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In Support of Industry-Conscious Disclosure Standards for Pharmaceutical and Biotechnology Patents

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IN SUPPORT OF INDUSTRY-CONSCIOUS DISCLOSURE STANDARDS FOR PHARMACEUTICAL AND BIOTECHNOLOGY PATENTS

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ABSTRACT

One of the fundamental requirements for a patent application is a disclosure of the invention via an accurate written description with sufficient detail to enable the recreation of the invention. The U.S. patent system has historically reviewed patent applications from various industries with a uniform set of requirements and standards. However, the biotechnology and pharmaceutical industries operate on notably extended product development timelines and face unique administrative pressures related to their products when compared with other industries. In response to these pressures, biotechnology and pharmaceutical companies have traditionally applied for patent protections through liberal use of genus claims and other strategies that allow for early and broad protection of groups of related products. However, three recent decisions by the Federal Circuit, and a subsequent appeal to the Supreme Court, have notably heightened patent disclosure requirements for technologies from these industries. This Comment discusses the Federal Circuit's and Supreme Court's decisions, compares these decisions to prior trends in the judiciary, and considers the potential impact of the decisions on the patent environment in the biotechnology and pharmaceutical industries. In light of the decisions' potential impact on these industries, this Comment argues that the federal judiciary should align the disclosure standard more closely to the requirements of the Patent Act while protecting the usefulness of genus claims for the pharmaceutical and related industries.

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I. INTRODUCTION

At its core, patent law's primary purpose is to establish a system that incentivizes technical innovation while simultaneously making the principles of such innovation available to the public.[1] Patent law enacts this dual-focus purpose—captured in the idea of the patent—to provide temporary periods of exclusivity to inventors of novel, nonobvious inventions in exchange for a public disclosure that details how to practice said invention.[2] Patent applications serve as the mechanism by which a patentee alerts the public to the patentee's invention, namely through disclosure of the invention via an accurate written description of the innovation with sufficient detail to enable the invention's recreation in the future.[3] As such, the Supreme Court has described the patent system's goal to be to "bring new . . . technologies into the public domain through disclosure" and disclosure's attendant requirements.[4]

The specification in a patent application is the fundamental mechanism by which an inventor discloses his claimed invention and thereby shares it with the public.[5] These claims must be narrow enough to provide a commensurate enrichment of public knowledge compared with the benefit conferred upon the inventor himself.[6] Naturally, an inventor's tendency to establish broad claims—thereby obtaining a greater scope of protection—conflicts with the general public interest in narrower, more specific claims that readily allow for free public use and experimentation in the conceptual space surrounding the protected invention. Requirements for disclosure in patents and patent applications serve to balance these competing interests and enforce the underlying agreement between the inventor and the public.[7] As such, disclosure requirements set standards for how much an inventor must reveal in his claims in order to effectively disclose and teach the relevant information to the public.[8]

The fundamental principles underlying patent law are enforced against patents regardless of the industry associated with the invention.[9] This creates situations in which the uniform

[1] *See* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) (citing Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974)).

[2] *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998).

[3] *See* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 546 (2009).

[4] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

[5] *See* Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101, 103 (2005).

[6] *See* Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (1999).

[7] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 922 n.5 (Fed. Cir. 2004) (emphasizing the role of claims to teach the public what the invention is and how to make it).

[8] *Id.*

[9] *See generally* Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845 (2006) (discussing the uniformity of standards applied across industries in U.S. intellectual property law) [hereinafter Carroll, *One for All*]; Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L.J. 1361 (2009) (discussing the presumption

application of patent review standards—such as the written description and enablement disclosure requirements—may create unanticipated challenges when applied to different types of technology across industries.[10] Such challenges surface, in part, because of the specific nature of disclosures that are possible and appropriate for technologies within a given industry. For example, many innovations in the pharmaceutical and biotechnology industry—such as chemical agents or therapeutic biological formulations—are likely to have closely related chemical or compositional equivalents that can be readily derived by other practitioners to perform similar useful functions to the claimed innovation.[11] The existence of such readily derived compounds may break down the incentive mechanism of the patent system in these industries unless broader protections are allowed for a given disclosure. In addition, the long development cycles and regulatory requirements for medical inventions may further motivate inventors to seek broad patent protections at earlier stages in an invention's development cycle.[12] Without the adoption of disclosure standards tailored to these industries and technologies, inventors may face an uncomfortable decision: whether to risk prosecuting an easily challenged but sufficiently broad patent application, or to prosecute a narrow patent application that is likely to be accepted but unlikely to effectively exclude potential competitors from the market. While courts previously applied some alternative review standards to disclosure analyses for pharmaceutical and biotechnology patents, recent trends in courts' reviews of patent applications have moved away from such industry-specific review standards.[13]

This Comment focuses on recent trends in the Federal Circuit and Supreme Court that favor strict standards of review for patent disclosure in pharmaceutical and biotechnology patents. In particular, this Comment explores the Federal Circuit's invalidation of pharmaceutical patents based on inadequate disclosure in *Amgen v. Sanofi*, *Juno Therapeutics v. Kite Pharma*, and *Biogen International v. Mylan Pharmaceuticals*.[14] Furthermore, this Comment will explore the implications of these decisions for patent prosecution in the pharmaceutical and biotechnology industries, as well as the subsequent decision by the Supreme Court in *Amgen v. Sanofi*.[15] This is not a simple set of interests to fully analyze or reconcile, but the objective here is to explore the potential impact of these cases—and associated trends—on the pharmaceutical industry and on the fundamental incentive scheme of patent law.

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of uniformity across industries in patent law and copyright law); Glynn S. Lunney, Jr., *Patent Law, the Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 SUP. CT. ECON. REV. 1 (2004) (discussing the uniformity in patent protection across industries and the associated costs of uniformity).

[10] Industry-specific challenges related to the uniform application of patent standards have been recognized by the legislature. For example, the passage of the Drug Price Competition and Patent Term Restoration Act in 1984 (the Hatch-Waxman Act) added additional considerations which allow extension of the patent term for certain products that are subject to regulatory approval. *See* 35 U.S.C. § 156(f).

[11] Previously, genus claims were frequently used to circumvent this weakness in chemical and pharmaceutical patent disclosure. These claims used functional language, generic formulas, and representative examples to describe a group of related species. *See* Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 13–14 (2021) (discussing the historic use of genus claims and subsequent court trends undermining their use).

[12] *See* Maximillian Schellhorn, *The Promise and Peril of Industry-Specific Patent Law*, 22 VA. J.L. & TECH 228, 168–69 (2019) (discussing the FDA drug approval process and the related impact on patent application timing).

[13] *See generally* Karshtedt et al., *supra* note 11 (discussing the weakening of genus claims in the chemical, biotechnology, and pharmaceutical industries).

[14] Amgen Inc. v. Sanofi, 987 F.3d 1080 (Fed. Cir. 2021), *aff'd*, 598 U.S. 594 (2023); Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021); Biogen Int'l GMBH v. Mylan Pharms. Inc., 18 F.4th 1333 (Fed. Cir. 2021).

[15] Amgen Inc. v. Sanofi, 598 U.S. 594 (2023).

In Part II, this Comment discusses the disclosure function of patents. The patent quid pro quo will be defined more specifically, including the balancing of interests between the patentee and the public in the modern context. The elements for disclosure of a patented invention—written description and enablement—will be described as courts apply them against challenged patents.

In Part III, this Comment discusses the unique conditions influencing innovation in the pharmaceutical and biotechnology industries and the ways in which courts have considered these conditions in the past. Policy implications for failure to consider these conditions will also be discussed in length. Furthermore, this discussion will focus on recent Federal Circuit and Supreme Court decisions that apply heightened written description and enablement standards against patents in the pharmaceutical and biotechnology industries.

