BITING OFF MORE THAN YOU CAN CHEW: THE NEW LAW OF ENABLEMENT

By Jason Romrell

I. INTRODUCTION

In the recent decisions of *Liebel-Flarsheim Co. v. Medrad, Inc.*¹ and *Automotive Technologies International, Inc. v. BMW of North America, Inc.*,² the U.S. Court of Appeals for the Federal Circuit significantly strengthened the enablement requirement for inventions in the "predictable arts." Predictable arts comprise mechanical and electrical inventions that rely upon well understood scientific principles where experimental results are consistent and repeatable.³ Because of this predictability and the depth of knowledge of those having ordinary skill in such arts, the Federal Circuit has traditionally allowed inventors to fully enable multiple embodiments of inventions in these arts without reciting all of those embodiments in the specification. In contrast, the Federal Circuit has applied a stringent standard of enablement to patents involving "unpredictable arts."⁴ These patents include many biotechnology and chemical inventions that rely on developing scientific principles where results are often inconsistent and unreliable.⁵ In *Medrad* and *BMW*, the Federal Circuit adopted this stringent enablement standard for the predictable arts, insisting that the specification contain a "reasonable enablement of the scope of the range"⁶ of the claims.

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1. 481 F.3d 1371 (Fed. Cir. 2007).
2. 501 F.3d 1274 (Fed. Cir. 2007).
3. See ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 680 (4th ed. 2007) (explaining that in fields "such as mechanic, electronics, and even computer programming, the effect of modifying or combining features may be more predictable [than in chemistry and pharmaceutical research]").
5. See MERGES & DUFFY, supra note 3 ("[S]ome fields, especially chemistry and pharmaceutical research, are known to be highly unpredictable. Indeed, these fields are sometimes called 'the unpredictable arts' because slight changes in a chemical composition can lead to vastly different reactions.").
6. *Medrad*, 481 F.3d at 1380 (citing AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003)).
The Federal Circuit's new enablement standard may even go beyond that needed for one skilled in the art to practice the invention. The BMW court required that all novel aspects of an invention be enabled in the patent specification, regardless of whether one of skill in the art needs such a disclosure to practice the invention. However, requiring disclosure beyond what is necessary to practice an invention has traditionally been the burden of the written description requirement. Thus, this approach to enablement further blurs the respective roles of enablement and written description.

Part II of this Note briefly describes the enablement requirement, its European counterpart, and how the U.S. enablement standard has varied according to the technological field of invention. Part III summarizes the recent Medrad and BMW decisions addressing issues of enablement in the predictable arts. Part IV discusses how these decisions alter the enablement standard for patents in the predictable arts by requiring a degree of enablement beyond what is necessary for one skilled in the art to practice an invention without undue experimentation. Part IV also discusses how the Federal Circuit's stricter enablement analysis unnecessarily complicates the division between the written description requirement and the enablement requirement, thus leaving patentees uncertain as to what constitutes an adequate disclosure. Finally, Part IV cautions patentees asserting broad claims, which can now easily be invalidated for lack of enablement, even in the predictable arts. Although an overly strict disclosure requirement has the potential to stifle research and development, a balanced and well-defined enablement requirement can prevent unwarranted extension of claim scope and therefore promote innovation from second-generation inventors.

II. THE EVOLUTION OF THE ENABLEMENT REQUIREMENT

The enablement and written description requirements are set forth in the first paragraph of Section 112 of the Patent Act of 1952 ("§ 112").

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7. BMW, 501 F.3d at 1283.
8. See id. ("Although the knowledge of one skilled in the art is indeed relevant, the novel aspect of an invention must be enabled in the patent.").
9. See In re Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989) (explaining that to fulfill the written description requirement, the patent specification "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.").
The specification shall 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.\textsuperscript{11}

The Federal Circuit interprets § 112 as mandating three distinctive requirements: (1) the written description requirement; (2) the enablement requirement; and (3) the best mode requirement.\textsuperscript{12} Although the best mode requirement is designed to prevent a patentee from concealing part of the invention while obtaining patent protection for the whole,\textsuperscript{13} the written description and the enablement requirements serve to guard against overly broad patent rights.

This Part discusses the purpose behind the enablement requirement and the differences between enablement and written description. This Part also discusses the European Patent Office's disclosure requirements and compares the European approach to that of the United States. Finally, this Part analyzes the more lenient approach typically applied to enablement in the predicable arts as opposed to the stricter approach taken in the unpredictable arts.

A. Defining the Written Description and Enablement Requirements

The current disclosure requirement in the United States has separate enablement and written description requirements. Written description ensures that the inventor was actually in possession of the claimed invention at the time of filing.\textsuperscript{14} Enablement certifies that one of ordinary skill in the art can practice a claimed invention without undue experimentation.\textsuperscript{15} Analysis of whether a patent disclosure is enabling consists of several factors, including the predictability of the technology at issue. The dividing line between written description and enablement is at best, a blurry one.

