more nucleotides of the sequences provide[d]."[85] In particular, the specification disclosed:

> [T]he present invention is also concerned with DNA sequences coding for proteins and soluble or non-soluble fragments thereof, which bind TNF. Thereunder, there are to be understood; for example, DNA sequences coding for non-soluble proteins or soluble as well as non-soluble fragments thereof, which bind TNF, such as DNA sequences being selected from the following:
>
> (a) DNA sequences as given FIG. 1 or FIG. 4 as well as their complementary strands, or those which include these sequences;
>
> (b) DNA sequences which hybridize with sequences defined under (a) or fragments thereof;
>
> (c) DNA sequences which, because of the degeneracy of the genetic code, do not hybridize with sequences as defined under (a) and (b), but which code for polypeptides, having exactly the same amino acid sequence.
>
> That is to say, the present invention embraces not only allelic variants, but also those DNA sequences which result from deletions, substitutions and additions from one or more nucleotides of the sequences given in FIG. 1 or FIG. 4, whereby in the case of the proteins coded thereby there come into consideration, just as before, TNF-BP.[86]

This holding incentivizes life sciences innovation by allowing inventors to exclude copyists while permitting others to innovate outside of patentees' invention. Inventors may claim more than just the sequences disclosed in the specification by expressly identifying the structural modifications resulting in comparable functionality. This lower written description bar does not chill innovation in the space adjacent to the invention because patentees may only exclude others from functionally minor (though potentially structurally large)

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[85] *Id.*

[86] U.S. Patent No. 8,063,182 col. 5 ll. 1–22 (filed Nov. 22, 2011).

tweaks to their sequence. Section IV(C)(2), *infra*, discusses this policy-aligned strategy in more detail.

D. Juno

Like *Boston Scientific*, the Federal Circuit held combination genus claims invalid for insufficient disclosure of a known element in *Juno*. Unlike *Boston Scientific* and *Immunex*, the *Juno* claims included an inventive element.[87]

As background, the *Juno* patent claimed improved CARs, proteins used to engineer the immune system to fight diseases like cancer.[88] When foreign material (e.g., proteins from viruses or bacteria) infects human cells, the cells have tools to digest the protein and "display" a piece of it on their cell surface.[89] T cells are immune cells with receptors that bind to these displayed protein bits (i.e., antigens).[90] Upon binding to an antigen, some T cells can initiate a mechanism to kill the infected cell displaying the antigen.[91]

Scientists can engineer T cells to act as cancer therapeutics by modifying their receptors to recognize proteins on cancer cells' surfaces.[92] Native T cell receptors comprise a portion jutting out from the cell surface to recognize antigens (the "extracellular" portion) and a portion projecting into the cell to initiate a chemical signaling pathway once the extracellular portion binds to an antigen (the "intracellular" portion).[93] CARs are modified versions of native T cell receptors.[94] CARs differ from native T cell receptors in two key ways: (1) CARs substitute the native T cell receptor extracellular region with an extracellular region designed to bind an antigen related to a target disease, and (2) CARs have a second intracellular region (i.e., a "costimulatory" region)—in addition to a native intracellular signaling region—to improve signaling upon

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[87] *See* 10 F.4th 1330, 1341-42 (Fed. Cir. 2021) ("Dr. Brocker testifying that scFvs were 'not part of this invention. The real invention was the backbone.'").

[88] *See* Christine R. O'Brien Laramy, *The CAR-T Cell Therapy Innovation Drivers: A Yescarta Case Study*, 39 BERKELEY TECH. L.J. 553, 565-67, 69-75 (2024).

[89] Alex D. Waldman, Jill M. Fritz & Michael J. Lenardo, *A Guide to Cancer Immunotherapy: From T Cell Basic Science to Clinical Practice*, 20 NATURE REVS. IMMUNOLOGY 651, 652 (2020).

[90] Jacques F. A. P. Miller, *The Golden Anniversary of the Thymus*, 11 NATURE REVS. IMMUNOLOGY 489, 491-92 (2011).

[91] *See* Waldman, *supra* note 89, at 652.

[92] U.S. Patent No. 7,446,190 (filed May 28, 2003).

[93] *See* Peter Braendstrup, Bruce L. Levine & Marco Ruella, *The Long Road to the First FDA-Approved Gene Therapy: Chimeric Antigen Receptor T Cells Targeting CD19*, 22 CYTOTHERAPY 57, 67 (2020).

[94] *Id.* at 58.

binding the target antigen.[95] A CAR-T cell is a T cell engineered to make a CAR and incorporate it into the T cell's membrane.[96]

The *Juno* claims recited a "nucleic acid polymer encoding a" CAR comprising: (1) an intracellular signaling region; (2) a "costimulatory" region having a particular amino acid sequence; and (3) an extracellular "binding element."[97] The inventive element was the second element: a new costimulatory "backbone" region—defined by the claimed sequence—that improved intracellular signaling relative to other known costimulatory regions.[98] Dependent claims narrowed the binding element (3) to two known binding element genera: (1) an antibody fragment called an "scFv"; and (2) an scFv targeted to a particular protein (CD19).[99] The *Juno* patentee asserted claims against a competitor manufacturing a CAR-T therapeutic with a CD19-binding scFv known in the field at the time Juno filed their patent application, though a different CD19-binding scFv than the one disclosed in the *Juno* specification.[100] The Federal Circuit invalidated the claims for insufficient written description of a known element—the extracellular binding element.[101]

1. Juno *Specification Failed to Supplement Several Known Prior Art Species Commensurate with Claim Scope*

The Federal Circuit found insufficient written description for the scFv binding element, because (1) the specification disclosed only two scFv binding elements and did not provide "details regarding the characteristics, sequences, or structures that would allow a person of ordinary skill in the art to determine which scFvs w[ould] bind to which target" and (2) the prior art provided only general knowledge about scFvs.[102] The Federal Circuit found insufficient written description for the narrower scFv targeted to CD19 binding element, because (1) the specification disclosed only one anti-CD19 scFv and (2) "the realm of

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[95] *Id.*
[96] *Id.*
[97] *See* '190 Patent col. 25 ll. 30–38.
[98] *See* Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1341-42 (Fed. Cir. 2021); *see generally* John Maher et al., *Human T-lymphocyte Cytotoxicity and Proliferation Directed by a Single Chimeric TCRζ/CD28 Receptor*, 20 NATURE BIOTECHNOLOGY 70 (2002).
[99] *See* '190 Patent col. 25 ll. 39–40, 45–46; *Juno Therapeutics, Inc.*, 10 F.4th at 1336–42.
[100] *Juno Therapeutics, Inc.*, 10 F.4th at 1340.
[101] *See id.* at 1341–42.
[102] *Id.* at 1336–40.

possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most)."[103]

Like *Boston Scientific*, this outcome disincentivizes inventors from innovating by setting the written description bar too high. The *Juno* holding limits patentees' ability to exclude copyists from capitalizing on their invention and, thereby, limits their ability to recover the investment required to improve a life-saving class of therapeutics. Section IV(A), *infra*, illustrates a policy-misaligned solution to comply with the written description requirement encouraged by *Juno*. Sections IV(B) and IV(C) offer more policy-aligned methods to comply with the written description requirement for *Juno*-like claims.