Part IV then discusses potential solutions to these issues, such as updated procedures for the prosecution of biotechnology patents and the restoration of court support for traditional industry-specific review standards such as the genus claim.[16] In particular, this Comment proposes that federal courts abandon the heightened disclosure requirements represented by the Federal Circuit's recent decisions. Finally, this Comment concludes with a discussion of potential changes to the traditional review standards for genus claims, with the aim of maintaining the usefulness of genus claims for particular industries while mitigating concerns regarding their potential chilling effect on innovation.

II. DISCLOSURE AND THE PATENT

The U.S. patent system is fundamentally based on the idea that there is an exchange between an inventor's interest in his invention and society's interest in free access to information regarding new innovations.[17] An inventor is incentivized to reveal information about his invention when he receives something—such as a limited period market exclusivity—in exchange for publicly revealing the details of his invention.[18] It is this mutual exchange, a benefit to the inventor in exchange for a disclosure to the public, that fully embodies the underlying bargain between an inventor and the public in the U.S. patent system.[19]

A. *The Disclosure Function of Patents*

Disclosure is a central consideration in patent policy, as it directly affects the incentive scheme promoting the interests of inventors and the public.[20] By requiring an inventor to fully disclose the details of his invention, the patent system promotes public access to information that may otherwise remain hidden.[21] A patent application's disclosure "add[s] to the sum of useful knowledge" to communicate information that others, including rival inventors, can use for further development.[22] This is especially important in the modern industrial context, where a large portion of patented technologies may not be readily reproducible without detailed accounts of an

[16] *See* Karshtedt et al., *supra* note 11.

[17] *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998).

[18] *Id.*

[19] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

[20] *See* John M. Olin, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2011 (2005).

[21] *See* J. Jonas Anderson, *Nontechnical Disclosure*, 69 VAND. L. REV. 1573, 1585 (2016).

[22] *See* Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 6 (1966); Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 267 (1994).

inventor's methods and processes (e.g., complex molecule synthesis, industrial processes, genetically engineered organisms).[23] Therefore, disclosure is an integral component of maintaining the public's interests, as disclosure provides the information the public needs to fully benefit from the bargain. Understandably, this also means that requirements for disclosure result in conflict when patentees attempt to obtain patents that protect large groups of products, as is considered necessary in certain industries.[24]

B. *Sufficiency of Disclosure: Enablement and Written Description*

The bargain underlying patent law is only served when a patent's specification—the description of the invention—is sufficiently detailed to disclose the relevant technical information to the public. The Patent Act requires that the claims of the application "contain a written description of the invention, and of the manner and process of making and using it . . . as to enable any person skilled in the art . . . to make and use the same."[25] As courts have interpreted this section, the statutory language requires that a patent application provide a sufficiently detailed disclosure to teach a person of ordinary skill in the art (a "POSITA") "how to make and use" the invention without undue experimentation.[26] This teaching requires that a patentee's disclosure enable others in the industry to reproduce the invention while also including a written description that clearly identifies the claimed invention.[27] Though related, each of these requirements is distinct.[28] Together, they ensure that a patent sufficiently discloses a claimed invention and prevents overreaching by the patentee.[29]

To sufficiently disclose an invention, a patent application must enable a POSITA to recreate and use the described invention without undue experimentation.[30] Enablement ensures that an inventor's disclosure adds to public knowledge and helps guarantee that the public will be able to recreate the invention following the expiration of the patent.[31] At the same time, enablement serves to constrain the inventor's patent claims and prevents unsupported, broad claims from stifling innovation.[32] The Federal Circuit set forth clear factors for the enablement question in *In re Wands*.[33] The *Wands* factors indicate that the enablement question should consider the following:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature

[23] *See* Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 105–06 (2004).

[24] *See* Karshtedt et al., *supra* note 11 (discussing the broad protections sought through genus claims in the chemical and pharmaceutical industries).

[25] 35 U.S.C. § 112(a).

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

[27] *See id.* (describing the enablement requirement in patent disclosure analyses).

[28] *In re* Ruschig, 379 F.2d 990, 995 (C.C.P.A. 1967) (defining "written description" as a distinct disclosure requirement).

[29] *See* Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991).

[30] *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (discussing that it is "well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation").

[31] *See* Evans v. Eaton, 20 U.S. 356, 418 (1822).

[32] *Id.*

[33] *In re* Wands, 858 F.2d at 737 (discussing that it is "well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation").

> of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability in the art, and (8) the breadth of the claims.[34]

Any determination regarding enablement must consider whether the disclosure was enabling "as of the effective filing date of the patent."[35] Taken together, the *Wands* factors provide a standard by which the required degree of disclosure is dependent, in part, upon the specific invention at issue and the relevant technical field.

By contrast, the written description sets a requirement that a patent's specification contain a written description with "such full, clear, concise, and exact terms" as to describe what exactly is claimed within the patent's specification.[36] A claimed invention meets the written description requirement if there is an adequate description within the patent specification such that a POSITA could recognize that the inventor "was in possession of the invention" when the inventor originally filed their application.[37] Notably, an invention may be enabled without having an adequate written description, in which case the inadequately described—yet still enabled—invention will not be protected under the patent.[38] For example, if a process is developed that can synthesize compounds A, B, and C, compound A will be sufficiently disclosed if it is clearly described within the specification.[39] In contrast, compounds B and C would be enabled by such a disclosure.[40] They are, after all, products of the process described. However, if the patent specification does not describe compounds B and C, the specification will not satisfy the written description requirement for these compounds.[41] Therefore, compounds B and C would not be sufficiently disclosed under the claim language, and the patentee would only obtain protection for compound A and the process as a whole.[42] The written description is thus an independent requirement from enablement, and both are required for an invention to be fully disclosed.[43]

The enablement and written description requirements, as described above, generally apply to all patent applications—regardless of the industry associated with the invention—as part of the uniform approach to patent review standards.[44] While the *Wands* factors theoretically allow the flexibility to consider the nature of a technology during the enablement analysis, courts may vary substantially in how they implement or weigh these individual factors in their decisions. For example, some courts in recent decisions have chosen not to consider the factors at all.[45] This inconsistency could result in a sea of precedent that is inconsistent or otherwise unclear regarding the amount of disclosure necessary to establish that an inventor possessed their invention when

[34] *Id.*

[35] Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339 (Fed. Cir. 2003).

[36] 35 U.S.C. § 112(a); *In re* Ruschig, 379 F.2d 990, 995–96 (C.C.P.A. 1967) (holding that although the specification described appellants' invention, the specification did not convey that "appellants invented th[e] specific compound").

[37] Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563–64 (9th Cir. 1991).

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

[39] *Cf. id.* at 1405 n.1.

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *See In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *In re* Ruschig, 379 F.2d 990, 995–96 (C.C.P.A. 1967).

[44] *See generally* Carroll, *One for All*, *supra* note 9.

[45] *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (refusing to consider *Wands* factors and referring to the factors as "illustrative").

they submitted their patent application. Furthermore, the choice not to consider industry-relevant factors—or to apply those factors too selectively—may ultimately impact companies' ability to obtain effective patent protections for technologies in the complex pharmaceutical or biotechnology industries. Therefore, the courts' recent decisions against broad claiming strategies in *Amgen*, *Juno*, and *Biogen* merit additional discussion concerning the enforcement of disclosure requirements, the actual disclosures required by the courts, and the potential impact of such requirements on the patent process in these industries.

