A Patent Doctrine without Bounds: The "Extended" Written Description Requirement

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Adequate disclosure is the "quid pro quo" of the patent system: the public grants exclusive rights to the patent holder for a limited time, and in exchange, the patent holder divulges the operating principles of the invention to the public.¹ Since adequacy of disclosure determines a patent's validity and scope, the Supreme Court has cautioned against "[f]undamental alterations in [disclosure] rules" that may "risk destroying the legitimate expectations of inventors in their property" by invalidating pending or issued patents.² The current standard for adequate disclosure, set forth in 35 USC § 112, requires that the specification . . . contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.³

Courts have interpreted this statute to include two separate requirements that valid patents must fulfill: "written description" and "enablement." ⁴ Traditionally, the written description requirement served as a priority policing doctrine, preventing patent applicants from improperly amending claims after submitting an initial application. In this way, the written description requirement foiled attempts to add new matter to a patent through the amendment process while retaining the benefit

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¹ Kewanee Oil Co v Bicron Corp, 416 US 470, 484 (1974).
³ 35 USC § 112 (2000) (emphasis added). A patent specification begins with the written description and concludes with the patent claims. The written description describes the what and the why of the invention in paragraph form and may also include drawings and diagrams. The patent claims are numbered and define the scope of the patent rights in a formal manner.
⁴ In re Curtis, 354 F3d 1347, 1357 (Fed Cir 2004) ("We interpret 35 U.S.C. § 112, ¶ 1 to require a written description requirement separate and apart from the enablement requirement."). The adequate disclosure standard also requires that the specification set forth the "best mode" for carrying out the invention. 35 USC § 112. The best-mode requirement is beyond the scope of this Comment.
of an earlier filing date.' Thus, the written description requirement has traditionally served procedural goals in the patent system, allowing the government to effectively administer the priority of competing patents.

In contrast to the policing function of the written description requirement, the enablement requirement ensures that "public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." Thus, the enablement requirement seeks to fulfill the substantive goal of adequate disclosure in the patent system: the patent specification must enable one skilled in the art "to make and use the claimed invention without undue experimentation."

The enablement requirement, as articulated in In re Wands, once served as the primary method for determining whether a patent claim was adequately disclosed. However, recent and rapid developments in technology have stretched the Federal Circuit's enablement analysis. The Wands test for enablement of a claim fails to capture the nuances of determining adequate disclosure in complex and emerging fields. While the test considers the predictability of the relevant art, it does not enumerate specific criteria for determining adequate disclosure in unpredictable arts. As a result of the test's inadequacy, patents granted in unpredictable fields such as biotechnology may include overbroad claims that exceed the scope of what was known at the time the patent application was filed. The enablement analysis must be sufficient to distinguish overbroad claims from claims that are adequately disclosed by the patent specification.

In 1997, the Federal Circuit set out to cure the deficiencies in Wands by extending the scope of the written description requirement. The court's revised analysis treated written description as an adequate disclosure doctrine to be applied in addition to the test for enablement. When the Federal Circuit extended the application of the written description requirement beyond priority policing and as a substantive test for adequate disclosure, it attempted to provide courts with a way to invalidate patent claims that withstood the original

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7 Adang v Fischhoff, 286 F3d 1346, 1355 (Fed Cir 2002) (emphasis added).
8 858 F2d 731 (Fed Cir 1988).
10 See id.
11 See Regents of the University of California v Eli Lilly and Co, 119 F3d 1559, 1567 (Fed Cir 1997) (invalidating a claim for lack of written description).
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Wands enablement analysis but failed to adequately disclose the operation of complex new technologies.

Unfortunately, the court overshot its goal, creating a nebulous doctrine that could be used in a discretionary fashion by courts or juries to invalidate almost any patent claim. In so doing, the Federal Circuit appears to have ignored the Supreme Court's warning that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." Indeed, by creating a new substantive requirement for adequate disclosure without sufficient guidelines to cabin judicial discretion, the Federal Circuit has introduced new risk into the patent process. A doctrine granting too much discretion to the decisionmaker renders results uncertain and reduces an inventor's ex ante expectation for the scope of her patent's protection. Moreover, the lack of factors guiding the court's analysis might give rise to constitutional problems, since the unbounded discretion created by this new substantive requirement holds "the potential to deny similarly situated individuals equal treatment under the laws."

This Comment attempts to cure the problems with the Federal Circuit's current use of the written description requirement as a substantive test for adequate disclosure by limiting judicial discretion and clarifying adequate disclosure requirements. Part I explores the development of the written description requirement and its relationship to the enablement requirement. Part II considers the extended written description requirement's lack of clear boundaries and retroactive application, which allow the decisionmaker to invalidate almost any patent claim for lack of written description. Part III proposes that the test for written description be combined with the original Wands enablement factors, using the goal of adequate disclosure to cabin discretionary application of the written description requirement. This solution limits judicial discretion, lends clarity to the adequate disclosure requirements, and simultaneously harmonizes existing case law and alleviates concerns about adequate disclosure in emerging technologies.