IV. POLICY IMPLICATIONS FOR METHODS TO SATISFY THE WRITTEN DESCRIPTION REQUIREMENT FOR COMBINATION GENUS CLAIMS

Policy considerations favor combination genus claims for life sciences inventions. For one, this claim type practically reflects the nature of scientific advancement: inventors frequently, perhaps always, "stand[] on the shoulders of giants."[104] The work of previous inventors serves as a foundation for subsequent innovation.[105] Further, inventors seek genus claims to protect against "copyists who could otherwise make a minor change to the [invention] and thereby avoid infringement while still exploiting the benefits of [the] invention."[106] And, known elements in combination claims contextualize innovation and narrow claim scope.[107] The *Juno* co-stimulatory sequence (i.e., inventive element) may have utility in various immune system regulating applications, but the combination claims limited the patent monopoly to immune cells engineered to express the sequence as part of a CAR protein (i.e.,

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[103] *Id.* at 1340–42.

[104] Chaomei Chen, MAPPING SCIENTIFIC FRONTIERS THE QUEST FOR KNOWLEDGE VISUALIZATION 163–64 (2d ed. 2013); *see also* Mark A. Lemley, *Point of Novelty*, 105 NW. U. L. REV. 1253, 1256–57 (2011) ("In a sense, virtually all inventions are Jepson inventions: very few patents cover entirely new things as opposed to improvements on existing things.").

[105] *See* Chen, *supra* note 104, at 163–64; *see also* Dmitry Karshtedt, et al., *The Death of the Genus Claim*, 35 HARV. J. L. TECH. 1, 7 (2021) ("Patent theory posits that the disclosure will stimulate other researchers to improve upon the invention, design around it, and make wholly new inventions — all during the patent term — and also to use the invention as claimed after the patent's expiration.").

[106] *See* Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 966 (Fed. Cir. 2002).

[107] *See, e.g.*, Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 667–68 (1944) ("Since none of the separate elements of the combination is claimed as the invention, none of them when dealt with separately is protected by the patent monopoly . . . Whether the parts are new or old, the combination is the invention and it is distinct from any of them").

known elements).[108] Finally, the opportunity for combination claims incentivizes inventors to think about old inventions in new and non-obvious ways. The *Boston Scientific* inventors looked at a known stent and a known class of drugs and conceived of a new combination device to treat cardiovascular disease.[109]

Several decades of Federal Circuit opinions expressly or implicitly encourage strategies to satisfy the written description requirement for combination genus claims. The strategies most aligned with written description policy aims fall into two categories: (1) claim more narrowly and (2) disclose more. Importantly, one strategy, in most cases, is at odds with written description policy aims–eliminating "known" elements from claims. This Part evaluates each of these strategies.

A. Eliminate Known Claim Elements

The first strategy implicitly encouraged by Federal Circuit written description jurisprudence is for patentees to eliminate known elements from claims, subject to other patentability requirements, including the subject-matter eligibility,[110] novelty,[111] and non-obviousness[112] requirements. Eliminating elements generally increases claim scope. Because increasing scope without the additional disclosure does not align with written description policy aims, this Note discourages patentees from this approach and advocates for courts to avoid encouraging it except in circumstances like *Boston Scientific*. Both *Juno* and *Boston Scientific* exemplify the idea that less is more when it comes to claim drafting.

1. Juno

The *Juno* claims could likely have satisfied all patentability requirements without reciting the known element that resulted in invalidation of the claims. The *Juno* inventors identified an improvement to existing CARs: a "backbone" sequence that improved signaling to the cell upon binding. The Federal Circuit held the claims invalid for insufficient written description because the claims

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[108] *Juno Therapeutics, Inc.*, 10 F.4th at 1333–34.
[109] Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1356–57 (Fed. Cir. 2011).
[110] *See* 35 U.S.C. § 101.
[111] *See* 35 U.S.C. § 102.
[112] *See* 35 U.S.C. § 103.

were "not limited to just the claimed backbone" but "also included the" insufficiently disclosed prior art element (i.e., the "functional scFv for binding the target").[113] Essentially, the inventors claimed their inventive backbone and said: "use it in a CAR."

The subject matter eligibility requirement likely would not have precluded Juno from seeking claims to only a co-stimulatory amino acid sequence encoded by the claimed DNA sequence (i.e., the inventive element). "Laws of nature, natural phenomena, and abstract ideas are not patentable" on their own.[114] But while the Supreme Court has held naturally occurring DNA to be "a product of nature and not patent eligible," it held non-naturally occurring DNA to be eligible.[115] The *Juno* inventors derived the inventive co-stimulatory sequence from a naturally occurring human protein.[116] But, they might have claimed an edited, non-naturally occurring DNA sequence, such as a DNA sequence encoding the naturally-occurring co-stimulatory sequence fused to the naturally-occurring CD3ξ domain—essentially the same claim as in *Immunex*.[117] Thus, the Juno claims would likely be patent eligible without claiming the known binding element.[118]

Analogy to a simple mechanical invention illustrates how the *Juno* patentee might have survived a written description challenge with broader claims. Consider if the *Juno* inventors had invented a new steering wheel instead of a new CAR "backbone."[119] Assume their specification disclosed the steering wheel, the existence of cars, and named one car model (e.g., a Honda CRV) without any description for the car. Now assume they claimed:

An improved car comprising:

(a) an "inventive"[120] steering wheel;

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[113] *Juno Therapeutics, Inc.*, 10 F.4th at 1341; *see also* Section III.D, *supra*.

[114] Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 70 (2012) (quoting Diamond v. Diehr, 450 U.S. 175, 185 (1981)).

[115] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 579, 594–95 (2013).

[116] '190 Patent.

[117] *See, e.g.*, Immunex Corp. v. Sandoz Inc., 964 F.3d 1049, 1063–65 (Fed. Cir. 2020) (upholding claims to a fusion protein comprising two naturally occurring proteins).

[118] '190 Patent.

[119] This analogy was inspired by an analogy raised during oral argument. Oral Argument at 42:45, Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021) (No. 20-1758).