\textsuperscript{12} See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991).
\textsuperscript{13} See In re Gay, 309 F.2d 769, 772 (C.C.P.A. 1962) ("[T]he sole purpose of [the best mode] requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived.").
\textsuperscript{14} Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).
\textsuperscript{15} In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).
Although the relationship between the written description requirement and the enablement requirement of § 112\(^{16}\) has been the subject of debate,\(^{17}\) written description and enablement represent distinct requirements under current law.\(^{18}\) The doctrine of enablement has been embedded in U.S. law at least since 1832,\(^{19}\) but the written description requirement is a relative newcomer to the playing field. This latter requirement appeared in limited case law dating back to the early 1970s,\(^{20}\) but was initially "met with a cool reception" and "had faded almost completely from subsequent decisions in the late 1970's and 1980's."\(^{21}\) Beginning in the late 1990's, however, the Federal Circuit resurrected and strengthened the written description requirement.\(^{22}\) The Federal Circuit sought to prevent overreaching claims through excessive amendment practice and to prohibit patentees from later claiming what they did not possess at the time they filed their applications by requiring a patent disclosure to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [that the patentee] was in possession of the invention."\(^{23}\)

Unlike the written description requirement, which exists mainly to prevent a patentee from claiming more than she possesses at the time of filing, the enablement requirement "helps ensure that a person of ordinary skill in the art will be able to practice the full scope of the invention."\(^{24}\) Society thereby receives the information necessary to practice the invention in exchange for granting exclusive rights during the patent term. To be enabling, the patent specification must teach those skilled in the art


\(^{17}\) See Denise W. DeFranco & Ashley A. Weaver, Written Description and Enablement: One Requirement or Two?, 15 FED. CIR. B. J. 101, 113-114 (2006) (arguing that even though the requirements remain distinct, several judges have suggested that there is no statutory basis for separating them).

\(^{18}\) Id. at 101.

\(^{19}\) See Grant v. Raymond, 31 U.S. 218, 241-42 (1832) ("The public yields nothing which it has not agreed to yield; it receives all which it has contracted to receive. The full benefit of the discovery. . . . ").

\(^{20}\) See, e.g., In re DiLeon, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971) ("[C]onsider a 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.").

\(^{21}\) See MERGES & DUFFY, supra note 3, at 302.

\(^{22}\) See id.


\(^{24}\) Andrea G. Reister, Enablement & Written Description: We Know It When We See It and a Word About Obviousness, in PATENT LITIGATION 2007, at 479, 487 (PLI Pats., Copyrights, Trademarks, & Literary Prop., Course Handbook Series No. 11589, 2007).
"how to make and use the full scope of the claimed invention without undue experimentation."\textsuperscript{25} The first paragraph of § 112\textsuperscript{26} further demands that "the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."\textsuperscript{27}

In In re Wands, the Federal Circuit set forth a list of factors to consider in determining whether the disclosure requires "undue experimentation."\textsuperscript{28} These include:

(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 of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.\textsuperscript{29}

Although the Wands factors are "illustrative, not mandatory,"\textsuperscript{30} they provide a basis for defining the boundaries of undue experimentation. As discussed in Section II.C below, the predictability or unpredictability of the art is especially important in analyzing claims spanning multiple embodiments.

Despite the resurgence of the written description requirement, the necessity of two separate disclosure doctrines—enablement and written description—is unclear. Several scholars and judges have called for a single unified disclosure doctrine,\textsuperscript{31} and the Federal Circuit has acknowledged that to the "uninitiated," a separate written description requirement within 35 U.S.C. § 112 may seem "anomalous."\textsuperscript{32} Nothing in the language of 35 U.S.C. § 112 suggests the need for a separate written description requirement beyond enablement. The statutory language requires written descrip-

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\textsuperscript{25} In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).
\textsuperscript{28} See In re Wands, 858 F.2d 731 (Fed. Cir. 1988).
\textsuperscript{29} Id. at 737 (emphasis added).
\textsuperscript{31} See Mark D. Janis, On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines), 2 WASH. U. J.L. & POL'Y 55, 62-69 (2000) (arguing that the distinction made by the Federal Circuit between written description and enablement is artificial); DeFranco, supra note 17, at 101.
\textsuperscript{32} Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991) ("To the uninitiated, it may seem anomalous that the first paragraph of 35 U.S.C. § 112 has been interpreted as requiring a separate 'description of the invention.'").
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tion sufficient to enable the claimed invention. If a patent disclosure enables claims as filed or as amended during prosecution, then further disclosure that satisfies the judicially created written description requirement seems superfluous. Unfortunately, the Federal Circuit has failed to develop a consistent rationale for perpetuating the written description requirement. Because written description has little historical or statutory justification, it is almost entirely reliant upon judicial construction. Without a tether to statutory limits, patentees might fear that a written description requirement controlled solely by the judiciary leads to uncertainty as to what constitutes sufficient disclosure.

B. Comparison With the European Standard of Enablement

This Section discusses the European Patent Office's (EPO) requirements for an enabling disclosure and analyzes a European doctrine similar to written description, but which is embedded within the enablement requirement.

European Patent Convention (EPC) Article 83 states that "[t]he European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." Although the EPO lacks a formally recognizable written description requirement, Article 84 of the European Patent Convention provides that "[t]he claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description." For example, under the European system:

The invention must be sufficiently disclosed to enable it to be performed over the complete width of the claim. Disclosure of one [method of carrying out the invention] is only sufficient if it allows a person skilled in the art, using his common general

33. "The specification shall 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 . . . ." 35 U.S.C. § 112, ¶ 1 (emphasis added).
34. See Janis, supra note 31, at 62–69 (explaining that historical or logical rationales based on dissuading fortuitous enablement are incomplete and unconvincing).
35. See MERGES & DUFFY, supra note 3, at 302.
36. See Janis, supra note 31, at 80–81 (explaining that one consequence of an unrestricted written description requirement "is an unpredictable, and even arbitrary, application of the [written description] requirement, especially as a result of overzealous appellate review.
39. European Patent Convention, supra note 37, art. 84.
knowledge, to carry out the invention within the whole range that is claimed.\(^{40}\)