I. DEVELOPMENT OF THE ADEQUATE DISCLOSURE STANDARD

A. The Written Description Requirement

The original purpose of the written description requirement was to police priority in new or amended claims. Subject to certain limita-

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12 Festo, 535 US at 739.
tions, patent applicants may amend their claims after submitting their initial application, while retaining the original filing date for priority purposes. This amendment process allows patent applicants to alter existing claims without losing their place in the priority line. To preserve fairness, amendments must not introduce new matter into the application. Priority policing statutes prevent patent holders from misusing the amendment process. Thus, the original purpose of the written description requirement set forth in 35 USC § 112 was identical to that of 35 USC § 132, which prohibits addition of "new matter into the disclosure of the invention."15

B. The Extended Written Description Requirement

In the 1997 decision Regents of the University of California v Eli Lilly and Co,16 the Federal Circuit extended the scope of the written description requirement. Before Eli Lilly, the written description requirement was used only procedurally as a priority policing doctrine for claims amended or added after the original filing date. After Eli Lilly, the written description requirement could also be used to invalidate originally filed claims for "failure to provide an adequate written description,"17—that is, for lack of adequate disclosure. Thus, the written description requirement is currently applied in two contexts: priority policing and adequate disclosure.18

Since the Eli Lilly court found a lack of written description "[w]hether or not [the specification] provides an enabling disclosure," Eli Lilly requires patent applicants to show adequate disclosure through both the enablement and the written description requirements.19 This use of the written description requirement was entirely novel. In Enzo Biochem, Inc v Gen-Probe Inc,20 a divided Federal Cir-

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15 35 USC § 132 (2000). Courts initially used both doctrines identically, noting that "[a] new matter rejection under 35 USC § 132, predicated on claim language, is tantamount to a rejection for lack of a written description of the claimed invention under 35 USC § 112." Application of Hogan, 559 F2d 595, 608 (CCPA 1977), citing Bowen, 492 F2d at 864, and Application of Smythe, 480 F2d 1376, 1385 (CCPA 1973). In 1981, the United States Court of Customs and Patent Appeals (CCPA) noted the confusion caused by the redundant doctrines. See In re Rasmussen, 650 F2d 1212, 1214 (CCPA 1981). The CCPA distinguished "the adding of new matter to the disclosure" from "the broadening of a claim," explaining that "[b]roadening a claim does not add new matter to the disclosure." Id. The court then concluded that § 112 (written description) was "[t]he proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure," while § 132 applied to amendments to the specification. Id (emphasis added).
16 119 F3d 1559 (Fed Cir 1997).
17 Id at 1567.
18 See Moba v Diamond Automation, Inc, 325 F3d 1306, 1319 (Fed Cir 2003) ("Federal Circuit case law reflects two applications of 35 USC § 112, ¶ 1.").
19 Eli Lilly, 119 F3d at 1567 (emphasis added).
20 296 F3d 1316 (Fed Cir 2002).
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C. The Relationship between the Enablement and Extended Written Description Requirements

The Federal Circuit has had difficulty articulating a function for the extended written description requirement that is distinct from that served by the enablement requirement. Indeed, one Federal Circuit judge suggested that the court "has begun to convert [the written description requirement] into the enablement doctrine with a different label."\(^2\) Decisions prior to \textit{Eli Lilly} asserted that written description and enablement were separate requirements. In those cases, however, the doctrines were always applied in discrete spheres: written description related to priority while enablement related to adequate disclosure. When the written description requirement was extended, its function became uncertain. Recent developments show that under the Federal Circuit's current \textit{Eli Lilly} test, the function of the extended written description requirement is difficult to distinguish from that of enablement.

1. \textit{Eli Lilly}.

The dispute in \textit{Eli Lilly} concerned broad claims for vertebrate and mammalian cDNA encoding insulin, as well as a claim for a modified microorganism that would produce human insulin.\(^3\) Rather than perform an enablement determination, the Federal Circuit found that the district court did not err in finding the claims invalid "for failure to provide an adequate written description."\(^4\)

The fact pattern in \textit{Eli Lilly} is similar to past Federal Circuit enablement determinations. In the context of cDNA encoding insulin, the \textit{Eli Lilly} court noted that it was not clear that "a description of a species always constitutes a description of a genus of which it is a part."\(^5\) This reasoning easily applies to enablement, where enablement of one species that is part of a broader genus is not necessarily an enablement of the entire genus, especially in unpredictable arts.\(^6\) The enablement requirement mandates that patent disclosures be sufficient "to enable one skilled in the art to carry out the invention commensu-

\(^{21}\) Id at 1324–25.
\(^{22}\) \textit{Id.} at 1325 (Rader concurring).
\(^{23}\) \textit{Id.} at 1326 (Rader concurring).
\(^{24}\) Id at 1568.
\(^{25}\) Id.
\(^{26}\) See \textit{Spectra-Physics, Inc v Coherent, Inc.} 827 F2d 1524, 1533 (Fed Cir 1987) ("If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment.") (citations omitted).
rate with the scope of [the patent] claims.\textsuperscript{27} At the time the Eli Lilly patent was filed, the patentee had only developed a method for producing rat insulin cDNA, yet claimed methods for producing vertebrate, mammalian, and human insulin cDNA.\textsuperscript{2} The Eli Lilly court’s invalidation of the broad claims supported only by a single embodiment in an unpredictable art is standard in Federal Circuit enablement determinations.\textsuperscript{26} Nonetheless, the court relied on the written description requirement in invalidating the claims.