[120] "Inventive" here represents a generic placeholder for an inventive element, as defined in the claims and described in the specification.

(b) an engine;

(c) four wheels; and

(d) four doors.

Element *a* is the only inventive feature. *Juno* implies this hypothetical claim would be invalid for insufficient written description because each element other than the "inventive steering wheel" introduces many possible species and the specification discloses only one. Perhaps the existence of many more car models than "functional scFv[s] for binding the target" in the prior art would justify a greater predictability and thus lower disclosure requirement for the car claim. Even still, *Juno* suggests a claim that would better stand up to written description scrutiny is:

An improved car comprising:

(a) an "inventive" steering wheel.

Or even:

An "inventive" steering wheel.

After all, Juno's problem was that their claims were "not limited to just the" inventive backbone.[121] Thus, *Juno* encourages claiming only inventive element(s) without limiting their use to combination with known elements unless the specification "encompasses all [prior art elements], known and unknown."[122] Assuming patentees would struggle to disclose all "known and unknown" elements sufficiently, patentees might opt to eliminate known element limitations. Section IV.A.3. discusses the policy implications for incentivizing patentees to eliminate known elements.

2. Boston Scientific

Boston Scientific claims, too, might have avoided invalidation by omitting the insufficiently disclosed, arguably known, "analog" element. But, because, unlike for the *Juno* claims, eliminating the known element would narrow the

[121] *Juno Therapeutics, Inc.*, 10 F.4th at 1341.
[122] *Id.* at 1338.

claim scope, this strategy aligns with written description goals for *Boston Scientific*-like claims.

The novelty hurdle required the *Boston Scientific* applicants to narrow their claims by reciting a "rapamycin" limitation, but it did not require applicants to add the "or . . . analog[s]" element. The priority application faced novelty rejections over prior art disclosing "a stent . . . formed from a metal wire or strut . . . with pores loaded with therapeutic agents."[123] The applicants overcame these rejections by amending claims to recite "and wherein the therapeutic agent is rapamycin."[124] The "or . . . analog[s]" limitations, added in later child applications, actually broadened the claims.[125] Thus, the novelty bar likely would not have prevented allowance of claims without the insufficiently disclosed "analogs" limitation.

Indeed, applicants might have enforced a comparable claim scope without the "analog" limitation. For example, applicants might have enforced rapamycin claims against stents coated in a rapamycin "analog" under a non-literal infringement theory called the doctrine of equivalents.[126] The doctrine of equivalents[127] allows courts to tailor claim scope within the bounds of patentees' invention—defined by patent disclosure—while avoiding disincentivizing adjacent innovation.[128]

Boston Scientific illustrates facts where omitting a claim element may further written description policy aims.

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[123] Office Action Summary from USPTO Examiner Suzette Jackson to Applicants Carol Wright et. al, USPTO Final Rejection Letter at 3 (Apr. 26, 1999), *http://perma.cc/3ANC-M3UZ* (search for Patent 6,273,913, then follow Documents & Transaction tab) [herinafter *'913 Patent File History*].

[124] *'913 Patent File History*, *supra* note 123, 1/24/200 Claim Amendments at 2.

[125] *Compare* U.S. Patent No. 6,273,913 col. 7 ll. 44–53 ("A stent comprising . . . a therapeutic agent applied therein and wherein the therapeutic agent is rapamycin.") (emphasis added), *with* U.S. Patent No. 7,217,286 col. 8 ll. 15–23 ("A device comprising a metallic stent . . . and said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof . . . .") (emphasis added).

[126] Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997); *see generally* Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J. 994 (2023) (proposing claiming antibodies in means-plus-function claims and relying on the doctrine of equivalents to enforce claims).

[127] To infringe under the doctrine of equivalents, the accused product or method must have a feature that differs "insubstantial[ly]" from the corresponding claim element or "perform[] substantially the same function in substantially the same way to obtain substantially the same result" as the corresponding claim element. Voda v. Cordis Corp., 536 F.3d 1311, 1326 (Fed. Cir. 2008).

[128] *See, e.g.*, *Warner-Jenkinson Co.*, 520 U.S. at 29–30, 37.

3. In Most Cases, Eliminating Known Claim Elements Does Not Align with Written Description Policy Aims

Some policy justifications favor omitting known elements to satisfy the written description requirement. First, some precedent arguably supports it.[129] Second, the resultant broader exclusionary rights could motivate greater investment in research and development.[130] And, in *Boston Scientific*-like circumstances, eliminating known claim elements may narrow claim scope more commensurate with patentees' disclosure. Finally, because the U.S. Patent and Trademark Office (PTO)—the administrative agency responsible for determining whether to grant patents—rejects fewer than half of applications for life science inventions on § 112 grounds, such claims will likely be granted.[131] In any subsequent validity challenge, granted claims would benefit from the presumption of validity.[132]

However, in most circumstances, far more policy considerations disfavor this strategy. First, this strategy would disfavor combination genus claims, which provide clearer notice and narrower scope than claims to only the inventive element. Combination genus claims leave room for others to innovate by using the invention in other, non-obvious contexts. They also acknowledge a key premise in scientific research: current innovation builds on previous innovation. Second, except in *Boston Scientific*-like circumstances, this strategy results in broader claim scope without requiring broader disclosure. This increased scope and less certain boundary definition could chill innovation adjacent to claimed inventions.[133] Boundary uncertainty requires adjacent inventors to reserve more funds to resolve future intellectual property disputes

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[129] *See* discussion *supra* Sections IV.A.1–2.

[130] *See* Peter S. Menell & Michael J. Meurer, *Notice Failure and Notice Externalities*, 5 J. LEGAL ANALYSIS 1, 1, 14 (2013).

[131] *See* Tim Hellmann, *The Most Common Rejections: 102, 103, and 112(b)*, JURISTAT, https://perma.cc/7AD4-3ZT6 (Dec. 23, 2023) (finding 38.73% of TC 1600 (biotechnology) patent applications faced 112(b) rejections between 2014 and 2018).

[132] *See* Microsoft Corp. v. I4I Ltd. P'ship, 564 U.S. 91, 95 (2011) (quoting 35 U.S.C. § 282).

[133] *See* Menell & Meurer, *supra* note 130, at 2, 5–7, 11, 15, 42–43; *see also* AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1299–1300 (Fed. Cir. 2014) (analogizing a range of disclosed antibodies to a plot of land); Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 369 (1938) ("The statute seeks to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their rights.").

rather than invest in research.[134] Lastly, this approach is logically inconsistent: broader claims should require more disclosure than narrower claims.[135]

Because omitting known claim elements generally rejects a key premise to scientific research and often results in broader claims, patentees should not use this approach and courts should avoid encouraging it, except for *Boston Scientific*-like claims.