In addition, “the purpose of [Article 84 EPC] must be seen as safeguarding that the claims do not cover any subject-matter which, after reading the description, still would not be at the disposal of the skilled person.”\(^{41}\)

The European Board of Appeals has suggested that the combined requirements of Article 83 and 84 may require more than an enabling disclosure:

Although the requirements of Article 83 and Article 84 are directed to different parts of the patent application, since Article 83 relates to the disclosure of the invention, whilst Article 84 deals with the definition of the invention by the claims, the underlying purpose of the requirement of sufficient disclosure is the same, namely to ensure that the patent monopoly should be justified by the actual technical contribution to the art. Thus, a claim may well be supported by the description in the sense that it corresponds to it, but still encompass subject matter which is not sufficiently disclosed within the meaning of Article 83 as it cannot be performed without undue burden, or vice versa.\(^{42}\)

Article 84 may create a *de facto* written description requirement that falls within the European enablement requirement, thus establishing an overall more rigid standard of enablement than the United States.\(^{43}\) This is because Article 84 requires correspondence between the claims and the specification, but the U.S. enablement requirement currently does not. In the United States, correspondence between claim and specification is achieved through a judicially created written description requirement and not through statute.\(^{44}\) Even though the combination of Article 83 and Arti-


\(^{42}\) See Janis, *supra* note 31, at 92-93 (quoting T409/91-6 and explaining that the EPO has confronted the same issues as the United States in grappling with two separate disclosure requirements) (emphasis added).

\(^{43}\) Paredes, *supra* note 38, at 503-04.

\(^{44}\) See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (explaining that in order to prohibit patentees from later claiming what they did not possess
Article 84 creates a more demanding European enablement requirement, the EPO's overall enablement analysis is roughly similar to the U.S. Patent & Trademark Office's (PTO) written description and enablement criteria.45

C. Different Requirements for Different Technologies

This Section discusses how the standard used to evaluate enablement depends in part on the predictability of the technology at issue. Traditionally, broad claims in the predictable arts may be fully enabled by disclosing a single embodiment.46 Experimentation is less likely to be unduly extensive in a field of technology with a substantial and well understood history, e.g. mechanical or electrical arts, than with newer, less predictable technologies. The biotechnology and chemical fields have historically been considered "unpredictable" arts and have thus required a more detailed specification to fulfill the enablement requirement.47

In unpredictable technologies, it is largely presumed that one of ordinary skill in the art would not have the expertise necessary to fill in the gaps left in a patent disclosure, especially gaps associated with novel subject matter.48 For example, in Genentech, Inc. v. Novo Nordisk A/S, the Federal Circuit held that claims covering a cleavable fusion expression process for producing human growth hormone (hGH) were invalid due to lack of enablement.49 The court reasoned that where the inventor claims the application of an unpredictable technology in the early stages of development (commonly referred to as nascent technology), an enabling description must provide those skilled in the art with a "specific and useful teaching."50 The Genentech panel further explained that "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enable-

at the time they filed their applications, the written description requirement demands that the patent specification "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [that the patentee] was in possession of the invention").


48. See id.; see also supra notes 3-5 and accompanying text.


50. Id. at 1367-68.
Moreover, a specification in the unpredictable technologies must "teach those skilled in the art how to make and use the full scope of the invention."52

Similarly, in AK Steel Corp v. Sollac & Ugine, the Federal Circuit invalidated claims directed to a chemical method of coating stainless steel with an aluminum/silicon compound because the patent disclosure did not enable practice of the full claim scope.53 Like Genentech, the chemical claims of AK Steel were directed toward an unpredictable field of technology.54

In contrast, where the art is largely predictable and the skills of the artisan broad, knowledge of the prior art and routine experimentation have traditionally allowed claims to reach beyond the embodiments disclosed in the specification.55 In Spectra-Physics, Inc. v. Coherent, Inc., the Federal Circuit found that a claim directed to a means for attaching copper cups inside the ceramic tube of a laser was enabled to cover a TiCuSil brazing method that wasn’t specifically discussed in the patent disclosure.56 The Federal Circuit concluded that a claim is not invalid for lack of enablement simply because it "reads on another embodiment of the invention which is inadequately disclosed."57

### III. SUMMARY OF CASES

This Part examines two recent Federal Circuit decisions that signify a dramatic departure from the historically relaxed enablement standard for the predictable arts. In Liebel-Flarsheim Co. v. Medrad, Inc., the Federal Circuit applied a strict standard of enablement to invalidate a mechanical claim where the full scope of the claim was not enabled within the patent specification. In Automotive Technologies International, Inc. v. BMW of North America, Inc., the Federal Circuit extended this stringent analysis of enablement in the predictable arts by demanding that all novel aspects of

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51. Id. at 1366.
52. Id. at 1365 (citing In re Wright, 999 F.2d 1561 (Fed. Cir. 1993)).
53. 344 F.3d 1234, 1244 (Fed. Cir. 2003).
54. See id. at 1244 (holding that using Type 2 instead of Type 1 Aluminum is not within the scope of ordinary skill in the art); AK Steel Corp. v. Sollac & Ugine, 234 F. Supp. 2d 711, 719 (S.D. Ohio 2002) (explaining that the district court rejected the argument that "adjustments that may be required to switch from Type 2 to Type 1 [Aluminum] were known, and their effects predictable, based on the information published in the relative field and the . . . specification").
56. Id.
57. Id.
an invention be enabled within the specification without relying on the knowledge available to one of ordinary skill in the art. The stricter standard of enablement in the predictable arts is now poised to invalidate claims that have a broad scope even if one of ordinary skill in the art could practice the full invention.