III. REJECTION OF BIOTECHNOLOGY PATENTS ON DISCLOSURE GROUNDS

A. *Pharmaceutical and Biotechnology Development Cycles*

Historically, the pharmaceutical and biotechnology industries have faced pressures—both internal and external—that have uniquely shaped these industries when compared with other engineering-based disciplines. For example, the pharmaceutical and biotechnology industries may be distinguished from more traditional industries based on the inherent degree of understanding that practitioners possess concerning the underlying mechanisms of their innovations.[46] Innovation in traditional engineering tends to focus on the direct application of processes and techniques developed using well-understood principles from disciplines such as physics and the computer sciences.[47] Pharmaceutical and biotechnological innovations, on the other hand, are based upon fundamental discoveries in biology, a scientific discipline in which the discovery process is beset by unique issues related to the inherent "messiness" of the research and available experimental techniques.[48] The difficulties associated with underlying biological research can result in unusual situations that would normally not be seen in other industries, such as the development of useful products for which the underlying mechanism of action is not well understood.[49] As such, patent applicants from the pharmaceutical and biotechnology industries face the unique challenge of drafting patent applications that fulfill disclosure requirements without always having a clear picture of the product's underlying chemical or biological functions.

The pharmaceutical and biotechnology industries also face unique pressures during product development when compared with more traditional engineering firms.[50] In particular, product development in the pharmaceutical and biotechnology industries is a long, uncertain, and highly

[46] *See* Jackie Hutter, *A Definite and Permanent Idea? Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law*, 28 J. MARSHALL L. REV. 687, 687–89 (1995).

[47] For examples of the development and application of such principles historically, *see generally* NEWTON COPP & ANDREW ZANELLA, DISCOVERY, INNOVATION, AND RISK: CASE STUDIES IN SCIENCE AND TECHNOLOGY (1993) (discussing the interplay between engineering and related scientific disciplines during the development of telegraphy and the airplane, among others).

[48] *See* Dan S. Tawfik, *Messy Biology and the Origins of Evolutionary Innovations*, 6 NATURE CHEM. BIOLOGY 692 (2010) (discussing the inherent "messiness" tied to the complexity of biological systems and the impact of such messiness on the accuracy of experiments).

[49] *See, e.g.*, Heidi Ledford, *Many Cancer Drugs Aim at the Wrong Molecular Targets*, NATURE (Sept. 11, 2019), https://www.nature.com/articles/d41586-019-02701-6 [https://perma.cc/M63U-ZHYV] (discussing studies that indicate the molecular targets of anti-cancer therapeutics are not always understood).

[50] *See* DAN L. BURK & MARK. A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT, 37–41 (2009) (discussing differences in incentives as well as research and development costs across different industries).

competitive process.[51] Commercialization of a discovery in biotechnology can, on average, take upwards of 15 years.[52] Similarly, research and development for a new pharmaceutical product can take more than a decade for clinical trials alone and can cost hundreds of millions of dollars in research investment.[53] The inherent complexities of the scientific process in these industries, as mentioned above, can also create significant uncertainty during research efforts. To combat this uncertainty, companies often must invest enormous amounts of resources and time to vet large groups of compounds in order to develop a single product with the appropriate characteristics for further development.[54] In comparison with modern engineering firms that focus on quick product turnaround in a rapidly developing market,[55] this extended, expensive period of development exposes life science-oriented companies to significant ongoing risks that can jeopardize years of investment in the absence of sufficient patent protections.

Companies that develop pharmaceutical or biotechnology products with therapeutic applications face a number of costly regulatory hurdles that are rarely relevant for inventions in engineering-focused industries. For example, prospective therapeutic products must pass a series of costly clinical trial phases regulated by the Food and Drug Administration ("FDA").[56] The clinical phase of a drug's development can last over nine years, on average, and represents a significant portion of the time and monetary investment required to develop and market a therapeutic product.[57] These costs are further amplified due to the large proportion of products that fail to make it through clinical trials and, therefore, represent additional lost expenditures on the part of an innovating company.[58] Yet another complicating factor acting against market motivation for research and development investment in these industries is the ease with which derivative compounds with similar therapeutic functions can be developed by third parties following the release of clinical data to the public.[59] In this market environment, companies are understandably incentivized to seek whatever protections they can in order to secure sufficient financial outcomes following their investments.

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[51] *See* Shaista E. Khilji et al., *From Invention to Innovation: Toward Developing an Integrated Innovation Model for Biotech Firms*, 23 J. PROD. INNOVATION MGMT. 528, 529 (2006) (discussing cost and development time required for products in the biotechnology industry, as well as the risks of investment).

[52] *Id.*

[53] *See* Dean G. Brown et al., *Clinical Development Times for Innovative Drugs*, 21 NATURE REV. DRUG DISCOVERY 793 (2022), https://doi:10.1038/d41573-021-00190-9; Olivier J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 J. AM. MED. ASS'N 844 (2020), https://doi:10.1001/jama.2020.1166.

[54] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1581–82 (2003) (discussing the uncertainty and investment buy-in necessary for pharmaceutical development).

[55] *See, e.g.*, Vlad Kytainyk, *Software Development Time Estimation: How Long Should It Take to Develop a Product?*, FORBES (Dec. 2, 2022, 8:30 AM), https://www.forbes.com/sites/forbesbusinesscouncil/2022/12/02/software-development-time-estimation-how-long-should-it-take-to-develop-a-product/?sh=5c1c4ff476ce [https://perma.cc/EB69-S9B2] (discussing expected product development times for software products).

[56] For an overview of the FDA's approval process, see *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective [https://perma.cc/TP92-RZNB].

[57] *See* Brown et al., *supra* note 53, at 844.

[58] *See generally* Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40 (2014), https://doi:10.1038/nbt.2786 (discussing the overall success and failure rates for drugs during clinical trials).

[59] *See* Shayana Kadidal, *Digestion as Infringement: The Problem of Pro-Drugs*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 241, 245–48 (1996) (discussing derivative compounds in the context of pro-drugs).

Relatedly, the FDA has the authority—under the Hatch-Waxman Act—to approve Abbreviated New Drug Applications for generic drug products based on earlier pioneer products produced by other parties.[60] These applications allow generic drug products to obtain accelerated approval for clinical use so long as the product is equivalent to the initial pioneer drug.[61] This authority, however, does not allow the FDA to approve generic products while the pioneer product retains active market exclusivity.[62] Product exclusivity is largely dependent upon the patent protections obtained over the original therapeutic product.[63] Since any pharmaceutical compound is likely to have a number of readily synthesizable derivative compounds, the interplay of regulations promotes an industry patent practice in which companies aim for patent protections over as wide a sweep of related compounds as possible.[64] Without reasonable protections over compounds related to a pioneer product, a generics producer could create a related, competing product that is different enough not to fall under the scope of the original company's patent while remaining sufficiently equivalent to the original compound to obtain the benefit of an abbreviated FDA application. These considerations—alongside the significant costs of taking even a single drug to market—create conditions in which pharmaceutical and biotechnology companies seek broad patent claim strategies in order to obtain adequate protections for their investments.[65]

The unique characteristics underlying the science at work in the pharmaceutical and biotechnology industries—as well as the unique product development and regulatory constraints in these industries—leave room for industry-specific issues when companies attempt to obtain adequate patent protections over their technologies. The patent system was originally conceived to establish uniform requirements for patent applications across any number of disciplines. However, the difficulty in describing and developing products within the pharmaceutical and biotechnology industries places innovators in a unique situation distinct from the day-to-day innovation practices of traditional engineering and other fields. As such, greater consideration of those unique challenges should be made when reviewing patent applications within these industries. Otherwise, innovators may not feel the need to reveal crucial details of their inventions in exchange for patent protection, thereby acting against the fundamental purpose of the patent system.

B. *Early Doctrine—Genus Claims*

Historically, companies in the pharmaceutical and biotechnology industries have sought patents that claim groups of related products/compounds rather than single individual species of compounds.[66] In particular, patent practice in these industries focused on the liberal use of the "genus claim."[67] Genus claims are those claims in a patent application that cover a group of

[60] *See* Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011) (discussing the provisions of the Hatch-Waxman Act).