This new use of the written description requirement is problematic. Consider, for example, a patent claim that involves a well-known DNA sequence commonly known as the obesity gene. Under Eli Lilly, the specification must contain a sequential listing of each nucleotide in the claimed DNA sequence in order for the claims to meet the written description requirement.\textsuperscript{30} Unlike the enablement requirement, which is satisfied so long as those skilled in the art can reproduce the patented item, this requirement is not cabined by any limiting principle. In the obesity example, one skilled in the art would know exactly which nucleotides were involved if the claim referred to the obesity gene. But under Eli Lilly’s written description requirement, any patent claim that did not disclose every nucleotide in the gene could be invalidated for lack of written description, regardless of the well-established principle of patent law that “a patent need not teach, and preferably omits, what is well known in the art.”\textsuperscript{31} The Federal Circuit has since backpedaled from this stringent standard for biotechnology patents, holding that “the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.”\textsuperscript{29} While this allows the inventor to refer to a well-known amino acid sequence by name or basic structure to satisfy the extended written description requirement, such disclosure would be sufficient to enable the invention for one skilled in the art.

\textsuperscript{27} Amgen, Inc v Chugai Pharmaceutical Co, Ltd, 927 F2d 1200, 1213 (Fed Cir 1991) (emphasis added).

\textsuperscript{28} Eli Lilly, 119 F3d at 1562–63.

\textsuperscript{29} See, for example, Adang v Fischhoff, 286 F3d 1346, 1359–60 (Fed Cir 2002) (invalidating claims where the working example involved a tobacco plant, while the patent claimed application of the technology to multiple plants); Enzo Biochem, Inc v Calgene, Inc, 188 F3d 1362, 1374 (Fed Cir 1999) (invalidating broad claims of antisense technology for prokaryotes, eukaryotes, cellular organisms, and viruses when E. coli was the only organism involved in the patent’s working examples of antisense technology); In re Wright, 999 F2d 1557, 1564 (Fed Cir 1993) (invalidating patent claims for all vaccines in all organisms against all RNA viruses when the patent’s working example involved a vaccine that immunized chickens against one RNA virus).

\textsuperscript{30} See Eli Lilly, 119 F3d at 1569 (holding that a claimed DNA sequence “is not defined or described by the mere name ‘cDNA’: . . . but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA”).

\textsuperscript{31} Hybritech, Inc v Monoclonal Antibodies, Inc, 802 F2d 1367, 1384 (Fed Cir 1986).

\textsuperscript{32} Amgen, Inc v Hoechst Marion Roussel Inc, 314 F3d 1313, 1332 (Fed Cir 2003).
The *Eli Lilly* court might have chosen to make enablement and the extended written description requirement redundant: two sets of factors yielding the same results and fulfilling the same goals. But the court did not combine the doctrines. Instead, it created an additional requirement for adequate disclosure; patent claims can be invalidated for lack of written description whether or not they are enabled.\(^{33}\)


In 2001, the United States Patent and Trademark Office (PTO) issued guidelines to aid its personnel "in their review of patent applications for compliance with the 'written description' requirement of 35 U.S.C. 112."\(^{34}\) The guidelines attempt to explain the Federal Circuit standard for written description, which requires that the applicant "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention."\(^{35}\) These guidelines provide factors used to determine satisfaction of the written description requirement in a post-*Eli Lilly* environment. The guidelines also demonstrate the difficulty in articulating a distinct function for the extended written description requirement.

The PTO first attempted to distinguish the goals of the written description and enablement requirements: "The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention."\(^{36}\) Still, the PTO's guidelines for determining adequate written description appear to serve the same function as enablement. Additionally, a clear standard for possession in the context of adequate disclosure has not been articulated. For the purposes of patent law, inventors cannot show possession of an invention unless they also demonstrate that they know how to make and use it, which necessarily means enabling others to use it. Hence the difficulty in articulating a distinction between the possession standard for written description and the make-and-use standard of enablement.

Despite the PTO's attempt to resolve the problems created by *Eli Lilly*, this slight difference in wording does not translate into a practical distinction in function. In fact, the PTO method for evaluating written description overlaps in part with an enablement determina-

\(^{33}\) See *Eli Lilly*, 119 F3d at 1567.


\(^{36}\) 66 Fed Reg at 1100 (cited in note 34) (emphasis added).
tion. This extended written description requirement thus "compounds the confusion, increases the chances for error, and augments the expense of the trial process." The lack of distinction between the enablement and written description requirements and the separate tests for each create problems for both trial courts and juries. One Federal Circuit judge noted that the jury was asked "to decide that the patent's disclosure can enable a skilled artisan to make and practice the entire invention, but still not inform that same artisan that the inventor was in possession of the invention. Puzzling." The table below illustrates the relationship between the doctrines. The left column contains PTO factors for evaluating the extended written description requirement. The right column contains the Federal Circuit's factors for evaluating enablement (the *Wands* factors*). Ostensibly, the PTO factors place focus on demonstrating the patent applicant's possession of the invention, while the *Wands* factors place focus on whether the disclosure is sufficient to enable others to make and use the invention. But both sets of factors lead to the same end: disclosure that adequately demonstrates how to make and use the invention. Thus, both sets of factors attempt to ensure that adequate disclosure—the quid pro quo of patent law—is fulfilled. As such, the extended written description requirement cannot have a purpose that is separate and distinct from enablement. The extended written description requirement could, however, add valuable considerations to the enablement test, especially in the unpredictable arts. The PTO guidelines place a specific focus on reduction to practice, drawings and diagrams, and distinguishing characteristics that is lacking in the current enablement analysis.