A. Liebel-Flarsheim Co. v. Medrad, Inc.

In Medrad, Liebel brought an action against Medrad alleging infringement of four medical device patents owned by Liebel. Two of the patents, referred to as the “front-loading patents,” were directed to a front-loading fluid injector with a replaceable syringe capable of withstanding high pressures. Liebel learned of Medrad’s jacketless injector system during the prosecution of the front-loading patents and deleted all claim references to a pressure jacket in order to encompass Medrad’s product. At trial, the district court found that Liebel’s patent claims did not cover a jacketless injector system. The Federal Circuit reversed and remanded, determining that the front-loading patent claims did in fact cover a jacketless injector system.

Despite Liebel’s success on claim construction at the Federal Circuit, the district court once again found that Medrad was not liable for infringement of the front-loading patents because the claims were invalid under the written description and enablement requirements. The district court emphasized that all of Liebel’s tests of jacketless systems were unsuccessful. Furthermore, Liebel’s engineers testified that “one skilled in the art would not know how to make a jacketless system.” Liebel appealed the finding of invalidity.

This time the Federal Circuit affirmed, relying solely upon the enablement requirement while declining to address written description. The

59. Id. The front-loading patents are U.S. Patent No. 5,456,669 (the ’669 patent) and U.S. Patent No. 5,658,261 (the ’261 patent). Id.
60. Id. at 1374.
61. Id.
62. Id.
63. Id. at 1375.
64. Id.; see also In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Liebel’s unsuccessful testing of a jacketless system would be particularly damaging in assessing the first three Wands factors: 1) the quantity of experimentation necessary; 2) the amount of direction or guidance presented; and 3) the presence or absence of working examples.
65. Medrad, 481 F.3d at 1375.
66. Id. at 1377.
67. Id. at 1378.
court rejected Liebel's comparisons to Spectra-Physics, which would have permitted a lower enablement standard, instead comparing Liebel's situation to that in AK Steel, wherein a chemical process patent was held invalid for not enabling the full scope of its claims. When it applied the AK Steel standard to Liebel's invention, the Federal Circuit noted that the front-loading patent specifications did not describe a disposable syringe without a pressure jacket. Moreover, the specifications taught away from a disposable syringe without a pressure jacket by describing such a syringe as "impractical." Liebel's argument that its single embodiment could enable broad claim support failed in large part because of testimony from its own scientists who admitted to trying a jacketless pressure system without success. In sum, the Federal Circuit bluntly stated that:

The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, 'beware of what one asks for,' might be applicable here.

Medrad demonstrates decreasing willingness of the Federal Circuit to rely upon "ordinary skill in the art" to fill in the gaps of a disclosure simply because the invention is mechanical. Because Liebel's specifications did not disclose the exact configuration of a syringe device without a pressure jacket and even admitted impracticality of such a configuration, the Federal Circuit was unwilling to find sufficient support in the "ordinary skill" to enable the claims despite their mechanical nature. The Federal Circuit's explicit warning against asserting overly broad claims in the course of litigation is the most notable portion of the Medrad decision. Liebel's admitted difficulties in manufacturing a jacketless syringe may have proven too much for their claim to enablement; however, a subsequent case building upon the Medrad decision further indicates a tightening enablement standard in the mechanical arts.

68. Id. at 1380 ("Because we are resolving this issue on the enablement ground, we do not need to consider the written description holding of invalidity.").
69. Id. at 1380 (citing AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003)). For more information about AK Steel, see supra Section II.C.
70. Id. at 1378.
71. Id. at 1379.
72. Id. However, "[a]ccording to Liebel, the testimony that the court relied upon only showed that additional work, not undue experimentation, was required to develop an injector without a pressure jacket." Id. at 1378.
73. Id. at 1380.
B. Automotive Technologies International, Inc. v. BMW of North America, Inc.

In Automotive Technologies International, Inc. v. BMW of North America, Inc., the plaintiff Automotive Technologies International (ATI) appealed a district court decision that invalidated 44 claims in its U.S. Patent 5,231,253 (the '253 patent) pertaining to side-impact vehicle air bag sensors.\(^\text{74}\) The court found that the '253 patent specification enabled mechanical sensors, but did not enable a means-plus-function claim limitation encompassing both mechanical and electronic sensors.\(^\text{75}\) The district court therefore granted summary judgment of invalidity to a host of defendants including BMW, DaimlerChrysler, Honda, Toyota, Mazda, Saab, Nissan, Kia, GMC, Ford, and Volkswagen.\(^\text{76}\)

The '253 patent specification includes a two-column description of the mechanical embodiment of the side impact sensors.\(^\text{77}\) However, the description of the electrical embodiment of the side impact sensor consists of only a paragraph and a single figure.\(^\text{78}\) On appeal, the Federal Circuit emphasized this difference, stating that “[i]f such a disclosure is needed to enable making and using a mechanical side impact sensor, why is not a similar disclosure needed to enable making and using an electronic side impact sensor, which is an essential aspect of the invention?”\(^\text{79}\) Moreover, the inventor admitted that “he had never built an electronic sensor for side impact,” thereby supporting the finding that the electronic sensor was not enabled.\(^\text{80}\)

The Federal Circuit held that the electronic sensor invention was not enabled even if one skilled in the art could have practiced the electronic sensor invention based upon this short description.\(^\text{81}\) In reaching this conclusion, the Federal Circuit parroted its analysis in Genentech v. Novo Nordisk A/S, a case concerning the “unpredictable” art of nascent biotechnology.\(^\text{82}\) Citing Genentech, the Federal Circuit found that “it is the specification, not the knowledge of one skilled in the art, that must supply the


\(^{75}\) Id. at 1285.