B. Claim More Narrowly

Three strategies align with written description policy aims by encouraging patentees to claim more narrowly: (1) claim combination genera in the Jepson claim structure; (2) claim chemical and biological species by their structure, not their function; and (3) provide written description sufficient to support narrower constructions upon enforcement.

1. Jepson Claim Structure

Instead of eliminating known claim elements, *Juno* may encourage patentees to draft claims in the Jepson claim structure. A Jepson claim includes a "preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known" followed by "[t]hose elements, steps and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion."[136] In other words, the applicant explicitly identifies prior art and distinguishes their claimed improvement to it.

Consider a hypothetical Jepson-style claim to the *Juno* technology:

> In a nucleic acid polymer encoding a chimeric antigen receptor, said chimeric antigen receptor comprising (a) a zeta chain portion comprising the intracellular domain of human CD3ζ chain, (b) a costimulatory signaling region, and (c) an scFv binding element that specifically interacts with a selected target, the improvement comprising the costimulatory signaling region comprising the amino acid sequence encoded by SEQ ID NO:6.

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[134] *See* Menell & Meurer, *supra* note 130, at 9–10.
[135] *See* Lemley & Sherkow, *supra* note 130, at 1055; *see also* Lefstin, *supra* note 26, at 1171.
[136] 37 C.F.R. § 1.75(e) (2009).

This strategy offers several policy benefits. The Jepson claim structure clarifies claim scope by distinguishing from prior art.[137] As a result, it provides relatively effective and certain notice to adjacent inventors.[138] Further, depending on courts' interpretation of the Jepson preamble, this claim structure could set a reasonable limit on known genus elements. The preamble expressly identifies prior art and the Federal Circuit does not require patentees to disclose conventional and well-known information.[139] Courts could interpret prior art elements in the preamble as limiting claim scope to known species and their obvious modifications.[140] For example, using the hypothetical Jepson claim, *supra*, the *Juno* patentee might have argued for construction of the "scFv binding element" limited to all scFvs known in the art to "specifically interact[] with a selected target."[141] Under this narrower construction, the *Juno* patentee could still assert their claims because the accused CAR used a scFv known in the prior art before the patent's priority date.[142] And, when seeking infringement under the doctrine of equivalents, known elements may receive a broader range of equivalents.[143]

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[137] *See* Lefstin, *supra* note 26, 1191–92; *see also* Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CALIF. L. REV. 1, 40–41 (2005).

[138] *See* Menell & Meurer, *supra* note 130130, at 9–10, 12; *see also* Permutit Co. v. Graver Corp., 284 U.S. 52, 60 (1931).

[139] *See* Takeda Pharm. Co. v. Handa Pharms., L.L.C., No. 11-cv-00840 JCS, 2013 WL 9853725, at *67 (N.D. Cal. Oct. 17, 2013) (holding "'it is unnecessary to spell out every detail of the invention in the specification' to satisfy the written description requirement" and the written description requirement does not "require a re-description of what was already known") (quoting LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005); Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005)); *see also* Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1337 (Fed. Cir. 2021); Immunex Corp. v. Sandoz Inc., 964 F.3d 1049, 1064 (Fed. Cir. 2020) (stating "[i]t is well-established that a patent specification need not re-describe known prior art concepts" in written description analysis for non-Jepson claims); Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1463 (Fed. Cir. 1984) ("The question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art . . . The unchallenged evidence of record establishes that [the known Jepson preamble elements] were well known to those skilled in the art . . . .").

[140] *See* Lemley & Sherkow, *supra* note 126, at 1059–61; *see also* Christopher A. Cotropia, *After-Arising Technologies and Tailoring Patent Scope*, 61 N.Y.U. ANN. SURV. AM. L. 151, 165–68 (2005) (arguing claims cannot cover after-arising technology because each term "must be interpreted as it was understood at the patent's filing and as it is supported by the patent's specification").

[141] *See, e.g.*, Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1286 (Fed. Cir. 2015).

[142] *See Juno Therapeutics, Inc.*, 10 F.4th at 1340.

[143] *See* IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1436 (Fed. Cir. 2000) (explaining "when in a claimed 'means' limitation the disclosed physical structure is of little or no importance to the claimed invention, there may be a broader range of equivalent

However, practical and policy considerations could limit this strategy. First, this approach is relatively untested. The PTO recently rejected an antibody combination genus claim drafted in the Jepson structure over insufficient written description for prior art elements.[144] And, Federal Circuit precedent may support that rejection.[145] Further, patentees may not want to distinguish from prior art and thus limit their claim scope and exclusionary rights.[146]

With proper interpretation, a Jepson claim structure can retain the benefits of combination genus claims while fulfilling written description policy aims.

2. Structural Claiming

The second strategy is to draft claims with structural elements. The Federal Circuit distinguishes claims to functional properties from claims to chemical structures.[147] A functional limitation recites a property or effect. A structural limitation recites a molecular formula or configuration. For example, the Federal Circuit found sufficient written description for "solvates" as a generic element because it was structural (i.e., the species "need not produce a desired result or otherwise perform a certain function") and the specification defined, "however broad, . . . certain structures produced by certain processes."[148] The *Immunex* claims illustrate successful use of this approach.[149]

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structures than if the physical characteristics of the structure are critical in performing the claimed function in the context of the claimed invention").

[144] *Ex Parte* Aaron Keith Chamberlain, No. 2022-001944, 2022 WL 17830711, at *10 (P.T.A.B. Dec. 19, 2022) (rejecting argument that "reference to prior art publications in the Jepson claim format" sufficiently satisfied the written description requirement for claims to an antibody binding to a particular target), *reh'g denied*, 2023 WL 3749901, at *10 (P.T.A.B. May 30, 2023), *remanded sub nom. In re* Xencor, Inc., No. 2023-2048, 2024 WL 244319, at *1 (Fed. Cir. Jan. 23, 2024) (granting PTO motion to remand to agency to "clarify" the agency's position); *Ex Parte* Aaron Keith Chamberlain, No. 2022-001944, Decision on Appeal, at *18-28 (P.T.A.B. May 21, 2024) (rejecting a Jepson claim which recites "an anti-C5 antibody"in the preamble for insufficient written description because the specification disclosed only a single anti-C5 antibody).

[145] *See* Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 315 (Fed. Cir. 1985) (holding, for Jepson claims, "the claimed invention consists of the preamble in combination with the improvement"); *see also* Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997) ("When [the Jepson form] is employed, the claim preamble defines not only the context of the claimed invention, but also its scope.").