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<thead>
<tr>
<th>PTO Written Description Factors</th>
<th><em>Wands</em> Enablement Factors</th>
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<tr>
<td>* Evidence of support in the application</td>
<td>* Quantity of experimentation necessary</td>
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<tr>
<td>* Actual reduction to practice</td>
<td>* Amount of direction or guidance presented</td>
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<td>* Clear depiction in detailed drawings or chemical formulas</td>
<td>* Presence or absence of working examples</td>
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<tr>
<td>* Disclosure of relevant, distinguishing, and identifying characteristics</td>
<td>* Nature of the invention</td>
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<td>* Level of skill and knowledge in the art</td>
<td>* State of the prior art</td>
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<td>* Predictability of the art</td>
<td>* Relative skill of those in the art</td>
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<td>* Full scope of the claim</td>
<td>* Predictability or unpredictability of the art</td>
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<td>* Breadth of the claim</td>
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37 *Moba*, 325 F3d at 1323 (Rader concurring).
38 Id.
39 *Wands*, 858 F2d at 737.
40 66 Fed Reg at 1104-06 (cited in note 34).
41 *Wands*, 858 F2d at 737.

*Enzo Biochem* reveals the Federal Circuit’s struggle to articulate a clear standard for the extended written description requirement. Initially, the Federal Circuit affirmed the district court’s grant of summary judgment for invalidity of the patent claims for lack of written description.\(^2\) Three months later, the Federal Circuit vacated its prior decision and remanded.\(^3\) After entry of the decision, an en banc poll failed, with three judges concurring in and three judges dissenting from the decision against hearing the appeal.\(^4\) The concurring judges agreed that the law of written description was sound.\(^5\) The dissenters wished to resolve the confusion surrounding application of the written description requirement by overruling *Eli Lilly* and restricting written description to its original function as a priority policing doctrine.\(^6\) This tension within the Federal Circuit is emblematic of the difficulty in defining the extended written description requirement.

The Federal Circuit addressed an issue of first impression in *Enzo Biochem,*\(^7\) which further blurred the distinction between the enablement and extended written description requirements. The court held that “reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1.”\(^8\) Biological deposits have long been held to fulfill the enablement requirement.\(^9\) One can comply with enablement by depositing “living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues.”\(^10\) The *Enzo Biochem* court noted that a “deposit in a public depository most often has pertained to satisfaction of the enablement requirement,” but concluded that “reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material.”\(^11\)

\(^{42}\) *Enzo Biochem,* 285 F3d at 1015.

\(^{43}\) *Enzo Biochem, Inc v Gen-Probe Inc,* 296 F3d 1316, 1320 (Fed Cir 2002).

\(^{44}\) *Enzo Biochem, Inc v Gen-Probe Inc,* 42 Fed Appx 439 (Fed Cir 2002) (denial of petition to rehear the case en banc).

\(^{45}\) Id at 444-45.

\(^{46}\) Id at 445.

\(^{47}\) 296 F3d at 1325.

\(^{48}\) Id. A biological deposit is a sample of living material stored in a cell depository. See *Wands,* 858 F2d at 735. The depository distributes samples of this material to those who wish to practice the invention after the patent issues. Id.

\(^{49}\) See *Wands,* 858 F2d at 735, citing *Application of Argoudelis,* 434 F2d 1390, 1392–93 (CCPA 1970).

\(^{50}\) *Wands,* 858 F2d at 735.

\(^{51}\) *Enzo Biochem,* 296 F3d at 1326.
Enzo Biochem sued Gen-Probe for patent infringement. Gen-Probe moved for summary judgment, asserting that multiple claims in Enzo Biochem’s patent were invalid for lack of written description. In considering Gen-Probe’s assertions, the Federal Circuit adopted the PTO guidelines for the extended written description requirement. On remand, the Federal Circuit instructed the district court to determine whether “the written description, including information obtainable from the deposits of the claimed sequences” was “sufficient to demonstrate possession of the generic scope of the claims.” Because the patent specification referred to the biological deposits, “it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art.” Like Eli Lilly and other Federal Circuit enablement determinations, the Enzo Biochem decision involved broad claims relying on a narrow disclosure.

The court’s instructions and considerations did little to distinguish the purpose of the extended written description requirement from that of enablement. Relying entirely on the Eli Lilly version of the extended written description requirement, the court did not address whether the claims “implicate other validity issues, such as enablement.” Nevertheless, the court’s discussion of the adequacy of the biological deposits appears to turn on whether the biological deposits enable one skilled in the art to make and use the various subsequences, mutations, and mixtures of those sequences. The court’s analysis of the patent’s disclosure indicates that the underlying goal of extended written description mirrors that of enablement.

II. PROBLEMS AND CONCERNS WITH THE EXTENDED WRITTEN DESCRIPTION REQUIREMENT

A. Confusion in Practical Application

Since Eli Lilly and Enzo Biochem, the Federal Circuit has attempted to limit the extended written description requirement. In Amgen, Inc v Hoechst Marion Roussel, Inc, the court “clarified that Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement.” While this does reduce the ponderous disclosure re-
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quired by *Eli Lilly*, it does little to explain what extended written description actually requires.