\(^{76}\) Id. at 1274.

\(^{77}\) Id.

\(^{78}\) Id.

\(^{79}\) Id.

\(^{80}\) Id.

\(^{81}\) See id. at 1285.

\(^{82}\) See Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir. 1997). For more information about this case, see Section II.C, supra.
novel aspects of an invention in order to constitute adequate enablement.\textsuperscript{83}

Applying \textit{Genentech}, the Federal Circuit found that even if the knowledge readily available to one skilled in the art enabled the invention, the novel components still needed full disclosure in the specification.\textsuperscript{84} Just as Liebel had argued for a broader interpretation of its claims to include jackless syringe systems, ATI argued for a broader interpretation of its claims to include electrical as well as mechanical sensors. Instead of permitting ATI’s mechanical/electrical claims to be enabled by a detailed disclosure of a single embodiment\textsuperscript{85} in accordance with prior case law, the Federal Circuit applied a strict, non-predictable arts approach to enablement and found the claims invalid for lack thereof.\textsuperscript{86} Taken together, \textit{Medrad} and \textit{BMW} indicate a trend toward the limitation of the enabled “scope of the range” in electrical and mechanical patent specifications.\textsuperscript{87}

\textbf{IV. DISCUSSION}

This Part analyzes four ramifications of \textit{Medrad} and \textit{BMW}. First, both cases indicate that the Federal Circuit is moving away from a presumption of enablement in the predictable arts\textsuperscript{88} towards a strict enablement standard resembling that traditionally reserved for biotechnology.\textsuperscript{89} Second, \textit{BMW} suggests that this stricter enablement standard requires disclosure beyond the information necessary to enable one skilled in the art to practice the invention without undue experimentation. Third, the expansion of the enablement requirement without explicit renunciation of the questionable written description requirement further blurs the line between these two disclosure doctrines. Fourth, even though the new Federal Circuit enablement standard may prevent unfair extension of patent scope, patentees may be left with a less predictable disclosure requirement that could impede future innovation.

\textsuperscript{84} \textit{Id.}
\textsuperscript{85} \textit{Id.} at 1281.
\textsuperscript{86} \textit{Id.} at 1285 (emphasizing that the electrical sensor was a “distinctly different sensor compared with the well-enabled mechanical side impact sensor”).
\textsuperscript{87} \textit{Id.} (citing Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007)).
\textsuperscript{88} See Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987).
A. New Enablement Standard for Predictable Arts

*Medrad* and *BMW* signal the Federal Circuit’s departure from its lenient standard of enablement in the predictable arts. Broad claim scope for inventions in the predictable arts traditionally could be enabled without disclosing multiple embodiments, whereas the unpredictable arts have typically required a more thorough disclosure to satisfy enablement. *Medrad* and *BMW* suggest that the Federal Circuit will now require enablement of the entire claim scope even for predictable technologies.

Traditionally, the distinction between predictable and unpredictable arts has been crucial in establishing the level of disclosure required in a patent specification. Where an inventive art is less predictable, the Federal Circuit has consistently established that the enablement of a single species within a genus is likely insufficient to enable that genus. Even when a specification outlines the theoretical application to a wide variety of organisms, the actual application of those principles is often unpredictable. For example, experts in *Enzo Biochem, Inc. v. Calgene, Inc.* testified that genetic antisense technology “is not universally applicable, it hasn’t proven to be, and that’s why it’s such an interesting area of research, because scientists don’t understand the rules.” In the unpredictable arts, the lack of stable governing scientific principles often requires undue experimentation to practices claims with broad scope where only a single embodiment is disclosed.

In contrast, the Federal Circuit in *Spectra-Physics* concluded that inventions in the mechanical and electrical arts typically rely on more predictable scientific principles that are better understood. The *Spectra-Physics* court emphasized that an invention in the mechanical arts is not invalid for lack of enablement simply because it covers embodiments not specifically enabled by the patent specification because ordinary skill in the art can supply the missing information.

Although *Spectra-Physics* adopted a lenient approach to enablement in the mechanical arts, *Medrad* and *BMW* demand enablement of “the scope

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90. *See supra* notes 3-5 and accompanying text.
91. *See Sampson,* supra note 4, at 1248.
92. See id.
93. *See id.* (citing *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362, 1371 (Fed. Cir. 1999)).
95. *Id.* (citing *In re Cook,* 439 F.2d 730, 735 (C.C.P.A. 1971); *In re Vickers,* 141 F.2d 522, 527 (C.C.P.A. 1944)).
of the range" covered by the claims.\textsuperscript{96} To be sure, the \textit{Medrad} court distinguished \textit{Spectra-Physics} by emphasizing that one skilled in the art could practice the full scope of the claims asserted in the earlier case.\textsuperscript{97} In contrast, the disclosure in \textit{Medrad}, while enabling an injector system with a pressure jacket, "[did] not permit one skilled in the art to make and use the invention as broadly as it was claimed, including without a pressure jacket."\textsuperscript{98} However, both \textit{Medrad} and \textit{BMW} reflect the Federal Circuit's unwillingness to give inventions in the traditional arts the benefits of assumed predictability.