[146] *See* Evans v. Eaton, 20 U.S. 356, 387–89 (1822); *see also* Menell & Meurer, *supra* note 130, at 1, 14.

[147] *See, e.g.*, AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1301 (Fed. Cir. 2014); GlaxoSmithKline LLC v. Banner Pharmacaps, Inc., 744 F.3d 725, 731 (Fed. Cir. 2014).

[148] *GlaxoSmithKline*, 744 F.3d at 729–32.

[149] *See* Section III(C), *supra*.

Structural claiming offers several policy benefits. First, it provides more effective notice than functional claiming.[150] Other inventors can identify species falling within and outside of the claims with only analytical testing and without functional testing.[151] Such analytical testing, for both the applicant and other inventors, is now widely available.[152] Second, structural claiming better limits scope to subject matter that patentees invented and disclosed, enforcing the quid pro quo bargain. Third, substantial precedent supports this strategy. The Federal Circuit is more likely to find functional claims as improperly claiming a hypothesis or a challenge to be solved, while structural claims properly claim a solution.[153]

The policy benefits of structural claiming outweigh policy concerns. Narrower claims could discourage investment or, if too narrow, prevent disclosure altogether.[154] Patentees may prefer, if possible, to keep their inventions as trade secrets instead.[155] However, structural claiming does not necessarily mean patentees must lose claim scope. Patentees can recover exclusivity breadth through multiple claims and through continuation applications.[156] Indeed, a greater number of claims also aligns with written description policy aims by increasing notice to other inventors.

Because structural claiming directly addresses written description policy aims, patentees should draft combination genus claims through structural elements. To ensure sufficient breadth, patentees should include more claims or file continuation applications.

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[150] *See* Menell & Meurer, *supra* note 130, at 9–10, 12 (explaining owner entitled to build right up to their property line), 33–34 (arguing for increased notice with stronger written description enforcement at the U.S. Patent and Trademark Office).

[151] *See* Permutit Co. v. Graver Corp., 284 U.S. 52, 60 (1931) (holding that patent owners must "inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not").

[152] *See* Section IV.C(iii), *infra*.

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

[154] *See* Menell & Meurer, *supra* note 130, at 1 ("Property rights encourage investment in resource development by granting property owners rights to exclude and develop their resources . . . ."); *see also* Williams, *supra* note 30, at 446 ("Firms report in some surveys that they choose not to patent some inventions because of the disclosure requirement.").

[155] *See* Peter S. Menell, *Economic Analysis of Network Effects and Intellectual Property*, 34 BERKELEY TECH. L.J. 219, 244–45 (2019).

[156] *See, e.g.*, Brief for Peter S. Menell as Amici Curiae Supporting Neither Party at 37, Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898 (2014) (No. 13-369).

3. Enforce Narrower Constructions

The third strategy is for patentees to seek narrower constructions during litigation. The written description requirement is commensurate with the scope of the claims. Thus, courts are more likely to find sufficient written description for narrower claims.

During prosecution, applicants should ensure the specification supports claim constructions only as broad as supported by written description. Section IV(B)(1), *supra*, proposed the Jepson claim structure as one strategy to achieve supported claim constructions. Alternatively, the specification may include express, narrow constructions. If the specification provides broad definitions, a court may adopt these during construction, even if the specification does not provide sufficient written description to support claims with broad constructions.[157]

During enforcement, patentees should consider written description sufficiency in claim construction. *Juno* illustrates. The patent claimed a CAR with any CD19-binding scFv, but disclosed only one CD19-binding scFv.[158] The court construed the CD19-binding scFv element broader than supported by the specification.[159] By contrast, the hypothetical Jepson claim as discussed in Section IV(B)(1), *supra*, would have supported a narrower CD19-binding scFv construction. Because a Jepson claim structure would likely have limited construction to CD19-binding scFvs known in the prior art, the *Juno* patentee may have provided sufficient written description for the narrower scope of prior art CD19-binding scFvs. And, because the competitor's CD19-binding scFv

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[157] *See Ariad Pharms.*, 598 F.3d at 1365 ("[T]his court's new written description doctrine only has meaning if this court ignores its own claim construction rules. This court essentially claims unfettered power to err twice-both in construing the claims so broad as to exceed the scope of the rest of the specification and then to invalidate those claims because it reads the specification as failing to 'support' this court's own broad conception of the claimed subject matter.") (Rader, J., concurring); *see also* Baxalta Inc. v. Genentech, Inc., 972 F.3d 1341, 1349 (Fed. Cir. 2020) (finding broader construction of "antibody" supported by dependent claims even though the specification failed to demonstrate possession); Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1173 (Fed. Cir. 2019) ("There was substantial evidence that Gilead's fluorinated product is not within the scope of the claims as they reasonably could have been viewed by the jury . . . I would decide this appeal on the ground that the claims, correctly construed, are valid and not infringed.") (Newman, J., dissenting)*; but see* Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC, 824 F.3d 999, 1004 (Fed. Cir. 2016) ("Because the specification makes no mention of wireless communications, construing the instant claims to encompass that subject matter would likely render the claims invalid for lack of written description.").

[158] Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1340 (Fed. Cir. 2021); *see also* '190 Patent col. 25 ll. 45–46.

[159] *Juno Therapeutics*, 10 F.4th at 1336–42.

was known prior to the asserted patent's filing date, the narrower construction would not foreclose the patentee's infringement argument.[160]

Narrower constructions provide several policy benefits. First, as for structural claiming, this strategy aligns with the written description policy aim to limit claims to the inventors' actual invention. It encourages more disclosure to support the narrower construction.[161] Second, narrower constructions reduce notice uncertainty for other inventors. When the specification supports a narrower construction, other inventors can rely on that construction to determine the bounds of patentees' exclusivity.[162]

The policy challenges for structural claiming apply to this strategy as well. Narrower individual claims could require patentees to draft applications with many claims or file continuation applications to achieve proper exclusivity breadth.[163] If claims must be very narrow (e.g., limited to just the disclosed sequence(s)), this approach may become impractical.

Patentees should argue for, and judges should grant, narrow constructions supported by the specification. Narrow constructions afford policy benefits and patentees can tailor invention breadth during prosecution.

C. Disclose More

Three additional strategies align with written description requirement policy aims by encouraging patentees to disclose more: (1) incorporate prior art by reference and, if relevant, provide sequence reference numbers to public databases; (2) disclose relationships between chemical and/or biological structures and their functions; and (3) deposit samples in a public repository.

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[160] *Id.* at 1340.

[161] *See generally* J. Jonas Anderson & Peter S. Menell, *Informal Deference: A Historical, Empirical, and Normative Analysis of Patent Claim Construction*, 108 N.W. U. L. REV. 1, 71–73 (2013).