The holdings in several district court cases indicate the various courts' confusion as to the meaning and boundaries of the doctrine. In *Abbott Laboratories v Inverness Medical Technology*, an expert demonstrated that it would have been obvious to one skilled in the art that the description of a one-step assay in the patent specification would be applicable to the multiple assays claimed in the patent. Regardless, the court invalidated the claims for the other assays, holding that the written description requirement is met only when any variants of what is described are "not only obvious, but actually described." At the same time, the court noted that the specification does not have to provide explicit support for the claimed subject matter. These notions are contradictory: a court cannot require actual description without requiring any explicit support. Such a holding provides little guidance for prospective patent applicants.

The district court in *University of Rochester v G.D. Searle & Co, Inc* confused the distinction between enablement and written description. The court's discussion, while couched in terms of the written description requirement, was really about enablement. In ostensibly discussing the adequate written description requirement, the district court stated that it "means little to 'invent' a method if one does not have possession of a substance that is essential to practicing that method." This reasoning is standard in an enablement determination. When a method requires a particular apparatus or certain starting chemicals, the patent application must provide a sufficient disclosure of that apparatus or those chemicals in order to be enabled.

B. Retroactive Application

The extended written description requirement raises questions about the validity of claims in existing patents. It purports to require more than an enabling disclosure in the specification, imposing an additional burden on patent applicants. This additional requirement applies retroactively to patents issued when the primary disclosure

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60 2002 US Dist LEXIS 15290 (D Mass).
61 Id at *6.
62 Id at *7.
63 249 F Supp 2d 216 (WD NY 2003).
64 Id at 221–30.
65 Id at 228.
67 See *Eli Lilly*, 119 F3d at 1567 (finding a claim invalid for lack of written description even if it was found to be enabled).
doctrine was enablement. In 1997, Eli Lilly extended the written description requirement and invalidated patent claims filed in 1977 and 1979; the 2002 Enzo Biochem decision applied the requirement to a patent filed in 1986.

Inventors have no opportunity to remedy deficiencies in disclosures that comply with the enablement requirement but may be inadequately described under Eli Lilly’s nebulous standard. There is a high probability that retroactive application of the extended written description requirement will become a common problem in patent litigation. Because Eli Lilly requires description beyond that needed to fulfill the enablement requirement, defendants will likely invoke the broad reach of the extended written description requirement when litigating adequacy of disclosure. This retroactive application is a fundamental alteration of the requirements for disclosure and affects patent holders’ expectations in the scope of their rights.

C. Lack of Boundaries

The extended written description requirement is currently applied without a limiting principle, leaving much discretion to judges in determining the validity of patent claims. This expansive discretion disrupts the expectations of inventors and increases the risk involved in obtaining a patent, as claims can be arbitrarily invalidated. The original written description requirement was limited by the search for new matter. The enablement requirement is limited by the goal of adequate disclosure (that is, “enabling” one skilled in the art to make and use the claimed invention). But the boundary of the extended written description requirement is perplexing: an inventor must convey that “he or she was in possession of the invention” or that he or she “invented the claimed invention” through the written description itself. The Federal Circuit has done little to elaborate on these boundaries, giving judges potentially limitless discretion to invalidate claims in both predictable and unpredictable arts. In Carnegie Mellon

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68 See id at 1562–63. See also Enzo Biochem, 296 F3d at 1326.
69 See Eli Lilly, 119 F3d at 1562–63.
70 See Enzo Biochem, 296 F3d at 1326.
72 See, for example, Application of Hogan, 559 F2d 595, 608 (CCPA 1977).
73 Adang v Fischhoff, 286 F3d 1346, 1355 (Fed Cir 2002).
74 Vas-Cath v Mahurkar, 935 F2d 1555, 1564 (Fed Cir 1991).
75 Eli Lilly, 119 F3d at 1566.
University v Three Rivers Biologicals, Inc., the district court invalidated biotech claims for lack of written description. The court held that application of Eli Lilly is not limited to claims involving novel genes or DNA sequences. By suggesting that even claims in the predictable arts require explication of every detail, the court contradicted the well-established principle that “a patent need not teach, and preferably omits, what is well known in the art.” Though the Federal Circuit has since explained that Eli Lilly does not invalidate known sequences or genes, that change in the law could not alter the district court’s outcome. Still, the written description requirement could conceivably invalidate any invention that claims more than it specifically describes. This creates significant validity problems for patents issued before Eli Lilly, and increases the burden on patent applicants for future inventions.

The unclear boundaries of the extended written description requirement mean inventors have no way of knowing if their patents are adequately described. To compensate for this uncertainty, inventors will likely attempt to guarantee the validity of their patents through voluminous patent disclosures. Such disclosures would be unduly burdensome, both on the patentee and on those who wish to practice the invention. Furthermore, it is well established in patent law that the specification may leave out what is known in the art. Inventors who successfully convey to others how to make and use their claimed inventions may nonetheless find their rights in enabled claims eliminated. The Federal Circuit has not yet articulated any clear reason for requiring additional description from the inventor when a patent already allows one skilled in the art to make and use the full scope of the claimed invention without undue experimentation.