In \textit{Medrad}, the Federal Circuit relied heavily on testimony that Liebel's inventors tried a jacketless pressure system without success, thus showing that a jacketless pressure system was beyond ordinary skill in the art.\textsuperscript{99} This testimony proved crucial despite the mechanical nature of the syringe at issue. Although the Federal Circuit could have relied solely on this damning evidence to invalidate the patent, the panel nevertheless stated that "there must be reasonable enablement of the scope of the range" even for mechanical inventions.\textsuperscript{100} This "scope of the range" language seemingly contradicts the Federal Circuit's declaration in \textit{Spectra-Physics} that "[i]f 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."\textsuperscript{101}

Similarly, in \textit{BMW}, the Federal Circuit used a stricter enablement standard than in \textit{Spectra-Physics}, giving specific attention to testimony regarding the state of the art at the time the invention was made.\textsuperscript{102} The \textit{BMW} court concluded that testimony supporting the premise that undue experimentation was not necessary to practice the full scope of the invention was inadequate because the testimony did not provide specific examples of tests that could be used to adapt existing electronic sensors to the '253 patent's claimed invention.\textsuperscript{103} Even though an electronic sensor em-

\textsuperscript{96} Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007) (citing Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007)).

\textsuperscript{97} \textit{Medrad}, 481 F.3d at 1379-80.

\textsuperscript{98} \textit{Id.} at 1380.

\textsuperscript{99} \textit{Id.} at 1379.

\textsuperscript{100} \textit{Id.} at 1380 (quoting AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003)) (emphasis added).

\textsuperscript{101} \textit{See Spectra-Physics, Inc. v. Coherent, Inc.}, 827 F.2d 1524, 1533 (Fed. Cir. 1987).

\textsuperscript{102} Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1284 (Fed. Cir. 2007).

\textsuperscript{103} \textit{Id.}
bodiment was supported with a figure and cursory explanation of how an electronic sensory could be used,\textsuperscript{104} the Federal Circuit panel questioned the adequacy of the disclosure.\textsuperscript{105} As illustrated by the thorough analysis of testimony in \textit{Medrad} and \textit{BMW}, the Federal Circuit now appears less willing to allow the predictability of a technology to enable the breadth of a claim beyond the scope of disclosure.

\section*{B. Beyond Enabling One Skilled in the Art}

The \textit{BMW} decision requires applicants to disclose even \textit{more} information than necessary to enable one skilled in the art to practice an invention in the predictable arts. In so holding, the Federal Circuit moved away from its own precedent and assumed a more active role in ascertaining undue experimentation in the predictable arts. The Federal Circuit declared that the knowledge of one skilled in the art is "relevant" to an enablement analysis, but in the end "the novel aspect of an invention must be enabled in the patent."\textsuperscript{106} Accordingly, a patent could violate the enablement requirement \textit{even if} one skilled in the art could practice the full range of the claims. Although the \textit{quid pro quo} structure of the patent system requires adequate disclosure, \textit{BMW} overlooks the possibility that one of ordinary skill in the art might not need an elaborate disclosure to practice a novel embodiment.

The \textit{BMW} standard of enablement is a direct affront to earlier Federal Circuit decisions holding that a patent specification need only disclose sufficient information to enable those skilled in the art to make and use the claimed invention.\textsuperscript{107} Even in more recent biotechnology settings, the court only required disclosure beyond what was necessary for one skilled in the art "when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out" and thus, "undue experimentation is required."\textsuperscript{108}

In requiring a heightened standard of enablement, the Federal Circuit adopted a proactive role in defining "undue experimentation" in the predictable arts. For example, the \textit{BMW} court reasoned that novel aspects of an invention are necessarily new to the art and thus require thorough explanation in the specification regardless of whether one skilled the art

\begin{itemize}
\item \textsuperscript{104} \textit{Id.} at 1277-78.
\item \textsuperscript{105} \textit{Id.} at 1284.
\item \textsuperscript{106} \textit{Id.} at 1283 (citing Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).
\item \textsuperscript{107} \textit{See} Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987).
\item \textsuperscript{108} \textit{See} Genentech, 108 F.3d at 1366.
\end{itemize}
needs such description to practice the invention.\textsuperscript{109} Accordingly, novel aspects of an invention lacking adequate description in the actual patent require undue experimentation even if one skilled in the art can practice the invention as disclosed. Moreover, the \textit{BMW} panel observed that the thorough description of a mechanical sensor provided stark contrast to the lack of description for the electrical embodiment.\textsuperscript{110} The panel reasoned that if both embodiments were truly novel, the electrical embodiment would require a similarly detailed disclosure to avoid the imposition of undue experimentation upon a practitioner.\textsuperscript{111}

Although a patent’s exclusivity rights are understandably inappropriate when a patentee has not enabled one skilled in the art to practice a claimed invention, the Federal Circuit’s reasoning in \textit{BMW} sets aside this fundamental enablement concern. Instead of relying solely on testimony that adopting an electrical sensor was beyond ordinary skill in the art, the Federal Circuit complicated its enablement analysis by applying the reasoning of \textit{Genentech}, a case involving biotechnology.\textsuperscript{112} The \textit{Genentech} panel held that “the novel aspect of an invention must be enabled in the patent,”\textsuperscript{113} but this statement was referring to the unpredictable art of nascent biotechnology, and involved a situation where the “specification provide[d] only a starting point, a direction for further research.”\textsuperscript{114} The Federal Circuit in \textit{BMW} similarly found that the ATI specification provided “only a starting point.”\textsuperscript{115} But unlike Genentech, ATI included a figure in its specification and information that was clearly more than just a starting point: “[t]he motion of the sensing mass 202 can be sensed by a variety of technologies using, for example, optics, resistance change, capacitance change or magnetic reluctance change.”\textsuperscript{116}

Arguably, the predictability of the electrical arts, coupled with the mechanical \textit{and} electrical examples in the ATI patent specification, should have provided enough information to enable one of ordinary skill in the art to practice an electrical sensor without undue experimentation. By de-
manding that enablement of novel embodiments stem entirely from the patent specification, the Federal Circuit effectively made this practical possibility a confusing legal impossibility.