[162] *See* Athletic Alts., Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996) ("Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.").

[163] *See* Brief for Peter S. Menell as Amici Curiae Supporting Neither Party, *supra* note 156, at 37.

1. Incorporate by Reference and/or Sequence

The first disclosure strategy calls for patentees to incorporate relevant DNA, RNA, or amino acid sequences by reference in the specification to a listing in a public database or a prior art publication. Patentees can incorporate, by reference, prior art sequences and inventive sequences, as illustrated by *Immunex*.[164]

Incorporation by reference affords several policy benefits. First, it improves notice to other inventors. Other inventors may identify patentees' sequences in a public database that is more searchable than patent databases.[165] Incorporating prior art publications by reference often highlights key features of inventions by distinguishing from publication disclosures. Second, databases and publications often provide greater detail about sequences to supplement patent disclosures. For example, in addition to a protein's amino acid sequence, a database may provide an interactive three-dimensional protein model. Third, incorporation by reference affords more certainty for patentees so that a court will understand the prior art context for their invention. For example, in evaluating written description sufficiency, courts recognize that patentees "need not redescribe known prior art concepts."[166] Defining the prior art is especially important to support Jepson claims.[167] Incorporation by reference affords an opportunity to patentees to inform patent examiners and judges about the most relevant prior art. Fourth, incorporation by reference could reduce the burden on PTO patent examiners. While patentees have a duty to disclose known, relevant art to the PTO, they do not have a duty to explain to examiners why that art is relevant.[168] When patentees incorporate prior art by reference in the specification, they explain that art's relevance to their invention.

The policy benefits of incorporation by reference outweigh policy concerns. First, as with the narrower claiming strategies in Section IV(B), incorporating

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[164] *See* Section III(C), *supra*.

[165] One example of a public database for sequences is GenBank hosted by the National Institutes of Health (https://perma.cc/2QKN-ZTKT).

[166] Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1338 n.2 (Fed. Cir. 2021).

[167] *See* Section IV(B)(i), *supra*.

[168] *See* 37 C.F.R. § 1.56(a) (Aug. 14, 2012) ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section."); *see also* 37 C.F.R. § 1.98 (Sept. 21, 2004) (satisfying 37 C.F.R. § 1.56 requires disclosure of "[a] list of all patents, publications, applications, or other information submitted for consideration by the Office").

sequences and art by reference may reduce investment by narrowing claim scope. Patentees will need to convince PTO examiners their claims are sufficiently narrow to avoid prior art and sequences incorporated by reference. However, while narrower claims could afford less exclusivity, they also afford greater certainty to patentees. Second, this strategy increases the disclosure burden for patentees. However, the increase is relatively minimal as incorporation by reference requires only a single sentence. And patentees should use the incorporation as an opportunity to guide judges' later understanding of how their inventions differ from the prior art.

Because incorporation by reference aligns with written description policy aims, patentees should use this approach to improve specifications and courts should rely on these incorporations in adjudicating novelty, non-obviousness, and claim construction.

2. Disclose Structure-Function Relationships

The second disclosure strategy encourages patentees to, when known or knowable, disclose the relationship between chemical and/or biological structures and their functional properties. While most strategies discussed in this Note involve narrowing claim breadth, this strategy offers a method to increase claim breadth by disclosing more. And, disclosing structure-function relationships strongly aligns with written description policy aims. *Centocor* and *Juno* illustrate insufficient structure-function disclosure while *Immunex* illustrates effective structure-function disclosure.

The Federal Circuit has explained that a "sufficient description of a genus…requires [1] the disclosure of either a representative number of species falling within the scope of the genus or [2] structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus."[169]

Prong 1 may require an impractical time and resource investment. The first prong requires disclosing sufficient species to demonstrate possession of the entire genus claim breadth:

> One describes a plot of land by its furthest coordinates, in effect drawing a perimeter fence around it. That may be akin to the function of patent claims to particularly point out and distinctly circumscribe the

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

> outer boundaries of a claimed invention. With the written description of a genus, however, merely drawing a fence around a perceived genus is not a description of the genus. One needs to show that one has truly invented the genus, i.e., that one has conceived and described sufficient representative species encompassing the breadth of the genus. Otherwise, one has only a research plan, leaving it to others to explore the unknown contours of the claimed genus.[170]

Taken to its extreme, prong 1 motivates a "laundry list"-type disclosure of possible species.[171]

The second prong arguably requires lesser resources and aligns more closely with the spirit of the written description quid pro quo. First, applicants need not actually design or make a representative number of species and may rely on structure-function relationships known in the art as illustrated by the *Immunex* holding in Section II(C), *supra*.[172] Applicants may disclose, or reference prior art disclosing, structural features corresponding to a claimed functional genus. Second, while species disclosures are useful, correlational relationships guide a POSA "into what [species] beyond the examples and formulas, if any, would provide the same result."[173]

Neither an antibody's target antigen structure nor its binding affinity for that antigen sufficiently disclose an antibody under the second prong.[174] The *Centocor* court held disclosure of antigen structure as insufficient written description for a human antibody.[175] As recently as 2017, the Federal Circuit affirmed this view:

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[170] AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1300 (Fed. Cir. 2014); *see also* Alcon Rsch. Ltd. v. Barr Lab'ys, Inc*.,* 745 F.3d 1180, 1190–92 (Fed. Cir. 2014) (finding genus claims adequately supported by disclosing "a range of various formulation parameters" across several exemplary formulations).

[171] *See* Regents of the Univ. of Minnesota v. Gilead Scis., Inc., 61 F.4th 1350, 1357 (Fed. Cir. 2023).

[172] *See AbbVie Deutschland*, 759 F.3d at 1301 ("[F]unctionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established, whether by the inventor as described in the specification or known in the art at the time of the filing date.").

[173] Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1339 (Fed. Cir. 2021) (quoting Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1164 (Fed. Cir. 2019)).

[174] *See* Lemley & Sherkow, *supra* note 126, at 1014–37 (providing an excellent history of antibody claiming strategies).

[175] Centocor Ortho Biotech, Inc. v. Abbott Lab'ys, 636 F.3d 1341, 1352 (Fed. Cir. 2011).