The extended written description requirement disrupts the quid pro quo of the patent system and is confusing to the courts that must apply Federal Circuit law. Unlike the other appellate courts, “[w]henever a Federal Circuit panel makes an error interpreting the patent code, every district court in the nation, and even every later Federal Circuit panel, is obliged to follow and perpetuate the error.”

78 Id at 1014.
79 Hybritech, Inc v Monoclonal Antibodies, Inc. 802 F2d 1367. 1384 (Fed Cir 1986).
80 See Amgen. 314 F3d at 1332.
81 See Razzano. 11 Fed Cir Bar J at 725 (cited in note 76) (“[T]he strictest approach requires the written description to delineate all of the claimed elements.”).
82 See Paperless Accounting, Inc v Bay Area Rapid Transit System. 804 F2d 659. 664 (Fed Cir 1986).
83 Moba v Diamond Automation, Inc. 325 F3d 1306. 1322 (Fed Cir 2003) (Rader concurring).
This structure burdens district courts and juries with the problems of the extended written description requirement.

III. CONSIDERING THE SOLUTIONS

A. The Proposed Solution

The Federal Circuit’s reasoning in *Eli Lilly* indicates that the extension of the written description requirement was an attempt to compensate for deficiencies in the enablement requirement; the enablement factors alone do not provide sufficient guidance to courts making decisions at the margins of technology. By requiring description beyond fulfillment of the enablement factors, the court created a way to invalidate those broad claims that fulfill the technical test for enablement but nonetheless fail to adequately disclose the subject of the claim. Still, the *Eli Lilly* decision is flawed. The court’s extension of the written description requirement lacks a clear standard and purpose, resulting in unbounded judicial discretion to invalidate claims. Such a doctrine does not advance “the goal of the patent system to actually put the claimed invention into the hands of the public.”

It is not viable to ask the Federal Circuit simply to move back to the pre-*Eli Lilly* interpretation of the written description requirement as suggested by several commentators. The court has affirmed *Eli Lilly* and applied the extended written description requirement in subsequent cases. Not only would such a solution force Federal Circuit judges to concede error, it also would not solve the problems that spawned the extended written description requirement. Nor is it viable to ask the court to ignore and eventually discard the requirement. In affirming *Eli Lilly*, the Federal Circuit has clearly perceived a need to reach beyond the enablement test to resolve issues of ade-

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85 See Sven J.R. Bostyn, Written Description after Enzo Biochem: Can the Real Requirement Step Forward Please?, 85 J Patent & Trademark Off Socy 131, 152 (2003) (suggesting limiting “the application of the written description requirement to cases where priority issues are involved”); Shraddha A. Upadhyaya, The Postmodern Written Description Requirement: An Analysis of the Application of the Heightened Written Description Requirement to Original Claims, 4 Minn Intel Prop Rev 65, 121 (2002) (“The written description requirement cannot and should not serve any function other than to guarantee that subsequently filed claims are entitled to the benefit of the original application.”).

86 See Bostyn, 85 J Patent & Trademark Off Socy at 152 (cited in note 85) (suggesting, as one possible solution, that courts “do away with the requirement”); Mark D. Janis, On Courts Herding Cats: Contending with the “Written Description” Requirement (and Other Unruly Patent Disclosure Doctrines), 2 Wash U J L & Pol 55, 108 (2000) (suggesting that courts use enablement as the dominant disclosure principle, making “reliance on the written description requirement... so rare that [it] could finally be discarded”).
The "Extended" Written Description Requirement

The court has identified a problem in the adequate disclosure requirements and cannot ignore the problem even though its initial solution was flawed. At the same time, the extended written description requirement's problems preclude maintaining the status quo. One commentator has argued that the requirement could be retained as "a fail-safe mechanism that judges (or examiners) [could] use in their discretion in hard cases." This solution, however, does not resolve the problem of expansive judicial discretion triggered by the extended written description requirement's lack of boundaries, nor does it address cases where judicial discretion has already improperly invalidated claims.

A better solution would distinguish between the abstract goal of adequate disclosure and the practical tests for determining adequate disclosure. Adequate disclosure would be the ultimate principle or purpose; the tests are an approximation by which a court determines whether that ultimate principle or purpose is fulfilled. The current enablement test is an insufficient approximation of the abstract goal of adequate disclosure, while the extended written description requirement overcompensates for this insufficiency.

The new considerations provided by the extended written description requirement should be combined with the Wands enablement factors, creating a single test. The PTO factors place a specific focus on the written description that is lacking in the current test for enablement, emphasizing the "words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." Combining these factors with the enablement test factors would compensate for the current test's deficiencies while creating a logical boundary: the goal of adequate disclosure sufficient to enable one skilled in the art.

B. The Solution in Practice

To the extent that this solution will apply retroactively, it will invalidate far fewer patents than the current extended written description requirement. As this solution is a modification in the test for enablement, it will have, in effect, a "retroactive" application. However, since this solution is merely a clarification of the law and a provision of additional guidelines to the enablement test, the supposed "retroactivity" should not affect valid claims. This solution ameliorates the problems of the extended written description requirement by making the standard for adequate disclosure clear-cut and explicit. The patent

87 But see Bostyn, 85 J Patent & Trademark Off Socy at 152 (cited in note 85) (suggesting, in the alternative, "leav[ing] everything as it is under present case law").
88 Janis, 2 Wash U J L & Pol at 107 (cited in note 86).
89 Lockwood v American Airlines, Inc. 107 F3d 1565, 1572 (Fed Cir 1997).
claims that would be invalidated under this new test should be invalidated for failure to fulfill the goal of adequate disclosure.