**C. Complicating the Written Description Dilemma**

The stringent enablement standard epitomized in *Medrad* and *BMW* further obscures the line separating enablement from the written description requirement.\(^{117}\) Although the *Medrad* case provided ample opportunity to apply the written description requirement, the Federal Circuit instead chose to focus on enablement. In developing a rigorous enablement analysis based on novelty, the Federal Circuit could have created a viable alternative to the written description requirement that more closely resembles the European enablement standard. However, without the Federal Circuit explicitly stating this intention, the exact scope of the U.S. disclosure doctrine remains unclear.

As described above, commentators have long challenged the origin and scope of the written description requirement.\(^{118}\) *Gentry Gallery v. Berkline Corp.*\(^{119}\) exemplifies the often criticized expansion of the written description requirement. In *Gentry Gallery*, the patentee amended a claim to cover a competitor’s product by expanding the placement of recliner-chair controls.\(^{120}\) The Federal Circuit invalidated the claim because the broadened scope lacked sufficient written description in the specification as filed.\(^{121}\) Traditionally, the Federal Circuit afforded mechanical claims full claim scope even if the written description did not describe all species encompassed by the claims.\(^{122}\) In the wake of *Gentry Gallery*, patent applicants were left in “doubt over the ability of patent applicants to obtain claim protection any broader than the originally filed broadest claim.”\(^{123}\)

*Medrad* presented the Federal Circuit with a straightforward opportunity to invalidate the claims using the written description analysis from *Gentry Gallery*. During prosecution, Liebel removed all references in the claims to a pressure jacket component, even though the claims included this limitation at the time of filing. Liebel introduced these broadening

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118. For more information, see *supra* Section II.A.
120. *Id.* at 1474-75.
121. *Id.* at 1480.
123. *Id.* at 476-77.
amendments specifically to encompass Medrad’s product.\textsuperscript{124} Traditionally, such a maneuver represents exactly the kind of conduct that the written description requirement aims to prevent, namely the modification of claims to cover a competitor’s embodiments that were not originally contemplated within the patent disclosure.\textsuperscript{125} However, the Federal Circuit panel in \textit{Medrad} did not resolve the issue based on the written description requirement and instead invalidated the claims for lack of enablement.\textsuperscript{126}

The \textit{Medrad} decision demonstrates the plausibility of using enablement—rather than written description—to verify that the inventor possessed the claimed invention at the time of filing. The continuing debate among the Federal Circuit regarding the separate written description doctrine may be a contributing factor in the shift toward a more comprehensive enablement standard.\textsuperscript{127} Consequently, this shift may help resolve the redundancy of the two disclosure doctrines.\textsuperscript{128}

Unfortunately, the Federal Circuit has not explicitly stated any intent to merge written description and enablement into a unified disclosure doctrine. Strengthening the enablement standard, however, may lead to a unified disclosure doctrine resembling that of the European Patent Office. As discussed earlier, the European enablement standard encompasses a \textit{de facto} written description requirement \textit{based in statute}.\textsuperscript{129} In particular, EPO enablement analysis relies in part on the notion that “the patent monopoly should be justified by the actual technical contribution to the art.”\textsuperscript{130} This standard may be difficult to apply, but it also avoids the problems associated with the written description requirement.\textsuperscript{131} The European standard may also resemble \textit{BMW}’s requirement that the patent specifica-

\begin{itemize}
  \item \textsuperscript{124} Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1374 (Fed. Cir. 2007).
  \item \textsuperscript{125} \textit{See Janis, supra} note 31, at 60-61.
  \item \textsuperscript{126} \textit{Medrad}, 481 F.3d at 1380.
  \item \textsuperscript{127} \textit{See} Lizardtech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting) (stating that “[the] court’s written description jurisprudence has become opaque to the point of obscuring other areas of this court’s law”); DeFranco, \textit{supra} note 17, at 113-14. Judge Rader, a known critic of the jurisprudence of written description, served on the \textit{Medrad} and \textit{BMW} panels.
  \item \textsuperscript{128} \textit{See} Harris A. Pitlick, \textit{The Mutation on the Description Requirement Gene}, 80 J. PAT. \& TRADEMARK OFF. SOC’Y 209, 222-23 (1998) (criticizing the \textit{Eli Lilly} decision as the court “has lost sight of the real culprit—lack of enablement—and directed its ire at an innocent bystander—the description requirement . . . [and] takes description requirement jurisprudence in an unjustifiably new and reckless direction”).
  \item \textsuperscript{129} \textit{See} Section II.C, \textit{supra}.
  \item \textsuperscript{130} \textit{Janis, supra} note 31, at 92-93 (quoting \textit{T409/91-6} and explaining that the EPO has confronted the same issues as the United States in grappling with two separate disclosure requirements).
  \item \textsuperscript{131} \textit{See} Section II.A, \textit{supra}.
\end{itemize}
tion enables novel aspects of an invention even if the novelties fall within the ordinary skill in the art. By using the enablement standard to limit unsupported claim scope added in post-filing amendments, the Federal Circuit could directly embrace a unified disclosure doctrine similar to that employed by the EPO and avoid the confusion of two competing disclosure doctrines.