[61] *Id.*

[62] *Id.* at 418.

[63] *Id.*

[64] *See* G.W.A. Milne, *Very Broad Markush Claims; A Solution or a Problem? Proceedings of a Round-Table Discussion Held on August 29, 1990*, 31 J. CHEM. INFO. COMPUT. SCI. 9, 9 (1991) (discussing broad claiming strategies in the relevant industries).

[65] *Id.*

[66] *See* Lucille J. Brown, *The Markush Challenge*, 31 J. CHEM. INFO. COMPUT. SCI. 2, 2–3 (1991).

[67] *Id.*

products (a "genus") that are "closely related both in structure and in properties."[68] The primary benefit of genus claims is the extension of a patent's protective ability over both the primary compound(s) of commercial interest as well as other easily derived compounds.[69] This extended scope of protection makes it more difficult for other parties to avoid patent infringement by making basic changes to the structure of the disclosed therapeutic compound and marketing the derivative compound as a separate product. Genus claims therefore strengthen the patent holder's ability to exclusively market his or her innovations during the limited period of patent protection afforded for the invention.[70] Because of these beneficial properties, genus claims represent an important tool for pharmaceutical and biotechnology companies to obtain their financial kickback for disclosing the details of their costly and research-intensive inventions.

A natural concern regarding genus claims is whether such claims cover individual species—individual products within a genus—that are not enabled or described sufficiently within the specification. Overbroad claims could extend a patent holder's rights over too wide a field of compounds, resulting in negative consequences such as the impairment of basic research.[71] Early court opinions displayed a willingness to consider industry-specific factors when determining the validity of genus claims, even while recognizing that there should be some sort of limit to a genus claim's scope. Like the court in *In re Wands*, other courts went through significant effort to consider factors that were particularly relevant to the pharmaceutical, chemical, and biotechnology industries during the industries' early years.[72] In particular, the United States Court of Customs and Patent Appeals demonstrated this willingness to accept industry-specific considerations for broad genus claims in *In re Angstadt*.[73] In *Angstadt*, a chemical manufacturer's patent claimed a genus of reaction mixtures for the conversion of organic compounds using metallic catalysts.[74] The genus in question covered thousands of potential species and was demonstrated in the patent application via forty disclosed examples.[75] The patent examiner and the USPTO board of appeals determined that "the specification leaves too much to conjecture, speculation and experimentation" and that the examples did not effectively represent the full genus.[76] However, the majority panel of the court disagreed, holding that "to require such a complete disclosure would apparently necessitate a patent application or applications with 'thousands' of examples."[77] The majority panel determined that such a significant requirement would "discourage inventors from filing patent applications in an unpredictable area" because the patent applicant would need to limit their claims to "those embodiments which are expressly disclosed" in the patent application.[78] The court

[68] *See In re* Kalm, 378 F.2d 959, 963 (C.C.P.A. 1967).

[69] *See, e.g.*, Brown, *supra* note 66, at 2.

[70] The realistic duration of patent protections for pharmaceutical patents is further complicated by simultaneous requirements for FDA approval of therapeutic compounds. The Hatch-Waxman Act allows for limited extension of a patent term to account for time lost due to the long clinical trial period, but the total extension period is limited to five years, with the effective patent life of the product limited to 14 years after patent term extension. *See* Kelly, *supra* note 60, at 425–26.

[71] *See* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 158 (2006) (discussing the chilling effect of patent breadth on innovation).

[72] *See, e.g.*, *In re* Angstadt, 537 F.2d 498 (C.C.P.A. 1976); Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569 (Fed. Cir. 1984).

[73] *Angstadt*, 537 F.2d at 498.

[74] *Id.* at 499–500.

[75] *Id.* at 502.

[76] *Id.* at 508.

[77] *Id.* at 502.

[78] *Id.* at 502–03.

expressed an unwillingness to force an inventor to "carry out a prohibitive number of actual experiments" even though that would instead force a POSITA to engage in some experimentation in order to practice the invention in the future.[79] This willingness was predicated on the fact that the kind of experimentation required to identify workable embodiments of the invention was not unusual for the industry.[80] As such, the court's analysis took into account the unique conditions of the industry when considering whether the disclosure in a genus claim was sufficient. Decisions like *Angstadt* ultimately helped to set the stage for typical patent practice in the pharmaceutical and biotechnology industries, resulting in the ubiquitous use of genus claims to obtain adequate patent protections for therapeutic products.[81]

C. *Heightened Disclosure Requirements for Biotechnology Patents*

Despite initially favorable responses to biotechnology patents in courts, recent trends in patent litigation have begun to raise significant roadblocks to patent practice in the biotechnology and pharmaceutical industries. This reversal of prior, more industry-conscious treatment of biotechnology and pharmaceutical patents has been accompanied by more stringent application of enablement and written description requirements for such patents.[82] Beginning in the 1990s and extending into several recent appeals to the Supreme Court, this trend constitutes a substantial doctrinal shift that could undermine the traditional patent practices that have evolved alongside the emergence of these relatively new industries.[83] As demonstrated in this section, the strengthening of enablement and written description requirements represents a consistent doctrinal shift with great potential to impede the patent process in an industry-specific manner. This trend, notably demonstrated in *Amgen v. Chugai*, has continued into more recent cases such as *Amgen Inc. v. Sanofi*, *Juno Therapeutics v. Kite Pharma*, and *Biogen International v. Mylan Pharmaceuticals*.[84] Through an analysis of these decisions, as well as the Supreme Court's review of the decision in *Amgen v. Sanofi*, this Comment will demonstrate the evolution of this restrictive trend against pharmaceutical and biotechnology patents with broad claim strategies. Afterward, this Comment will discuss the specific impacts of this trend on biotechnology and pharmaceutical patent practice. Emphasis is placed on the trend's impairment of industry-specific claim strategies—such as the genus claim—that allowed companies in these industries to obtain effective patent protections as their part of the bargain underlying patent law.

Amgen v. Chugai represents an early manifestation of heightened disclosure requirements for biotechnology patents.[85] In this case, Chugai Pharmaceuticals successfully challenged Kirin-Amgen's patent governing gene-mediated production of a family of medically significant hormones.[86] Chugai challenged Amgen's patent on the basis that the patent's claims were overly broad and lacked enablement.[87] Specifically, the court found that the patent inappropriately

[79] *Id.*

[80] *See id.* at 504.

[81] *See* Brown, *supra* note 66, at 2–3.

[82] *See* Karshtedt et al., *supra* note 11, at 22.

[83] *See, e.g.*, Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1215–16 (Fed. Cir. 1991); Amgen Inc. v. Sanofi, 987 F.3d 1080, 1081 (Fed. Cir. 2021), *aff'd*, 598 U.S. 594 (2023); Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021); Biogen Int'l GMBH v. Mylan Pharms. Inc., 18 F.4th 1333 (Fed. Cir. 2021).

[84] *Sanofi*, 987 F.3d at 1080; *Juno Therapeutics, Inc.*, 10 F.4th at 1330; *Biogen*, 18 F.4th at 1333.

[85] *Chugai Pharm. Co.*, 927 F.2d at 1215–16.

[86] *Id.* at 1215–17.

[87] *Id.*

covered any potential gene sequence that resembled a representative hormone and had similar biological activity to the hormone.[88] The court emphasized that while a patent applicant may be "entitled to claim his invention generically," the applicant in this case had not provided sufficient enabling disclosure of the hormone's variants or the method of their production.[89] In particular, the court focused its concern on the potential breadth of the claims, concluding that the disclosure of only a few examples of DNA compounds did not adequately enable the large genus claim.[90] The court found a review of the *Wands* factors to be unnecessary on the basis that the factors were illustrative rather than mandatory.[91] The conclusion stands in contrast with earlier cases such as *In re Angstadt*, which required a lesser showing of representative species when the art would require a substantial amount of experimentation to identify such species.[92] This shift away from the application of the *Wands* factors would undermine the foundation of genus claim protections and prepare the way for the further diminishment of industry-specific patent considerations during disclosure analyses.