> We cannot say that this particular context, involving a "newly characterized antigen" and a functional genus claim to corresponding antibodies, is one in which the underlying science establishes that a finding of "make and use" (routine or conventional production) actually does equate to the required description of the claimed products. For us to draw such a conclusion, and transform a factual issue into a legally required inference, we would have to declare a contested scientific proposition to be so settled as to be entitled to judicial notice.[176]

Similarly, antigen binding strength also does not sufficiently disclose an antibody because structurally diverse antibodies may bind an antigen with similar strength.[177] Rejection of antigen structure and binding strength as sufficient aligns with written description policy. If only antigen disclosure were sufficient, patentees could "claim antibodies by describing something that is not the invention, i.e., the antigen."[178]

Instead, applicants should disclose the structural characteristic(s) which permit *claimed* species to perform a claimed function.[179] For example, to achieve claim scope beyond known, prior art species, the *Juno* patent specification could have provided sufficient written description for scFvs by disclosing "the characteristics of the exemplary scFvs that allow them to bind to particular targets or nucleotide sequences." A general scFv structure was insufficient.[180] The disclosed structural commonalities must be sufficient to "distinguish those scFvs capable of binding from scFvs incapable of binding those targets" such as through "amino acid sequences or other distinguishing characteristics."[181] However, the structure-function relationship requirement does not demand "perfect correspondence between members of the genus and

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[176] Amgen Inc. v. Sanofi, 872 F.3d 1367, 1378 (Fed. Cir. 2017) (in the context of a disclosure requirement related to written description called enablement).

[177] *See AbbVie Deutschland*, 759 F.3d at 1300–01 (finding insufficient written description because "structurally diverse antibodies" satisfied the claimed functional attributes, but the specification disclosed only "species of structurally similar antibodies").

[178] *Amgen*, 872 F.3d at 1378.

[179] Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1337 (Fed. Cir. 2021) ("Without more in the disclosure, such as the characteristics of the exemplary scFvs that allow them to bind to particular targets or nucleotide sequences, the mere fact that scFvs in general bind does not demonstrate that the inventors were in possession of the claimed invention.").

[180] The specification disclosed scFv structure as "a variable region derived from the light chain of an antibody and a variable region derived from the heavy chain of an antibody, where these two portions are connected with a linker." *Id.* at 1338–39.

[181] *Id.* at 1339.

the asserted common structural feature," just a "more modest[] 'correlation between structure and function.'"[182] In the context of protein- or DNA-based claims, applicants could distinguish sequence regions critical to a claimed functionality (e.g., the antibody variable region) from those in which a modified sequence is unlikely to affect function (e.g., the antibody constant region). Within less critical regions, applicants could specify the types of variation least likely to affect function.[183] For example, scientists frequently group amino acids by shared properties like size and charge.[184] Similar to the *Immunex* specification, specifications could embrace variations when one amino acid replaces a similar amino acid in a less critical region.[185] Applicants may further support structure-function disclosures with reference to prior art structure-function disclosures.[186]

Several policy arguments support disclosing structure-function relationships. First, such disclosure ensures patentees receive exclusivity commensurate with their disclosure. As in the Antibody α example in Section II(C), *supra*, a patentee could invent a genus comprising, e.g., 6^{1540} species capable of performing the same or a similar useful function. The patentee can support claims covering substantial claim breadth by disclosing structure-function relationships. Consider three scenarios (Figure 3). In the first scenario, the specification discloses only a single Antibody α sequence and one functional property (let's call it "Function β"). A court will likely not limit claim scope to *only* the disclosed sequence but is unlikely to afford much scope beyond minor tweaks to that sequence.[187] In the second scenario, the patentee discloses how Antibody α performs Function β, regions key to Function β (as well as less important regions), and amino acid substitutions with minimal effect on Function β. At a minimum, the patentee "embraces allelic variants and

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[182] Ajinomoto Co. v. Int'l Trade Comm'n, 932 F.3d 1342, 1360 (Fed. Cir. 2019).

[183] *See* Immunex Corp. v. Sandoz Inc., 964 F.3d 1049, 1064 (Fed. Cir. 2020) (finding sufficient written description, in part, because "[t]he specification . . . 'embraces allelic variants and DNA sequences resulting from deletions, substitutions, and additions of one or more nucleotides of the sequences provided in Figures 1 and/or Figure 4.'").

[184] *See, e.g.*, Jean-Luc Fauchère et al., *Amino Acid Side Chain Parameters for Correlation Studies in Biology and Pharmacology*, 32 INT. J. PEPTIDE RES. 269 (1988) ("Fauchère 1988").

[185] *See* Section III(C), *supra*.

[186] *See Ajinomoto*, 932 F.3d at 1359–60 (holding a structure-function relationship disclosed only by the prior art sufficient to overcome a written description challenge to a functional genus because "[s]ubstantial evidence," including two scientific publications, affirmed the structure-function relationship).

[187] *See* AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1299–1301 (Fed. Cir. 2014) (analogizing a claimed genus to a plot of land and finding insufficient disclosure if disclosed species "only abide in a corner of the genus").

DNA sequences resulting from deletions, substitutions, and additions of one or more nucleotides of the sequences" disclosed as in *Immunex*.[188] The patentee identifies amino acids involved in Function β activity and amino acids irrelevant to Function β.[189] They also identify substitute amino acids with similar properties expected to result in comparable antibody folding and Function β activity. Because the patentee explained how and why a POSA might create functionally similar equivalents to Antibody α, a court should find support for greater claim scope around Antibody α than in scenario 1. In the third scenario, the patentee discloses everything from scenario 2 as well as similar disclosures for three additional antibodies. Assuming these four antibodies are structurally distinct but capable of performing Function β similarly, a court should find support for a broad claim scope approaching that of functional claims.[190]

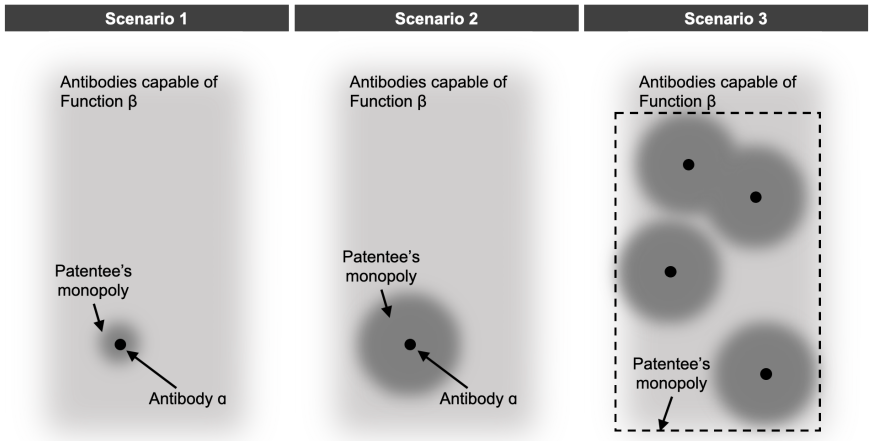

Figure 3. Structure-function disclosure supports greater claim breadth. In scenario 1, the patentee disclosed only the Antibody α sequence (black dot) and Function β (light grey box). Many other antibodies may also perform Function β, but a court would likely limit the patentee's monopoly to antibodies structurally like Antibody α (medium grey shading around black dot). In scenario 2, courts may allow the patentee to claim antibodies slightly more diverse than in scenario 1 (larger

[188] *Immunex*, 964 F.3d at 1064.
[189] To the extent this information is not available in the prior art, the patentee may have to invest substantial resources to identify this information.
[190] *See AbbVie Deutschland, KG*, 759 F.3d at 1299–1301.

medium grey shading around black dot) because the patentee disclosed some Antibody α structural modifications which retain Function β. In scenario 3, courts may allow patentees claim scope comparable to functional claiming (dashed black box) because the patentee disclosed Antibody α and three other structurally dissimilar antibodies (black dots) capable of Function β and structural modifications of each which retain Function β.