Consider the jury situation mentioned in Part I.C.2 involving the issues of enablement and written description. There, the “jury faced the cumbersome task of separating two doctrines for sufficiency of disclosure in a patent.” Because the Federal Circuit has had difficulty articulating the distinction between the enablement and extended written description requirements, a jury can hardly be expected to understand the doctrines. Under the proposed solution, the only adequate disclosure doctrine to consider would be enablement. The modified enablement test would have a set of clearly defined factors, including those currently under the heading of the extended written description requirement. This would greatly clarify the disclosure requirements for the benefit of trial courts and juries.

Consider also the hypothetical posed in Part I.C.1 involving a well-known DNA sequence commonly known as the obesity gene. Under *Eli Lilly*, claims involving the obesity gene would be incorrectly invalidated unless the specification listed all nucleotides in the sequence. While the Federal Circuit no longer requires a sequential listing of each nucleotide in a claimed DNA sequence in order for the claims to meet the extended written description requirement, it has not set forth what disclosure would fulfill the requirement. Suppose a patent claim involves a novel DNA sequence, a newly discovered gene that correlates with the incidence of breast cancer. In almost any gene sequence, “[m]any of the amino acids in the chain have substitutes that may take their place without altering the functional properties of the protein.” Under the extended written description requirement, a court may very well decide that every substitute must be included in the specification, regardless of whether the patent was enabled. This result does not consider that while an art as a whole may be unpredictable, certain elements of that art may be very predictable, including elements of a newly created gene sequence.

The extended written description requirement could potentially be used to incorrectly invalidate claims in wholly predictable arts. In *Moba v Diamond Automation, Inc*, the Federal Circuit affirmed a district court’s application of the extended written description requirement without much analysis. This was the first time the Federal Circuit applied the extended written description requirement to a mechanical art, that of “high-speed egg processing machines.” In *Moba*, the jury

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90 *Moba*, 325 F3d at 1323 (Rader concurring).
91 See *Amgen*, 314 F3d at 1332.
92 *Moba*, 325 F3d at 1325 (Rader concurring).
93 325 F3d 1306 (Fed Cir 2003).
94 Id at 1309.
found that a claim directed to "lifting eggs from a moving conveyor" demonstrated "possession of the invention at the time of filing" and was "not invalid for lack of an adequate written description." While the appropriate result was achieved, in predictable arts the extended written description requirement could be applied to achieve particularly absurd results. In the extreme, a patent application for a wooden mousetrap could be invalidated for lack of description of the nails and hammer. Clearly this example would not occur, but similar results may occur in slightly more complex yet predictable fields.

Suppose a patent's written description and drawings describe and depict prefabricated shingles fixed together in groups of six. Suppose further that the main patent claim is directed to prefabricated shingles fixed together without specifying a particular number. This claim would include prefabricated shingles in groups of any number. Under the extended written description requirement, however, the claim could be invalidated entirely or limited to shingles in groups of six. The drawings and diagrams showed six shingles fixed together. The written description discussed six shingles fixed together. Under the proposed solution, a court would consider enablement under the Wands factors and the extended written description factors combined. Though the diagrams and written description teach six shingles fixed together, the broad claim puts the public on notice that the inventor is claiming all numbers of shingles fixed together. The predictability of the art is also high, such that one skilled in the art would understand that the shingles could be fixed together in any number.

C. Purported "Enabled but not Described" Claims

Some have argued that there is a class of claims that is enabled but not described, providing the patent holder with rights not contemplated (or deserved) at the time of filing. Under this line of reasoning, the extended written description requirement would eliminate this class of claims. This argument, however, is based on a flawed view of the enablement requirement. Enablement requires that an inventor enable one skilled in the art to make and use the claimed invention without undue experimentation through "full, clear, concise, and exact terms." It is difficult to comprehend how an enabled specification can still fail to sufficiently describe the invention; if the inventor's disclosure suffices to enable others to reproduce the invention, it necessarily

\[\text{Id at 1321.}\]
\[\text{Though the legal issue has been changed, the shingle patent hypothetical is taken from the facts of Application of Barker, 559 F2d 588, 589–91 (CCPA 1977).}\]
\[\text{See Application of DiLeone, 436 F2d 1404, 1405 n 1 (CCPA 1971).}\]
\[\text{35 USC § 112.}\]
demonstrates that the inventor has possession of the claimed invention. The CCPA has attempted to elucidate: “[C]onsider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B, and C has not been described.”

The CCPA illustration is accurate, yet misleading. If the specification describes and claims only A with no broadening language, but enables A, B, and C, the inventor cannot add claims for B and C under the original written description requirement as a priority policing doctrine. In this context, the written description requirement would serve the same purpose as the new matter prohibition of 35 USC § 132. If the patent describes A and claims the class of A, B, and C, the patent is either: (1) not enabled because one skilled in the art would not be able to make B and C without undue experimentation; or (2) enabled because one skilled in the art would be able to make B and C without undue experimentation. While A, B, and C have not been literally described, the broad claim puts the public on notice regarding the scope of the claimed invention. Enablement would then determine whether the written description is sufficient.