Subsequently, the application of more stringent written description requirements have further restricted the breadth of biotechnology patent claims, beginning with the oft-cited *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*[93] In addition to reaffirming a distinction between the enablement and written description requirements, the court in *Ariad* found that issues related to written description were "especially acute" in genus claims that define the relevant genus through functional language.[94] Following *Ariad*, the Federal Circuit continued to raise the written description standard for genus claims.[95] In *Boston Scientific*, inventors attempted to claim patent protections for medical stent devices covered in the compound rapamycin or closely-related chemical analogs of the compound.[96] In contrast with the predominantly functional claims in *Ariad*, the inventors in *Boston Scientific* claimed a working embodiment of their therapeutic compounds and included specific references to the relevant structural features required for a rapamycin analog.[97] However, the court still determined that there was insufficient written description despite the patent's description of rapamycin analogs in terms of their structural features.[98] The court reasoned that there was a lack of data indicating a correlation between the described structural features of rapamycin analogs and their claimed therapeutic properties.[99] According to the court, this lack of correlation demonstrated that Amgen was not in "possession" of the analogs for the purposes of written description, despite Amgen's mapping of those features that would define the genus of rapamycin analogs.[100] In effect, the court's reasoning indicated that (1) even a well-defined representative species may not satisfy the written description requirement and that (2) functional claims for a genus of therapeutic compounds require direct evidence of an underlying correlation between described features of the genus and the purported therapeutic

[88] *Id.* at 1212–13.
[89] *Id.* at 1213–14.
[90] *Id.* at 1213.
[91] *Id.*
[92] *In re* Angstadt, 537 F.2d 498, 504 (C.C.P.A. 1976).
[93] *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010).
[94] *Id.*
[95] *See, e.g.*, Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1369 (Fed. Cir. 2011).
[96] *Id.* at 1357–58.
[97] *Id.* at 1357.
[98] *Id.* at 1369.
[99] *Id.* at 1366.
[100] *Id.* at 1364.

properties.[101] In supporting its opinion, the court focused on what it perceived as the excessive breadth of the claims for the amount of disclosure provided.[102] The Federal Circuit's decision in this case once again highlights courts increasing willingness to restrict the scope of pharmaceutical genus claims based on inadequate disclosure. This willingness would set the stage for ongoing contests over patent disclosure in subsequent cases.

D. *Recent Decisions in the Federal Circuit and Supreme Court*

The Federal Circuit's recent rulings on disclosure—through enablement and written description—continue to add new requirements to the disclosure analysis, with several related appeals filed with the Supreme Court in recent years.[103] In the first of these, *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, a jury held that the claims in a patent for chimeric T-cell receptors met the written description requirement.[104] However, the Federal Circuit reversed the District Court's decision and found that the jury verdict regarding the written description was not based on substantial evidence.[105] The patent in question claimed a family of fusion proteins containing portions of antibodies that bind to therapeutic targets, with this binding capability representing a critical feature of the chimeric receptors' therapeutic function.[106] As part of the claims, Juno attempted to obtain patent protections for those chimeric receptors with "a binding element that specifically interacts with a selected target" and provided two working representations of species within the claimed genus.[107] However, the Federal Circuit was unconvinced that the provided species were truly representative of the genus.[108] More specifically, the Federal Circuit determined that a lack of description for the specific functional features of representative compounds (as opposed to genus-wide features) demonstrated that the inventor lacked—at the time of filing—information regarding those features that were necessary to describe the compounds' therapeutically relevant functions.[109] The court reasoned that the Patent Act requires inventors to show that they "possessed the full scope of the claimed invention," including any and all "known and unknown" representatives of the genus.[110] While the Federal Circuit's interpretation left room for functional claims over biological compounds, the court's emphasis on the disclosure of specific, therapeutically relevant structural features narrowed the scope of potential claims while providing little guidance for future applicants on how to demonstrate possession of the "full scope" of a claimed genus.[111]

The Federal Circuit once again invalidated a patent for multiple related therapeutic products during the court's review in *Biogen International GMBH v. Mylan Pharmaceuticals Inc*.[112] In this case, Biogen's patent for therapeutic formulations of dimethyl fumarate claimed a

[101] *See id.* at 1357, 1366.
[102] *See id.* at 1365.
[103] *See* Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021), *aff'd*, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023); Juno, Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336 (Fed. Cir. 2021); Biogen Int'l GMBH v. Mylan Pharms. Inc., 18 F.4th 1333, 1343–44 (Fed. Cir. 2021).
[104] *Juno Therapeutics, Inc.*, 10 F.4th at 1334.
[105] *Id.* at 1332.
[106] *Id.* at 1333.
[107] *Id.* at 1334.
[108] *See id.* at 1336–41.
[109] *Id.* at 1339–40.
[110] *Id.* at 1336, 1338.
[111] *See id.* at 1336
[112] Biogen Int'l GMBH v. Mylan Pharms. Inc., 18 F.4th 1333, 1335–36 (Fed. Cir. 2021).

method of treatment "wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 [milligrams] per day."[113] A divided panel at the Federal Circuit held that Biogen's patent failed to satisfy the written description requirement.[114] The Federal Circuit focused on several distinct observations to support the court's position. First, the Federal Circuit emphasized that the initial filing contained no data in support of the clinical efficacy of the claimed invention.[115] The court further clarified that it "did not find it necessary to distinguish between therapeutic effects and clinical efficacy" when determining whether Biogen possessed their invention when they filed their patent application.[116] Furthermore, the court brought attention to the fact that the stated efficacious dose of 480 mg/day was only mentioned once in the specification.[117] The court emphasized that this single reference to the claimed dosage was included in the initial filing as part of a large series of prospective therapeutic ranges, with no additional attention brought to the specific 480 mg/day dosage in comparison with the other values included in the range.[118] Taken together, each of these determinations imposes additional tests for written description in therapeutic patents. These additional tests would require an applicant to (1) repeatedly announce the specific dose of the therapeutic treatment in the specification, (2) clearly distinguish the claimed dose from other such dosages listed in the specification, and (3) show possession of a compound through clinical data supporting the efficacy of a clinical formulation, even if data is already included to support the therapeutic efficacy of the compound. This combination of requirements would further shift judicial review of written descriptions for pharmaceutical patents involving therapeutic—and eventually clinical—applications away from consideration industry-specific norms and challenges, including the highly complex FDA clinical approval process for therapeutic compounds.[119] Such a shift would pose potential problems for biotechnology and pharmaceutical patents with practical and economic value tied to their therapeutic potential.