Even though the enablement standard created in *Medrad* and *BMW* has the potential to maintain the *quid pro quo* exchange of the patent system in both predictable and unpredictable arts, the confusing analysis employed to achieve these results is difficult to reconcile with existing case law. Nevertheless, the Federal Circuit should overrule its written description precedent and replace it with an all-encompassing enablement requirement. As a result, patent applicants would enjoy a more predictable disclosure standard.

D. Be Careful What You Ask For

Under *Medrad* and *BMW*, a patentee who gains broad scope at claim construction risks having the same claims invalidated for lack of enablement. A strict enablement standard may thereby dissuade some inventors from seeking patent protection. Alternatively, the amount of technological innovation may increase and frivolous litigation could diminish.

In *Medrad*, the Federal Circuit sent a blunt message to litigants who argue for claim scope beyond their originally filed disclosures: “beware of what one asks for.”\(^{132}\) When faced with a challenge to the enablement of a patent, patentees face a critical dilemma. An assertion that one skilled in the art could practice the invention without undue experimentation may aid in circumventing an enablement attack, but also prove fatal in defending against an assertion of obviousness.

For example, in *BMW*, the Federal Circuit found that novel aspects of an invention, by definition, require enablement within the disclosure of a patent, even if one skilled in the art could practice the invention without further instruction.\(^{133}\) The plaintiff, ATI, was thus placed in a precarious situation. The same testimony used to assert that the implementation of electronic sensors was well known in the prior art could be used against ATI as evidence that the embodiment was obvious. Similarly, if ATI were to assert that an electronic sensor was nonobvious and novel, then it possibly bears the burden of fully enabling the sensor within the patent specification without relying on the level of ordinary skill in the art to fill in the

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gaps. Reasonably, ATI is not entitled to all "means" for detecting side-impact crashes if it disclosed only one such means in detail and then admitted in the specification that the field is new. As one commentator noted, ATI "can't have [its] non-obviousness cake and be enabled to eat it, too.'

The Federal Circuit's new approach to enablement might deter some inventors from seeking patent protection. Empirical studies have shown that in research and development intensive industries such as the pharmaceutical industry, patent protection provides the second most effective mechanism for protecting intellectual property, closely trailing secrecy. The same studies also indicate that many companies are dissuaded from filing a patent application for fear that the information disclosed allows a competitor to easily and legally invent around the patent. As one chemical company executive asked, "[w]ill a patent teach our competitors and give the shop away?" A stricter enablement requirement may prove to exacerbate this fear and encourage inventors to utilize trade secret protection rather than patents.

As an alternative to invalidating an entire claim for lack of enablement, the courts could limit a claim to enabled scope only. Superficially at least, this approach appears fair to the rights of the patentee inasmuch as he continues to enjoy the quid pro quo benefit of his contribution to society. However, the patentee would have nothing to lose in attempting to assert broad claim scope. Courts would subsequently face the time-consuming and expensive responsibility of rewriting claims to fit the scope of enablement. In addition, rewriting a claim to fit its enabled scope contradicts the axiom that claims are "the portion of the patent document that defines the patentee's rights."

On balance, the tightened enablement standard epitomized in Medrad and BMW has the potential to greatly benefit the patent system. A strong enablement requirement ensures that the quid pro quo structure of the patent system remains viable, whereas a weak enablement requirement would deter the second generation of research because second generation patents

136. Id. at 15.
137. Id. at 14, n.31.
will be subservient to the overly broad claims of the first generation.\textsuperscript{139} Because second generation patentees may be required to share royalties with first generation patentees, the incentive to innovate for later generation inventors will be reduced.\textsuperscript{140} Furthermore, a stricter enablement requirement may actually stimulate research and development by diverting resources away from low value patents.\textsuperscript{141} Finally, the risk of complete claim invalidation under enablement law will arguably dissuade patentees from asserting overly broad claims, thus deterring frivolous patent litigation.

V. CONCLUSION

Traditionally, a more lenient standard of enablement was applied to inventions in the predictable arts as compared to the unpredictable arts. The recent Federal Circuit decisions in \textit{Medrad} and \textit{BMW} indicate a departure from this dichotomy. These decisions suggest that the Federal Circuit is tightening the enablement requirement in the predictable arts by demanding that all novel aspects of an invention contain adequate enablement within the specification.

The tightening of the enablement requirement for the predictable arts will deter applicants from asserting overly broad claims and may fuel the innovation of second generation inventors. Furthermore, the new standard has the potential to unite the doctrines of enablement and written description into a single disclosure doctrine. Unfortunately, the Federal Circuit has not explicitly overruled written description case law, and applicants are left with confusing and difficult to apply rules that blur the line between enablement and written description.

\textsuperscript{139} See Merges & Duffy, supra note 3 at 298-99.


\textsuperscript{141} See Robert M. Hunt, \textit{Economics and the Design of Patent Systems}, 13 Mich. Telecomm. & Tech. L. Rev. 457, 464 (2007) (explaining that "firms that concentrated on obtaining software patents experienced a statistically and economically significant decline in their R&D intensity relative to other firms" and to remedy the situation, "[i]t is clearly most important to modify the patent process to ensure that there is a closer relationship between what a firm invents and the property rights . . . this may involve modification to patent law's disclosure and enablement requirements").