Second, structure-function disclosure provides competitors with reasonable notice about claim bounds. They could design around the patentee's invention by identifying antibodies substantially structurally different from Antibody α or by modifying Antibody α in ways not expected to produce the same function.[191] And, the disclosed structure-function relationships could provide the foundation for designing other antibodies with a different useful function.

The downsides of structure-function disclosure are outweighed by the benefits. This strategy places more disclosure burden on patentees. Patentees must invest more time and money into research to identify structure-function relationships prior to filing for a patent. The additional time will result in a later filing date, potentially narrowing patentees' available claim scope due to additional prior art. However, assuming limited intervening prior art, increased disclosure commensurately benefits patentee with the ability to seek broader claims. And, patentees can tailor their disclosure to the desired claim breadth, based on prior art knowledge, their resources to develop structure-function relationships, and the pace of competitors' innovation. Scenario 1's minimal disclosure is always an option if patentees feel competitive pressure to seek a patent quickly.

Because disclosing structure-function relationships closely aligns with the quid pro quo bargain for chemical and biotechnology inventions, patentees should adopt this approach when seeking broad combination genus claims. Courts should view such disclosure as sufficient to satisfy the written description requirement, even in cases when claims cover vast genera with millions of species.

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[191] *See id.* at 1300–01.

3. Deposit Samples

The third disclosure strategy is for patentees to deposit chemical or biological samples in a public repository. Applicants can demonstrate adequate written description by depositing samples of species (e.g., proteins, strands of DNA, engineered cells) within the claimed genus.[192] *Immunex* illustrates.[193] To support claim scope beyond the deposited species, applicants may further disclose structure-function relationships as described in Section IV(C)(2), *supra*.

This strategy affords modest policy benefits. First, some older precedent upheld claims as sufficiently supported when patentees deposited samples of the claimed invention.[194] Second, deposit affords some notice to competitors, depending on patentees' claim scope. If claim scope is narrowly tailored to deposited samples, others can access samples to perform testing (e.g., genetic sequencing or functionality testing) and design around patentees' rights. To the extent claim scope exceeds deposited samples, this strategy provides only minimal notice. Courts initially supported depositing samples to satisfy the written description requirement when genetic sequencing was harder, less widely available, and more expensive.[195] Today, patentees are much more likely to perform analytical characterization (e.g., sequences, three-dimensional structures).[196] Disclosure of analytical characterization provides at least as much notice, if not more, than depositing samples in a repository because competitors may directly know the claimed structure(s) without performing their own analytical testing on a deposited sample. Further, other strategies such as disclosing structure-function relationships, afford better notice than this strategy.

Because advances in analytical techniques enable patentees to describe their inventions through primary sequence and, often, three-dimensional structure, this strategy does little to advance written description policy aims.

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[192] *See, e.g.*, *Immunex*, 964 F.3d at 1065 ("And Immunex points to the reference in the specification to deposited vectors, which is an adequate description of the precise IgG1 sequence to be used in the claimed fusion proteins. We again agree with Immunex." (citation omitted)).

[193] *See* Section III(C), *supra*.

[194] *See* Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002) ("For biological inventions, for which providing a description in written form is not practicable, one may nevertheless comply with the written description requirement by publicly depositing the biological material . . . .").

[195] *See, e.g.*, Shendure et al., *DNA Sequencing at 40: Past, Present and Future*, 550 NATURE 345, 346–47 (2017) (explaining DNA and RNA sequencing became more widely available in the early 2000s).

[196] *See id.* at 345–47.

Patentees can provide samples of their invention to public repositories, but courts should not hold non-deposit against them if they provide sufficient analytical characterization in the specification.

V. CONCLUSION

Proper application of the written description requirement is essential to incentivize medical advances—innovation which requires substantial risk and investment to achieve breakthroughs. Tailoring the written description bar to the right height to achieve policy aims requires courts to account for inherent aspects of the science, such as redundancy in biological sequences. Current jurisprudence inconsistently applies too high a bar for life sciences inventions, often by failing to appreciate such inherent aspects of life sciences inventions. Inconsistency causes uncertainty. And, uncertainty may adversely affect investment to advance life-saving research.

Several strategies may further written description policy goals and mitigate recent uncertainty. Courts should refrain from encouraging broader claims, e.g., invalidating claims based on "known" elements like in *Juno*. More policy aligned approaches to avoiding *Juno* outcomes include drafting claims in the Jepson structure and construing "known" elements as limited to those disclosed by the prior art. Other strategies from Federal Circuit precedent provide patentees with a policy-aligned roadmap to satisfy the written description requirement. Patentees should claim by structure and disclose structure-function relationships in the specification as illustrated by the *Immunex* holding. These relationships should form the basis of a POSA's understanding during, e.g., claim construction and a doctrine of equivalents analysis. The specification should also provide the requisite detail to establish reasonably narrow constructions. The proposed strategies should provide patentees with sufficient certainty to ensure investment in research and development and afford competitors reasonable notice. In particular, the structure-function disclosure strategy especially benefits the public by providing knowledge for future innovation.

Courts should be wary of holding combination genus claims to life sciences invention to too high a written description bar. Monopolies are powerful tools to those in control. But, patent law narrowly tailors and time-constrains monopolies to incentivize innovation and disclosure for public benefit. Courts should continue to use the written description requirement to hold patentees to their end of the quid pro quo bargain and to protect innovation space for

future inventors. *Centocor* illustrates a successful use of written description to prevent chilling adjacent innovation. At the same time, courts should not overly restrict patent monopolies at the expense of stalling medical innovation. *Juno* illustrates one such outcome. To best incentivize life-saving medical breakthroughs, the law should strive to get the science right.