Unlike *Juno* and *Biogen*, *Amgen v. Sanofi* focused instead on the enablement requirement in a pharmaceutical patent case.[120] Once again, Amgen used generic functional language—rather than structural language—to describe its invention.[121] In this case, Amgen claimed antibodies that bound to at least one or two of a group of specified amino acids in the protein PCSK9.[122] As part of its application, Amgen's specification disclosed twenty-six specific antibodies and included three-dimensional structures depicting two of the disclosed antibodies.[123] Despite the disclosure of these representative species, the district court found—and the Federal Circuit affirmed—that a POSITA would require "substantial time and effort" in experimentation to "reach the full scope" of the embodiments claimed in the patent.[124] The district court recognized that the *Wands* factors were relevant when determining whether the amount of experimentation needed was "'undue'or

[113] *Id.* at 1337.
[114] *Id.* at 1346.
[115] *Id.*
[116] *Id.*
[117] *Id.* at 1343.
[118] *Id.*
[119] *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 56.
[120] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1082 (Fed. Cir. 2021), *aff'd*, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023).
[121] *See id.* at 1083.
[122] *Id.*
[123] *Id.*
[124] *Id.* at 1088.

sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out."[125] However, the district court interpreted the unpredictability of the art in question as evidence that the POSITA would have to perform excessive experimentation to obtain embodiments outside of the disclosed examples.[126] In effect, the Federal Circuit placed substantial emphasis on the quantity of experimentation necessary to discover additional embodiments rather than question whether the experimentation required was sufficiently routine within the context of the industry itself.[127] The court's decision, therefore, shifted the standard for enablement in genus claims away from any consideration of the norms associated with routine experimentation in the industry relevant to the patent application. Rather, the court's new focus was on the raw quantitative amount of experimentation required of a POSITA in the context of the patent holder's disclosures.[128] The Supreme Court's subsequent review of the Federal Circuit's decision in *Amgen v. Sanofi* placed significant emphasis on relatively early patent law cases when addressing Amgen's defenses.[129] Amgen proffered two arguments in support of enablement for the wide range of PCSK9 antibodies claimed in Amgen's patent.[130] The first, the "roadmap" method described by Amgen, directed scientists to generate a range of antibodies that could then be tested to determine whether the candidate antibodies bind to a specific "sweet spot" on PCSK9.[131] The second "conservative substitution" method proffered by Amgen directed scientists to start with an antibody known to perform the desired PCSK9 binding function—one of the twenty-six antibodies described in the Amgen patent—and replace select amino acids within those antibodies before testing the new derivative antibody's ability to inhibit PCSK9.[132] When addressing these arguments, the Supreme Court pointed to several cases from much earlier in the development of patent law. First, the Supreme Court invoked *O'Reilly v. Morse*, a case from 1854 in which the Court held that Samuel Morse could not patent all potential methods of telegraphic communication when only one method for doing so was described in the patent.[133] The Court also invoked *The Incandescent Lamp Patent*, an 1895 proceeding in which the Court found that a patent for an electric lamp with an incandescent conductor made of fibrous material could not claim every fibrous and textile material without disclosing a common quality to the materials that made them particularly adapted to incandescence.[134] Taking this and other prior case law into account, the Supreme Court emphasized that "[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class."[135] Worded more concisely by the Court immediately thereafter, the specification of the patent "must enable the full scope of the invention as defined by its claims."[136] In the words of the Supreme Court, the full scope requirement for patent enablement appears to be alive and well.

[125] *See id.* at 1084–85.
[126] *Id.* at 1087–88.
[127] *See id.*
[128] *See id.*
[129] *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 605–10 (2023).
[130] *Id.* at 603.
[131] *Id.*
[132] *Id.*
[133] *Id.* at 606.
[134] *Id.* at 607–08.
[135] *Id.* at 610.
[136] *Id.*

Notably absent in the Supreme Court's review is any reference to the *Wands* factors. The Court does acknowledge that a specification may not be inadequate simply because it leaves room for the POSITA to conduct some form of adaptation or testing, but the Court simultaneously appears to push back against the allowance for much-required experimentation, instead stating that such allowance may detract from the statutory requirement that a patent's specification describe the invention "'in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use'" the invention.[137] The Court further adds that the previous case law of the Supreme Court—as discussed immediately above—creates a principle governing the scope of enablement: "the more a party claims, the broader the monopoly its demands, the more it must enable."[138] When applying the above principles and precedent to Amgen's arguments—in the absence of the *Wands* factors or other considerations of industry norms—the Court rejected Amgen's case and affirmed the Federal Circuit's decision.[139] In the Supreme Court's opinion, the world of difference between the technologies in the *Amgen* appeal and earlier case law had little bearing on the necessary outcome.[140]

Taken together, recent cases at the Federal Circuit and Supreme Court highlight the judiciary's willingness to enforce a heightened standard for written description and enablement in pharmaceutical and biotechnology patent cases when compared with earlier, industry-conscious decisions. New requirements for disclosure—and the nebulous guidance accompanying them—extend the disclosure analysis beyond the Patent Act's mandate for a POSITA-centric disclosure standard.[141] In doing so, the new standards risk damaging innovators—such as those in the pharmaceutical and biotechnology industries—that rely on patents covering groups of related products due to the underlying nature of the technologies within the industries. To better understand the interests affected by these heightened standards, the discussion below continues with an analysis of these cases in the context of the Patent Act's disclosure requirements, as well as the potential impact of the recent holdings on the biotechnology and pharmaceutical industries.

E. *Implications of Recent Decisions*

The recent federal court decisions modify patent disclosure requirements for biotechnology and pharmaceutical patent applications in several ways. Notably, the Federal Circuit's decisions appear to add several requirements for additional data and experimentation on the part of patent applications for therapeutic compounds. For example, *Boston Scientific* raised the requirements for written description by requiring the applicant to demonstrate a direct correlation between structural features listed for representative species in a genus claim and the underlying therapeutic properties of the invention.[142] Similarly, the Federal Circuit in *Biogen* raised the requirements for written description by requiring clinical data in a patent application in support of a claimed formulation's therapeutic efficacy.[143] In each case, the Federal Circuit has moved toward requiring a more complete, almost scientific, accounting of the properties relevant to the claimed compounds at the time of a patent application. This stands in contrast to the traditional maxim that "[i]t is not

[137] *Id.* at 612.
[138] *Id.* at 613.
[139] *Id.* at 615.
[140] *See id.* at 606.
[141] *See* 35 U.S.C. § 112(a) (2012); *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (establishing and discussing the POSITA-centric disclosure standard).
[142] Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1366 (Fed. Cir. 2011).
[143] Biogen Int'l GMBH v. Mylan Pharms. Inc., 18 F.4th 1333, 1346 (Fed. Cir. 2021).

necessary that a patentee should understand the scientific principles underlying his invention, so long as he makes a sufficient disclosure to enable other persons skilled in the art to practice the invention."[144] Specific administrative mechanisms outside of the patent system—including FDA review and approval for putative therapeutic compounds—are directed toward ensuring a therapeutic product's efficacy and safety.[145] As such, the Federal Circuit's heightened written description requirement mostly serves to delay an inventor's ability to apply for patents until they complete notoriously lengthy and costly clinical experimentation for the entire suite of claimed compounds.[146] This burden would be compounded for genus claims, in which the new disclosure requirements would necessitate a clear demonstration of efficacy across a multitude of representative species. The associated burden would substantially impact genus claims in pharmaceutical patents, forcing drug developers to choose whether to face a risky delay in their initial application in order to obtain clinical data for all representative species.

Similarly, the Federal Circuit's and the Supreme Court's recent decisions have shifted the enablement requirement further away from an industry-specific analysis for genus claims. The Federal Circuit in *Sanofi* emphasized that an analysis of undue experimentation must consider the quantity of experimentation needed to discover additional embodiments in a genus rather than considering whether or not the experimentation itself was routine for a POSITA within the industry.[147] This ruling follows the court's earlier ruling in *Chugai*, which effectively ignored the *Wands* factors with regard to the influence of industry norms on the amount of experimentation that is reasonable within a given industry.[148] This disregard for the *Wands* factors appears to have been adopted by the Supreme Court as well.[149] However, the disclosure analysis—both through enablement and written description—is based upon the perspective of a POSITA.[150] By nature, a POSITA is a hypothetical individual—skilled in the relevant art—who operates within the context and norms associated with their given profession.[151] By removing the *Wands* factors and interpreting the question of undue experimentation outside of the industry context, the judiciary effectively renders the analysis generic with regard to all industries and removes the POSITA's industry-specific experience from the equation. This would act counter to the Patent Act's requirement for a POSITA-based analysis and ignore any major differences in development timelines and experimental techniques across industries.[152] This would, in effect, place the pharmaceutical and biotechnology industries—which operate with long development timelines

[144] *See In re* Libby, 255 F.2d 412, 415 (C.C.P.A. 1958).