The CCPA illustration essentially describes most patent applications. Inventors draft claims broadly in order to protect against infringement. If some claims are broader than what is enabled by the specification, those claims are invalidated. If claims broader than what is described in the invention were invalid, only the narrowest claims claiming specifically described embodiments would be valid. This cannot be what was contemplated by the CCPA. The Federal Circuit has stated that in a predictable art, “a broad claim can be enabled by disclosure of a single embodiment.” A corollary is that a patent need not describe every embodiment that falls within its claims.

In unpredictable arts, such as biotechnology, the specification for an invention requires detailed disclosure and guidance to achieve enablement. Description of one embodiment is likely insufficient to enable a broad claim. Thus, a logical conclusion for both predictable
and unpredictable arts is this: if the written description is sufficient to enable the full scope of the claims, then embodiments claimed but not described in the specification can be known to one skilled in the art without a verbatim description. The CCPA illustration provides no logical rationale for requiring more description than necessary to impart that knowledge.

D. Supposed “Fortuitous Enablement”

“Fortuitous enablement” supposedly occurs when an inventor’s patent enables an invention that was not known at the time the patent was filed. If the fortuitous invention were lucrative, an inventor would receive a windfall, reaping undeserved benefits by suing for infringement or licensing the patent. This concern commonly arises in unpredictable arts, where a broad claim may encompass more embodiments than expressly disclosed or even contemplated. One commentator has suggested that “[w]ithout a heightened written description requirement, inventors could receive patent rights to sequences of which they have no knowledge, in organisms with which they have never worked.” The same commentator asserted that the requirement will invalidate overly broad patent claims that would stifle new areas of research. A deeper analysis of enablement reveals that preventing “fortuitous enablement” is well within the bounds of the enablement requirement.

For an inventor to receive a “windfall,” the fortuitous invention must have been enabled “at the time the application was filed.” Patent claims are limited by the state of technology as of the application’s filing date. Embodiments that are legitimately enabled are not fortuitous; the inventor contemplated those inventions as evidenced by his or her broad claims. “In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws.” Therefore, in a predictable art, “a broad claim can be enabled by disclosure of a single embodiment.” In an unpredictable art, “the scope of enablement obviously varies inversely with the degree of unpredictability of the fac-

105 Id.
106 Adang v Fischhoff, 286 F3d 1346, 1355 (Fed Cir 2002).
107 Fisher, 427 F2d at 839.
108 Spectra-Physics, 827 F2d at 1533 (citations omitted).
tors involved." There can be no fortuitously enabled claims under the enablement requirement: any embodiment that was not known at the time the patent was filed would not be covered by the claims. There is no room for discretion, as the standard is clear.

Though the grant of overly narrow claims provides no incentive to invest in research and development, the grant of overly broad claims may provide an inventor with rights to an entire field of technology. The extended written description requirement works to the extreme: even the narrowest claims could potentially be invalidated. In *Eli Lilly*, for example, the Federal Circuit required a sequential listing of each nucleotide in a claimed DNA sequence in order for the claims to meet the written description requirement. As the court has since recognized, adopting this level of specificity as a patent standard for all claims is without justification in patent policy and onerous for inventors. Still, such specificity may be necessary under the enablement requirement in certain cases. If genetic sequencing is highly unpredictable, then a patent likely cannot claim more than the sequence of nucleotides it explicitly describes. After all, one must be enabled to make and use the claimed invention *without undue experimentation*. If the *Eli Lilly* court requires disclosure of sequences that are not known in the art, then it is merely requiring an enabling disclosure. Once certain areas of technology become more predictable, less disclosure will be required.

**Conclusion**

Contrary to the basic quid pro quo of patent law, the extended written description requirement requires more specific disclosure than necessary to enable the claimed invention. The limits of the extended written description requirement have yet to be clearly defined, sowing doubt and uncertainty among inventors without serving any beneficial purpose. Subsuming the extended written description requirement under the enablement requirement would greatly clarify the requirements of adequate disclosure by emphasizing that enablement is the limiting principle. When used in this way, the extended written description factors enrich the enablement analysis and help to ensure that the goal of adequate disclosure is fulfilled.

The arguments in favor of the freestanding extended written description requirement do not withstand scrutiny. There is little historical support for the *Eli Lilly* interpretation of the written description

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109 Fisher, 427 F2d at 839. There would of course be evidentiary issues in showing what was known in the art at that time.
110 Eli Lilly, 119 F3d at 1569.
111 Adang, 286 F3d at 1355.
requirement. In light of the quid pro quo of patent law, it is difficult to justify requiring written description beyond that which enables the claimed invention. Maintaining the current written description trend is confusing, vague, and unnecessary, and will result in overly extensive disclosures and unnecessary invalidation of existing patent claims. Combining the factors for the extended written description and enablement requirements would assist courts in invalidating claims that may satisfy the current enablement factors without fulfilling the requirement of adequate disclosure. Such a change would not disturb the general structure of patent law, but would merely collapse a recently created disclosure doctrine into the established enablement requirement. Altering the extended written description requirement in this manner would also preserve the expectations of inventors.

The extended written description requirement is not well established, well defined, or deeply rooted. Enablement is a powerful disclosure doctrine that should not be relegated to secondary importance. Collapsing the extended written description requirement into the enablement requirement is a positive, feasible, and necessary step in the development of patent law.