[145] For an overview of the FDA's approval process, see *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective [https://perma.cc/TP92-RZNB].

[146] *See* Richard C. Mohs & Nigel H. Greig, *Drug Discovery and Development: Role of Basic Biological Research*, ALZHEIMERS & DEMENTIA: TRANSLATIONAL RSCH. & CLINICAL INTERVENTIONS 651, 651 (2017) (discussing the drug development process, including time investment and costs per drug).

[147] Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1087–88 (Fed. Cir. 2021), *aff'd*, 598 U.S. 594 (2023).

[148] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1215 (Fed. Cir. 1991).

[149] *See supra* notes 129–41 and accompanying text.

[150] *See In re* Wright, 999 F.2d at 1561; Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1564 (Fed. Cir. 1991).

[151] *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417–19 (discussing the capabilities of a POSITA).

[152] For the basis of the POSITA-centric viewpoint, see 35 U.S.C. § 112(a) (2012); *In re Wright*, 999 F.2d at 1561.

and significant experimental costs—at a significant disadvantage when it comes to patent prosecution.[153]

Lastly, the Federal Circuit's recent decisions openly continue a trend of heightened disclosure standards for biotechnology and pharmaceutical genus claims with large claim scopes. Most notably, the Federal Circuit in *Juno* established that a patent applicant must show that the applicant possessed "the full scope of the claimed invention" at the time of the application, including both "known and unknown" embodiments, in order to satisfy the written description requirement, a requirement that the Supreme Court appears to support with its own reference to the "full scope" requirement.[154] Under this schema, merely identifying genus-wide features using a number of representative species would not be sufficient to satisfy the disclosure requirement under section 112(a). When further combined with the Federal Circuit's insistence on the disclosure of specific, therapeutically relevant features across the genus,[155] this heightened version of written description would require that therapeutically relevant features be identified and adequately described for every known and unknown embodiment of the genus. Genus claims in the pharmaceutical and biotechnology sectors often touch on families of compounds with enormous or difficult to ascertain numbers of species.[156] Therefore, the potential burden associated with this enhanced requirement would be significant, requiring companies to spend years testing possible embodiments of a genus before filing a patent application.[157] In a sector where patent attorneys are routinely taught to leverage genus claims to prevent easy circumvention of patent protections, this added burden for the application process would be devastating.[158]

In total, the federal judiciary's enhanced disclosure requirements increase the burden on pharmaceutical and biotechnology patent applicants by requiring more extensive pre-application experimentation, constraining the industry-contextualized POSITA, and substantially raising the burden of disclosure in genus claims. The judiciary's recent decisions collectively risk disproportionate damage to patent practice and protections in the pharmaceutical and biotechnology sectors. Therefore, a deeper discussion is needed to consider changes that would preserve patent protection within these sectors while addressing some of the issues highlighted by the Federal Circuit.

IV. ADJUSTING SPECIFICATION REQUIREMENTS FOR BIOTECHNOLOGY PATENTS

The judiciary's recent shift toward a heightened disclosure standard should be carefully reconsidered, as the newly created requirements are fraught with additional burdens and are likely to substantially impact the research, development, and patent practice of the biotechnology and pharmaceutical sectors in an industry-specific manner. Given the overall economic value of these

[153] *See* Shaista E. Khilji et al., *From Invention to Innovation: Toward Developing an Integrated Innovation Model for Biotech Firms*, 23 J. PROD. INNOVATION MGMT. 528 (2006) (discussing cost and development time required for products in the biotechnology industry).

[154] Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1336, 1338 (Fed. Cir. 2021); *see* Amgen Inc. v. Sanofi, 598 U.S. 594, 610 (2023).

[155] *See Juno*, 10 F.4th at 1336–38.

[156] *See* Milne, *supra* note 64.

[157] Such a burden would manifest through the need to take large numbers of embodiments through initial screening and the FDA approval process. Such screening would likely be necessary in order to fully describe and obtain protections for any and all closely related members of the genus that would serve as viable market substitutes.

[158] *See, e.g.*, CHRIS P. MILLER & MARK J. EVANS, THE CHEMIST'S COMPANION GUIDE TO PATENT LAW 7–8 (2010).

industries,[159] it is important to consider solutions that keep the industries intact while also maintaining the fundamental agreement between inventors and the public that sits at the heart of patent law.[160] Industry-specific considerations have been used in the past—most notably through the allowance of genus claims and consideration of the *Wands* factors—to allow the necessary tools for applicants seeking patent protections within these industries.[161] As such, the discussion below proposes a combination of modifications to the heightened disclosure standards enforced by the Federal Circuit alongside a revitalization of genus claims in biotechnology and pharmaceutical patents. The hope is that these proposals will provide a starting point for addressing the issues and uncertainties regarding the appropriate review standard for disclosure in life science-oriented industries.

A. *Mitigate Burdensome Standards for Disclosure*

The most fundamental proposal to address the judiciary's heightened disclosure requirements for biotechnology and pharmaceutical patents is the restoration of previous industry-conscious standards. Therefore, I propose a reassessment of the enhanced disclosure requirements outlined by the Federal Circuit and Supreme Court in recent decisions. As discussed below, these requirements are overly burdensome to patent applicants in the biotechnology and pharmaceutical sectors and will make it difficult for applicants to know what, exactly, is required as part of their disclosures.

Firstly, the court's requirement for representative clinical data in *Biogen* should not be sustained in future cases. The Federal Circuit's opinion affirmed a district court decision that required the patentee to include clinical data when the patentee claimed a series of compounds or products identified, in part, on underlying therapeutic properties.[162] The written description requirement's purpose is to ensure that an inventor is in possession of their invention when they file their patent application.[163] By focusing on evidence of clinical effectiveness, the Federal Circuit's decision did address whether a POSITA would be able to recognize the inventor's possession of an identifiable therapeutic at the time of filing. However, the Federal Circuit's decision also shifted the focus to whether the inventor had begun clinical trials and obtained direct evidence of the patented invention's potential as a marketable drug. Beyond basic data indicating therapeutic efficacy, clinical efficacy is a question that is more appropriate for the FDA and the scientific community.[164] A determination of clinical efficacy is an involved, expensive, and rigorous process that extends beyond the basic demonstration of possession of an invented compound as required for patent disclosure.[165] As such, the Federal Circuit's indication that clinical data may be required for the written description of a therapeutic compound makes the mistake of equating the patent application processes with more stringent processes such as drug approval and scientific publication. Such a change would greatly increase the amount of time and expense required to fully prepare a patent application for any set of therapeutic compounds, especially when one considers the significant resources required to pursue the drug approval

[159] *See The Use of Medicines in the U.S. 2022*, IQVIA, https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022 [https://perma.cc/XKU8-RHNF].

[160] *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998).

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

[162] Biogen Int'l GMBH v. Mylan Pharms. Inc., 18 F.4th 1333, 1346 (Fed. Cir. 2021).

[163] Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1560, 1564 (Fed. Cir. 1991).

[164] *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 56.

[165] *Id.*

process for even a single compound.[166] Furthermore, requiring large, mandatory clinical datasets would have the undesired effect of increasing the overall size and complexity of patent applications reaching the USPTO. Given ongoing concerns regarding patent examiners' available time to review any individual patent, such a change would exacerbate concerns regarding patent review timelines and rigor.[167]

Secondly, the Federal Circuit's and Supreme Court's emphasis on the quantity of experimentation in *Sanofi* should not be extended to future cases. In *Sanofi*, the Federal Circuit chose not to frame its analysis of undue experimentation through the point of view of a POSITA.[168] Instead, the court focused solely on the raw quantity of experimentation required to discover additional embodiments of a claimed genus, with no consideration of the *Wands* factors or the amount of experimentation normally anticipated within the industry.[169] Under section 112(a) of the Patent Act, the Federal Circuit should have determined the undue experimentation question as viewed through the perspective of a POSITA in the pharmaceutical industry to which the applicant belonged.[170] By shifting the focus away from the POSITA, the Federal Circuit effectively changed the enablement requirement to ignore the POSITA's perspective—and, by extension, the common practices in the POSITA's industry. Furthermore, in reviewing the Federal Circuit's decision, the Supreme Court's seemingly mitigated the relevance of the POSITA's perspective by largely ignoring the POSITA's relevance to the enablement question and prior methods for assessing the skill of a POSITA in a given industry.[171] Courts have previously recognized that a large amount of experimentation required to recreate an invention is not undue if that experimentation is reasonable within the context of the art.[172] For the pharmaceutical and biotechnology industries, where broad genus claims are commonly used to protect costly investments from market challenges, the norms of the industry—as seen through the perspective of a POSITA—should be weighed with particular care.[173] Under the Federal Circuit's heightened standard, pharmaceutical companies would be forced to choose between prosecuting narrow, poorly protective patents or risking rejection in the courts by submitting broad genus claims that are likely to be rejected for requiring undue experimentation. Instead, the courts should carefully apply the *Wands* factors for enablement when considering the perspective of a POSITA.

Lastly, the newly implemented "full scope" written description requirement in *Juno* should be mitigated or eliminated in future reviews of genus claims due to the enormous burden it would place on pharmaceutical and biotechnology innovators. In *Juno*, the Federal Circuit ruled that written descriptions required inventors to demonstrate that they "possessed the full scope of the claimed invention," which includes all of the "known and unknown" embodiments of a claimed genus.[174] This full-scope requirement would significantly decrease the strength of pharmaceutical

[166] *See* Mohs & Greig, *supra* note 146.

[167] *See, e.g.*, Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents? Evidence from Micro-Level Application Data*, 99 REV. ECON. & STAT. 550, 550–51 (2017).

[168] Amgen Inc. v. Sanofi, 987 F.3d 1080, 1083 (Fed. Cir. 2021), *aff'd*, 598 U.S. 594 (2023).

[169] *Id.*

[170] *See* 35 U.S.C. § 112(a) (2012); *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

[171] *See Amgen Inc.*, 598 U.S. at 605–10 (discussing the need for courts to follow basic statutory requirements, including language referencing persons skilled in the relevant art, but not further discussing the approaches used to determine the relative skill of the POSITA in a given discipline).

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

[173] *See, e.g.*, C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCI. 1386, 1386 (2013).

[174] *Juno*, 10 F.4th at 1336, 1338.

patent protections by narrowing the allowable scope of patent claims to only those compounds that the inventor has synthesized and tested prior to their application. This is problematic for both the pharmaceutical and biotechnology industries' practice of leveraging genus claims to achieve effective patent protection against derivative compounds following a patented product's commercial release.[175] The problem is especially salient in the pharmaceutical industry, where any given pharmaceutical compound is likely to have a number of readily synthesizable derivatives, any number of which could possess similar therapeutic activity.[176] De novo drug discovery and development is a costly and time consuming affair, often considered to be worthwhile to a company only when that company is reasonably guaranteed to reap a significant profit from the eventual sales of the drug.[177] Under the full-scope requirement in *Juno*, pharmaceutical companies would be forced to meticulously synthesize and test large libraries of related compounds—rather than obtaining a few representative species—in order to prove that the company was in possession of any and all viable chemical substitutes for their original effective therapeutic compound. Failing to do so would, as discussed above, open the door to rapid development of competitor products by other parties and a consequent diminishment of the expected financial windfall. The increased expenses associated with additional testing, on top of the other significant costs tied to drug development, would diminish the incentive for many companies to invest in the drug development process, harming the overall public good by decreasing innovation in the pharmaceutical arena.

B. *Revival of Genus Claims*

The Federal Circuit's decision to reign in genus claims in recent years may be motivated by a desire to prevent patents from stifling research and innovation through overreaching.[178] However, the patent system's underlying purpose is to simultaneously promote innovation while making the details of such innovation available to the public.[179] Historically, the pharmaceutical and biotechnology industries' use of genus claims represented the primary means by which companies secured financial benefits in return for their investment in research and development.[180] While some limitations on the scope of genus claims are likely beneficial, the nature of such limitations would be best defined through legislative action rather than judicial decisions. For example, Congress could act to limit the frequency of genus claims with excessively broad scope by adjusting examination fees to match the likely scale of the claimed genus.[181] Similarly, Congress could extend experimental use exceptions for patents so that third parties—including scientific institutions and industry actors—could use patented life science technologies for

[175] *Id.*

[176] *See* Kadidal, *supra* note 59, at 245–47.

[177] *See* Thomas Sullivan, *A Tough Road: Cost to Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development Is Less Than 12%*, POL'Y & MED. (Mar. 21, 2019), https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html [https://perma.cc/5ZU2-K3K9].

[178] Overreaching is a common concern when discussing the breadth of potential embodiments covered by a genus claim. *See* Jordan Paradise et al., *Patents on Human Genes: An Analysis of Scope and Claims*, 307 SCI. 1566, 1566–67 (2005) (discussing the potential impact of patent scope on research in human genetics).

[179] *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998).

[180] *See* Brown, *supra* note 66, at 2–3.

[181] Similar proposals have been made by other scholars in the field. *See* Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 147 (2008) (discussing adjustments to patent examination fees with reference to the scope of the work).

internal, non-commercial research purposes.[182] Congress could even go so far as to provide allowances for post-filing of experimental data in pharmaceutical and biotechnology patent applications containing genus claims, providing a time frame in which a patent applicant could "scale-back" the claims to more accurately reflect the scope of the invention when approaching commercialization. Each of these legislative approaches would help to delineate the requirements more clearly for patent disclosure in a manner that companies could effectively respond to in their patent practice. In contrast, the Federal Circuit's attempts to heighten the standard for disclosure in patent applications have resulted in continued confusion as to the requirements for disclosure and the associated best practices for patents in specific, complex industries.[183] To avoid continued confusion and further impairment of innovation incentives, the judiciary should adopt a position that is more accommodating of genus claims until Congress legislates otherwise. Failing to do so could instead impair innovation in the pharmaceutical and biotechnology industries by mitigating the incentives to fund research and development, hindering innovation in the industry despite the court's intended purpose of promoting innovation.

V. CONCLUSION

The federal judiciary's decisions in recent patent cases have heightened the apparent standard for patent disclosure. With respect to innovators in the pharmaceutical and biotechnology industries, these heightened disclosure standards have resulted in confusion regarding the amount of disclosure required for claims covering groups of related products. This, in turn, has impaired the use of genus claims as a key tool for protecting pharmaceutical and biotechnological inventions in the marketplace. While the courts' desire to prevent overreaching is understandable, the recent decisions result in too much uncertainty regarding disclosure requirements and impair the incentive structure for development in these industries. Therefore, the federal courts should reconsider these recent patent disclosure decisions with an eye toward restoring genus claims and considering more industry-specific factors relevant to the disclosure analysis. Through these and other changes, the judiciary can provide a more consistent assurance that drug developers will have the opportunity to benefit from their research investments and subsequent technology disclosures.

[182] *See generally* Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 59 ME. L. REV. 283 (2007) (discussing the experimental use exception as it applies to use within a research university).

[183] *E.g.*, Amgen Inc. v. Sanofi, 987 F.3d 1080, 1081 (Fed. Cir. 2021), *aff'd*, 598 U.S. 594 (2023); Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021); Biogen Int'l GMBH v. Mylan Pharms. Inc., 18 F.4th 1333 (Fed. Cir. 2021).